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INSIDE

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Check Your Clinical Practice for LARC Methods

Immediate postpartum placement offers safe, effective birth control

It is estimated that at least 70% of pregnancies in the first year postpartum are unintended.[1] What can family planning clinicians do to help decrease this number?

Both of the intrauterine devices (IUDs) and the contraceptive implant can provide safe, effective birth control. Postpartum use of such long-acting reversible contraceptive (LARC) methods now is recognized by the American College of Obstetricians and Gynecologists as a best practice because of their role in preventing rapid repeat and unintended pregnancy.[2] (Contraceptive Technology Update *reported on the move; see the January 2018 article, "Time to Update Your Knowledge of Long-acting Reversible Contraceptives," available at https://bit.ly/2rw9xCO.*) Postpartum insertion of the copper T380A IUD is supported by the package label, notes **Anita Nelson**, MD, professor and chair of the obstetrics and gynecology department at Western University of Health Sciences in Pomona, CA.

By receiving LARC insertions in the immediate postpartum period, women are assured of contraceptive protection following their hospitalization. Research indicates that many women, including those at highest risk of short interpregnancy intervals, have low rates of postpartum visit follow-up. It is estimated that 10-40% of women do not attend the postpartum visit, and 40-75% of women who plan to use an IUD postpartum do not obtain it.[3,4] Research indicates that typical-use pregnancy rates for LARC methods are lower when compared with those for oral contraceptives.[5]

New Data Offer IUD Insight

Results of a just-released study of women who received a postplacental copper T-380A IUD within 10 minutes

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after vaginal or cesarean delivery suggest that women are more likely to retain the device after cesarean delivery.[6] However, the data indicate that women who have an IUD placed after cesarean delivery are more likely to have nonvisible strings with a pelvic exam and to undergo pelvic ultrasound evaluation compared to those women with a device placed at the time of a vaginal delivery. The retrospective cohort study conducted by University of Pennsylvania researchers included 210 women; 169 were available for follow-up.

Expulsion rates for immediate postpartum IUD insertions are higher than for interval or postabortion insertions, with research suggesting percentages as high as 10-27%.[7-10] Despite the higher expulsion rate, evidence from clinical trials and cost-benefit analyses indicates that immediate placement is beneficial in lowering unintended pregnancy rates, especially for those at greatest risk of not receiving recommended postpartum follow-up.[2]

In another recent study, researchers examined pain scores self-reported by women before and during immediate postpartum placement of a copper or levonorgestrel IUD after vaginal delivery.[11] A total of 38 women received epidural analgesia, while 30 had no epidural. Data indicate that those who received epidurals had minimal pain before and during IUD placement, with about 50% of those who did not receive epidurals noting some pain during both vaginal delivery and IUD placement.

Consider the Timing

According to published guidance, the best practice for immediate postpartum IUD insertion is to place the device in the delivery room within 10 minutes of placental delivery in vaginal and cesarean births when possible.[2] The procedure for immediate postpartum IUD placement differs from the interval insertion technique, so hands-on didactic instruction is required.

Clinicians may place the contraceptive implant in the delivery room or at any other time during the woman's stay in the postpartum unit before hospital discharge. The technique for placing the implant in the immediate postpartum period does not differ from the technique for interval insertion.

There are no contraindications or risks for implants specific to the postpartum period with the exception of theoretical issues related to breastfeeding, according to American College of Obstetricians and Gynecologists guidance.[2]

Since progesterone withdrawal after delivery of the placenta is believed to trigger lactogenesis, theoretical concerns have been raised that exogenous progesterone, such as the progestin in hormonal IUDs or implants, could hinder the start of milk production. A review of observational studies of progestin-only contraceptives, including progestogen-only pills, injectables, implants, and hormonal intrauterine devices, indicates that they have no effect on the successful start and continuation of breastfeeding or on infant growth and development.[12]

The *U.S. Medical Eligibility Criteria for Contraceptive Use, 2016* classifies immediate postpartum provision of the levonorgestrel IUD and implant as Category 2 for women who are breastfeeding, with the advantages generally outweighing theoretical or proven

EXECUTIVE SUMMARY

The American College of Obstetricians and Gynecologists now recognizes immediate postpartum placement of either the intrauterine device or the contraceptive implant as a best practice because of the long-acting reversible contraceptive methods' role in preventing rapid repeat and unintended pregnancy.

- Results of a just-released study of women who received a postplacental copper T-380A IUD within 10 minutes after vaginal or cesarean delivery suggest that women are more likely to retain the device after cesarean delivery.
- The best practice for immediate postpartum IUD insertion is to place the device in the delivery room within 10 minutes of placental delivery in vaginal and cesarean births when possible. The contraceptive implant may be inserted in the delivery room or at any other time before hospital discharge.

risks.[13] The copper T380A IUD has no restrictions (Category 1) when it is inserted less than 10 minutes after delivery of the placenta, with a Category 2 rating for insertion 10 minutes after delivery of the placenta and less than four weeks after delivery.

Practice Is Supported

The LARC Program of the American College of Obstetricians and Gynecologists has established the Postpartum Contraceptive Access Initiative (PCAI) to provide clinical and operational support training for immediate postpartum LARC implementation. The initiative's website, https://pcainitiative.org, contains details about the initiative, information about immediate postpartum LARC, and an application to become a participating hospital site.

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FDA Issues Restrictions for Sterilization Option

The Food and Drug Administration (FDA) has issued new restrictions regarding the sale and distribution of the permanent contraceptive device, Essure.

The regulatory agency said it was making the move after some women were not being informed adequately of the risks before having the device implanted, even after there were "significant efforts" to educate patients and clinicians about its risks. (Contraceptive Technology Update *reported on the FDA's previous efforts; see the May 2016 article, "Food and Drug Administration takes steps to ensure safety of Essure," at https://bit.ly/2rzaXgP.*)

The agency says it is moving to enact restrictions after a review of new information on use of the device. The Essure System, approved for use in 2002, consists of an implantable insert and a delivery system to place the insert. In contrast to other procedures for permanent sterilization that require surgery, the Essure device involves using a hysteroscope to place inserts in each fallopian tube through the cervix. Once the device is in place, the fibers within the insert elicit a local reaction that causes fibrous tissue growth in and around the implant, thereby blocking the fallopian tubes. As part of the procedure, it is recommended that patients undergo a radiologic confirmation test using hysterosalpingography or ultrasound three months after placement of the insert to confirm correct placement and obstruction of the fallopian tubes.

Robert Hatcher, MD, MPH, professor emeritus of gynecology and obstetrics at Emory University School of Medicine in Atlanta, points out that this confirmation test to demonstrate successful tubal occlusion does not always occur. He lists three reasons: Some physicians are convinced that their techniques are so good, they do not need confirmatory hysterosalpingography. Second, the cost of the confirmatory procedure leads some women and some clinicians to decide not to perform the confirmatory test. Third, while the initial procedure may have been paid for by one of several forms of insurance, the confirmatory test may not be covered, leaving women to decide not to have it done.

As a hysteroscopic sterilization procedure, Essure has some advantages compared to laparoscopic sterilization: it avoids abdominal entry, it can be implanted during an office procedure, and it may avoid the use of general anesthesia.

However, according to the FDA, some patients who have received Essure have experienced adverse events, such as perforation of the uterus and/or fallopian tubes, migration of the inserts to the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. Other women also have reported symptoms such as headache, fatigue, weight changes, hair loss, and mood changes, including depression. However, it is not known whether these symptoms are related to Essure, the agency states.

Essure originally was brought to market by Conceptus of Mountain View, CA, but the product was acquired by Bayer in June 2013. According to the FDA, in late 2013, the agency received a significant increase in reports of adverse events related to Essure, in particular from patients who had received the device. Essure is available in the United States, Canada, Australia, several European countries, some Latin and South American countries, and some Asia Pacific countries.

"Despite previous efforts to alert women to the potential complications of Essure, we know that some patients still aren't receiving this important information," said FDA Commissioner **Scott Gottlieb**, MD, in a press statement. "That is simply unacceptable. Every single woman receiving this device should fully understand the associated risks."

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- The regulatory agency said it was making the move after some women were not being informed adequately of the risks before having the device implanted, even after there were "significant efforts" to educate patients and clinicians about its risks.
- Some women who received the Essure device have experienced adverse events such as perforation of the uterus and/or fallopian tubes, migration of inserts to the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. Other women also have reported symptoms such as headache, fatigue, weight changes, hair loss, and mood changes, including depression.

What Steps Have Been Taken?

The company has made changes to the "Patient-Doctor Discussion

Checklist," which was added to the Essure label in November 2016. This checklist now includes the sub-title "Acceptance of Risk and Informed Decision Acknowledgement" to indicate the document's importance. Clinicians must review the checklist with each prospective patient to ensure the patient understands the risks, benefits, and other information about Essure implantation. Clinicians will need to give each patient the opportunity to sign the acknowledgment, and the physician who is inserting the device must sign the checklist. Bayer, the device manufacturer, now is tasked with implementing the restrictions and ensuring that healthcare provider compliance falls in line with the restrictions.

In February 2016, the FDA ordered Bayer to conduct a new postmarket surveillance study of the device. The study, which is still ongoing, will provide information to help the agency understand the risks associated with Essure, including rates of complications such as unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the device, and compare them to those of laparoscopic tubal ligation. Although the agency says that Bayer's post-market study has demonstrated adequate progress, including tripling the total number of enrolled patients during the past six months, it also plans to require the company to raise the number of study sites to account for declining sales volume.

Ensuring informed decision making is just one aspect of the FDA's ongoing efforts to monitor use of the device, said **Terri Cornelison**, MD, PhD, assistant director for the health of women in the FDA's Center for Devices and Radiological Health.

"While some women may continue to choose Essure as their birth control option based on current information, as new information becomes available, the FDA will continue to keep the public informed of the agency's evaluation and findings, and consider regulatory options that appropriately balance benefits and risks for Essure," said Cornelison in a prepared statement. ■

Push Is on to Combat Drug-resistant Gonorrhea

Gonorrhea has progressively developed resistance to most antimicrobials used to treat the infection; as a result, the Centers for Disease Control and Prevention (CDC) recommends a dual regimen of ceftriaxone and azithromycin for treatment. In a recently released study, CDC researchers report that while 81% of patients diagnosed with gonorrhea were treated using dual therapy, nearly one in five were treated with a different regimen.[1]

Gonorrhea is the second most common notifiable disease in the United States. In 2016, 468,514 cases were reported to state and local health departments, an increase of 18.5% from 2015 figures.[2] *Neisseria gonorrhoeae*, the bacterium that causes gonorrhea, has developed resistance to each of the antimicrobials used for treatment, challenging public health officials. (Contraceptive Technology Update *reported on the situation; see the January 2017 article, "STDs at Unprecedented High in United States," available at http://bit.ly/2hrYtkh.*)

To check adherence to the current CDC recommendations for uncomplicated gonorrhea treatment, researchers looked at data collected on a random sample of reported cases of gonorrhea in seven jurisdictions participating in the STD Surveillance Network. They estimated the proportion of patients who received the approved regimen, analyzing patient characteristics and diagnosing facility type.

Although the majority of reported patients with gonorrhea (81%) received the recommended regimen, health officials express concern for those not getting the dual therapy regimen. In the majority of cases treated with other regimens, patients were treated with monotherapy, including 3% of all cases treated with azithromycin only.

"Gonorrhea should not be treated with azithromycin alone," says **Gail Bolan**, MD, director of the CDC's

EXECUTIVE SUMMARY

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- Gonorrhea has progressively developed resistance to most antimicrobials used to treat the infection; as a result, the CDC recommends a dual regimen of ceftriaxone and azithromycin for treatment.
- Researchers have identified mutations of *Neisseria gonorrhoeae* that enable ceftriaxone resistance. These mutations may lead to the spread of ceftriaxone-resistant strains globally.

Division of Sexually Transmitted Disease Prevention. "Doing so may accelerate emerging resistance and increase the possibility that the patient may not be cured of their infection."

The current article's findings indicate that STD and reproductive health clinics are providing quality care, noted Bolan in a "Dear Colleague" letter. Patients who were diagnosed in these healthcare settings were the most likely to receive the recommended regimen (91% and 94%, respectively), compared to 80% in other healthcare settings, she noted.

Mutations May Be Key

Researchers at the University of North Carolina at Chapel Hill (UNC) School of Medicine have identified mutations in *Neisseria gonorrhoeae* that enable ceftriaxone resistance. These mutations may lead to the spread of ceftriaxone-resistant strains globally.[3]

"The first step in stopping a drug-resistant bacterium is figuring out how it becomes resistant to antibiotics that once were able to kill it," notes **Robert Nicholas**, PhD, professor and vice chair of UNC's Department of Pharmacology. "Our results give us clues to how ceftriaxone-resistant gonorrhea is emerging, why this is such a looming problem, and what to focus on to limit it."

Although *N. gonorrhoeae* has not yet developed wide resistance to ceftriaxone, the isolates H041 and F89 have been found to be resistant to the medication.[4] If ceftriaxone-resistant gonorrhea should spread, gonorrhea would become much more difficult, if not impossible, to treat.

Nicholas and colleagues collaborated with researchers in the laboratory of **Ann Jerse**, PhD, at the Pentagon's Uniformed Services University, to demonstrate that ceftriaxone resistance mutations in HO41 and F89 impair the bacteria's growth rate. Then the researchers conducted laboratory experiments to illustrate that strains with resistance were outcompeted by a non-resistant strain of *N. gonorrhoeae*, resulting in a diminished amount of resistant bacteria compared to the standard strain.

The investigators infected mice with a mixture of equal amounts of the non-resistant reference strain and the ceftriaxone-resistant, growth-impaired strain. They found that some of the resistant strains rapidly developed higher growth rates and began to out-compete the quick-growing reference strain. This development led researchers to suspect that such bacteria had acquired mutations that improved their growth in spite of the growth-inhibiting effect of the mutations.

Nicholas and his colleagues then focused on one of the mutations that affects a bacterial enzyme, AcnB. The enzyme is known to play an important part in the energy production that powers growth of bacteria. Analysis indicates that the mutant form of the enzyme changes the metabolism of energy of *N. gonorrhoeae* and causes extensive alterations in the expression of bacterial genes.

The researchers are now looking at how mutant AcnB increases *N. gonorrhoeae* growth and what other mutations that restore growth may exist in the superbug strains evolved in the lab. ■

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Research Examines Self-administered DMPA

New research indicates that use of subcutaneous depot medroxyprogesterone (DMPA-SC, marketed as Sayana Press) may help women to continue using injectable contraception longer than women who receive traditional intramuscular injections.[1] Data collected during a 12-month study period in Uganda suggest that 81% of 561 DMPA self-injection participants continued to use the product, compared to 65% of the 600 women who received DMPA injections administered by a health worker.[1]

The study, conducted by PATH, a Seattle-based international nonprofit global health organization, was

EXECUTIVE SUMMARY

New research indicates that use of subcutaneous depot medroxyprogesterone (DMPA-SC, marketed as Sayana Press, Pfizer Inc.) may help women to continue using injectable contraception longer than women who receive traditional intramuscular injections.

- Data collected during a 12-month study period in Uganda suggest that 81% of 561 DMPA self-injection participants continued to use the product, compared to 65% of the 600 women who received DMPA injections administered by a health worker.
- In a separate study, self-administration led to a more than 50% increase in continuous DMPA-SC pregnancy protection through 12 months, compared with provider-administered injection.

designed to evaluate use of the device, which combines the drug and needle in the PATH-developed BD Uniject injection system. The small, prefilled device offers ease of use not only for providers with minimal training, but also for women themselves to administer via self-injection. Sayana Press is approved for use in more than 40 countries around the world.

The research, supported by the Bill & Melinda Gates Foundation and the Children's Investment Fund Foundation, gives impetus to expanding use of self-injection in Uganda. Since national regulatory approval of self-injection was issued in Uganda in 2017, self-injection now is available in four districts of Uganda outside of a research setting. Plans are in process for a national rollout of the practice.

"Our vision for Uganda: any woman can go to any service delivery site to receive quality information about a range of contraceptive methods," says **Dinah Nakiganda**, MD, MPH, assistant commissioner of reproductive health, Uganda Ministry of Health. "And self-injection will be one of them."

Review the Data

To conduct the non-randomized cohort study, researchers enrolled 1,161 women ages 18-45 who were seeking injectable contraception at 14 public sector health facilities. Patients were offered the option of injecting DMPA-SC themselves or receiving an injection of the intramuscular form of DMPA from a health worker. Women who selected to self-inject were provided training and given three units of the drug, an instruction guide, and a reinjection calendar to take home.

Data indicate that at the end of 12 months, significantly more women who self-injected DMPA-SC continued to use the product compared to those who returned to a facility every three months to receive DMPA-IM from a health worker. In an analysis that controlled for multiple factors, data indicate that self-injection reduced the risk of discontinuing by 46%. Researchers note that while younger women exhibited a higher risk of discontinuation in general, self-injection appeared to help them continue. In the analysis, women 18 to 24 years of age who were self-injecting had a 40% reduced risk of discontinuing, compared with a 25% reduced risk for those women 25 years of age and older.[1]

"Women and girls have the ability and the right to manage their own sexual and reproductive health needs, and contraceptive self-injection is one new way to make this possible," notes **Martha Brady**, MS, reproductive health program leader at PATH. "Supporting them to have greater control and decision-making through evidence-based 'self-care' approaches like this can benefit not only women and girls themselves, but health systems overall."

Data Confirm Safety, Effectiveness

Research released earlier in 2018 indicates that DMPA-SC may be a new way to help increase continued contraception use among women in low-resource settings.[2]

FHI 360 conducted a one-year, randomized controlled trial in Malawi with more than 700 women who opted into the study after seeking family planning services at six Ministry of Health clinics or from community health workers. Those who were enrolled were randomized to receive either DMPA-SC from providers, including community health workers, or were given training on how to self-inject DMPA-SC. Women who received DMPA-SC were sent home with three doses, while those in the provider-administered group were asked to return for subsequent injections. Researchers reported that self-administration led to a more than 50% increase in continuous DMPA-SC pregnancy protection through 12 months, compared with provider-administered injection. Researchers observed similar rates of pregnancies, adverse events, and overall side effects in the self-administered and provider-administered groups.[2]

The study results will be used to inform decision-making on the procurement and distribution of DMPA-SC through the Malawi national health system. The study, funded by USAID and

the Children's Investment Fund Foundation, was conducted under the Advancing Partners & Communities project in partnership with the University of Malawi College of Medicine.

"These results have implications for other areas of global health, especially as new drug delivery technologies allow for self-administration," says **Holly Burke**, PhD, MPH, FHI 360 scientist and principal investigator. "Self-injection of other medications may improve other health conditions affecting disadvantaged populations around the world. Adherence to medication is a global health problem that affects the entire medical field."

Collaboration Expands Access

In 2017, Pfizer Inc., the Bill & Melinda Gates Foundation, and the Children's Investment Fund Foundation enacted a multi-year extension of their collaboration to further broaden access to DMPA-SC. Through the collaboration, DMPA-SC has been made available to qualified purchasers at a guaranteed price of US $0.85 per dose, a reduction from the previous price of US $1 per dose.

The aim is to aid women who are most in need of contraception. Research estimates that approximately 225 million women in developing countries would like to prevent or delay pregnancy but they are not currently using any contraception.[3] Barriers such as travel to health facilities, social barriers, and lack of knowledge about available contraceptive methods prevent women from accessing contraception. By expanding access to DMPA-SC, more women can have access to a method that is safe, effective, and self-administered, advocates say. ■

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What's Your Approach to Abnormal Uterine Bleeding?

Statistics indicate that one-third of outpatient gynecologist visits are for abnormal uterine bleeding, with the condition accounting for more than 70% of gynecologic consultations in the perimenopausal and postmenopausal years.[1] Although medical therapies such as combined oral contraceptives commonly are used to treat the condition, the levonorgestrel-releasing intrauterine device (LNG-IUD) has become an increasingly popular treatment option.

Michael Thomas, MD, chief of the division of reproductive endocrinology and infertility at the University of Cincinnati College of Medicine, looks at the LNG-IUD as a safe and effective treatment option, particularly for patients who not only want to control their bleeding, but also want to maintain their fertility potential.

Thomas, a member of the research team responsible for developing the LNG-IUD, served as an advocate for the method during a recent debate at the 2018 American College of Obstetricians and Gynecologists' (ACOG) annual clinical meeting.[2]

Birth control pills or other oral options used in controlling abnormal uterine bleeding issues must be taken to be effective, says Thomas, a reproductive endocrinologist. The LNG-IUD remains in place, providing needed therapy, and can be removed when a woman chooses to become pregnant.

Research from seven studies indicates that the LNG-IUD is an effective intervention for reduction of abnormal cyclic uterine bleeding.[3] Data suggest 70-87% reductions in bleeding when comparing numbers for treated women with their baseline.[4-8] Eighty percent or more of women who were enrolled in studies because they met criteria for heavy menses achieved normal total blood loss, with such improvements showing significant movement when compared with women treated with nonsteroidal anti-inflammatory drugs (NSAIDs), combined oral contraceptives, progestogens, and usual care.[3]

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- Although medical therapies such as combined oral contraceptives commonly are used to treat the condition, the levonorgestrel-releasing intrauterine device has become an increasingly popular treatment option.
- Nonsteroidal anti-inflammatory drugs and tranexamic acid also offer oral options for treatment.

The LNG-IUD represents a good option for patients with abnormal uterine bleeding who wish to skirt the potential side effects of oral medications, Thomas says.

"People who have issues with progestin-related problems, such as mood changes, nausea, or bloating, may not have that with the IUD, because very little of the medication gets into the peripheral bloodstream," notes Thomas. "The advantage of this type of local device that is inside the uterus is that it actually has a direct effect, as opposed to taking something by mouth, which has to go through the liver and may not have a good effect."

Check Other Medical Options

There is no one-size-fits-all approach to the treatment of abnormal uterine bleeding, says **Kristen Matteson**, MD, MPH, director of the division of research for the department of obstetrics and gynecology at the Warren Alpert Medical School of Brown University and Women & Infants Hospital in Rhode Island. Matteson served as advocate for other medical options at the recent debate.

Heavy menstrual bleeding adversely affects women's lives, explains Matteson. It may cause them to change their work schedule or change plans with their friends and their family, making a major impact on their day-to-day lives, she notes.

"I think it's great that we have so many different treatment options, but any treatment that you are looking at giving to a woman with heavy menstrual bleeding needs to address what she is finding most bothersome about her symptom to reduce the adverse impact that bleeding has on her daily life," she states.

According to a recent survey of ACOG members, combined oral contraceptives were the most commonly chosen first-line choice for abnormal uterine bleeding treatment. Birth control pills can correct menstrual irregularities that result from oligo-ovulation or anovulation, which helps to make menstruation more predictable. Combined oral contraceptives also can decrease excessive menstrual bleeding for most women, which makes them an initial management option in treat heavy menstrual bleeding.

Nonsteroidal anti-inflammatory drugs commonly are used to treat abnormal uterine bleeding because of the role of prostaglandins in the pathogenesis of heavy menstrual bleeding. These drugs inhibit the enzyme cyclooxygenase, thereby lowering endometrial prostaglandin levels and decreasing potential for vasodilation and angiogenesis.[3] When compared with placebo, data suggest such drugs decrease menstrual cramping and reduce menstrual blood loss by 33%.[10]

Tranexamic acid blocks lysine-binding sites on plasminogen, which prevents plasmin and fibrin polymer interaction. This results in degradation of fibrin, stabilization of clots, and reduction in bleeding.[11] Research indicates use of the drug results in significant decrease in the objective measurement of idiopathic heavy menstrual bleeding.[11] ■

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WASHINGTON WATCH

With Funding Announcement, Trump Begins Reshaping Title X

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In February 2018, the Trump administration took the first of several expected steps to reshape the Title X national family planning program to advance a socially conservative agenda. After a months-long delay, the Office of Population Affairs (OPA) released a funding opportunity announcement (FOA) for Title X service providers that, according to my Guttmacher Institute colleague Kinsey Hasstedt, has the potential to undercut the program's mission in multiple ways.[1,2]

First, the FOA is designed to steer Title X funding away from providers that specialize in reproductive healthcare and toward providers that offer family planning services in the context of primary care, such as federally qualified health centers (FQHCs). This shift in the provider network would be in line with a common talking point of social conservatives, who incorrectly argue that FQHCs could readily take on the clients of Planned Parenthood affiliates and other specialized providers.[3] In reality, the reach of the Title X program depends heavily on reproductive health-focused providers. Patients choose those providers because of their high-quality, respectful, and confidential care, and FQHCs already are struggling to meet their current demands for care.

Second, the Title X FOA focuses on fertility awareness methods (FAMs) while ignoring patients' need for a true choice of contraceptive methods. The vast majority (93%) of Title X sites already offer FAM instruction and supplies, but less than 0.5% of Title X clients choose these methods.[2] Nevertheless, the FOA repeatedly emphasizes FAMs and promotes the inclusion of sites that offer a single "family planning approach or method"; that may open the door to anti-abortion counseling centers and other sites that would undermine Title X's commitment to ensuring patients' contraceptive choices are free from coercion. Notably, the FOA does not ever use the words "contraception" or "birth control." Nor does it reference the Quality Family Planning guidelines, which OPA developed with the Centers for Disease Control and Prevention and which have served as standards for Title X.[4]

Third, the FOA promotes abstinence-only-until-marriage messaging in Title X, and does so using coded language such as "avoiding sexual risk" and "returning to a sexually risk-free status." OPA's current politically appointed head, Valerie Huber, is a long-time abstinence-only advocate who helped develop that language in an attempt to rebrand the approach, after its reputation had been tarnished by research indicating that abstinence-only programs have been ineffective and harmful for adolescents.[5] This abstinence-only emphasis is another departure from the Quality Family Planning guidelines, under which adolescents should be given comprehensive information about how to prevent pregnancy and sexually transmitted infections (STIs), including but not limited to information on abstinence.

Finally, the Title X FOA seems to promote family participation over the

right to confidential family planning care. In a departure from previous FOAs, this year's announcement prioritizes the involvement of parents, guardians, and even spouses, while failing to mention Title X's long-standing commitment to confidential care and its prohibition on requiring parental consent or notice. In addition, the FOA would have providers subject a minor who has an STI or who is pregnant to "preliminary screening to rule out victimization." Screening adolescent clients in this way is a step beyond previous Title X requirements to adhere to federal and state notification and reporting requirements and could discourage sexually active adolescents from seeking needed care.

More Shoes Will Drop

The Trump administration's funding opportunity announcement has been challenged in court by the National Family Planning and Reproductive Health Association and three Planned Parenthood affiliates.[6] As of mid-May 2018, the groups were seeking to block the federal government from using the fiscal year 2018 FOA as the criteria on which to award the next rounds of Title X service grants, and to continue funding current grantees in the meantime. If the administration is permitted to move forward using the FY 2018 funding opportunity announcement, new projects are slated to be funded starting on September 1.

Meanwhile, the Trump administration has signaled that additional attacks on Title X are in the works. The administration's budget request to Congress included language that would prohibit Planned Parenthood health centers nationwide from participating in all federal programs funded through the U.S. Departments of Labor and Health and Human Services.[7] This would include not only Title X grants, but also reimbursement for serving Medicaid clients and participation in funding streams to promote maternal and child health, prevent HIV and other STIs, and provide breast and cervical cancer screenings.

So far, Congress has failed to enact such a prohibition, but anti-abortion lawmakers and advocacy groups have been pressuring the administration to act on its own, and leaks from within the administration indicate that something may be imminent.[8] One possibility is imposing a so-called domestic gag rule within Title X. That policy was advanced initially by the Reagan administration in 1988 but was held up in court and eventually rescinded by the Clinton administration.[9] The domestic gag rule would force Title X providers to withhold information about and referral for abortion, in a reversal of the program's long-standing requirement that providers offer nondirective counseling on and referral for the full range of pregnancy options.[10] It also would impose unnecessary and onerous requirements that Title X sites be physically separate from sites that offer abortion care with non-federal money, going well beyond the statutory ban on Title X dollars being used for abortion care. ■

Editor's Note: On May 22, the Trump administration issued a notice of proposed rulemaking to further restrict and reshape the Title X program. The next Washington Watch column will provide details and analysis.

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CME/CE QUESTIONS

1. **What is the *U.S. Medical Eligibility Criteria for Contraceptive Use, 2016* classification for immediate postpartum provision of the levonorgestrel IUD and implant for women who are breastfeeding?**

   a. Category 1
   b. Category 2
   c. Category 3
   d. Category 4

2. **Which of the following is *not* an advantage of hysteroscopic sterilization over tubal sterilization?**

   a. Avoids abdominal entry
   b. Can be performed as an office procedure
   c. May avoid use of general anesthesia
   d. Offers immediate effectiveness

3. **What are the two drugs recommended as a dual regimen by the CDC for the treatment of uncomplicated gonorrhea?**

   a. Ceftriaxone and azithromycin
   b. Clindamycin and azithromycin
   c. Ceftriaxone and cefixime
   d. Tenofovir and ceftriaxone

4. **Which of the following is *not* a first-line treatment for abnormal uterine bleeding?**

   a. Levonorgestrel IUD
   b. Combined oral contraceptives
   c. NSAIDs
   d. Copper T IUD

CME/CE 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.