CONTRACEPTIVE TECHNOLOGY UPDATE®

The Trusted Source for Contraceptive and STI News and Research for More Than Three Decades

September 2013: Vol. 34, No. 9
Pages 97-108

IN THIS ISSUE

Financial Disclosure: Consulting Editor **Robert A. Hatcher**, MD, MPH, Author **Rebecca Bowers**, and Executive Editor **Joy Dickinson** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Sharon Schnare**, Nurse Reviewer, discloses that she is a retained consultant for Watson Laboratories and Dopomed; on the speakers' bureau for Meda Pharmaceuticals, Merck Sharpe & Dohme Corp., and Teva Women's Health; and on the speakers bureau and a retained consultant for Bayer HealthCare Pharmaceuticals. **Melanie Gold**, guest columnist, discloses that she is on the speakers bureau for Novartis Pharmaceuticals Corp. **Anita Brakman**, guest columnist, and **Diana Taylor**, RNP, PhD, FAAN, guest columnist, have no relevant disclosures.

AHC Media

Enhance your practice by adding Selected Practice Recommendations

Get recommendations for common contraceptive management issues

Providers have a new clinical resource: the U.S. Selected Practice Recommendations for Contraceptive Use, 2013 (US SPR).[1] The publication provides guidance on how contraceptive methods can be used, and it focuses on how to remove unnecessary barriers for patients in accessing and successfully using contraceptive methods.

Adapted from global guidance provided by the World Health Organization, the Centers for Disease Control and Prevention (CDC) publication is meant to serve as a source of clinical support for healthcare providers. In preparing the guidance, CDC staff conducted systematic reviews of the scientific evidence for each of the topics. It also convened a 2011 multidisciplinary meeting of experts who assisted in guideline development.

While the U.S. Medical Eligibility Criteria for Contraceptive Use (US MEC) provides guidance on who can use various methods of contraception, the US SPR provides guidance on how contraceptive methods can be used.[2]

"This new evidence-based guidance from the CDC will improve and streamline how we provide contraceptive services to our patients," says **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. Kaunitz was one of 36 outside participants who participated in the multidisciplinary meeting.

EXECUTIVE SUMMARY

The U.S. Selected Practice Recommendations for Contraceptive Use (US SPR), 2013 provides guidance on how contraceptive methods can be used, and it focuses on how to remove unnecessary barriers for patients in accessing and successfully using contraceptive methods.

- Adapted from global guidance provided by the World Health Organization, the Centers for Disease Control and Prevention publication is meant to serve as a source of clinical support for healthcare providers.
- While the U.S. Medical Eligibility Criteria for Contraceptive Use provides support on who can use various methods of contraception, the US SPR provides guidance on how contraceptive methods can be used.

The CDC is disseminating the US SPR in several ways, including announcements to more than 110,000 individuals signed up to receive alerts when new contraceptive guidance is released, says **Kathryn Curtis**, PhD, a health scientist in the CDC's Women's Health and Fertility Branch in the Division of Reproductive Health. *(To sign up for such alerts, go to http://bit.ly/12WRuj4.)* Information about the SPR is being presented at conferences of professional organizations, and it is being published in professional newsletters and journals, says Curtis. Continuing education credits are being offered as well. Go to http://1.usa.gov/RnxUKo. Under "U.S. Selected Practice Recommendations for Contraceptive Use, 2013," select "CE available at TCEO." Tools also are being developed, such as electronic resources and speaker-ready slides, says Curtis. *(As resources are provided, they will be posted at http://1.usa.gov/12WO1FD.)*

"We also rely heavily on our federal and professional partner organizations to get the word out to the constituents," states Curtis. "Many of our partners have sent e-blasts to members, added links to the US SPR on their websites, and are planning their own presentations on the new guidance at annual meetings."

How to use the SPR

Healthcare providers can use the US MEC and the SPR when counseling women, men, and couples about contraceptive method choice and use, and in the management of problems with contraceptive use, says Curtis. Specifically, the U.S SPR provides evidence-based guidance on how providers can best help patients initiate and continue contraceptive method use by removing unnecessary barriers to access, she states.

"The US MEC and SPR are sources of clinical guidance. Healthcare providers should always consider the individual clinical circumstances of each person seeking family planning services," Curtis says.

In the SPR, routine testing requirements have been reduced, but clinicians still need to individualize care, 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. "For example, routine blood pressure [BP] measurements for intrauterine devices [IUDs] is not necessary, but the day a woman with hypertension comes in to have her IUD placed, it would be good to know her BP is not 200/100," observes Nelson. "Just keep it real."

Your questions answered

The CDC guidance governs hormonal, intrauterine, surgical, and natural methods of contraception, notes Kaunitz. It offer practical advice for everyday issues encountered by clinicians, such as what to do when an woman with IUD is diagnosed with pelvic inflammatory disease (PID) and timing of repeat depot medroxyprogesterone acetate (DMPA) injections.

When a woman using an IUD is found to have PID, many clinicians immediately will remove the device as they initiate antibiotics, observes Kaunitz. The

Contraceptive Technology Update® (ISSN 0274-726X), including STI Quarterly™, is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, NE, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Contraceptive Technology Update®, P.O. Box 105109, Atlanta, GA 30348.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291. E-mail: (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday, EST. Subscription rates: U.S.A., one year (12 issues), $449. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Back issues, when available, are $75 each.(GST registration number R128870672.) Photocopying: No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact AHC Media. Address: P.O. Box 105109, Atlanta, GA 30348. Telephone: (800) 688-2421. World Wide Web: http://www.ahcmedia.com.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

AHC Media is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media designates this enduring material for a maximum of 18 *AMA PRA Category 1 Credits*™. Physicians should claim only credit commensurate with the extent of their participation in the activity.

This activity is intended for OB/GYNs, nurses, nurse practitioners, and other family planners. It is in effect for 24 months from the date of publication.

Editor: **Rebecca Bowers.**
Executive Editor: **Joy Daughtery Dickinson** (404) 262-5410 (joy.dickinson@ahcmedia.com).
Production Editor: **Kristen Ramsey.**
Interim Editorial Director: **Lee Landenberger.**

Editorial Questions

Questions or comments? Call Joy Daughtery Dickinson (229) 551-9195.

How to tell if a woman is not pregnant

A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses;
- has not had sexual intercourse since the start of last normal menses;
- has been correctly and consistently using a reliable method of contraception;
- is ≤7 days after spontaneous or induced abortion;
- is within 4 weeks postpartum; or
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds),[1] amenorrheic, and <6 months postpartum.

Source: Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, second edition. *MMWR Recomm Rep* 2013; 62(RR-05):7.

REFERENCE

1. Labbok M, Perez A, Valdez V, et al. The Lactational Amenorrhea Method (LAM): a postpartum introductory family planning method with policy and program implications. *Adv Contracept* 1994;10:93-109. ■

CDC indicates clinicians should treat the PID according to the Sexually Transmitted Diseases Treatment Guidelines, and it states the IUD does not need to be removed immediately if the woman needs ongoing contraception.[3] If no clinical improvement has occurred at the time of clinical reassessment in two to three days, providers should continue antibiotics and, at that time, consider removal of the IUD, the guidance states.

Confusion occurs with the timing of repeat DMPA injections, Kaunitz observes. Routinely, clinicians should provide repeat DMPA injections every three months or 13 weeks. However, for patient convenience, it is fine to provide repeat DMPA injections early, notes Kaunitz.

A more common scenario is the patient returning late for her repeat injection. The CDC guidance indicates clinicians can repeat contraceptive injections up to two weeks late, or 15 weeks from the last injection, without requiring additional contraceptive protection.[1] If the woman is more than two weeks late for her repeat DMPA injection, which is to say more than 15 weeks from the last injection, the guidance indicates clinicians can proceed with reinjection if it is reasonably certain that the patient is not pregnant. *(See how to tell if a woman is not pregnant in box above.)* Such patients will need to use additional back-up contraceptive protection for the next seven days, the guidance notes.[1] *(For information on what the SPR means for teens, see column, right.)*

REFERENCES

1. Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, second edition. *MMWR Recomm Rep* 2013; 62(RR-05):1-60.
2. Centers for Disease Control and Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use. *MMWR* 2010; 59(RR04):1-6.
3. Workowski KA, Berman S. Centers for Disease Control and Prevention (CDC). Sexually transmitted diseases treatment guidelines, 2010. *MMWR Recomm Rep* 2010; 59(RR-12):1-110. ■

Teen TOPICS

What does the US SPR mean for adolescents?

By **Anita Brakman**, MS
Director of Education, Research & Training
Physicians for Reproductive Health
New York City

Melanie Gold, DO, FAAP
Clinical Professor of Pediatrics
University of Pittsburgh School of Medicine
Staff Physician
University of Pittsburgh Student Health Service

The Centers for Disease Control and Prevention (CDC) released its first U.S. Selected Practice Recommendations for Contraceptive Use (US SPR)

in the June 21, 2013, *Morbidity and Mortality Weekly Report*. These practice recommendations address common, yet complex, issues surrounding initiating and using several contraceptive methods, and they serve as a resource for clinicians, including those who care for adolescents.

The US SPR is a useful companion to the CDC's US Medical Eligibility Criteria for Contraceptive Use (US MEC), which provides detailed information on which types of contraception can be safely used by patients with a variety of medical conditions and other characteristics. The US MEC and the new US SPR are adaptations of similar documents published by the World Health Organization (WHO), but the U.S. versions are specific to patient populations in this country. For each method, the US SPR details appropriate timing of when to initiate the method and any necessary prerequisite examinations or testing, when and how long to use backup contraception, changes in practice when caring for women who are postpartum or postabortion, what follow-up care to offer, how to manage side effects, as well as guidance on switching between methods and how to address user errors such as missed pills or late injections.[1]

While the US SPR contains practical guidance on many areas of family planning, providers who care for teens might be especially interested two sections of the report: the recommendations on long-acting reversible contraception (LARC) and emergency contraception (EC).

Medical and public health organizations, including the American College of Obstetricians and Gynecologists, agree that long-acting methods should be considered a first-line choice of contraceptive method for healthy adolescents, regardless of parity.[2-3] The US SPR states that implantable and intrauterine contraceptives are appropriate for teens and provides specific guidance on addressing side effects that might lead to method discontinuation, such as bleeding irregularities. With the high up-front cost of these methods and their potential for long-term protection against unintended pregnancy with immediate reversibility upon removal, helping young patients manage troublesome side effects is preferable to immediate discontinuation.

The report's first recommendation in this area is to counsel all patients on potential changes in bleeding patterns so they will know what to expect and the possible duration of bleeding irregularities. Patients, including teens, using the copper intrauterine device (IUD) might find nonsteroidal anti-inflammatory drugs (NSAIDs) can provide short-term treatment for heavy or prolonged menstrual bleeding. The US SPR cautions, however, that while several studies show individual NSAIDs can be effective in reducing bleeding, there is not enough evidence to recommend one specific treatment regimen.

Bleeding changes are the primary complaint cited by patients who discontinue contraceptive implant use, especially teens.[4,5] Again, NSAIDs are a recommended option for managing the light and unscheduled spotting associated with implant use. Another option for managing bleeding related to implant use is to prescribe a hormonal treatment, such as a low-dose combined oral contraceptive, as long as the patient has no medical contraindications to estrogen use. Evidence is weak and mixed regarding the possible benefits of vitamin E or ibuprofen in reducing implant-associated bleeding. If any patient desires removal of an implant, it is recommended to help her choose and initiate another method that she will tolerate more easily.

Use guidance on EC

The US SPR gives clinicians important direction for counseling teens about using emergency contraception, including levonorgestrel regimens, combined hormonal regimens, ulipristal acetate, and the copper IUD. The topic is timely, as EC and adolescents recently have been in the news as Plan B One-Step is set to move onto store shelves without any age restrictions. (Read the Contraceptive Technology Update article, "US drops age limits for Plan B One-Step," August 2013, p. 88.) The CDC report continues to recommend providing advance supplies or prescriptions for EC pills when possible and instructs clinicians on how to initiate ongoing contraception after a patient has taken EC pills. Any contraceptive method can be started immediately after using levonorgestrel or ulipristal acetate formulations of EC. However, patients will need to use a backup contraceptive method or abstain from intercourse for seven days after using levonorgestrel pills and 14 days after using ulipristal acetate. A pregnancy test is recommended if a patient does not have a withdrawal bleed within three weeks of taking EC. When the copper IUD is used for EC, no backup method is needed.

Clinicians who treat adolescents will find valuable guidance in the US SPR about many contraceptives including combined hormonal oral, vaginal, and transdermal methods; injections; LARC; EC; and fertility-awareness based methods. The full report, as well as related articles and resources from the CDC and the WHO, can be accessed easily at http://1.usa.gov/14vF2xf.

REFERENCES

1. Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, second edition. *MMWR Recomm Rep* 2013; 62(RR-05):1-60.
2. American Congress of Obstetricians and Gynecologists. Intrauterine device and adolescents. *Obstet Gynecol* 2007; 110(6):1,493-1,495.
3. American Congress of Obstetricians and Gynecologists. Long-acting reversible contraception: implants and intrauterine devices. *Obstet Gynecol* 2011; 118(1):184-196.
4. Raymond EG. Contraceptive implants. In: Hatcher RA, Trussell J, Nelson AL, et al. Contraceptive Technology: 20th revised edition. New York: Ardent Media; 2011.
5. Deokar AM, Jackson W, Omar HA. Menstrual bleeding patterns in adolescents using etonogestrel (ENG) implant. *Int J Adolesc Med Health* 2011; 23(1):75-77. ■

Reproductive health and sexual services eyed

ARHP project to address access and availability

Increasing the capacity of U.S. clinicians to provide high quality sexual and reproductive health (SRH) care for all Americans is an urgent public health priority, and proponents are working fast to implement new strategies to meet the need.

Most of the patients receiving SRH services in the United States are cared for by teams of providers, which include such personnel as front office staff, clinical support staff, and the administrative team, as well as clinicians. Most SRH clinical services are not provided by physicians. Most providers are nurses, advanced practice registered nurses, nurse-midwives, physician assistants, and pharmacists. At the present time, there is no universal access to all of these potential providers. This lack of universal access limits efforts to reduce rates of unintended pregnancy and sexually transmitted infections, as well as to provide quality sexual and reproductive healthcare.

With the expected addition of 30 million newly insured patients to the primary care system under the Affordable Care Act (ACA), the U.S. health system will need additional clinicians trained to provide a broad range of sexual and reproductive health services. To be effective, all members of the interprofessional primary care team will need to provide or support evidence- based and competency-based sexual and reproductive health care to women and men.

Current primary care systems and the clinicians who work within them are not adequately prepared to meet this demand with efficient, comprehensive, high quality sexual and reproductive health care. Recognizing the urgent need for collective action, the Association of Reproductive Health Professionals (ARHP) developed the Sexual and Reproductive Health Workforce Project in collaboration with dozens of other non-profit, foundation, and agency partners.

The project's purpose is to increase the availability of and access to high quality sexual and reproductive health care in the United States. According to **Joyce Cappiello**, PhD, FNP-BC, co-chair of the SRH Workforce Project's expert advisory committee, "The changes put into place through the ACA give our field an opportunity and a sense of urgency to more fully integrate SRH into primary care."

Summit leads charge

Current primary care systems and the clinicians who support work within them are not adequately prepared to meet this demand with efficient, comprehensive, high quality sexual and reproductive health care. Recognizing the urgent need for collective action, the Association of Reproductive Health Professionals (ARHP) developed the Sexual and Reproductive Health Workforce Project in collaboration with dozens of other non-profit, foundation, and agency partners. The Project's purpose is to increase the availability of and access to high quality sexual and reproductive health care in the United States.

To gain perspective on the challenge, a Sexual and

EXECUTIVE SUMMARY

With the expected addition of 30 million newly insured patients to the primary care system under the Affordable Care Act, the U.S. health system will need additional clinicians trained to provide a broad range of sexual and reproductive health services.

- To be effective, all members of the interprofessional primary care team will need to provide or support evidence-based and competency-based sexual and reproductive health care to women and men.
- The Association of Reproductive Health Professionals, in collaboration with other non-profit, foundation, and agency partners, has developed the Sexual and Reproductive Health Workforce Project. The project's purpose is to increase the availability of and access to high-quality sexual and reproductive health care in the United States.

Reproductive Health Workforce Summit was held in January 2013. It included 40 experts from clinical practice, academia, medical societies, agencies, donors, and advocacy groups.

Summit participants were charged with developing recommendations to align and improve SRH health pre-licensure education, continuing professional development, and service delivery in the United States.

Recommendations include the following:

- Enhance SRH health professional education.
- Enhance SRH continuing professional development.
- Implement quality measures and standards for SRH care.
- Create incentives to expand and diversify the SRH workforce.
- Create incentives to optimize patient access to care.
- Develop a marketing/media campaign to reach out to advocacy groups to raise awareness of the importance of access to SRH care.

Three groups formed

Three working groups are now focused on putting the sworkshop's ummit's goals into action. The first working group is charged with defining SRH core competencies across key health professions, including advanced practice nurses, primary care physicians, physician assistants, pharmacists, and registered nurses. Group members will work with educational experts in key professions to identify curricular resources to enhance training in SRH core competencies across professions, conduct gap analyses, and disseminate findings to educational organizations.

The second working group is charged with developing an inter-professional National SRH Training Network. Group members will leverage existing training sites and networks to develop shared, interprofessional training, education, and simulation centers for SRH training. These sites may include Area Health Education Centers, community health centers, Title X and Planned Parenthood training centers, and academic centers.

Many federal groups, including the Interprofessional Education Collaborative, the Institute of Medicine, and the Health Resources and Services Administration, have identified interprofessional education and collaborative practice as a priority. In the initial workshop, the expert panel defined "team" to include all professionals working in a healthcare setting, including clinicians, medical assistants, community service providers, administrators, and office staff as well as other clinical, management, and support staff. Education and training initiatives will be developed for all team members. To address a wide range of needs, project officials look to develop shared training sites and a "traveling trainers" network for didactic education, simulation technology, and hands-on training.

The third working group is focusing on implementing SRH quality and performance measures and standards. Priorities include the development of a measure suitable for use as a Healthcare Effectiveness Data and Information Set (HEDIS) and identification of strategies to collect SRH data using electronic health records. Financial incentives will be implemented to reflect SRH quality and performance measures.

Project officials also are looking at creating incentives to expand and diversify SRH workforce and optimize patient care. This step would include such strategies as expanding loan repayment for clinicians providing SRH care in areas of need, including Title X clinics and community health centers, addressing credentialing and regulatory barriers that limit the SRH scope of practice, and identifying and evaluating creative models to enhance access to SRH services, such as co-locating SRH clinicians in primary care settings and creating integrated systems of referral, services, and electronic health records that facilitate care coordination and seamless or integrated referral for SRH services.

Officials also look to engage with insurers to determine what evidence or policies would move them to support providing SRH in primary care. Finally, Summit experts recommended that ARHP work with the field to compile existing resources into an open access, central repository for general use.

"All members of the healthcare team, including all of the professional organizations that represent them, can benefit from an easily accessible database of tools and resources in sexual and reproductive health," says Cappiello.

Get involved

What is the next step? Project officials are looking to convene expert project teams representing the field for each initiative to advance work and map out strategies for continued progress. *(See the guest column by **Diana Taylor**, RNP, PhD, FAAN, summit participant, on the importance of the project, p. 103.)*

Efforts also are being made to engage with key constituencies and partners to identify synergies and develop specific strategies for action. Officials are looking at organizations and alliances already working in key areas of SRH, the ACA, primary care, and training and certification. An emphasis will be

made on organizations with ties to state-level activity, in recognition that the ACA will be implemented largely at the state level. Melissa Nothnagle, MD, SRH Workforce Project co-chair, said, "It is essential that this effort be truly inclusive and involve the entire workforce to be effective. This is not about reinventing the wheel. It is about being truly collaborative, efficient, and goal-directed as a field."

Innovative demonstration projects will be identified to support their adaptation, evaluation, and expansion. Mechanisms will be developed to ensure alignment of efforts across SRH education, training, and service delivery.

How can programs get involved? Creative service delivery strategies, relevant activities comments, suggestions, and questions to should be submitted via e-mail to SRHWorkforce@arhp.org. ARHP will continue to act as a clearinghouse of teaching-learning resources through its Curricula Organizer for Reproductive Health Education (CORE), an online collection of peer-reviewed, evidence-based teaching materials. (To access CORE material, visit the ARHP web site, www.arhp.org, and click on the CORE icon.)

Wayne Shields, ARHP president and CEO, says, "If you have produced high quality SRH educational materials, we encourage you to go to http://core.arhp.org/submit and submit them for inclusion so that they can be made widely available to others." ■

GUEST COLUMN

We should work together on SRH care – Here's why

By **Diana Taylor**, RNP, PhD, FAAN
Professor Emerita, University of California, San Francisco (UCSF) School of Nursing
Faculty, Research & Evaluation, UCSF Primary Care Initiative
Advancing New Standards in Reproductive Health Program (ANSIRH)
UCSF Bixby Center for Global Reproductive Health
San Francisco

Integrating sexual and reproductive health (SRH) into public health and primary care is one of those vexing problems: complex, multifaceted, and requiring disparate groups to work together to develop strategies and policy activities that align pre-licensure SRH education, continuing professional development, and service delivery for all healthcare professionals within an integrated primary healthcare framework.

Although the integration of SRH practice and education has lagged behind other specialty and population care guidelines such as gerontology, public health, genetics/genomics, and interprofessional practice, there are several global and national recommendations and models in action to guide us.

Over the past 20 years, several national commission reports have focused on the future of health professions education. More recent reports have focused specifically on primary care, public health, population-based health, as well as women's preventive services, including gender-based services under the 2010 Affordable Care Act. Specific to SRH services, the World Health Organization published standards and core competencies based on a foundation of public health and primary care; and in the United States, a new report out of the RAND Corp. recommends policy interventions to align SRH practice, education, and credentialing to address workforce needs.[1-3]

SRH care is sometimes narrowly thought of as maternal-child health, family planning, or women's healthcare. However, to produce optimal health outcomes, many experts believe SRH care should include the reproductive health of men and women throughout their lifespan, and adolescents of both sexes. Under a definition accepted by the World Health Organization and implemented in several national health systems, a minimum package of SRH care would include preconception care, contraception, pregnancy and unplanned pregnancy care, women's health/common gynecology care, genitourinary conditions of men, assessment of specialty gynecology problems including infertility, and sexual health promotion. These services would be delivered within a system of public health and primary care services accessible to all with a focus on eliminating health disparities.

Looking to global and national models for how to make real and lasting change for what seem to be intractable problems, we now have a roadmap and recommendations for specific actions. These transformative paradigms can move us beyond our current siloed, competitive, and inefficient systems of education and practice. Interprofessional collaboration is today's buzz term, yet this is what is urgently needed. No one profession can accomplish this alone.

The SRH Workforce Summit brought together a diverse group of organizations and individuals committed to developing and implementing new ways to

prepare future clinicians. By expanding skills within the existing workforce in primary care, incorporating SRH into new models of healthcare delivery and reimbursement, and leveraging the existing expertise of SRH health professionals to improve delivery of sexual and reproductive health care, we can bring SRH care into reality for all Americans.

REFERENCES

1. World Health Organization. Sexual and Reproductive Health Core Competencies in Primary Care: Attitudes, Knowledge, Ethics, Human Rights, Leadership, Management, Teamwork, Community Work, Education, Counselling, Clinical Settings, Service, Provision. Geneva: World Health Organization, 2011. Accessed at: http://bit.ly/12mvyme.
2. World Health Organization. The Role of Primary Health-Care Providers in Sexual and Reproductive Health: Results from an Intercountry Survey (Supplement 1). Geneva: World Health Organization, 2011b. Accessed at: http://bit.ly/1abCvIz.
3. Auerbach DI., Pearson ML, Taylor D, et al. Nurse Practitioners and Sexual and Reproductive Health Services: An Analysis of Supply and Demand. Santa Monica, CA: RAND Corp., 2012. Accessed at: http://bit.ly/14JewOE. ■

New intrauterine device now is in research

An experimental levonorgestrel 20 mcg intrauterine device (LNG20 IUD) is under development by Medicines360, a San Francisco-based nonprofit pharmaceutical company. The company recently entered into a partnership with Actavis (formerly Watson Pharmaceuticals), a Parsippany, NJ-based pharmaceutical company, with an eye to allow Medicines360 to make the IUD available at a low price to U.S. public sector clinics. Should the device be approved by the Food and Drug Administration, the IUD could be launched in the United States as early as 2014.

The Phase 3 clinical trial of the Medicines360 IUD began in 2009. Its enrollment is complete; however the study is ongoing and is projected to conclude in 2018, says **Victoria Hale**, PhD, founder and president of Medicines 360. A total of 27 sites are participating in the study, which is designed as a randomized, multi-center, open-label study comparing the Medicines360 20 mcg levonorgestrel-releasing intrauterine system and the currently available Mirena IUD (Bayer HealthCare Pharmaceuticals, Wayne, NJ) for long-term, reversible contraception up to five years.

As part of its agreement with Medicines360, Actavis has licensed the U.S. commercial rights for the LNG20 IUD, while Medicines360 retains rights to market the product in the U.S. public sector, including family planning clinics that provide services to low-income women.

Take a closer look

Originally developed by Uteron Pharma Operations of Liege, Belgium, the LNG20 IUD consists of a T-shaped polyethylene frame with a steroid reservoir around its vertical stem. Its steroid reservoir is covered with a polydimethylsiloxane membrane that controls the release rate of levonorgestrel from the reservoir, and a polypropylene monofilament blue thread is attached to the end of its vertical stem. The device's reservoir contains 52 mg levonorgestrel, which provides a daily release rate of 20 mcg.

European researchers compared the safety and efficacy of the LNG20 and the Mirena IUDs in a 12-month study for treatment of menorrhagia. A total of 280 women with menorrhagia were recruited at 15 European sites to conduct the study. Women with a mean blood loss per cycle of at least 80 ml over three baseline cycles were randomized in a one-to-one ratio to LNG20 or Mirena. Patients were seen at weeks one, two, four, 13, 24, 38, and 52.

Mean change in blood loss for each individual from baseline was 150 ±85 ml for LNG20 users (n=108) and 152±105 ml for Mirena users (n=100), for a ratio of 0.99. Continuation rates were 88.7% (125/141) for LNG20 and 87.1% (121/139) for Mirena (p=.7). Expulsion rates were 4.3% (6/141)

EXECUTIVE SUMMARY

An experimental levonorgestrel 20 mcg intrauterine device, the LNG20 IUD, is under development by Medicines360, a San Francisco-based nonprofit pharmaceutical company. The device's Phase 3 clinical trial began in 2009. It is projected to conclude in 2018.

- The company recently entered into a partnership with Actavis (formerly Watson Pharmaceuticals), a Parsippany, NJ-based pharmaceutical company, with an eye to allow Medicines360 to make the IUD available at a low price to U.S. public sector clinics.
- Should the device be approved by the Food and Drug Administration, the IUD could be launched in the United States as early as 2014.

and 3.6% (5/139), respectively (p=.8). One pregnancy, after device expulsion, occurred in the LNG20 group, and no pregnancies occurred in the Mirena group. The incidence of adverse events was similar between groups. Only one reported serious adverse event (bilateral ovarian cysts), reported in a LNG20 subject, was considered possibly related to device use. The two devices have similar safety and efficacy profiles when used for treatment of menorrhagia, researchers conclude.[1]

In a planned substudy of the menorrhagia trial, the LNG20 and Mirena produced equivalent plasma levonorgestrel levels in women with menorrhagia over the first six months of use.[2] A study that compared the in vitro release rates of LNG20 and the Mirena also was performed. Scientists looked at the release rate performance of seven LNG20 and seven Mirena devices, each with a reservoir length of 20 mm surrounded by a release rate controlling membrane, in an in vitro diffusion test in sink conditions for approximately three years. The in vitro release rates were found to be similar over three years, data indicates.[3]

Meeting a need

Intrauterine devices in general have been shown to be a very effective contraceptive, but they have been too expensive for most women, says Hale. Medicines360's motivation is to provide access to effective birth control options regardless of a person's income, Hale said in a press statement announcing the corporate partnership.

"Actavis shares our vision of a world in which a woman's access to birth control is not compromised by lack of education, product availability or price," Hale stated. "Having control over if and when she becomes pregnant empowers a woman to make choices that positively impact her life and the lives of others."

By leveraging Actavis' expertise in development, distribution, and manufacturing, Medicines360 is better prepared to address a primary unmet healthcare need for many American women, Hale noted. If more women could switch to long-acting reversible contraceptives (LARCs), such as intrauterine contraception, impact could be made on unintended pregnancy, according to a recently published study. It evaluated the total costs of unintended pregnancy in the United States from a third-party healthcare payer perspective. If 10% of U.S. women ages 20-29 switched from oral contraception to LARCs, total costs would be reduced by $288 million per year, the study found.[4]

REFERENCES

1. Gordenne V, Wijzen F, Foidart J-M, et al. Comparison of LNG20, a new levonorgestrel intrauterine system, and Mirena for treatment for menorrhagia. *Contraception* 2010; 82:213.
2. Gordenne V, Wijzen F, Foidart J-M, et al. Comparison of LNG20, a new levonorgestrel intrauterine system, and Mirena for treatment for menorrhagia. *Contraception* 2010; 82:193.
3. Wijzen F. Levonorgestrel release rates with LNG20, a new levonorgestrel intrauterine system, and Mirena. *Contraception* 2010; 82:193.
4. Trussell J, Henry N, Hassan F, et al. Burden of unintended pregnancy in the United States: potential savings with increased use of long-acting reversible contraception. *Contraception* 2013; 87:154-161. ■

Teen births decline — What's behind the drop?

Good news: Recent data from the Centers for Disease Control and Prevention (CDC) show that teen birth rates fell at least 15% for all but two states (North Dakota and West Virginia) during 2007-2011, with rates falling 30% or more in seven states: Arizona, Colorado, Florida, Idaho, Minnesota, Nevada, and Utah.[1] *(See box on p. 106 for overview.)*

Declines were steepest for Hispanic teens (34%), followed by declines of 24% for non-Hispanic black teens and 20% for non-Hispanic white teenagers.

Public health emphasis has been placed on teen pregnancy prevention, because infants born to adolescents are at elevated risk of low birth weight, preterm birth, and dying in infancy, compared with infants born to women ages 20 and over.[2-4] Teen births are

EXECUTIVE SUMMARY

New data shows that teen birth rates fell at least 15% for all but two states (North Dakota and West Virginia) during 2007-2011, with rates falling 30% or more in seven states: Arizona, Colorado, Florida, Idaho, Minnesota, Nevada, and Utah.

- Declines were steepest for Hispanic teens (34%), followed by declines of 24% for non-Hispanic black teens and 20% for non-Hispanic white teens.
- Public health emphasis has been placed on teen pregnancy prevention, because infants born to adolescents are at elevated

risk of low birth weight, preterm birth, and dying in infancy, compared with infants born to women ages 20 and over.

associated with significant public costs, estimated at $10.9 billion annually.[5]

Teen birth rates dropped for all racial and ethnic groups, but fell the most among Hispanic teens: from 75.3 per 1,000 in 2007 to 49.4 per 1,000 in 2011. For Hispanic teens, analysts believe their behavior might be aligning more closely with their views of teen pregnancy. According to a 2009 national survey, three-quarters of Hispanic teens ages 16-19 called teen pregnancies "a bad thing for society," and seven in ten (69%) agreed that becoming a teen parent prevents people from reaching their goals in life. Among young adults, ages 18-25, 76% of Hispanics called teen pregnancies bad for society, versus 90% of all 18- to 25-year-olds.[6]

Decline resumes

The new report reflects a resumption of a downward trend in teen births that began in 1991, but was briefly interrupted in 2006 and 2007. What might be some of the potential factors that led to this return to declining numbers?

One of the nation's great success stories of the past two decades has been the "truly extraordinary" declines in teen pregnancy and childbearing, says **Sarah Brown**, chief executive officer of the Washington, DC-based National Campaign to Prevent Teen and Unplanned Pregnancy. She sees the slight uptick in the teen birth rate in 2006 and 2007 as perhaps an aberration in an otherwise uninterrupted period of progress.

Even taking into account the mid-2000s increase, teen childbearing has been cut nearly in half nationally, says Brown. There has been significant progress among all racial/ethnic groups, and all 50 states have posted impressive declines, she notes. "Simply put, the magic formula of less sex and more contraception has driven down the rates of too-early pregnancy and parenthood over the past 21 years," states Brown.

Although pinpointing the reasons why teens have become more careful is not easy, Brown outlines some possible explanations:

- Women in general are having fewer children and having them later in life. Teens might be mirroring older women's overall shift toward lower birth rates.
- The declines in teen births might be explained in part by the power of positive peer influence. As more teens delay having sex, as more sexually active teens use contraception, as teen pregnancy and birth rates continue to plummet, teens' behavior is probably being shaped in part by what is, or is not, happening around them, says Brown.
- Teens now have more birth control options than ever before and more effective methods as well. Methods such as the intrauterine device are nearly 100% effective and don't require a game-time decision to use them, notes Brown.

"The declines in the past five years have been particularly steep — a time that coincides with a severe economic downturn," Brown points out. "As the recession kicked in, it may also be that more teens were somewhat sobered by the economic reality around them."

Ease of access to contraception is an important factor in driving down teen pregnancy, says **Robert Hatcher**, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta. The success of the Contraceptive CHOICE Project proves this point, says Hatcher. The project was a prospective cohort study providing reversible contraception at no cost to 10,000 women ages 14-45 in the St. Louis area. It was designed to evaluate method satisfaction and continuation and to reduce unintended pregnancies in the region. Data from the project shows that the rate of teen birth within the CHOICE cohort was 6.3 per 1,000, compared with the U.S. rate of 34.3

Take a closer look at declines in teen birth

- Declines in teen birth rates from 2007 through 2011 generally were largest in the Southeast, Mountain, and Pacific areas, and in the upper Midwest.
- Rates fell at least 30% in seven states during 2007–2011: Arizona, Colorado, Florida, Idaho, Minnesota, Nevada, and Utah. Rates in Arizona and Utah declined the most: 35% each.
- The smallest declines, ranging from 15% to 19%, were reported in Arkansas, Indiana, Kansas, Kentucky, Louisiana, Michigan, Montana, New York, Pennsylvania, Oklahoma, South Dakota, and the District of Columbia.
- Changes were not significant in just two states: North Dakota and West Virginia.

Source: Hamilton BE, Mathews TJ, Ventura SJ. Declines in state teen birth rates by race and Hispanic origin. *NCHS Data Brief, No. 123.* Hyattsville, MD: National Center for Health Statistics. 2013.

per 1,000.[7] This represents about an 82% drop, notes Hatcher. *(To read more about the project, see the* Contraceptive Technology Update *articles "The 'Get It and Forget It' methods are here: Remove obstacles to use," April 2012, p. 37; "Research proves LARC methods are best — What happens now in practice?" July 2012, p. 85; and "Abortion rates fall with free contraception," December 2012, p. 136.)*

Whatever the underlying explanations for the current national decline in births, the bottom line is that teens get the credit for the progress, reflects Brown. Be sure to give adolescents the credit, says Brown.

"The next time you're with a teen, how about saying a simple `thank you'?" she states.

REFERENCES

1. Hamilton BE, Mathews TJ, Ventura SJ. Declines in state teen birth rates by race and Hispanic origin. *NCHS Data Brief, No. 123*. Hyattsville, MD: National Center for Health Statistics. 2013.
2. Martin JA, Hamilton BE, Ventura SJ, et al. Births: Final data for 2010. *National Vital Statistics Reports 2012*; 61(1). Hyattsville, MD: National Center for Health Statistics.
3. Martin JA, Osterman MJK, Sutton PD. Are preterm births on the decline in the United States? Recent data from the National Vital Statistics System. *NCHS Data Brief, No. 39*. Hyattsville, MD: National Center for Health Statistics. 2010.
4. Mathews TJ, MacDorman MF. Infant mortality statistics from the 2009 period linked birth/infant death data set. *National Vital Statistics Reports 2013*; 61(8). Hyattsville, MD: National Center for Health Statistics.
5. The National Campaign to Prevent Teen and Unplanned Pregnancy. Counting it up: the public costs of teen childbearing. Fact sheet. Accessed at http://bit.ly/184ld2v.
6. Pew Hispanic Center. Between Two Worlds: How Young Latinos Come of Age in America. Washington, DC; 2009.
7. Peipert JF, Madden T, Allsworth JE, et al. Preventing unintended pregnancies by providing no-cost contraception. *Obstet Gynecol* 2012; 120(6):1,291-1,297. ■

COMING IN FUTURE MONTHS

- Research eyes estetrol oral contraceptive
- Nomegestrel pill now in clinical trials
- What's in store for vaginal ring development?
- Progestin-only patch for contraception?

CNE/CME OBJECTIVES & INSTRUCTIONS

To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

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.

CNE/CME QUESTIONS

1. According to the U.S. Selected Practice Recommendations for Contraceptive Use, 2013, a woman with an intrauterine device (IUD) who develops pelvic inflammatory disease
   A. Should have the IUD removed immediately and be treated with antibiotics.
   B. Should be given antibiotics, clinically reassessed in two to three days, with IUD removed if no improvement and antibiotics continued.
   C. Should be immediately hospitalized with intravenous antibiotics administered.
   D. Should be given antibiotics, and should be clinically reassessed in one week.

2. What is the daily release rate of the intrauterine device under development by Medicines360?
   A. 10 mcg
   B. 15 mcg
   C. 20 mcg
   D. 25 mcg

3. According to recent research in NCHS data brief, no. 123. (2013), the sharpest declines in teen births were among
   A. Non-Hispanic black teens
   B. Non-Hispanic white teens
   C. Asian or Pacific Islander teens
   D. Hispanic teens

4. According to the Journal of Infectious Diseases (2013; Doi: 10.1093/infdis/jit192), vaccine-type HPV prevalence has decreased by how much among U.S. females ages 14-19?
   A. 56%
   B. 60%
   C. 75%
   D. 80%

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 healthcare professionals.