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Research adds more insight into newer OCs and risk of VTE

Results from two United Kingdom population-based, case-control nested studies using two large primary care databases indicate risks of venous thromboembolism (VTE) associated with combined oral contraceptives were, with the exception of norgestimate, higher for newer drug preparations than for second generation drugs.[1]

To examine the association between use of combined oral contraceptives and VTE risk, researchers from the University of Nottingham in England used prescription data from the Clinical Practice Research Datalink and QResearch primary care database to measure the associations between use of combined oral contraceptives and risk of VTE in women ages 15-49, adjusting for other known risk factors. Women ages 15-49 with a first diagnosis of VTE in 2001-2013 were each matched with up to five controls by age, practice, and calendar year.

... WOMEN STARTING PILLS OR RESTARTING AFTER A PERIOD OF NO USE SHOULD BE TAUGHT THE PILL WARNING SIGNALS ... — ROBERT HATCHER, MD, MPH

The main outcome measures were odds ratios for incident VTE and use of combined oral contraceptives in the previous year, adjusted for smoking status, alcohol consumption, ethnic group, body mass index, comorbidities, and other contraceptive drugs. Results were combined across the two datasets.

In all, 5,062 cases of VTE from the Datalink and 5,500 from the QResearch database were analyzed. Current exposure to any combined oral contraceptive was associated with an increased risk of VTE (adjusted odds ratio 2.97, 95% confidence interval 2.78 to 3.17) compared with no exposure in the previous year. Corresponding risks associated with current exposure to desogestrel (4.28, 3.66 to 5.01),

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gestodene (3.64, 3.00 to 4.43), drospirenone (4.12, 3.43 to 4.96), and cyproterone (4.27, 3.57 to 5.11) were significantly higher than those for second generation contraceptives with levonorgestrel (2.38, 2.18 to 2.59), norethisterone (2.56, 2.15 to 3.06), and norgestimate (2.53, 2.17 to 2.96). The number of extra cases of VTE per year per 10,000 treated women was lowest for levonorgestrel (6, 95% confidence interval 5 to 7) and norgestimate (6, 5 to 8), and highest for desogestrel (14, 11 to 17) and cyproterone (14, 11 to 17).[1]

"This is the largest study to date to investigate risk of thrombosis for different types of combined oral contraceptive drugs using the two largest UK primary care databases," said lead author **Yana Vinogradov**a, MSc, a research statistician in the Faculty of Medicine & Health Sciences at the University of Nottingham, in a release accompanying the report. "We hope the results, in due course, will help doctors with prescribing decisions."

Professor **Julia Hippisley-Cox**, MD, a co-author on the research paper and a general practitioner at the University, noted, "We have found a higher risk of thrombosis for some newer types of oral contraceptive pill in this research project. However, to put this in perspective, the risk is lower than the risk of thrombosis which naturally occurs during pregnancy."

Hippisley-Cox said there is "no suggestion that women should stop or change their treatment without medical advice since this could have undesirable consequences such as an unplanned pregnancy." Instead, patients with concerns should discuss alternatives with their providers at their next routine appointment, she stated.

Look at the risks

The UK researchers estimated that use of levonorgestrel and norgestimate resulted in six extra cases of VTE each year per 10,000 treated women ages 15-49 and seven extra cases for women ages 25-49. Desogestrel and cyproterone each contributed 14 additional cases of VTE each year per 10,000 treated women ages 15-49, and drospirenone, desogestrel, and cyproterone each contributed to an extra 17 cases of VTE each year per 10,000 women ages 25-49.

In an accompanying editorial, **Susan Jick**, DSc, MPH, director of the Boston Collaborative Drug Surveillance Program at Boston University School of Medicine and professor of epidemiology at the Boston University School of Public

EXECUTIVE SUMMARY

Results from two United Kingdom population-based, case-control nested studies using two large primary care databases indicate risks of venous thromboembolism associated with combined oral contraceptives were, with the exception of norgestimate, higher for newer drug preparations than for second generation drugs.

- Data from the study indicate a higher risk of thrombosis for some newer type of oral contraceptive pills; however, the risk is lower than the risk of thrombosis that naturally occurs during pregnancy, researchers note.
- There is no suggestion that women should stop or change their current pill prescriptions without medical advice, the researchers note.

Health in Lexington, writes that the current study "addresses important questions about the risk of venous thromboembolism in women taking oral contraceptives, concluding that the risk is around twofold higher than the risk associated with older contraceptives."[2] Jick was lead author of one of two 2011 case-control studies that suggested that women without risk factors for VTE who use pills containing drospirenone have an increased risk for nonfatal VTE compared with those who use levonorgestrel pills.[3,4]

Valerie Beral, FRCOG, FMedSci, professor of epidemiology and co-director of the Cancer Epidemiology Unit at the University of Oxford in England, in a statement, said, "There is nothing new about these findings — they just confirm what we have known for more than two decades now. The MHRA [Medicines and Healthcare Products Regulatory Agency] have prescribing guidelines directly relevant to the issue, which already incorporate previous evidence, and which were updated quite recently." *(Review the February 2014 guidance at http://bit.ly/1F11uuw.)*

Even though the relative risk of thrombosis with oral contraceptives is increased, pill users face a low absolute risk because VTE is a rare event.[5] The incidence rate in reproductive-age women is half the rate reported for women of all ages.[6] The VTE risk during pregnancy is 98.5 per 100,000 women-years, but rises to 511.2 per 100,000 women-years in the postpartum period.[7]

In a 1999 study of 46,000 women, half of whom were using oral contraceptives at recruitment, pills seem to have their main effect on mortality while they are being used and in the 10 years after use ceases.[8] Ten or more years after use ceases, mortality in past users is similar to that in never users, data indicate.

PILL WARNING SIGNS FOR WOMEN: ACHES

Abdominal pain
- Blood clot in pelvis or liver
- Benign liver tumor or gallbladder disease
- Pregnancy in your tubes

Chest pain
- Blood clot in the lungs
- Heart attack
- Angina (heart pain)
- Breast lump

Headaches
- Stroke
- Migraine headache, blurred vision, spots, zigzag lines, weakness, difficulty speaking
- High blood pressure

Eye problems
- Stroke
- Blurred vision, double vision, or loss of vision
- Migraine headache, blurred vision, spots, zigzag lines
- Blood clots in the eyes
- Change in shape of cornea (contacts don't fit)

Severe leg pain
- Inflammation and blood clots of a vein in in the leg

Source: Nelson AL, Cwiak C. Combined oral contraceptives. In: Hatcher RA, Trussell J, Nelson AL, et al. *Contraceptive Technology*: 20th revised edition. New York: Ardent Media; 2011.

What does the *U.S. Medical Eligibility Criteria for Contraceptive Use* (*U.S. MEC*) say about use of combined pills and VTE?[9]

For women with acute DVT/pulmonary embolism (DVT/PE) or previous DVT/PE, who are not on anticoagulant therapy and have risk factors for recurrence, combined pills are classed as Category 4 (unacceptable risk). If women have previous DVT/PE with no risk factors for recurrence, use is classed as Category 3 (theoretical or proven risks usually outweigh the advantages of using the method).

In 2011, the Centers for Disease Control and Prevention updated its recommendations to state that postpartum women should not use combined hormonal contraceptives during the first 21 days after delivery because of high risk for VTE during this period. During days 21-42 postpartum, women without risk factors for VTE generally can initiate combined hormonal contraceptives. Women with risk factors for VTE, such as VTE or recent cesarean delivery, generally should not use these methods. After 42 days postpartum, no restrictions on the use of combined hormonal contraceptives based on postpartum status apply.[10]

Robert Hatcher, MD, MPH, professor emeritus of gynecology and

obstetrics at Emory University School of Medicine in Atlanta, offers these comments about combined pill use:

First, tobacco smoking increases the risk of VTE, especially in young combined pill users who are heavy smokers.[5] Smokers who are prescribed pills should be strongly encouraged to decrease or stop smoking.

Second, the risk of VTE with combined pills is greatest in the first 3-12 months of use and declines thereafter. For this reason, women starting pills or restarting after a period of no pill use should be taught the Pill warning signals, using the mnemonic ACHES. *(See box in this issue.)*

REFERENCES

1. Vinogradova Y, Coupland C, Hippisley-Cox J. Use of combined oral contraceptives and risk of venous thromboembolism: Nested case-control studies using the QResearch and CPRD databases. *BMJ* 2015; doi:10.1136/bmj.h2135.
2. Jick SS. Fresh evidence confirms links between newer contraceptive pills and higher risk of venous thromboembolism. *BMJ* 2015; doi:10.1136/bmj.h2422.
3. Jick SS, Hernandez RK. Risk of non-fatal venous thromboembolism in women using oral contraceptives containing drospirenone compared with women using oral contraceptives containing levonorgestrel: Case-control study using United States claims data. *BMJ* 2011; 342:d2151.
4. Parkin L, Sharples K, Hernandez RK, et al. Risk of venous thromboembolism in users of oral contraceptives containing drospirenone or levonorgestrel: Nested case-control study based on UK General Practice Research Database. *BMJ* 2011; 342:d2139.
5. Nelson AL, Cwiak C. Combined oral contraceptives. In: Hatcher RA, Trussell J, Nelson AL, et al. *Contraceptive Technology*: 20th revised edition. New York: Ardent Media; 2011.
6. Heinemann LA, Dinger JC. Range of published estimates of venous thromboembolism incidence in young women. *Contraception* 2007; 75(5):328-336.
7. Heit JA, Kobbervig CE, James AH, et al. Trends in the incidence of venous thromboembolism during pregnancy or postpartum: A 30-year population-based study. *Ann Intern Med* 2005; 143(10):697-706.
8. Beral V, Hermon C, Kay C, et al. Mortality associated with oral contraceptive use: 25 year follow up of cohort of 46,000 women from Royal College of General Practitioners' oral contraception study. *BMJ* 1999; 318(7176):96-100.
9. Centers for Disease Control and Prevention. U.S. medical eligibility criteria for contraceptive use. *MMWR* 2010; 59(RR04):1-6.
10. Centers for Disease Control and Prevention (CDC). Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Revised recommendations for the use of contraceptive methods during the postpartum period. *MMWR* 2011; 60(26):878-883. ■

New research indicates promise of nine-valent human papillomavirus vaccine

The recently approved nine-valent human papillomavirus (HPV) vaccine potentially can prevent 80% of cervical cancers in the United States if given to all 11- or 12-year-old children before they are exposed to the virus, results of a new seven-center study suggest.[1] The vaccine also has the potential to protect against approximately 19,000 other cancers diagnosed in the United States, including anal, oropharyngeal, and penile cancers, which is an 11.1% increase in protection against HPV-related cancers in comparison to the previously approved vaccines.[1]

The Food and Drug Administration approved Gardasil 9 from Kenilworth, NJ-based Merck Sharp & Dohme Corp., a subsidiary of Merck & Co, in December 2014. The vaccine covers nine HPV types: HPV 6 and HPV 11, the two low-risk types that cause most cases of genital warts, as well as seven high-risk types: HPV 16, 18, 31, 33, 45, 52, and 58. The new vaccine is administered as three shots, with the initial dose followed by additional shots given two and six months later. *(To read more about the vaccine, see the* STI Quarterly *supplement article, "New HPV vaccine covers 9 types of HPV," inserted in the March 2015 issue of* Contraceptive Technology Update.*)*

Details of study

The Centers for Disease Control and Prevention partnered with seven U.S. population-based cancer registries to obtain archival tissue for cancers diagnosed from 1993 to 2005. Scientists performed HPV testing on 2,670 case patients that were fairly representative of all participating cancer registry cases by age and sex. Researchers then evaluated demographic and clinical data by anatomic site and HPV status. Current U.S. cancer registry data and the detection of HPV types then were used

to estimate the number of cancers potentially preventable through vaccination.

The research is the first comprehensive study of its kind and shows the potential not only to reduce the global cancer burden, but also to guide clinical decision-making with regard to childhood vaccinations, according to **Marc Goodman**, PhD, MPH, senior author of the study and director of cancer prevention and genetics at the Cedars-Sinai Samuel Oschin Comprehensive Cancer Institute in Los Angeles.

The study data suggest the nine-valent vaccine has the potential to protect against an additional 5.7% of oropharyngeal cancers, which include the base of the tongue and tonsils. This disease is the second most common HPV-associated cancer. "We found that 70% of patient DNA tissue samples with cancer of the oropharynx harbored HPV," says Goodman. "This is a much higher percentage of HPV than observed in other studies, likely because of changes in sexual behaviors, such as increased oral-genital contact."

The vaccine also was found to potentially increase protection from other HPV-related cancers including those of the vulva (48.6% to 62.8%), vagina (55.1% to 73.3%), penis (47.9% to 56.9%), and anus (79.4% to 87.6%).

What is the next step?

What does Goodman see as the next step in research in determining how well the current vaccines protect against HPV-associated cancers?

"The overarching goal is to monitor the impact of the HPV vaccine on the incidence of invasive cervical cancer and its precursors (defined as carcinoma in situ, cervical intraepithelial neoplasia 2-3, and adenocarcinoma in situ) in the United States as the cohort of the vaccinated population ages and vaccination coverage increases," wrote Goodman in comments sent via email to *Contraceptive Technology Update*.

EXECUTIVE SUMMARY

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- The vaccine is administered as three shots, with the initial dose followed by additional shots given two and six months later.

5 recommendations

According to Goodman, recommendations for establishing an enhanced surveillance system include:

- systematically monitoring age-specific rates of invasive cervical cancer and other invasive HPV-associated carcinomas (which exists with the cancer registries). Other HPV-associated carcinomas include anal, penile, vulvar, vaginal, oropharyngeal, and oral cavity cancers.
- systematically monitoring age-specific rates of cervical cancer precursors and precursors for other HPV-associated cancers;
- identifying the distribution of HPV types, such as HPV-16 and HPV-18, associated with HPV-associated carcinoma precursors and invasive carcinoma;
- monitoring the incidence of invasive and preinvasive carcinomas along with the prevalence of vaccination. Linkages between cancer and immunization registries could provide data on the vaccine status of women with diagnoses of these cancers;
- explore and evaluate methods for linking cancer registry data with screening and risk factor data that already are being collected by other surveillance systems.

"Although some of the recommendations are existing activities, ultimately, the identified disparate resources need to be brought together under a single umbrella to maximize the utility of the aggregated information for public health surveillance," says Goodman.

How to boost rates

A new study that compared the initiation and completion of the HPV vaccine among women in two Michigan community-based networks with electronic health records indicates that patients ages 9 to 18 were almost three times more likely to start the vaccine and 10 times more likely to complete the series if their health providers received automated prompts alerting them patients were due for a shot during any appointment. Patients ages 19-26 were six times more likely to start the vaccine and eight times more likely to complete the series, data indicate.[2]

"We found that simply alerting patients and providers during an office appointment increased uptake and completion of the HPV vaccine series," said lead author **Mack Ruffin** IV, MD, MPH, professor of family medicine at the Ann Arbor-based University of Michigan Medical

School, in a statement accompanying the study publication. "Our findings suggest that these prompts through the electronic health system may be a valuable tool in encouraging more people to protect themselves from cancer."

REFERENCES

1. Saraiya M, Unger ER, Thompson TD, et al. US assessment of HPV types in cancers: Implications for current and 9-valent HPV vaccines. *J Natl Cancer Inst* 2015; doi: 10.1093/jnci/djv086.
2. Ruffin MT 4th, Plegue MA, Rockwell PG, et al. Impact of an electronic health record (EHR) reminder on human papillomavirus (HPV) vaccine initiation and timely completion. *J Am Board Fam Med* 2015; 28(3):324-333. ■

Time to change Medicaid sterilization wait period

U.S. health policy requires Medicaid beneficiaries to wait 30 days before tubal sterilization. In a journal analysis, national experts argue that this practice violates healthcare justice, as elective tubal sterilization is readily available to women with a private source of payment.[1]

In 2011–2013, 61.7% or 37.6 million of the 60.9 million women ages 15-44 in the United States were using a method of contraception; of that group, 15.5% relied on female sterilization, surpassed only by birth control pills (16%).[2] Tubal sterilizations are performed after 10% of all hospital deliveries.[3] Postpartum sterilization has the advantage of one-time hospitalization, which results in ease and convenience for the woman. Its efficacy and effectiveness was demonstrated in the U.S. Collaborative Review of Sterilization Study, a prospective multicenter observational study of more than 10,000 women undergoing transabdominal sterilization who were followed up to 14 years.[4] Postpartum partial salpingectomy had the lowest 5-year and 10-year cumulative pregnancy rates: 6.3 per 1,000 and 7.5 per 1,000 procedures, respectively.[4]

While elective tubal sterilization is readily available to women with a private source of payment, this situation is not the case for Medicaid beneficiaries who are required to wait 30 days, which can be impractical unless the paperwork is concluded well in advance of the birth, note authors of the current analysis.

"Regardless of who pays, the ethical and legal standard for the performance of elective tubal sterilization for permanent contraception for all patients is oral and written informed consent," stated **Lawrence McCullough**, PhD, a co-author of the analysis in a statement released with its publication. McCullough is the associate director for education and holder of the Dalton Tomlin Chair in Medical Ethics and Health Policy in the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, where he also is professor of medicine and medical ethics, professor of family and community medicine, and faculty associate of Baylor's Huffington Center on Aging.

Compulsory sterilization programs existed in the United States until the middle decades of the 20th Century. Initially, such programs targeted intellectually disabled and mentally ill patients. However, many African American women and deaf, blind, epileptic, physically deformed, and low-income women were sterilized against their will.[5] In 1979, U.S. federal legislation was enacted that aimed to enhance women's health rights by regulating the process of consent and documentation before receiving publicly funded surgical sterilization.

Amirhossein Moaddab, MD, lead author and visiting post-doctoral fellow in Baylor's Department of Obstetrics and Gynecology, noted, "The intent was good, but the unintended consequence four decades later is to restrict access based on source of payment. The reality of clinical practice is that nearly 50% of annual deliveries are paid for by Medicaid and therefore necessitate the signed federal consent form and waiting period."

EXECUTIVE SUMMARY

U.S. health policy requires Medicaid beneficiaries to wait 30 days before tubal sterilization. In a journal analysis, national experts argue that this practice violates healthcare justice, as elective tubal sterilization is readily available to women with a private source of payment.

- Postpartum sterilization has the advantage of one-time hospitalization, which results in ease and convenience for the woman. Its efficacy and effectiveness were demonstrated in the U.S. Collaborative Review of Sterilization (CREST) Study, a large, prospective multicenter observational study of more than 10,000 women undergoing transabdominal sterilization who were followed up to 14 years.
- In the CREST study, postpartum partial salpingectomy had the lowest 5-year and 10-year cumulative pregnancy rates: 6.3 per 1,000 and 7.5 per 1,000 procedures, respectively.

In the current analysis, the authors examine the concept of healthcare justice in professional obstetric ethics. They then explain how it originates in the ethical concepts of medicine as a profession and of being a patient, and they explore its deontologic and consequentialist dimensions. The deontologic or rule-based dimension judges the morality of an action based on its adherence to a rule or rules, while the consequentialist dimension judges the morality of an action on its consequences.

"We conclude that Medicaid policy allocates access to elective tubal sterilization differently, based on source of payment and gender, which violates health care justice in both its deontologic and consequentialist dimensions," said senior author **Frank Chervenak**, MD, Given Foundation Professor and chairman of the Department of Obstetrics and Gynecology at Weill Medical College of Cornell University in New York City. "Obstetricians should invoke health care justice in women's health care as the basis for advocacy for needed change in law and health policy, to eliminate health care injustice in women's access to elective tubal sterilization."

The Committee on Health Care for Underserved Women of the American College of Obstetrics and Gynecology issued a committee opinion in January that reviewed barriers to contraceptive access and offered strategies to improve access.[6] Revision of the federal consent mandate in order to create fair and equitable access to sterilization services for women enrolled in Medicaid or covered by other government insurance would improve access, the opinion states.[6]

REFERENCES

1. Moaddab A, McCullough LB, Chervenak FA, et al. Health care justice and its implications for current policy of a mandatory waiting period for elective tubal sterilization. *Am J Obstet Gynecol* 2015; doi:10.1016/j.ajog.2015.03.049.
2. Daniels K, Daugherty J, Jones J. *Current Contraceptive Status among Women Aged 15–44: United States, 2011–2013.* Hyattsville, MD: National Center for Health Statistics; 2014.
3. Kaunitz AM, Harkins G, Sanfilippo JS. Obstetric sterilization following vaginal or cesarean delivery: A technical update. *OBG Manage* 2008; 20:S1-S8.
4. Peterson HB, Xia Z, Hughes JM, et al. The risk of pregnancy after tubal sterilization: Findings from the U.S. Collaborative Review of Sterilization. *Am J Obstet Gynecol* 1996; 174(4):1161-1168; discussion 1168-1170.
5. Diekema DS. Involuntary sterilization of persons with mental retardation: An ethical analysis. *Ment Retard Dev Disabil Res Rev* 2003; 9(1):21-26.
6. Committee on Health Care for Underserved Women. Committee opinion no. 615: Access to contraception. *Obstet Gynecol* 2015; 125(1):250-255. ■

Research indicates text messages can aid adolescent adherence to contraceptive use

Sending teen girls periodic text messages reminding them to follow through on their clinic appointments for periodic birth control injections aids in improving timing and adherence to contraception, research indicates.[1]

According to a 2012 report from the Pew Research Center in Washington, DC, 63% of all teens said they exchange text messages every day with people in their lives.[2] Texting surpasses the frequency with which they pick other forms of daily communication, including:

- phone calling by cell phone (39%);
- face-to-face socializing outside of school (35%);
- social network site messaging (29%);
- instant messaging (22%);
- talking on landlines (19%);
- e-mailing (6%).

What do researchers see as some of the greatest strengths of text messaging when it comes to reaching adoles-

EXECUTIVE SUMMARY

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- According to a 2012 report from the Pew Research Center, 63% of all teens said they exchange text messages every day with people in their lives, which surpasses the frequency with which they pick other forms of daily communication.
- The strength of text messaging is that it is a low cost and highly acceptable form of communication that allows for person-based communication and support with young people, say researchers.

cents with important health messages?

Adolescents face significant health disparities, but they often have difficulty accessing the care and support that they need for management of health-related issues, says **Maria Trent**, MD, MPH, associate professor of pediatrics in the Division of General Pediatrics and Adolescent Medicine at Johns Hopkins School of Medicine in Baltimore. There are also practical barriers such as transportation, conflicts with school/extracurricular activities, and/or concerns about confidentiality that might undermine delivering location-based communication and services in clinics/medical offices, notes Trent, who serves as lead author of the current paper.

"Cell phone penetration across communities and populations (including adolescents) is high in the United States," wrote Trent in comments emailed to *Contraceptive Technology Update*. "The availability of low-cost cell phone plans with both texting and internet access have substantially narrowed the digital divide, making access to information and novel communication strategies feasible across clinical settings."

Positive aspects of texting

The strength of text messaging is that it is a low-cost and highly acceptable form of communication that allows for person-based communication and support with young people, notes Trent. It allows providers to meet adolescents where they are and to effectively communicate with them between visits, she states.

"Our research shows that in-person medical visits are critical for relationship building, but that youth are flexible in terms of using technology to obtain assistance with health maintenance and for sustaining relationships with health providers," says Trent.

Adolescents often send and receive text messages, spending hours each day with their phones, so by providing important health messaging via text messaging, providers are taking the messages to the adolescents, agrees **Jessica Fitts Willoughby**, PhD, assistant professor in the Edward R. Murrow College of Communication at Washington State University in Pullman. By using text messaging, it makes the process of receiving health information convenient and accessible for them, Willoughby states.

She conducted a study assessing whether teens at a greater risk for negative sexual health outcomes would use a sexual health text message service.[3] She looked at a text message service that connects teens with sexual health educators that was promoted in six public schools in North Carolina. Results indicated that teens most likely to benefit were also those most likely to use such a text message service.

"In some other research I have done with teens on text messaging services, they have said that cell phones are mostly private, with just them seeing the messages that they send and receive, and this can be highly relevant when it comes to health as well," states Willoughby. "Also, cell phones seem to allow for this greater feeling of anonymity, and that may help to mitigate some of the possible embarrassment adolescents experience when discussing certain health topics."

The site http://bedsider.org offers text message reminders for contraceptive users. Women can click on "your reminders" to set up reminders, or text "MyBC" to 42411 from a U.S.-based mobile phone.

Check the research

To perform the current study, Trent and researchers affiliated with Johns Hopkins Children's Center enrolled 100 Baltimore females, ages 13-21, who use the contraceptive injection depot medroxyprogesterone acetate (DMPA). Subjects enrolled in the study were followed for nine months.

One-half of the group received standard automated calls on their home phones as reminders of their upcoming appointment. The other half received personalized daily text messages starting three days prior to their monthly appointment, and they were asked to text back their responses. Young women enrolled in the mobile phone group also received periodic texts with tips on condom use to prevent sexually transmitted infections, suggestions for maintaining healthy weight, and messages urging them to call providers with questions or concerns.

What did researchers find? Overall, 87% showed up for the first of three injections, 77% completed the second cycle of shots, and 69% came to the clinic for the third and final injection.

Data indicate teens who received text-message reminders were more likely to show up for their contraceptive shots on time than those who received traditional reminders. Almost 70% of those in the text message group came in on time for their first appointment, compared to 56% in the traditional reminder group, with 68% of text message patients coming in on time for the second shot, compared with 62% of those in the traditional reminder group. The differences between the two groups dissipated by the third appointment, though, researchers note.[1]

REFERENCES

1. Trent M, Thompson C, Tomaszewski K. Text messaging support for urban adolescents and young adults using injectable contraception: Outcomes of the DepoText Pilot Trial. *J Adolesc Health* 2015; doi: 10.1016/j.jadohealth.2015.03.008.
2. Pew Internet and American Life Project. *Teens, Smartphones and Texting*. Accessed at http://pewrsr.ch/1fUaZVG.
3. Willoughby JF. BrdsNBz: Sexually experienced teens more likely to use sexual health text message service. *Health Educ Behav* 2015; doi: 10.1177/1090198115577377. ■

At least 20 insurers aren't offering Affordable Care Act's breastfeeding benefits

Breastfeeding rates continue to rise. In 2011, 79% of U.S. newborn infants started to breastfeed, according to the Centers for Disease Control and Prevention.[1] However, breastfeeding did not continue for as long as recommended. Data indicate that of infants born in 2011, 49% were breastfeeding at six months, and 27% were breastfeeding at 12 months.[1] Professional lactation support can help mothers initiate and continue breastfeeding, yet a new report shows that at least 20 insurance companies are not offering the Affordable Care Act's (ACA) breastfeeding benefits.[2]

The report was prepared by the Washington, DC-based National Women's Law Center (NWLC). It highlights troubling trends in insurance company compliance that are likely to be systemic nationwide, such as limiting coverage of breast pump purchases and failing to have lactation counselors in network.

Denying women certain breastfeeding benefits is a clear violation of the law, and women are experiencing the consequences every day, stated **Gretchen Borchelt**, NWLC vice president for health and reproductive rights.

"The Affordable Care Act has made dramatic improvements in women's health coverage," noted Borchelt. "If insurance companies fail to comply, they are illegally blocking further progress toward helping women breastfeed successfully."

What the law covers

According to a breastfeeding toolkit developed by the Center, the ACA calls for new health plans to cover breastfeeding equipment and supplies without cost-sharing "for the duration of breastfeeding." Plans may not apply any co-payment, co-insurance, or deductible to the benefits. *(You can download the toolkit and other resources at the web site http://bit.ly/1pw9hMw.)*

The terminology "breastfeeding equipment and supplies" most commonly refers to a breast pump and related accessories. Breast pumps often are used to express milk that can be stored after mothers have returned to work, are traveling, or have to be away from their breastfeeding child. Employers are required to provide a clean, private place for women to pump while on the job.

> IT HIGHLIGHTS TROUBLING TRENDS IN INSURANCE COMPANY COMPLIANCE THAT ARE LIKELY TO BE SYSTEMIC NATIONWIDE ...

According to the NWLC, while a health insurer must cover breastfeeding equipment and supplies, it can impose some requirements on this coverage, such as requiring a purchase, rather than rental, of a breast pump.

What the report found

In its new report, the NWLC assessed coverage of breastfeeding support and supplies by analyzing coverage offered on health insurance marketplaces during 2014 and 2015 in 15 states (Alabama, California, Colorado, Connecticut, Florida, Maine, Maryland, Minnesota, Nevada, Ohio, Rhode Island, South Dakota, Tennessee, Washington, and Wisconsin). It supplemented its review with real-life situations reported through the Center's CoverHer nationwide hotline [(866) 745-5487 or prevention@nwlc.org].

Analysts found that some insurance plans put unallowable limits on coverage, such as:

- allowing women to get lactation services only within two months of delivery;

EXECUTIVE SUMMARY

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- In 2011, 79% of U.S. newborn infants started to breastfeed. However, breastfeeding did not continue for as long as recommended. Data indicate that of infants born in 2011, 49% were breastfeeding at six months, and 27% were breastfeeding at 12 months.
- The new report, prepared by the National Women's Law Center, identifies at least 20 insurance companies that are not offering ACA breastfeeding benefits. It highlights troubling trends in insurance company compliance that are likely to be systemic nationwide, such as limiting coverage of breast pump purchases and failing to have lactation counselors in network.

• not covering a breast pump until after the baby is born;

• not allowing women to obtain breastfeeding services out-of-network without out-of-pocket costs when in-network services are not available.

The information from the NWLC CoverHer hotline was "crucial" in terms of understanding problems women are facing in obtaining coverage for breastfeeding benefits, says **Anna Benyo**, NWLC senior health policy analyst.

"Women report spending hours trying to get clear answers from their insurance companies or preparing an appeal," says Benyo, who served as lead author of the current report. "Our research found ACA violation in the plan documents themselves, and then women who contact our hotline verify that they encounter the same problems when they try to use their coverage. This on-the-ground information has been very helpful in documenting the state of breastfeeding coverage and in our advocacy efforts at the state and federal levels."

According to Benyo, the Center is working with government regulators who oversee insurance plans to ensure that they comply with the ACA legislation. "We want to make sure that insurance companies remove unallowable limits on coverage and create a network for women to access breastfeeding benefits at no cost-sharing, as required by law," states Benyo. "At the same time, we know federal guidance detailing breastfeeding coverage falls short of what women need to breastfeed successfully. At the federal level, we are advocating for better coverage standards."

REFERENCES

1. Centers for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion. Breastfeeding Report Card. United States/2014. Web: http://1.usa.gov/UNKkRy.
2. National Women's Law Center. State of breastfeeding coverage: Health plan violations of the Affordable Care Act. Web: http://bit.ly/1AyZqPv. ■

Are women getting screened for osteoporosis? Just-released research suggests answer is 'no'

Too few women at high risk for osteoporosis are being tested for the condition, while too many women at low risk are being screened, results of a California-based study suggest.[1]

As part of a University of California, Davis, research fellowship, **Anna Lee Amarnath**, MD, MPH, and a research team examined the electronic health records of some 51,000 women between the ages of 40-85 who received healthcare in the Sacramento region. The evaluation included osteoporosis risk factors and dual-energy X-ray absorptiometry (DXA), whether or not the women received a screening technique that measures bone mineral density. What prompted the team's inquiry into this subject?

"I was curious about whether or not guidelines for osteoporosis were being followed in clinics," says Amarnath. "The current recommendation is for screening to begin at age 65 for most women, or earlier for women with specific fracture risks."

Osteoporosis is a medical condition that causes bone density to diminish and fracture risk to increase. Since gender and age are the factors most associated with the disease, the U.S. Preventive Services Task Force recommends screening for women who are age 65 and older. Younger women with certain risk factors, such as a small body frame, a history of fractures, or taking medication that thins the bones, also should be screened.[2] *(See box with recommendations from the American College of Obstetricians and Gynecologists on when to screen women below age 65.)*

According to the data, in a seven-year period, more than 42% of eligible women between ages 65-74 were not screened, and neither were

EXECUTIVE SUMMARY

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• Researchers at University of California, Davis, examined electronic health records of some 51,000 women between ages 40-85 who received healthcare in the Sacramento region. The evaluation included osteoporosis risk factors and dual-energy X-ray absorptiometry, whether or not the women received a screening technique that measures bone mineral density.

• In a seven-year period, more than 42% of eligible women between ages 65-74 were not screened, and neither were nearly 57% of those older than 75. Researchers also found that 46% of low-risk women between ages 50-59 were screened, as were 59% of those ages 60-64 years without risk factors.

nearly 57% of those older than 75, despite the favorable cost-effectiveness of screening in these age groups. Researchers also found that 46% of low-risk women between ages 50-59 were screened, as were 59% of those ages 60-64 years without risk factors.[1]

Findings from previous studies indicate that many providers might not be adhering to Task Force recommendations. In studies of Medicare beneficiaries ages 65 and older, screening has been reported to be as low as 30% to 48% over a seven-year period.[3,4] Overuse of DXA screening in younger, lower-risk women has been a focus of the Choosing Wisely initiative, which was launched in 2012 to advance a national dialogue on avoiding wasteful or unnecessary medical tests, treatments, and procedures.[5]

Both the American Academy of Family Physicians and the American College of Physicians have included use of DXA screening in their top five lists of frequently misused diagnostic tests or treatments, and they advise primary care physicians not to perform DXA screening in women younger than age 65 without osteoporosis risk factors.[6]

What might aid providers in doing a better job with screening? Technology-based solutions could help, according to study senior author **Joshua Fenton**, MD, MPH, associate professor of family and community medicine at the University of California, Davis School of Medicine. "Alert fields in electronic health records systems can match current preventive care guidelines with risks," says Fenton. "Screening 'flags' or prompts can alert physicians when a specific test is recommended for a particular patient."

As an addition to screening, FRAX, a fracture risk assessment tool developed by the World Health Organization, can help to further predict a person's risk of bone fracture in the next 10 years. It can be used to determine if a patient is at high risk for fracture if her initial scan indicates low bone mass. The assessment tool is based on such risk factors as age, body mass index, history of fracture, daily alcohol intake, and whether or not a patient smokes, has rheumatoid arthritis, or any other secondary causes of osteoporosis. *(To learn more about the tool, visit its web site, http://bit.ly/1CjBfzJ.)*

When to Screen Bone Mineral Density in Women under Age 65

- Medical history of a fragility fracture
- Body weight less than 127 pounds
- Medical causes of bone loss (medications or diseases)
- Parental medical history of hip fracture
- Current smoker
- Alcoholism
- Rheumatoid arthritis

Source: American College of Obstetricians and Gynecologists. Osteoporosis. Practice Bulletin. *Obstet Gynecol* 2012; 120(3):718-734.

REFERENCES

1. Amarnath AL, Franks P, Robbins JA, et al. Underuse and overuse of osteoporosis screening in a regional health system: A retrospective cohort study. *J Gen Intern Med* 2015; doi: 10.1007/s11606-015-3349-8.
2. U.S. Preventive Services Task Force. Screening for osteoporosis: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2011; 154(5):356-364.
3. Curtis JR, Carbone L, Cheng H, et al. Longitudinal trends in use of bone mass measurement among older Americans, 1999–2005. *J Bone Miner Res* 2008; 23(7):1061-1067.
4. King AB, Fiorentino DM. Medicare payment cuts for osteoporosis testing reduced use despite tests' benefit in reducing fractures. *Health Aff (Millwood)* 2011; 30(12):2362-2370.
5. Good Stewardship Working Group. The "top 5" lists in primary care: Meeting the responsibility of professionalism. *Arch Intern Med* 2011; 171(15):1385-1390.
6. Cassel CK, Guest JA. Choosing wisely: Helping physicians and patients make smart decisions about their care. *JAMA* 2012; 307(17):1801-1802. ■

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- Sharpen your patient-centered counseling skills
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- Get up to speed on new STI treatment guidance

CONTRACEPTIVE TECHNOLOGY UPDATE®

CNE/CME INSTRUCTIONS

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CNE/CME QUESTIONS

1. What is the risk for venous thromboembolism during pregnancy?

A. 98.5 per 100,000 women-years
B. 150.4 per 100,000 women-years
C. 225.6 per 100,000 women-years
D. 511.2 per 100,000 women-years

2. What is the name of the recently approved nine-valent human papillomavirus (HPV) vaccine?

A. Cervarix 9
B. Gardasil 9
C. Certiva 9
D. Twinrix 9

3. According to the U.S. Collaborative Review of Sterilization Study, what were the 5- and 10-year cumulative pregnancy rates for postpartum partial salpingectomy?

A. 4.7 per 1,000 and 5.8 per 1,000 procedures
B. 5.2 per 1,000 and 6.4 per 1,000 procedures
C. 6.3 per 1,000 and 7.5 per 1,000 procedures
D. 7.3 per 1,000 and 8.5 per 1,000 procedures

4. What is the acronym for the fracture risk assessment tool developed by the World Health Organization to help to further predict a person's risk of bone fracture in the next 10 years?

A. OSTEO
B. BONE-X
C. BTEST
D. FRAX

CNE/CME OBJECTIVES

After reading *Contraceptive Technology Update*, the participant will be able to:

1. identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services;
2. describe how those issues affect services and patient care;
3. integrate practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts;
4. provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.