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RELIAS MEDIA

Guidance Helps Clinicians Counsel Transgender Patients on Contraception

Clinicians can change gender language

One of the challenges facing family planning clinics and obstetricians/gynecologists when serving transgender and gender-diverse patients is the lack of research and evidence-based guidelines to inform their clinical decisions.

“One of the biggest issues is we just don’t have enough data about trans folks on testosterone,” says **Chance Krempasky**, WHNP-BC, FNP-BC, AAHIVS, associate director of medicine — education at Callen-Lorde Community Health Center in New York City.

Too few studies exist for providers to give patients evidence-based risk

information. “Patients want to know, and there’s frustration because there’s not enough research across the board,” Krempasky says.

This deficit is notable at a time when the numbers of transgender and gender-diverse people are increasing.

“We know that at the very minimum, one in 200 adults are transgender,” says **Juno Obedin-Maliver**, MD,

MPH, MAS, FACOG, assistant professor in the department of

“ONE OF THE BIGGEST ISSUES IS WE JUST DON’T HAVE ENOUGH DATA ABOUT TRANS FOLKS ON TESTOSTERONE ... THERE’S FRUSTRATION BECAUSE THERE’S NOT ENOUGH RESEARCH ACROSS THE BOARD.”

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obstetrics and gynecology at Stanford University School of Medicine. She also is the co-director of the PRIDE Study.

There is some evidence that more young people identify as gender diverse. Estimates based on 2017 data about California teenagers suggest that up to 27% are either a gender minority or have nonconforming gender identity, Obedin-Maliver says. (*More information is available at: <https://bit.ly/2BhmQ2D>.*)

Amount of Data 'Slim to None'

Obedin-Maliver and coauthors recently published clinical recommendations on contraceptive counseling for transgender and gender-diverse populations.¹

"This paper was worked on with collaboration with the Society of Family Planning, so these guidelines are a very first step," she says. "My hope is people will pick up the call in these guidelines to do this research that we need on a biochemical, physiological level."

The recommendations provide some answers to clinical questions, including the first question on which data are available to guide

contraceptive counseling with transgender and gender-diverse individuals who were assigned female sex at birth. The short answer is there are limited data on the patterns, safety, and efficacy of various contraceptive methods for use in these populations.

"The amount of data is slim to none," says **Adam Bonnington**, MD, associate position and volunteer clinical faculty in the department of obstetrics, gynecology, and reproductive sciences at the University of California, San Francisco. Bonnington is the lead author of the recommendations.

There are some data on transgender and nonbinary individuals, who were assigned female at birth, becoming pregnant. For instance, one study of 26 transgender men found 13 were at risk of an unintended pregnancy, and reported using condoms more than any other contraception. About one-third were amenorrheic.²

Results of existing studies about testosterone reveal some effects in transgender individuals who also use hormonal contraceptives, Bonnington explains. "There are qualitative pieces that show transgender, nonbinary people using contraception, but there is no data on safety, efficacy, and long-term

EXECUTIVE SUMMARY

More research is needed about contraceptive needs and health effects on transgender and gender-diverse people, experts say.

- Reproductive health clinicians especially need more data on how testosterone, often used by transgender men, might affect patients' health when they also take an estrogen-based contraceptive.
- Clinicians need to help transgender patients identify the best contraceptive to meet their needs. This should be a shared decision-making process.
- All contraceptives are safe for transgender populations, but many unknowns remain.

outcomes of these products when used in the setting of testosterone,” he adds. “What we’re left with is we have to extrapolate what we know about testosterone on its own and what we know about hormonal contraceptives. Then, we make educated assumptions based on those findings.”

More research about the effect of testosterone on fertility is necessary, Obedin-Maliver says.

“There are some small studies in terms of in vitro fertilization outcomes, but we need much larger studies on fertility and prevention of pregnancy, in terms of thinking about what the impact of testosterone is,” she says. “We need to know what testosterone does, how it impacts fertility.”

Learn Patients’ Health Goals

While there are many unanswered questions about transgender and gender-diverse people and contraception use, one common theme is that each person’s experience and reproductive health goals are different.

For example, some transgender men might desire to keep their uterus and/or ovaries. Some might take hormonal contraceptives to stop their menstruation. Other transgender patients might prefer estrogen-containing contraceptives because they want to stop monthly bleeding, at least until testosterone injections achieve the same goal. Others might prefer progestin-only pills to avoid estrogen.

Some transgender patients might prefer a quarterly contraceptive shot because they are accustomed to injections due to daily testosterone shots. Other patients might prefer something long-term so they do not have to visit a gynecological clinic

often. A clinic or doctor’s office might make them feel uncomfortable in the way it is designed to accommodate cisgender women, says **Frances W. Grimstad**, MD, MS, faculty in the division of gynecology in the department of surgery at Boston Children’s Hospital, and instructor of surgery at Harvard Medical School. Grimstad specializes in transgender reproductive healthcare, focusing on adolescents and youth.

“I perform gender-affirming hysterectomies at Boston Children’s Hospital,” she says. “I help with menstrual suppression and complex management of gynecological issues, particularly for transmasculine youth, both those on testosterone and those not on testosterone.”

A clinician’s goal should be to help transgender patients identify the best contraceptive to meet their physical and emotional needs. Clinicians should reassure patients that they can change their mind.

“The way I approach it with my patients is I first remind them that I’m not holding them to anything they’re saying today,” Grimstad says. “They can come back in three to six months and have a completely different idea of what they want in their future, and I’ll never criticize them.”

For example, some transgender patients might want a hysterectomy, but they may wish to keep their ovaries because of a possible future desire to have a genetic child.

“They can have their ovaries in and still get a penis,” Grimstad says. “We need to affirm the patient’s gender and the way they desire, and also leave open doors they might want to have open in the future because people’s minds do change.”

Physicians should discuss risks, even if they are rare and not well-researched. For example,

both testosterone and/or some contraceptive methods can cause elevations in cholesterol levels, lipids, triglycerides, and cause weight gain, Bonnington says.

“Those changes are not thought to be clinically significant for cisgender women, but the question becomes, ‘Do two nonsignificant scenarios create something of concern?’” he asks. “We need to closely watch these patients.”

All methods of contraception are safe for transgender and nonbinary patients, but there are a lot of unknowns. It is good to advocate for shared decision-making, Bonnington adds.

“Have frank conversations with patients, saying, ‘This is what we know; this is what we don’t know. What is important to you, and how can we find a method that will be acceptable to you?’” he explains.

A clinician can provide data based on cisgender women, and can help patients extrapolate for transgender patient populations, too, Bonnington adds.

Be Sensitive to Patients’ Dysphoria

One important part of treating a transgender patient involves sensitivity to their experiences of dysphoria. Transgender people experience dysphoria when their appearance or behavior — as perceived by others — are not concordant with the gender with which they identify, Krempasky says. This can happen when someone calls them the wrong pronoun, or when they have a discordant experience.

For example, a transgender man might feel dysphoria if someone sees his package of birth control pills fall out of a bag, as happened to someone

Krempasky knew. “They felt exposed, unsafe, and it made them want to change their method of taking birth control,” he explains.

Reproductive health providers can help prevent dysphoria among transgender patients by being sensitive to their language and expectations.

“Every transmasculine patient has a different experience with dysphoria,” Krempasky says. “Meet with each patient and determine what their priorities are.”

Clinicians can talk with them about what makes them uncomfortable, such as their chest, undergoing pelvic procedures, or buying products like menstrual pads that are associated with femininity, he explains.

“Have these conversations with patients and ask them what are their sources of dysphoria and what gives them discomfort with their body,” Krempasky says. ■

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Clinicians Can Follow Recommendations to Better Serve Transgender Populations

Family planning clinicians and obstetrician/gynecologists likely will see transgender or gender-diverse patients seeking contraceptive care. It is a good idea to learn how to best advise and care for these populations.

The first step is for clinicians to apply to transgender patients the same competence they have in speaking to cisgender people (patients who were assigned female gender at birth and identify as females).

“When I talk to gynecologists who are new to this, I remind them of the competence they already have in talking to cisgender people, and

tell them they can apply this to trans folks,” says **Frances W. Grimstad**, MD, MS, faculty in the division of gynecology, department of surgery at Boston Children’s Hospital, and instructor of surgery at Harvard Medical School. Grimstad specializes in transgender reproductive healthcare, focusing on adolescents and youth. “There is no reason to be worried,” she adds.

Reproductive health services for transgender or gender-diverse patients is more about taking care of those individuals than it is about providing specific health services to a transgender patients. “If you can

walk into a room and confidently list all the pluses and minuses for a cis patient, you can do it for trans patients,” Grimstad explains.

“Transgender people are different, and have had different experiences than cisgender people by nature of the fact of walking around in a world that is gendered and assuming people are this gender,” says **Juno Obedin-Maliver**, MD, MPH, MAS, assistant professor in the department of obstetrics and gynecology at Stanford University School of Medicine. She also is the co-director of the PRIDE Study.

“Every transgender and gender-diverse person is different from one another,” Obedin-Maliver says. “We would not say we met one woman and now know all women, but physicians might think that because they have met one transgender man they now know how to take care of them.”

While a patient’s experience and needs are different, reproductive health providers can improve their care of transgender patients by changing their preconceptions about

EXECUTIVE SUMMARY

Clinicians should learn more about transgender and gender-diverse patients to better inform their care of these populations.

- Transgender people have diverse needs. Clinicians should always ask what they want and how they prefer to be called.
- Ask about the patients’ reproductive history and medications that help with their transition.
- Learn about words transgender populations prefer, and words that are micro-misgendering and harmful.

gender and the language they use with patients who are not cisgender.

Grimstad, Obedin-Maliver, and other researchers and clinicians who work with transgender patients offer these additional tips:

- **Find out what the patient wants.** Transgender and gender-diverse patients have diverse needs and desires with contraception and reproductive health. For instance, there is not one simple solution that will work for every transgender man.

Grimstad sees patients who are taking both testosterone and estrogen-containing contraception. Some were using the contraception before they began testosterone, and they used estrogen birth control to stop their menstruation. “Then, they took testosterone and continued with contraception,” Grimstad says.

Some patients might use estrogen contraception to suppress menstruation while they wait a couple of years for the testosterone to stop their periods, she explains. Some patients might prefer to avoid estrogen and use progestin-only hormone contraceptives.

“I’ve only had one patient in my career ask for a nonhormonal contraceptive,” Grimstad says. “Most people want the added benefit of stopping their periods, which the copper IUD [intrauterine device] can’t do.”

The most important thing a reproductive health clinician can do is to ask patients about their goals with reproductive health, she says. “What are their goals right now, and what do they think their goals might be in the future?” she asks. “I have patients, ages 17 to 19, who have long known that one of their goals is to have genital surgery, and they are already seeing a genital surgeon. Part of the surgery for transgender men involves removal of the uterus and having a penis developed.”

For these patients, their goal might be to avoid pelvic exams and insertion of an IUD. They might prefer birth control pills or a contraceptive shot every few months.

“For a patient who has tried the shot, but struggled with regular bleeding and has no desire to remove their uterus, we might discuss placing an IUD while they are under sedation,”

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Grimstad says. “With sedation, trans patients do not have to be awake and experience the pelvic exam, which may be dysphoric or painful and discomfort them.”

Some transgender people do not want to think about that part of their body because they do not think of a vagina as being part of their body.

“Think about what the patient knows and feels about their current, short-term, and long-term reproductive health goals,” Grimstad says.

- **Consider the person’s past reproductive history.** Clinicians should ask about the patient’s contraceptive use, pregnancy, abortion, and other reproductive health issues, using

language that is affirming and respectful of the patient’s preferred words. Obedin-Maliver and co-researchers developed an affirming and customizable electronic survey that can be used with transgender and gender nonbinary people. The questionnaire includes 328 items across 10 domains that include gender identity, language to describe reproductive and sexual anatomy, gender affirmation process history, sexual orientation, sexual activity, contraceptive use, and more.¹

Transgender and gender-diverse patients’ reproductive history could include prepubescent treatment that helped them with their transition plan. For instance, transgender men might use blockers such as GnRH agonists, which are a group of drugs that treat endometriosis. They also prevent testicles and ovaries from making sex hormones by blocking other hormones. (For more information, visit: <https://bit.ly/2Ye9Sf6>.)

For transgender patients, use of these blockers can be their first stage of transition. GnRH agonists pause puberty and can cause temporary menopause in older adults, Grimstad explains.

“Blockers are used for treating endometriosis and to stop precocious puberty by pausing it until they’re older,” she explains. For instance, when used in a very young person who has identified as male since age 2, it can stop puberty until the person is ready to use normal hormones, she adds.

“It allows them to grow, develop, and determine hormones later in life,” Grimstad says. “Blockers are fully reversible and can be used for a couple of years to buy time in terms of the person’s maturity and understanding.”

Clinicians should ask if patients have used blockers. If patients take

these when they are very young, they might have a pre-puberty uterus. This means they might not be able to have an IUD and will need another type of contraceptive, Grimstad explains.

Clinicians also should ask about patients' menstruation, including length and pain levels. If they have a history of heavy or painful periods, they might respond differently to different contraceptives, Grimstad explains.

• **Ask patients which words they use to describe themselves and their bodies.** Providers should ask patients which pronouns they use, what name they prefer to be called, and how they describe themselves. Increasingly, providers are putting their own preferred pronouns with their titles and contact information in emails, such as "she, her, hers." Some gender-diverse people might prefer neutral pronouns: they, their, themselves. These preferences should be included in the patient's charts, and staff should make sure they call out the patient's preferred name.

"Collect information on the patient's gender identity, sex assigned at birth, and correct pronouns, and have it reviewed and updated, as necessary," says **Adam Bonnington**, MD, associate position and volunteer clinical faculty in the department of obstetrics, gynecology, and reproductive sciences at the University of California, San Francisco. "There has to be a system

in place to allow that information to be known by everyone in the clinical setting and to mirror language that patients use for different body parts."

Also, it is important to understand that a transgender patient's preferred name and legal name could be different, which would mean the insurance information will have a name different from what the clinic staff call the patient, Obedin-Maliver says.

"There are a lot of reasons why people may not change their insurance name," she says. "For example, someone may get their insurance through work, and the person is not out [about being transgender] at work."

Or the person might want to get pregnant soon, and the insurance policy will not cover pregnancy for a man, Obedin-Maliver adds.

"Instead of fighting that battle, they say 'Let's keep the name and marker the way it is even if that's not how I live my day-to-day life,'" she explains. "Have a conversation with the patient and ask what name the insurance is under and what name the person should be called in the clinic."

Most electronic medical records include a field for a patient's nickname or preferred name, as well as the legal name.

• **Train staff to avoid misgendering.** Clinicians and clinic staff should avoid microaggressions, including

misgendering their patients by referring to them with the wrong names, pronouns, or gender. If they make a mistake, they should apologize and correct the mistake. (*More information is available at: <https://bit.ly/2YLsPEL>.)*

To a transgender or gender-diverse person, misgendering can be compared to a bee sting, an analogy that Grimstad once heard from a trans leader. "You get stung once a year, you say it hurts, and you get over it," she explains. "But think about how it would feel if you walk through your day and you get stung by a bee and then you go to a bus stop and get stung, and then you open your emails and get stung by three more bees."

The stinging pain builds up and does not go away. Each micro-misgendering is small and isolated, but when they occur once a person wakes up and continue through the day, they hurt.

"The patient is not responding to that one bee sting in the clinic, but they've been stung 40 times today, and so they're responding to that," Grimstad says. ■

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Words and Phrases Related to Transgender Care

Know what — and what not — to say

Researchers and organizations that advocate for the transgender and gender-diverse communities provide these words and definitions to educate people about the transgender community. They offer suggested sexual health language that is respectful of transgender and gender-diverse patients:

- Transgender men are individuals who identify as male but were assigned female sex at birth.¹
- Transgender women are individuals who identify as female but were assigned or labeled as male sex at birth.²
- “Trans” is a shorthand for transgender people.²
- Use the terms “people who menstruate,” “people who are pregnant,” instead of “female,” “women,” or “pregnant women.”³
- Gender nonbinary persons do not identify as either male or female and may have a gender that blends those elements or is different from either male or female.⁴
- Use “people who produce sperm” instead of “male” or “men.”³
- “Cisgender” is a preferred term for men and women who identify with the gender they were assigned at birth.³
- “Assigned female or male at birth” is preferred to saying “biological female or male.”³

- Say “external genitals, external pelvic area” instead of “vulva, clitoris.”³
- Say “outer parts” instead of “penis, testicles.”³
- Instead of “vagina,” use the terms, “genital opening, frontal opening, internal canal.”³
- Say “chest” instead of “breasts.”³
- Gender dysphoria is the term used in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders*, replacing the previously used term “gender identity disorder.” Gender dysphoria may be used as a diagnosis for the purpose of insurance coverage.⁵
- Use the term “absorbent product” instead of “pad/tampon.”³
- A female condom should be referred to as an internal condom.³
- Instead of referring to a patient’s period or menstruation, say “uterine bleeding.”³
- “Transition” is preferred to the terms “sex change,” “preoperative,” and “postoperative.”⁵

Terms to Avoid

Transgender advocacy groups recommend people avoid using certain terms to describe transgender individuals unless a person prefers those terms. These include

“transsexual,” “transvestite,” and “sex change.” Other terms that are considered defamatory and damaging to transgender individuals include “deceptive,” “posing,” “pretending,” “tranny,” “masquerading,” “she-male,” “he/she,” “it,” “shim,” and “bathroom bill,” which is used by far-right extremists to oppose nondiscrimination laws that protect transgender people.⁵ ■

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Can COVID-19 Be Transmitted Sexually?

Researchers are beginning to investigate whether COVID-19 can be transmitted sexually. Early data from the study, as well as data from research in China, show the virus is present in some men's semen.¹

But other researchers who studied men who had recovered from COVID-19 did not find virus in semen samples.² Authors of a new study hope to settle the question and answer questions about the transmissibility in semen.

"This is an ongoing study, and we intend to collect 200 samples," says **Ranjith Ramasamy**, MD, associate professor of urology at Miller School of Medicine, and director of male reproductive medicine and surgery at the University of Miami (FL) Health System.

These are the questions investigators want to answer:

- If the virus is present in semen, is it alive, and can it be transmitted?
- How long does the virus remain in semen? Does it ever completely disappear?

Researchers will analyze results according to whether the men were symptomatic or asymptomatic when tested, and whether they experienced any symptoms, Ramasamy says.

"We collect samples from them, checking saliva samples and urine samples, as well," he adds.

Most of the men recruited in the study tested positive after being exposed to COVID-19, or during routine testing. They had not experienced symptoms. "We're seeing more asymptomatic carriers than we were six weeks ago," Ramasamy says.

As a precaution while data are collected and analyzed, people with COVID-19 symptoms should avoid any activities that could transmit the virus, including both through droplets and sexual transmission, he suggests.

"The question is with asymptomatic, positive patients," Ramasamy says. "What percentage of asymptomatic men, who don't know they have COVID in their blood, have it in the semen?"

It is unknown whether virus in the semen can be transmitted to partners via sexual intercourse. The best advice reproductive health practitioners can give their patients is to recommend using condoms if they are uncertain whether they could be exposed to the virus, Ramasamy suggests.

The New York City Health Department published a three-page guide, titled "Safer Sex and COVID-19." According to the guide, researchers still have a lot to learn about COVID-19 and sex, but people should take precautions by having sex only with a small circle of consenting partners and taking a break from

in-person dates during the pandemic. Their advice also suggests people avoid kissing anyone who is not part of their small circle of close contacts, wear face masks during sex, avoid rimming, masturbate together with physical distance (as much as possible), wash up before and after sex, and wear condoms and dental dams to reduce contact with saliva, semen, or feces. (*The guide is available at: <https://on.nyc.gov/2YpVz5V>.*)

Pregnant women and fetuses also are at risk. "There are case reports of maternal-to-fetal transmission," Ramasamy says. "For those actively trying to conceive, maybe they should wait a month or two, get tested, and speak with their doctor until we can answer this question definitely."

Telling patients to use condoms is the best advice physicians can offer, for now, Ramasamy says. ■

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Intervention Reduces Pregnancy and STI Risk Among Young Women with Depression

Young women with depression experience a higher rate of unintended pregnancy and sexually transmitted infections (STIs) than young women, in general.¹ The challenge for family planning

clinicians is to find an effective intervention to help them prevent pregnancy and maintain their health.

Results of one study revealed that an intervention using counseling

and mobile health can reduce the risk of both pregnancy and STIs.¹

"We developed this intervention, which involves a counseling session in a clinical setting and four weeks of receiving prompts to take brief

surveys on a personal smartphone,” says **Lydia Shrier**, MD, MPH, director of research in the division of adolescent/young adult medicine at Boston Children’s Hospital.

The intervention also includes a booster session after four weeks. This session features the original counselor in the clinic in which the original counseling session took place, or held via video call, she adds.

At a three-month follow-up vs. baseline, investigators found participants reported lower frequency of sex, lower proportion of condom-protected sex events, and more consistent condom use among those who were using effective contraception.¹

“We saw a decline in depressive symptoms over three months. While we can’t attribute that decline to anything we did, it could have been a natural course of events for the participants,” Shrier says. “We were certainly glad to see that.”

The participants also demonstrated improvement in depressive conditions after three months. They showed more confidence in using cognitive restructuring.¹

The study enrolled young women at high risk of sexual behavior and featured a pilot intervention. The participants were engaged with the intervention and found it helpful, Shrier says.

“Part of the intervention is delivered through a smartphone,” she says.

The intervention can be translated, partially, to a remote platform, which would prove important during the COVID-19 pandemic, Shrier notes.

“We lose a little something when we’re not in person,” she adds. “In this case, the intervention hinges on the counselor developing rapport with the young woman, and that hinges on an in-person meeting.”

Shrier and co-investigators hope to receive funding for a larger feasibility trial. They also plan to produce an intervention that can be widely replicated.

“The timing of our larger feasibility trial would be in the fall when we hope we’re back to providing in-person care in some form,” Shrier says. “There is only so much people can do remotely. My hope is we’ll eventually return to live care, and we wouldn’t start recruitment until the fall — if we’re fortunate enough to be funded this summer.”

Teach Participants Cognitive Restructuring

The intervention’s target population of young women is based on the researchers’ clinical experience with that population, which experiences a high prevalence of sexual risk behaviors, she notes.

“The highest rates of STIs are seen in young adult women,” Shrier says. “We know that adolescent and young adult women experience very high rates of depression. That doesn’t mean all those things overlap, but there is a lot of evidence that they do.”

When young adult women experience depression, they are more likely to experience difficulty with social communication. They may have substance abuse issues that affect their decision-making ability, she says.

“They can have cognitive difficulties — a foggy brain, distortions about information that they’re receiving in their environment, and problems with risk perception and information processing,” Shrier says.

Young women with depression also experience more partner violence than women who are not depressed. “They have more problems negotiating condom use than other women,

and they may be ambivalent about taking steps to prevent pregnancy,” Shrier explains. “Pregnancy is a very meaningful and normal, healthy event in a woman’s reproductive life under the right circumstances. But when a woman is struggling with depression, she may be of two minds about whether a pregnancy at this time in her life is good for her.”

Young adult and adolescent women with depression also are more likely to have sex with multiple partners and to have sex under the influence of substances.^{1,2} They are less likely to use long-acting, reversible contraception (LARC), which would be more effective for them.¹

The intervention’s counseling sessions are designed to be in the context of sexual reproductive health counseling, but they specifically acknowledge the role that depression may be playing in a woman’s health and decision-making, Shrier says.

“One of the main skills we teach is cognitive restructuring from cognitive behavioral therapy,” she explains. “It’s the process of learning to identify and challenge negative thoughts and depression and to change your own thinking to be more positive, which can improve your mood.”

Counseling sessions, which were administered to females with depressive symptoms, ages 15 to 23 years, consisted of an in-person or video call session. One investigator conducted the session, while another investigator observed the sessions and took field notes. The counselor met with each participant a second time to review the changes and solicit feedback, assessing whether the participant’s specific concerns, comments, and recommendations were addressed.¹

Cognitive restructuring also can improve decision-making. “If a young woman is having negative thoughts about herself, and she thinks she is

not worthy because of something that happened that day, then she does not feel she deserves to be healthy and she will not advocate for her own sexual relationship,” Shrier says. “If she doesn’t want to have sex, she might not be able to say, ‘No, I don’t want to have sex.’”

It also can be difficult for the young woman to ask her partner to use a condom, to schedule an appointment for contraception, or to take a contraceptive pill each day.

When these young women learn cognitive restructuring skills, they learn to think about things in a different way. This helps them live a healthier life. It teaches them to think of themselves as worthy to take self-care steps, Shrier says.

“We teach these skills through education, examples, and practice, prompted by the smartphone,” she explains. “The part about the smartphone is based on what young women say in their survey.”

Their messages are designed by their own responses about what they want these messages to be. For example, women can select messages that are in the first person, using the word, “I,” or in the second person, using the word, “you.” They can select messages that are more encouraging and validating, and there are different styles of messages to choose, Shrier says.

“If a woman says she is really sad, she might get a message that encourages her to look at positive things in her life or to do things that help her feel good,” she says. “The messages can provide reminders that she is valuable, that she is worthy — depending on what she said in the survey.”

The messages continually encourage women to use the cognitive restructuring skills they learned. “We found in the pilot

study that the young women who participated felt more confident in their ability to do that skill, and reported using that skill,” Shrier says. “All but one woman, who reported on the smartphone, had used the skill at least once. Many used it on more than one day.”

Women are taught to understand their own needs. “We assess their desire to have sex for mood-related reasons,” Shrier says. “People may be less safe in their choices if they are seeking out sexual encounters to feel valued or to feel loved; they might make compromises with themselves about partner choices or the use of contraception.”

The counseling sessions are designed to assess women’s confidence in using condoms and contraception. They focus on the interplay between depression and sexual risk, and also use motivational interviewing techniques, she says.

“Motivational interviewing may be very helpful in pregnancy- and disease-prevention interventions,” Shrier says. “In counseling, the young woman and counselor are identifying what type of behavior she wants to change. She develops a plan for change with the counselor.”

The counselor can be someone who regularly counsels on sexual and reproductive health. For the pilot study, counselors include a registered nurse and family nurse practitioner, but they could include someone with

a master’s degree in social work who also performs case management, Shrier says.

One of the challenges — and the strengths — of the intervention is that it crosses areas of health, combining sexual and reproductive health with mental health.

“Finding people who have comfort with how to manage both of those areas, or at least be willing to learn both, is definitely a challenge,” Shrier says. “It takes a special person to do that. To help with that, we’ve made a manual of the counseling sessions, so someone could read the manual and deliver the intervention.”

The goal is to make the intervention widely available, Shrier says.

“We would only want to offer something to scale if we were really confident it would help people and if we had a robust understanding of risk and mitigation plans,” she adds. ■

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2. Lehrer JA, Shrier LA, Gortmaker S, et al. Depressive symptoms as a longitudinal predictor of sexual risk behaviors among US middle and high school students. *Pediatrics* 2006;118:189-200.

COMING IN FUTURE MONTHS

- Update on development of male hormonal contraceptive
- Strategy integrates family planning and routine child immunization
- Study reveals unique challenges for women seeking contraception while on opioid agonist therapy

An Over-the-Counter Progestin-Only Pill Would Appeal to Millions

In a model based on a national survey of 2,539 reproductive-age women in the United States, an over-the-counter, progestin-only contraceptive pill would appeal to 12.5 million adults and 1.75 million teens, assuming there were no out-of-pocket costs.¹

“We convened a coalition of researchers and advocacy organizations that support moving a birth control pill over the counter [OTC] — both progestin-only and combined pills,” says **Alexandra Wollum**, MPH, senior project manager with Ibis Reproductive Health in Cambridge, MA.

Other than barrier contraceptives and emergency contraception, there are no over-the-counter birth control methods available in the United States. More than 140 countries offer OTC birth control pills. (*More information is available at: <https://reut.rs/3dc4ugu>.*)

The Food and Drug Administration (FDA) would need to approve OTC contraception under the OTC Monograph Process or the New Drug Application (NDA) process. A sponsor seeking to market a product as OTC applies to the Division of Non-prescription Drug Products (DNBP) in the Office of Drug Evaluation IV. (*Find out more at: <https://bit.ly/311bryP>.*)

“Each pill formulation should be submitted to be over-the-counter, one at a time, given the FDA process. We believe the progestin-only pill is most likely to be OTC first,” Wollum says.

Progestin-only pills are effective at preventing pregnancy, but are safe for more people because there are fewer health conditions for which the pill is unsafe, she says.

“Progestin-only pills and combined pills are very safe. But because progestin-only pills don’t have estrogen, they don’t have complications of stroke, heart attack, and blood clot. They’re safer for the broader population to take,” she adds.

Ibis Reproductive Health partnered with a pharmaceutical company to conduct research about bringing a birth control pill OTC. “We hope in three to five years this will be possible, and we’re excited about that potential,” Wollum says.

The chief benefit of an OTC contraceptive pill would be accessibility. “Access to affordable birth control is really important to the health and well-being of people and families,” Wollum says.

Contraceptive access issues have been exacerbated during the COVID-19 pandemic. “This moment has highlighted the need for over-the-counter birth control,” she notes.

Research shows that requiring people to obtain a medical prescription for birth control pills is a steep barrier for people with limited financial resources. For example, even if the birth control pill is covered through Medicaid or insurance, the patient might have to pay for a doctor’s visit, take time off work, and get child care, she explains.

It would improve contraceptive access if a person could pick up a birth control pill at a grocery store or pharmacy without a prescription — especially if it were covered by insurance or at an affordable retail price, Wollum says.

“Our hope is that an over-the-counter birth control pill would be affordable,” she adds. “From another study we’ve conducted, the median

price people are willing to pay is \$15. Among younger teens, it’s \$10 per month.”

The study’s results reveal that among a population of adults at risk of unintended pregnancy, 38.5% were interested in using an OTC progestin-only pill, provided it has no out-of-pocket cost. If there was a cost for the OTC pill, then the percentage of people who would use it dropped.¹

While an OTC progestin-only pill would be simple to use, consumer education is needed. “For any pill to be available over the counter, people have to follow directions on the package,” Wollum explains. “There are great resources online that people can access, and we do think people are able to read and assess when the pill might be right for them, and then follow the directions for the product.” People also can access information about contraceptives online and through advice from pharmacists and providers.

The researchers concluded a low-to-no-cost progestin-only pill available OTC would provide equitable access for low-income populations across the United States, and it would fill in gaps in contraceptive access.¹

“I think this research is really encouraging and really supportive of a progestin-only birth control. It highlights the need for an equitable price to help people control their health and their lives,” Wollum says. ■

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CME/CE QUESTIONS

1. **Why might transgender and gender-diverse people prefer estrogen-containing contraceptives over nonhormonal contraceptive methods?**
 - a. Sometimes, estrogen-containing contraceptives are the only ones they can access.
 - b. They might be concerned about the efficacy of nonhormonal methods of contraception.
 - c. Research shows that clinicians often only offer estrogen-containing options.
 - d. They might desire to suppress their menstruation.
2. **A recent study shows young women with depression and who are at high risk of pregnancy and sexually transmitted infection (STI) reported which outcomes when treated with a counseling and safer sex intervention?**
 - a. They reported fewer STIs, but the pregnancy rate remained the same.
 - b. They reported a reduced frequency of sex, fewer condom-protected sex events, and a decrease in depressive symptoms.
 - c. There was a decrease in reported sexual risk behaviors, but an increase in STIs and pregnancies.
 - d. There was an increase in the use of antidepressants.
3. **A survey-informed model of women's preferences regarding an over-the-counter contraceptive found that 12.5 million adults would use an over-the-counter, progestin-only pill under what condition?**
 - a. It has no out-of-pocket costs.
 - b. It cost only \$10 per month.
 - c. It was recommended by their physician.
 - d. It was mailed monthly to their homes.
4. **When reproductive health clinicians speak with and refer to their transgender and gender-diverse patients, which terminology is preferred to describe someone who identifies as a male but was assigned female sex at birth?**
 - a. Transgender woman
 - b. Gender nonbinary person
 - c. Transgender man
 - d. Cisgender person