The menopausal transition: Counsel on changes in bleeding patterns

Results of a new national study indicate it is not uncommon for women to have prolonged bleeding of 10 or more days, spotting for six or more days, and/or heavy bleeding for three or more days during the transition to menopause.1 Of the more than 1,300 women ages 42-52 in the study, 91% recorded one to three occurrences in a three-year period of bleeding that lasted 10 or more days, nearly 88% reported six or more days of spotting, and close to 78% recorded three or more days of heavy flow.

Data for the Study of Women’s Health Across the Nation (SWAN) involved participants recording their experiences over a period of time during the years 1996 to 2006. The women were identified as African-American, Japanese, Chinese, and white, and they were from southeast Michigan, Los Angeles, and northern California.

For most women, menstrual cycles in the reproductive years before the menopausal transition starts are very predictable, observes Sioban Harlow, PhD, professor of epidemiology at the University of Michigan.

EXECUTIVE SUMMARY

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- Knowledge of what to expect provides an important frame of reference and can help clinicians better understand and evaluate the bleeding changes women experience during the menopausal transition.
in Ann Arbor. With the onset of the menopausal transition, their menstrual cycles change, often dramatically, she says. “Knowledge of what to expect provides an important frame of reference and can help clinicians better understand and evaluate the bleeding changes women experience during the menopausal transition,” states Harlow, who served as lead author of the current paper.

The paper provides clinicians with quantitative data that describe the likelihood women will experience long and heavy bleeding during the menopausal transition, notes John Randolph, Jr., MD, professor of obstetrics and gynecology at the University of Michigan. Most women will experience one or more periods that are longer than what they are accustomed to, but these long periods are often self-limiting, notes Randolph, a paper co-author. Periods of 10 days are not uncommon, unlike what most women experience during their reproductive years, says Randolph.

“Such long and/or heavy bleeding would prompt clinical investigation by the accepted standards of care in women prior to the menopausal transition,” states Randolph. “These data can be used to explain why clinicians may suggest watchful waiting during the transition.”

Discuss bleeding patterns

The report from SWAN investigators regarding bleeding patterns across the menopause transition is a “great addition” to the literature, says Margery Gass, MD, NCMP, executive director of the North American Menopause Society in Mayfield Heights, OH. It will be comforting to women to know they are not alone in dealing with irregularity, she notes.

However, as the paper’s authors point out, pathology reports were not available, so neither women nor clinicians should fail to discuss bleeding patterns in perimenopause, states Gass. Clinicians must use good judgment in deciding when to try hormonal control of the bleeding and when to evaluate the endometrium, she notes.

Clinicians also should take into account the relative progesterone deficiency during this phase of, and remember that obesity is not only a risk factor for heavy bleeding, but also a risk factor for endometrial cancer, states Gass.

The current paper’s findings might help clinicians reduce the numbers of endometrial biopsies performed on perimenopausal women who have single episodes of heavy or prolonged bleeding, says 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.

According to Nelson, the current paper’s findings follow in the same line as research published in 2010, which showed that the highest blood losses are seen in late menopausal transition with ovulatory cycles and high estradiol levels. Nelson also points to a 2012 publication, where in a survey of
2,051 naturally menstruating women, two-thirds reported heavy menstrual bleeding in the previous six months. Follow-up showed that 30% of the remaining third developed problems in the next two years, which indicates heavy menstrual bleeding to be a very common problem indeed, Nelson notes.4

What’s your approach?

The current study demonstrates the importance of asking women about their bleeding pattern during the menopausal transition, says Susan Wysocki, WHNP-BC, FAANP, president & chief executive officer of iWomansHealth in Washington, DC, which focuses on information on women’s health issues for clinicians and consumers.

Questions about bleeding can become so routine that important information might be lost if additional information isn’t elicited, Wysocki observes. Clinicians need to ask, “What has changed about your menstrual bleeding pattern since your last visit? What do these changes mean to you?” Each woman is going to have a different concept of what the changes mean to her, whether the changes are bothersome or worrisome, and how they might be having an impact on her life, says Wysocki.

It also is important to consider that some bleeding might not be related to the transition into menopause and should be investigated, because it could be related to some pathology or sexually transmitted infection, Wysocki states. Consider that several things can transition during this time of life, including relationship changes, she says.

Hormonal contraceptive methods can be important options in managing bleeding, notes Wysocki. No contraceptive method is contraindicated based on age alone; however, estrogen-containing methods should be reserved for women without cardiovascular or thrombotic risk factors.5 Progestin-only methods as a group can be used by virtually every perimenopausal woman. Only women with a recent history (five years or less) of breast cancer carry a category 4 (a condition that represents an unacceptable health risk if contraceptive method is used) for progestin-only pills.6

The levonorgestrel intrauterine system has particular benefits during perimenopause and is safe for use in nearly all women.5 Use of the device is approved for treatment of heavy menstrual bleeding, a common concern during the perimenopause. In a randomized study of women who presented with excessive menstrual bleeding, the levonorgestrel intrauterine system was more effective than other medical treatments, such as tranexamic acid, nonsteroidal anti-inflammatory drugs (NSAIDS), combined oral contraceptives, progestin-only pill, and the contraceptive injection, in reducing the effect of heavy menstrual bleeding on quality of life.7 (Contraceptive Technology Update reported on the research. See “See nonsurgical options for abnormal bleeding,” June 2013, p. 67.)

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HPV test approved as first-line screening

The Food and Drug Administration (FDA) has for the first time approved a human papillomavirus (HPV) test that can be used alone instead of the Pap test to screen for cervical cancer. The cobas HPV Test, manufactured by Roche Molecular Systems in Pleasanton, CA, received the agency’s nod for use as a first-line primary screening test for cervical cancer in women ages 25 and older.

The regulatory approval offers women and physicians a new option for cervical cancer screening, said Alberto Gutierrez, PhD, director of the FDA’s Office of In Vitro Diagnostics and Radiological Health.
“Roche Diagnostics conducted a well-designed study that provided the FDA with a reasonable assurance of the safety and effectiveness when used as a primary screening tool for cervical cancer,” said Gutierrez in a statement accompanying the agency’s action.

The cobas test initially received FDA approval in 2011 for use with or as a follow-up to cytology testing. (Contraceptive Technology Update reported on the approval. Read “New HPV test gains approval from FDA,” July 2011, p. 77.) The test specifically identifies HPV genotypes 16 and 18, which are responsible for about 70% of all cervical cancers, and concurrently detects 12 other high-risk genotypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68).

The FDA points to data supporting the use of the cobas HPV Test as a primary screening test for cervical cancer as basis for its approval. These data include a study of more than 40,000 women age 25 and older undergoing routine cervical exams. To conduct the study, women who had a positive Pap test or whose cervical cells screened positive for HPV, as well as a subset of women whose Pap and HPV tests were negative, underwent a colposcopy and cervical tissue biopsy. All biopsy results were compared to the Pap and cobas HPV Test results. Data from this study, which included three years of follow-up on women who went to colposcopy, show that the cobas HPV Test is safe and effective for the new indication, states the FDA.1

Will guidance change?

The American Cancer Society and the American Society for Colposcopy and Cervical Pathology (ASCCP) issued guidance in 2012 recommending using Pap and HPV tests together every five years, called co-testing, or a Pap test alone every three years for women 30-65. For women ages 21 through 29, the guidelines recommend a Pap test every three years, with an HPV test only if the Pap is abnormal. Screening is not recommended for women younger than age 21.2 (To read more, see “Guidance issued on cervical cancer screening: update your practice now,” June 2012, p. 61.)

Will current guidance be revised to include the HPV test as a first-line test? The ASCCP, the Society for Gynecologic Oncology, and other organizations are developing an interim guidance document for further clarification on use of the newly approved test. “We’re energized by the attention to this important women’s health issue and the opportunity to increase available cervical cancer screening tools for the medical community,” said Herschel Lawson, MD, ASCCP chief medical officer and adjunct associate professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, in a released statement. “While existing guidelines for use of cervical cytology alone and cytology/HPV cotesting are not likely to change in the near future, we look forward to providing guidance for integrating primary HPV testing into our collection of recommended screening protocols to facilitate individual patient needs for appropriate cervical cancer screening and indicated follow up.”

In the meantime, the ASCCP and the Society for Gynecologic Oncology continue to direct clinicians to current guidance, which indicate use of the HPV test when Pap test results are inconclusive and in women age 30 and older in combination with a Pap test. (Download the screening and management guidelines at http://bit.ly/1j1x7zS.)

Between the 1940s and 2002, women in the United States were advised to have cervical cytology screening for cervical cancer performed annually at the time of their well woman visit, says Michael Policar, MD, MPH, clinical professor of obstetrics, gynecology, and reproductive sciences, at the University of San Francisco (UCSF) and medical director of UCSF’s Family PACT Evaluation program. “Over the past decade, however, national guidelines have changed substantially, such that routine screening is started later, completed earlier, and intervals extended to every three to five years for most women,” said Policar in a late breaker session at the 2014 Contraceptive Technology conferences in San Francisco and Boston.3

Because there has been no national consumer education campaign regarding the rationale for the changes in the 2012 guidelines, many women reject
them as being financially motivated and not in the best interest of their health, noted Policar. Some clinicians are reluctant to change their screening practices as well, said Policar. In one study, results indicate physicians thought that patients were uncomfortable with extended screening intervals and were concerned that patients would not come for annual exams without concurrent cytology screening.4

Despite these obstacles, clinicians should take the time to discuss with each woman the interval that applies to her and to counsel her that being screened too often can be harmful to her health, stated Policar.

“Over-screening minimally improves lesion detection rates, but it results in an excess risk of false positive tests, which can lead to unnecessary colposcopy and biopsies, with attendant anxiety and inconvenience, as well as unnecessary financial costs to the patient and the health delivery system,” noted Policar.

REFERENCES

Injectable contraception in the form of depot medroxyprogesterone acetate (DMPA) offers effective option

The next patient in your office is a 17-year-old young mother whose busy schedule conflicts with remembering to take a daily birth control pill, the method she chose at her postpartum visit. She is not interested in using such top-tier effective methods as the contraceptive implant and intrauterine device. What methods might offer the best fit for her?

Injectable contraception in the form of depot medroxyprogesterone acetate (DMPA) provides birth control for women who desire convenience, but are unable to use or do not want to commit to a long-acting reversible contraceptive. According to a new commentary on the subject, among users who return for repeat injections, DMPA represents an effective contraceptive.1 The perfect use first-year failure rate for DMPA, including the weighted average of the results from seven trials of the intramuscular (IM) formulation (available in the United States as generic) and two trials of the 104 mg subcutaneous (SC) formulation, has been reported as two per 1,000 women.2 In large Phase 3 trials of the SC formulation, no pregnancies have been reported.3

Whether a woman chooses to use the intramuscular or subcutaneous formulation of DMPA, clinicians have traditionally counseled for return for reinjections every three months. Reinjects do get missed. The percentage of women experiencing an unintended pregnancy during the first year of typical use with DMPA is 6%.1,2

Good news: The grace period for repeat injections is longer than previously thought. The 2013 “Selected Practice Recommendations for Contraceptive Use” (SPR)4 indicates that while routine repeat DMPA injections should be administered every three months or 13 weeks, injections can be provided before this time when needed, and repeat injections can be given up to two weeks late (15 weeks from the last injection) without requiring additional contraceptive protection.” The SPR goes on to state that a woman more than two weeks late (beyond 15 weeks from the last injection) can have the shot if it is reasonably certain she is not pregnant. Such women should abstain from sexual intercourse or use back-up contraception for the next seven days.4

EXECUTIVE SUMMARY

Injectable contraception in the form of depot medroxyprogesterone acetate (DMPA) provides birth control for women who desire convenience, but are unable to use or do not want to commit to a long-acting reversible contraceptive.

• The perfect use first-year failure rate for DMPA has been reported as two per 1,000 women. In large Phase 3 trials of the subcutaneous formulation, no pregnancies have been reported.
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Self-injection option?

What if women could administer their own shots of SC DMPA? In the first reported randomized trial of self-administration versus office-based administration of SC DMPA, findings were consistent with earlier reports that many U.S. DMPA users are interested in self-administration.6

Although several small studies were published prior to the trial, the study was conceived during the annual Fellowship in Family Planning Meeting in 2008, says Anitra Beasley, MD, MPH, assistant professor in the Department of Obstetrics and Gynecology in the Baylor College of Medicine in Houston.

“The thought behind the study was that DMPA is an incredibly effective contraceptive and has great uptake with a good portion of the population; however, its use is greatly limited by the need for regular provider visits,” observes Beasley. “The hope was that we could show that self-administration was acceptable to users, feasible, and that eliminating the need for provider visits would increase method continuation.”

A total of 137 women ages 18 and older enrolled in the study; of these, 91 were allocated to self-administration, and 90 out of 91 were able to correctly self-administer SC DMPA. Eighty-seven percent completed follow-up. DMPA use at one year was 71% for the self-administration group and 63% for the clinic group (p = 0.47). Uninterrupted DMPA use was 47% and 48% for the self and clinic administration groups at one year (p = 0.70), respectively. Serum analyses confirmed similar mean DMPA levels in both groups and therapeutic trough levels in all participants, demonstrating that efficacy in women who self-injected SC DMPA should be as high as that seen with injections given in an office setting.1

Although DMPA represents a second-tier contraceptive when compared with IUDs and the implant, some women seeking effective contraception don’t have access to these latter methods or choose not to use them, observes Andrew Kaunitz, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. Kaunitz served as a co-author of the current commentary.

“The safety, effectiveness experienced by women who return for repeat injections, convenience — along with the potential for self-administration of SC DMPA, and noncontraceptive benefits underscore injectable contraception’s importance for women in the U.S. and worldwide,” states Kaunitz. While DMPA does cause declines in bone density, such declines are reversible, he states. DMPA has not been found to cause osteoporosis or fractures.6-9

“The Food and Drug Administration’s addition of the black box warning label, which is not evidence-based, has inappropriately prevented many clinicians from recommending and patients from using/continuing DMPA,” states Kaunitz. “Skeletal health concerns should not prevent initiation or continuation of DMPA contraception.” (To read more on the warning label, see the Contraceptive Technology Update article, “DMPA: Time to repeal black box warning?” October 2011, p. 112.)

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Teen births decline, but more work left to be done

Although births to younger teens ages 15-17 have declined, they still represent more than a quarter of births to teens ages 15-19, which is nearly 1,700 births a week, according to new data from the Centers for Disease Control and Prevention (CDC).1

While progress has been made in reducing teen pregnancy rates, far too many adolescents still are...
having babies, said Tom Frieden, MD, MPH, CDC Director, in a statement accompanying the publication of the data.

“Births to younger teens pose the greatest risk of poor medical, social, and economic outcomes,” noted Frieden. “Efforts to prevent teen childbirth need to focus on evidence-based approaches to delaying sexual activity and increasing use of the most effective methods of contraception for those teens who are sexually active.”

**Important points from data**

To perform the current analysis, CDC researchers looked at birth data from the National Vital Statistics System, drawn from vital registration systems throughout the United States, and adolescent health behavior data gathered from the National Survey of Family Growth, a national compilation of information on family life, marriage and divorce, pregnancy, infertility, use of contraception, and men’s and women’s health. The analysis yielded several points of interest, including:

- The rate of births per 1,000 teens ages 15-17 declined 63%, from 38.6 in 1991 to 14.1 in 2012.
- The birth rate to younger adolescents is higher for Hispanic, non-Hispanic black, and American Indian/Alaska Native teens. In 2012, the birth rate per 1,000 adolescents ages 15-17 was 25.5 for Hispanic teens, 21.9 for non-Hispanic black adolescents, 17 for American Indian/Alaska Native teens, 8.4 for non-Hispanic white adolescents, and 4.1 for Asian/Pacific Islander teens.
- Most teens (73%) ages 15-17 had not had sex yet.
- Nearly one in four adolescents in this age group never spoke with their parents or guardians about sex.¹

**EXECUTIVE SUMMARY**

While progress has been made in reducing teen pregnancy rates, many adolescents still are having babies, according to new data from the Centers for Disease Control and Prevention. While births to younger teens ages 15-17 have declined, they still represent over one-quarter of births to teens ages 15-19, which is nearly 1,700 births a week.

- The birth rate to younger adolescents is higher for Hispanic, non-Hispanic black, and American Indian/Alaska Native teens, the new data show.
- In 2012, the birth rate per 1,000 adolescents ages 15-17 was 25.5 for Hispanic teens, 21.9 for non-Hispanic black adolescents, 17 for American Indian/Alaska Native teens, 8.4 for non-Hispanic white adolescents and 4.1 for Asian/Pacific Islander teens.

**Talk about LARC methods**

According to the new findings, among those teens who were sexually active, while more than 90% used some form of contraception the last time they had sex, most of them relied on methods that are among the least effective. Just 1% used long-acting reversible contraceptive (LARC) methods; the most common methods used were condoms and birth control pills.¹

The U.S. Selected Practice Recommendations for Contraceptive Use and an American College of Obstetricians and Gynecologists (ACOG) committee opinion state that LARC methods such as intrauterine contraception and the contraceptive implant are safe, effective, and appropriate options for adolescents.²³

(To read more on the guidance, see the Contraceptive Technology Update articles, “What does the US SPR mean for adolescents?” September 2013, p. 99, and “Long-acting methods safe for teens: Include options in your counseling,” December 2012, p. 133.)

With the current analysis indicating that more than half (58%) of sexually active younger teens made a reproductive health visit for birth control services in the past year, such visits give clinicians the opportunity to discuss advantages and disadvantages of different contraceptive methods and the importance of condom use during every sexual encounter, CDC officials note.

**Take steps with teens**

What are some steps that providers can take to help prevent younger teens from becoming pregnant? Shanna Cox, MSPH, a health scientist in the CDC’s Division of Reproductive Health, says that providers can work to provide a teen-friendly setting that offers convenient, confidential, respectful, and culturally appropriate services to meet the needs of teen clients. (To obtain resources for creating a teen-friendly clinic, visit the healthcare providers’ section of the CDC’s Teen Pregnancy website, http://1.usa.gov/1mHi8bC. Also see the CTU article, “How to get into heads of teens in initial visit,” January 2014, p. 8.)

Discuss normal physical, emotional, and sexual development with teens and parents, says Cox, who served as lead author of the current analysis. Encourage teens to delay sexual activity. If teens are sexually active, offer them a broad range of contraceptive methods, and encourage them to use the most effective methods, notes Cox.

Visit the CDC’s web page on contraceptive guidance for healthcare providers (http://1.usa.gov/1nlOKvj) to access links to the “U.S. Medical Eligibility Criteria for Contraceptive Use, 2010” and the “U.S. Selected Practice Recommendations for Contraceptive Use, 2013.”
“Talk about using condoms correctly every time during sex to prevent sexually transmitted diseases, including HIV/AIDS, even if another birth control method is used,” says Cox.

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Use retest reminders on chlamydia and gonorrhea

Bedsider (www.bedsider.org), an online birth control support network operated by the National Campaign to Prevent Teen and Unplanned Pregnancy, has expanded the InTOUCH reminder system that was successfully piloted in California to a national scale. This newly-expanded “reminders portal” is designed to help providers increase rates of chlamydia and gonorrhea retesting in their clinics, says Laura Lloyd, MPH, MS, assistant director of digital media for The National Campaign.

“Our mission at The National Campaign is about helping young women to plan pregnancies, having young women be pregnant when they want to be, yet the sexually transmitted infection issue hits our population as well, with its impact on future infertility,” says Lloyd. “Since we already had a national platform built for these reminders, it made sense to us to enter into this collaboration and scale [up the] InTOUCH reminder system.”

The National Campaign collaborated with the Richmond-based California Department of Public Health STD Control Branch and the Los Angeles-based California Family Health Council. With the partnership with The National Campaign’s Bedsider team, text and e-mail reminders for chlamydia and gonorrhea retesting are available to providers across the nation via Bedsider’s free provider portal system, says Gil Chavez, MD, MPH, deputy director and state epidemiologist for the California Department of Public Health’s Center for Infectious Diseases. Promotion of new retesting best practices and resources has occurred through distribution of guidelines, informational webinars, in-person and online clinical trainings, and various organizational newsletters, notes Chavez. (California’s best practices on retesting are located at http://bit.ly/LogIuY. Also check out the California STD/HIV Prevention Training Center’s video, “Retesting for Chlamydia and Gonorrhea,” at http://bit.ly/1IglqHFl.)

Promotion of Bedsider’s provider portal reminder system has recently begun in California following its launch of the retesting reminder option in December 2013, Chavez reports.

How does it work?

The reminders add to the online contraceptive support, tools, and content that Bedsider offers to young adults and providers. Providers can sign up for the Bedsider Provider Network free of charge for access to the secure reminders portal.

How does the retesting reminders system work?
• Providers sign up with Bedsider to gain access to their own unique, secure reminders portal.
• When a patient is treated for gonorrhea or chlamydia, the clinic enters the date of treatment, as well as a contact phone number or e-mail address, into the portal.
• Two and a half months after the initial test, the patient receives a text message or email with a retesting reminder. The clinic’s name and phone number are prominently listed in the reminder so the patient has fingertip contact information.

The reminders portal also allows providers to
enter patient prompts for birth control, prescription refills, and specific appointments. Future plans include reminders for human papillomavirus vaccination, says Lloyd.

Why retesting is key

Rapid repeat infection with chlamydia and gonorrhea generally occurs one to six months after treatment for infection and significantly increases the risk for adverse reproductive health outcomes among women, such as pelvic inflammatory disease, ectopic pregnancy, and infertility, notes Chavez. Repeat infection is very common across all patient demographics, with rates as high as 15-20% among women who are retested a few months after treatment for their initial infection.1

As the vast majority of reinfections among women occur without discernable symptoms, routine chlamydia and gonorrhea retesting three months after treatment for initial infection has been recommended for more than a decade by the Centers for Disease Control and Prevention (CDC), says Chavez. However, despite general efforts to educate providers about CDC guidelines, retesting rates in family planning and other clinical settings remain low, typically well below 50%.2

What contributes to low retesting rates? The primary barriers to institutionalizing retesting practices are lack of prioritization of retesting services in clinic protocols and among staff, lack of systems to prompt retesting when patients return to clinic, insufficient patient education counseling, limited resources for patient appointment reminder systems, the burden of additional clinic visits on scheduling and staff resources, and patients’ failure to return to clinic for retesting because they don’t understand their risk or have other barriers to accessing care, notes Chavez. Effective, easy-to-implement strategies to improve retesting in family planning and other clinical settings have been elusive, he observes.

How InTOUCH made impact

The 2010-2012 InTOUCH Study, funded by the Department of Health and Human Services’ Office of Population Affairs, was an applied research study designed to identify effective and feasible interventions to improve retesting for chlamydia and gonorrhea within the California Title X clinical setting, states Chavez. Interventions targeting the clinic and the patient were implemented and evaluated on their effectiveness in improving retesting rates within six family planning clinics across California.

Interventions in the study included the introduction of chart flag reminders (automated electronic pop-ups) to alert clinic reception staff when a presenting patient was due for retesting, improved patient education materials and health education counseling messages, protocols to allow collection of sexually transmitted infection (STI) testing samples (via urine or self-collected vaginal swab) at all clinic visits regardless of reason for visit or the presence of a clinician, and the availability of drop-in STI-test-only visits, says Chavez.

Patients are provided more comprehensive health education related to reinfections, partner treatment options, and the importance of retesting. In addition, during the final phase of the study, patients also were given the option to receive a reminder message via self-addressed postcard, text message, and/or e-mail three months after their treatment to remind them of their need to return to the clinic for retesting, Patients were provided the option to take their retest in the clinic or at home using a mailed-in self-collected vaginal swab specimen kit.

While only 5% of patients chose the home-testing option, 90% requested a reminder message, with 90% of these preferring a text and/or email-based auto-reminder, which was facilitated by the InTOUCH-developed reminder system, says Chavez. The clinic-side and patient-side interventions separately and significantly improved retesting rates within the study clinic sites, with the combined interventions increasing retesting rates overall by just more than 30%, notes Chavez.

Retesting data for approximately 5,000 non-pregnant female patients age 16 or older who had tested positive and were treated for a chlamydia or gonorrhea infection at one of six family planning clinic sites across CA were included in the study. The study included almost 600 who were enrolled in the patient-targeted study phase and offered the options for a retest reminder and home-test kit.

“While the InTOUCH clinic-side interventions can be feasibly implemented in most clinical care settings for no or little cost, home-testing and automated reminder messages have not been available to providers and patients without investments in infrastructure,” observes Chavez. “Due to our partnership with The National Campaign to Prevent Teen and Unplanned Pregnancy’s Bedsider team, text and email reminders for chlamydia and gonorrhea retesting are now available to providers across the nation via Bedsider’s free provider portal system.”

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Insurance coverage of abortion was one of the final sticking points during enactment of the Affordable Care Act (ACA), and it has continued to be a rallying cry for ACA opponents in the years since. Now that the major components of the ACA are in full effect, the question of whether consumers have the option of plans covering abortion — and whether they can even figure that out — has become a topic of great interest to policymakers and advocates on both sides of the abortion debate, as well as the public at large.

Under the ACA, states are allowed to ban coverage of abortion within plans sold through the new online marketplaces, and 25 states have done so, typically with exceptions for the extreme cases of rape, incest, and endangerment of the woman’s life. In the remaining states, the decision about whether to cover abortion is left to the plan issuer. Plans that do cover the service must follow specific accounting mechanisms designed to prevent any federal subsidies received by enrollees from being used for abortion coverage and care, which must instead come from enrollees’ own premium payments. In a further concession to antiabortion lawmakers, the ACA requires that at least one of the “multi-state” plans, which are federally contracted plans that must be sold through every state’s marketplace by 2017, as a way to expand consumer choices, must exclude abortion coverage. There is no parallel requirement that any plan cover the service. So far, of the more than 150 multi-state offerings in 30 states and the District of Columbia in 2014, only two cover abortion, both of which appear to be specific to Alaska’s marketplace.

According to my colleague, Kinsey Hasstedt, who reports on the subject in far more detail than I can cover here, consumers on the marketplaces often have inadequate information to identify plans that do or do not cover abortion. Guttmacher staff reviewed available plan documents — the standardized summary of benefits and coverage (SBC) forms and additional documents for consumers available through links on the marketplaces — in 12 of the state marketplaces where abortion coverage is permitted (Alaska, Illinois, Rhode Island, Washington, Colorado, Connecticut, Georgia, Nevada, Minnesota, New Hampshire, New Jersey, and West Virginia). Issuers in only four of the states (Colorado, Connecticut, Rhode Island, and Washington) clearly offer plans covering abortion (beyond cases of rape, incest, or life endangerment). Issuers in only two of those states (Colorado and Washington) and four others (Alaska, Illinois, Georgia and Nevada) clearly offer plans excluding that coverage. In fact, most plan documents, including those for all of the plans in the remaining four states, say nothing at all about abortion, which leaves consumers in the dark.

Transparency is no better in the states that have barred abortion coverage in their marketplaces. Almost all of those states rely on the federal government’s HealthCare.gov website. That portal includes no information about the state abortion coverage bans. Similarly, in the two states barring such coverage that run their own marketplaces (Idaho and Kentucky), there is no notice to consumers that abortion coverage is unavailable.

Clarity is achievable

Antiabortion lawmakers and activists have taken political advantage of the dearth of information about abortion coverage in marketplace plans. For example, the U.S. House of Representatives passed a so-called disclosure measure in late January 2014. However, it was included within a broader bill designed to drive abortion coverage out of the marketplace plans altogether, making the issue of disclosure irrelevant. The measure also would require plans to emphasize whether or not they cover abortion in their marketing materials — treating it differently from other covered services — and would require plans to incorrectly describe an “abortion surcharge.” In fact, that “surcharge” is an amount related to the accounting mechanisms set up by the
law specifically to appease antiabortion lawmakers’ insistence that federal dollars not go toward abortion. Given the Senate leadership’s refusal to take up the House-passed legislation and the president’s veto threat, this bill has no chance of becoming law anytime soon.

Meanwhile, a lawsuit filed in May 2014 in Connecticut by antiabortion activists follows the same line of attack. It asserts that federal and state officials have violated their religious rights in the following ways:

• by requiring them to purchase insurance through which their premiums will subsidize abortion coverage that may be used by other plan enrollees;
• by apparently not providing them with any plan options that exclude abortion (in part because no multi-state plans are yet offered on Connecticut’s marketplace);
• by denying them the information about abortion coverage and “surcharges” they would need to identify a plan that excludes abortion coverage, if one exists.5

In truth, transparency for consumers about abortion coverage is legal already under the ACA and could be guaranteed in an unbiased manner through several simple government actions. Already, the ACA requires plans that cover abortion to disclose that in their SBCs, and more generally requires SBCs to include any major coverage exclusions. Simple changes to the SBC form and instructions could make information about abortion coverage universal and appropriately situated among other services related to common medical events.3 The marketplaces, including HealthCare.gov, also could easily provide notice about state laws prohibiting abortion coverage. Given the ongoing national debate, confusion, and interest about abortion coverage under the ACA, it is in everyone’s interest that the government take these steps before the next open enrollment period this fall.

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   B. Contraceptive injection
   C. Contraceptive implant
   D. Levonorgestrel intrauterine system

2. What is the name of the human papilloma virus (HPV) test that has been approved as a first-line test for cervical cancer in women ages 25 and older?
   A. cobas
   B. Cepheid
   C. Affirm
   D. Simplexa

3. What is the perfect use first-year failure rate for the contraceptive injection, depot medroxyprogesterone acetate?
   A. Less than 1 per 1,000 women
   B. 2 per 1,000 women
   C. 7 per 1,000 women
   D. 10 per 1,000 women

4. What are the reported rates of repeat infection of chlamydia and gonorrhea among women who are retested a few months after treatment for their initial infection?
   A. Less than 5%
   B. 7%
   C. 10%
   D. 15-20%

COMING IN FUTURE MONTHS
- Female sterilization: Research eyes effectiveness
- Contraceptive coverage: What’s the midyear status?
- Same-day IUD placement: Option for women at high STI risk?
- Intrauterine contraception: Focus is on risk of perforation

CONTRACEPTIVE TECHNOLOGY UPDATE® / July 2014
Antiretroviral treatment guidance updated: Revise your practice now

For clinicians who are involved in care of HIV-infected patients, the newly-revised “Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents” contains key treatment updates, as well as a new section on costs, including discussion of cost-sharing, prior authorizations, and use of generic drugs.

The Department of Health and Human Services (HHS) guidelines provide an updated and concise review of the most recent evidence-based data concerning the use of antiretroviral therapy (ART), says William Short, MD, MPH, assistant professor in the Division of Infectious Diseases and Environmental Medicine in the Jefferson Medical College at the Thomas Jefferson University in Philadelphia and board member of the Washington, DC-based American Academy of HIV Medicine.

The May 1, 2014, revision includes a change in the classification of recommendations for initial treatment of HIV infection, explains Short. In the past few years, the Food and Drug Administration (FDA) has approved several new ART agents and coformulations for treatment-naive individuals. Based on data from long-term follow-up studies and experience in clinical practice, the panel involved with developing the guidance now refers to options for initial treatment as “recommended” rather than “preferred” regimens.

The guidance is further broken down into two categories: regimens recommended for ART-naive patients, regardless of baseline CD4 cell count or viral load, and regimens that are recommended only for patients with baseline viral loads less than 100,000 copies/mL.

In the first category, clinicians will note three new recommended regimens, all involving the use of new integrase inhibitors:

- dolutegravir plus abacavir/lamivudine (only for patients who are HLA-B*5701 negative)
- dolutegravir plus tenofovir disoproxil fumarate/emtricitabine and tenofovir disoproxil fumarate/emtricitabine (only for patients with pre-ART creatinine clearance equal to or above 70 mL/min).

“There is also a section on switching regimens.

EXECUTIVE SUMMARY

For clinicians who are involved in care of HIV-infected patients, the newly revised “Guidelines for the Use of Antiretroviral Agents In HIV-1-Infected Adults and Adolescents” contains key treatment updates, as well as a new section on costs, including discussion of cost-sharing, prior authorizations, and use of generic drugs.

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for patients who may be intolerant of their current ART,” says Short. “The recommendation empha-
sizes that the key to switching regimens is to main-
tain viral suppression without compromising future
options.”

Short points to an additional new table added to
the “Adverse Effects of Antiretroviral Agents” sec-
tion that offers recommendations on antiretroviral
drug options when switching drugs due to adverse
effects. Clinicians should consider a patient’s prior
treatment history and responses, resistance profiles,
and drug tolerance when selecting a new antiretrovi-
ral drug, the guidance recommends.

**Monitoring is decreased**

Viral load is the most important measure of
response to ART, and it should be monitored dur-
ing therapy to assure consistent viral suppression,
according to the new guidance. Measurement of
CD4 T lymphocyte cell count (CD4 count) is neces-
sary when a patient enters into care, both to deter-
mine the urgency for ART initiation and the need
for prophylaxis against opportunistic infections, the
guidance states.1

Once therapy is initiated, CD4 count monitor-
ing is most helpful in patients with advanced HIV
infection to guide the timing of discontinuation of
opportunistic infections prophylaxis or treatment,
the guidance notes. Frequent monitoring of CD4
counts, especially in those with higher counts (> 300
cells/mm³) and consistently suppressed viral loads, is
generally not required for patient management, the
guidance states.

“Given the successes of ART, the guidelines now
address the frequency at which CD4 count and viral
load need to be monitored,” says Short. “In the past,
these were done every three months; now based on
the patient’s history, less frequent monitoring is rec-
ommended.”

For patients who have been on ART for at least
two years with consistent viral suppression, the guid-
ance states that those with a CD4 count between
300–500 cells/mm³ can have a CD4 count monitoring
every 12 months, while monitoring is optional
for those with a CD4 count of more than 500 cells/
mm³.1

The guidance recommends resumption of more
frequent CD4 count monitoring in three situations:
• when patients experience virologic rebound;
• when patients develop new HIV-associated
clinical symptoms;
• when patients develop conditions or initiate
therapy that might lead to reduction of CD4 cell
count.

Monitoring of lymphocyte subsets other than
CD4, such as CD8 and CD19, is not clinically use-
ful, is more expensive, and is not routinely recom-
mended, the guidance states.1

**Costs come into play**

Look for a new section on drug costs and how
they relate to ART, says Short. This discussion
includes an overview of cost as it relates to adher-
ence, prior authorizations, and the use of generic
drugs, he notes.

In the past, the guidelines have not formally dis-
cussed costs related to antiretroviral therapy. The
new section provides information, and it also elabo-
rates on potential strategies for cost containment
that do not compromise treatment effectiveness.

Clinicians who treat HIV-infected women of
reproductive age should check the updated guid-
ance for key drug to drug interactions, notes Short.
Examples include oral contraceptives, medroxypro-
gesterone acetate, statins, and antimicrobials.

There can be potential interactions between anti-
retroviral drugs and hormonal contraceptives that
can lead to lower contraceptive efficacy. Several pro-
tase inhibitors and non-nucleoside reverse transcrip-
tase inhibitors have drug interactions with combined
oral contraceptives; interactions include a decrease
or an increase in blood levels of ethinyl estradiol,
norethindrone, or norgestimate. These interactions
potentially can decrease contraceptive efficacy or
increases estrogen- or progestin-related adverse
effects, such as thromboembolism. In the case of the
contraceptive implant, contraceptive failure has been
reported in two patients on efavirenz-based therapy.2

“Concerns about pharmacokinetic interactions
between oral and implant hormonal contraceptives
and antiretroviral [drugs] should not prevent clini-
cians from prescribing hormonal contraceptives for
women on ART if that is their preferred contracep-
tive method,” states the guidance. “However, when
women wish to use hormonal contraceptives and
drug interactions with antiretroviral [drugs] are
known, additional or alternative contraceptive meth-
ods may be recommended.”

What about other contraceptive options?
Intrauterine devices (IUDs) appear to be a safe and
effective contraceptive option for HIV-infected
women.3–6 While most studies have looked at non-
hormonal devices such as the Copper T380 IUD, data from several small studies also indicate levonorgestrel-releasing IUDs to be safe and not associated with increased genital tract shedding of HIV.7-8

No matter what contraceptive method is chosen, the guidance advises that clinicians should counsel all HIV-infected women and their partners on consistent use of male or female condoms to prevent transmission of HIV and protect against other sexually transmitted infections.

REFERENCES


Get up to speed on genital herpes

It’s time to refresh your knowledge base on genital herpes. At least one in six adolescents and adults in the United States are infected with herpes simplex virus type 2 (HSV-2), with an estimated 776,000 new cases occurring each year.1 A chronic viral infection, most cases of recurrent genital herpes in the United States are caused by HSV-2. However, an increasing proportion of anogenital herpetic infection in some populations has been attributed to HSV-1 infection, according to the Centers for Disease Control and Prevention (CDC). There currently is no cure for the infection.

The CDC has just issued updated resources for genital herpes clinical training. (A self-study module for clinicians can be found at http://1.usa.gov/1fXcwvi. A ready-to-use curriculum, including a slide presentation, a student handout, case studies, and more are available at http://1.usa.gov/1uNDkm6.)

While there are no simple solutions for preventing herpes, there are steps everyone can take to reduce the spread of the disease, says Robyn Neblett Fanfair, MD, MPH, medical officer of the CDC’s Division of Sexually Transmitted Disease (STD) Prevention. It is critical to enhance awareness of possible prevention options, especially among youth before they are infected and among affected populations, notes Fanfair. Healthcare providers, specifically, play an important role in the prevention of genital herpes, she states.

Messages are critical

Fanfair says it is imperative that individuals with herpes be counseled about transmission and prevention of the disease. (Use a CDC brochure for patient education; go to http://1.usa.gov/QrICmC, and select “Genital Herpes.” The brochure is available in English and Spanish.)

“There is not a cure for genital herpes; however, providers should speak with their patients about available and effective treatment options that help manage the disease and protect the health of sexual partners,” states Fanfair. “In fact, daily therapy can reduce the risk of transmission by about 50%.”

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention has just issued updated resources for genital herpes clinical training. At least one in six adolescents and adults in the United States are infected with herpes simplex virus type 2 (HSV-2), with an estimated 776,000 new cases occurring each year.

• Patients should be counseled that HSV can be transmitted when sores are not present, and most cases are transmitted during asymptomatic periods. Research indicates that disclosure of infection status to partners can reduce the transmission rate.
• Science is eyeing several therapeutic vaccines for genital herpes; three companies have vaccines in U.S. clinical trials.
Patients should be counseled that HSV can be transmitted when sores are not present, and most cases are transmitted during asymptomatic periods, states Fanfair. Research also shows that disclosure to partners can reduce the transmission rate, so it is important that healthcare providers encourage patients to inform current and future sexual partners about their diagnosis, says Fanfair. Patients also should abstain from sexual activity during outbreaks (when sores begin to appear or are present), because of the likely increased risk of transmission, says Fanfair.

**How to prevent herpes?**

Prevention remains key for those who are not infected or who are unaware of their status. Providers should discuss STDs, including genital herpes, with their patients and ensure they understand what places them at risk and how to protect themselves, says Fanfair. It also is important that individuals talk openly with sexual partners, ask whether they have been diagnosed with genital herpes, and avoid sexual contact with individuals who have visible sores, she states.

“Regardless of infection status, general risk reduction strategies are important. Patients need to know that the surest ways to prevent infection are abstinence or mutual monogamy with a partner,” Fanfair comments. “Reducing their number of sexual partners also can be helpful.”

Be sure patients understand correct condom use. Because the HSV virus can be transmitted even when sores are not present, routine use of latex condoms consistently and correctly during oral, anal, or vaginal sex with partners of unknown infection status can reduce the chances of infection, states Fanfair.

**Vaccines in view?**

Science is eyeing several therapeutic vaccines for genital herpes, reports Anna Wald, MD, MPH professor of medicine at the University of Washington.

Three companies have vaccines in United States clinical trials:

- Lexington, MA-based Agenus is developing its HerpV recombinant therapeutic vaccine for the treatment of genital herpes caused by HSV-2. In a Phase 2 study testing the biological efficacy of HerpV measuring genital viral shedding 45 days before and after three injections of HerpV, primary analysis, (which looked at viral shedding after the initial three injections) shows that subjects who received HerpV had a statistically significant reduction in viral shedding ($P = 0.015$; relative risk $= 0.85$). These results suggest a 15% reduction in viral shedding after the initial treatment period before the administration of the booster injection. The results also demonstrate a reduction in viral load of 34% ($P = 0.08$). Placebo patients showed no reduction compared to baseline in either parameter.

- Genocea Biosciences of Cambridge, MA, is developing its first-in-class, investigational, protein subunit vaccine, GEN-003. In data presented at the 2013 Interscience Conference on Antimicrobial Agents and Chemotherapy, findings indicate that patients who received three doses of GEN-003 had reductions in the frequency of viral shedding of up to 51% ($p < 0.001$). Patients who received a placebo had no decline in viral shedding. Findings suggest T cell immune responses increased more than twentyfold to one vaccine antigen (ICP4) and more than tenfold to the other (gD2). In addition, GEN-003 increased neutralizing antibodies to the HSV-2 virus fivefold, on average, compared to baseline values.

- Vical of San Diego is enrolling patients in its Phase 1/2 trial of its Vaxfectin HSV-2 vaccine. A total of 156 patients are scheduled to be enrolled in the randomized, double-blind, placebo-controlled trial to evaluate safety, tolerability, and efficacy in otherwise healthy HSV-2-infected patients ages 18-50 years at seven U.S. clinical sites.

**REFERENCES**

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