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INSIDE

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Adolescents with HIV Experience High Rates of Unintended Pregnancies

Adult rates are as high as youth rates

Adolescents living with HIV in the United States are among the groups with the highest rates of adolescent pregnancy. The latest research shows these pregnancies are likely to be unintended.[1]

"Unintended pregnancies are higher in adolescents, in general and globally," says **Jean Anderson**, MD, professor of gynecology and obstetrics and director of the Johns Hopkins HIV Women's Health Program. "In the United States, it's in the range of 45% of all [adolescent] pregnancies that are unintended."

Researchers found 83.6% of pregnancies among HIV-infected adolescents were unintended. Among adult women with HIV in this study, 68.7% experienced unintended pregnancy.

> RESEARCHERS FOUND 83.6% OF PREGNANCIES AMONG HIV-INFECTED ADOLESCENTS WERE UNINTENDED.

The study was a retrospective analysis of women in Baltimore living with HIV, ages 15 to 24 years at time of pregnancy, from 2003 to 2015. Of the 340 woman cohort, about one in five received a new HIV diagnosis at the time of pregnancy. Among adolescents, nearly 29% were first diagnosed with HIV during their pregnancy.[1]

"In prior studies of HIV-negative adolescents, we found similar rates of unintended pregnancy," says **Emily Murphy**, MD, clinical fellow, internal medicine and pediatrics at Harvard Medical School and resident in pediatrics at Boston Children's Hospital.

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"Prior to our study, we found in a literature review a good amount of studies documenting unintended pregnancy among women living with sexually transmitted infections [STIs]."

One-fifth of adolescents with HIV in this study were born with the virus. Their most common HIV risk factor was heterosexual contact. More than one-third of adolescents reported a history of substance use, and adolescents were more likely to report a history of marijuana use. For adolescents, marijuana use was 29.2% vs. 16.9% for adults.

Status Unknown

Researchers identified gaps in care between adolescents and adults with HIV. For example, adolescents are the least likely age group to know their HIV status, Murphy says.

The findings about unintended pregnancy are consistent with general data on adolescents and higher rates of unintended pregnancy, Anderson notes. For instance, unintended pregnancy rates are highest among low-income women, young women ages 18 to 24 years, cohabiting women, and women of color, according to the Guttmacher Institute.[2,3]

Studies also suggest unplanned pregnancies are prevalent among women diagnosed with HIV in the United States. A study of data from 1986 to 2015 revealed 78.1% of women in HIV care, ages 18 to 44 years, had an unplanned pregnancy.[4]

"Data and studies suggest that the rate of unintended pregnancy is higher among women with HIV than in the general population, although it's high in the general population, too," Anderson says.

One possible issue could be the complexity of maintaining their health and HIV care. "Something that is a real take-home message for people who are dealing with adolescents and adults with HIV is that in some cases, their HIV care takes precedent," Anderson says. "They are not having the gynecological follow-up that they should. Adolescents can be risk-takers. As they become sexually active, contraception may not be on their minds."

Reproductive health providers should keep this in mind when they see patients with HIV or HIV risk factors. Dedicated HIV clinics that also offer OB/GYN services might be the best case scenario.

The study results also produced an interesting twist: Even though the women reported high rates of unintended pregnancies, these were largely viewed positively.

"We found that even though there was a high rate of unintended pregnancy, the majority of women were still pleased to be pregnant,"

EXECUTIVE SUMMARY

Young people living with HIV experience high rates of unintended pregnancy as well as high rates of substance use.

- Reproductive health providers should screen all patients for HIV because research finds that a significant proportion of HIV-infected adolescents did not know they were infected until they were tested during pregnancy.
- All contraceptives are safe to use with antiretroviral therapy.
- Preconception care is essential for people with HIV.

Anderson says. "They didn't seek termination of pregnancy or anything like that."

About 83% of both adolescents and adults reported being satisfied with their pregnancies, Murphy says. Their biggest issue was with the timing of the pregnancy.

"How do we help adolescents time pregnancies in a way that is aligned with their reproductive goals?" Murphy asks.

Improve HIV Screening

The high percentage of young people diagnosed with HIV during pregnancy suggests the need for better screening for HIV, along with other STIs, at gynecological and family planning visits. "Everyone, ages 13 to 64, should be tested for HIV at least once," Anderson says. "We're still not great at implementing that in routine care settings."

HIV testing of pregnant patients is routine: "It's recommended that it be done in every pregnancy as an opt-out test," she says. "But these women could have been identified earlier, and maybe that would have changed certain things in terms of their health. They may have wanted to delay their pregnancy until they got their HIV under control."

Also, the latest evidence and science about HIV treatment recommends patients start antiretroviral therapy (ART) as soon as they are diagnosed. Patients no longer should wait until their viral loads reach a specific threshold.

"The goal is to get individuals with HIV virally suppressed to undetectable levels, which is associated with reduction in morbidity and mortality," Anderson explains. "It's very unlikely that if the viral load is undetectable that the mother will transmit HIV to her fetus."

For these reasons, it is important for reproductive health patients to be screened for HIV and referred to a specialist if necessary.

Preconception care is essential for everyone, but especially for those with HIV, Anderson says.

"Talk with patients about their goals and risk behaviors," Murphy suggests. "Identify the risk of unintended pregnancy."

Providers should encourage routine HIV testing. "Most family planning clinics do offer the HIV test," Anderson says. "But risk-based screening doesn't work very well because most women we see now are infected sexually and not through IV drug use, so they don't know that they're at risk because the risk comes from their partner."

All this points to the need for routine and ubiquitous HIV testing. "You need to think about HIV testing and how anybody who is sexually active is at risk, and obviously someone who has drug-using behavior is at risk," Anderson says.

Adolescents are more likely to become infected with HIV via heterosexual activity than are adults. "It's equally important to know when someone who is not infected but is at risk because of behaviors should consider pre-exposure prophylaxis [PrEP], which is very effective at preventing HIV," Anderson says.

Privacy Is an Issue

Privacy is a complicating factor. For adolescents, this can be difficult because they might be insured through their parents. Even if a rapid HIV test is used and no one has to call or email results, the insurance billing may breach the adolescent patient's privacy, Murphy says.

In addition to preconception counseling and HIV screening, reproductive health providers should address a post-pregnancy contraceptive plan with this population. "We found a surprisingly low number of adolescents and adults where, at the time of delivery and before discharge, a contraceptive plan was documented," Anderson says. "It could have been discussed, but it wasn't documented, which is concerning because a significant proportion did not come to a postpartum visit."

Since so many of these women already experienced an unintended pregnancy, they were at high risk of another unintended pregnancy. Women with HIV could use any contraceptive method, and none would affect their antiretroviral treatment. "Combined oral contraceptives may have pharmacokinetic interaction with antiretrovirals, but they don't impact ART effectiveness," Anderson adds. "They may lower the drug level of hormones — estrogen or progesterone — which could reduce the efficacy of the contraceptives."

But this does not mean the contraceptives should not be used. There are no clinical data on the efficacy — only data on drug levels. "Some providers possibly may have heard of that, or read about it, or had not used certain hormonal methods," Anderson says. "But, essentially, all the methods are on the table, and long-acting reversible contraception [LARC] should definitely be considered for adolescents with HIV, as well as those without HIV."

The researchers found fewer than one-fifth of adolescents received LARC after delivery, despite the postpartum period being an important time to encourage patients to use high-efficacy contraception.[1]

Another advantage to LARC for women with HIV is they already are on a daily ART regimen and might be interested in a contraceptive method that does not require a daily pill.

"We have several HIV regimens that are only one pill, once a day, so it's a lot easier than it was, but it's still challenging," Anderson says.

"Postpartum contraception counseling should focus on LARCs, introducing that into conversations about contraception planning in the postpartum period," Murphy says. "LARC is the preferred method for adolescents, and we found that 17% of adolescents with HIV ultimately received LARC." ■

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Cardiovascular Disease Risk Is Increasing Among Reproductive-Age Women

Cardiovascular disease among women of reproductive age has increased in recent years for a variety of reasons, and reproductive health providers should be aware of particular risk factors and issues involving this population. Clinicians should help this high-risk group prevent unplanned pregnancies, researchers noted.[1]

"There's a rapidly growing population of young adults with congenital heart disease, related to advancement in cardiopediatric surgery," says **Kathryn Lindley**, MD, associate professor of medicine, associate professor of OB/GYN and director of the Washington University Center for Women's Heart Disease in St. Louis, MO.

Also, there is a growing population of women with acquired cardiovascular disease related to issues such as obesity. "We have a steadily rising rate of hypertension among women of reproductive age, along with cardiovascular disease, heart failure, and diabetes," she explains. "This is something people will see more frequently over the next decade."

Women with cardiovascular issues are at risk for complications during pregnancy, and they can develop problems with certain contraceptives. For example, long-acting reversible contraceptives (LARCs) are a good choice for women with cardiovascular disease because they are highly effective in preventing pregnancy, and they are safe for this population. Progestin-only methods, including the hormonal intrauterine device (IUD), the subdermal implant, and progestin-only pills, have not been shown to be associated with increased risk of thromboembolism.[1]

"LARCs are safe for all underlying cardiovascular conditions," Lindley says. "IUDs and subdermal implants are safe for every medical condition, including high-risk conditions like heart failure and pulmonary hypertension."

Plus, hormonal IUDs have the added benefit of reducing menstrual bleeding, which may be a consideration for women taking blood thinner medication and who have anemia because of heavy periods.

"The main things to keep in mind, in terms of safety, are that combined hormonal methods — the pill, patch, and ring — do carry an increased risk

EXECUTIVE SUMMARY

More young adults are living with cardiovascular disease due to rising numbers of adults with congenital heart disease, obesity, and diabetes.

- Reproductive health providers should watch for potential problems when patients with cardiovascular disease use contraceptives.
- Progestin-only contraceptives, such as intrauterine devices and subdermal implants, are safe for people with cardiovascular conditions.
- When counseling patients with cardiovascular disease on contraceptives, take a thorough history and identify their risk factors.

of thrombosis or blood clots," Lindley says.

Since some cardiovascular conditions increase the risk of blood clots, contraceptives that contribute to this health risk are not recommended for some people with congenital heart conditions, mechanical heart valves, cardiomyopathies, vascular disorders, arrhythmias, and other conditions.[1]

"I recommend LARC for women with higher-risk conditions," she adds. "It's important to have careful risk-benefit discussions with patients and to keep in mind what their risks are with pregnancy."

Patients with these heart conditions should be reminded that hormonal contraceptives carry a lower risk than does pregnancy, Lindley says.

Cardiovascular disease is the leading cause of maternal death, and many deaths are preventable, research shows.[2] Overall, maternal morbidity and mortality have been rising in the United States over the past few decades, even as postpartum infections and hemorrhaging have declined. While severe bleeding and infections are the most common causes of maternal deaths worldwide, they no longer are the chief causes of maternal death in the United States.[2-5]

"My OB/GYN colleagues have done an amazing job of addressing hemorrhages and infections, which used to be the leading causes of maternal death," Lindley says. "Those are steadily improving, whereas there's a rising risk of cardiovascular death that has overtaken those obstetric causes as the leading cause of death."

It is important for providers to counsel women with cardiovascular disease about the risks of pregnancy, she adds.

Clinicians can take these measures to prevent problems with contraceptives and maternal morbidity:

• Take a thorough history. "Begin with multidisciplinary patient care from the preconception period," Lindley suggests. "Many times, women had heart surgery as an infant or child. Sometimes, they may not even have a good understanding of what their underlying condition is. Or, they think they were completely cured, whereas many of those [cardiac] conditions have long-term sequelae that put women at risk in pregnancy."

If the patient is at high risk of pregnancy complications because of heart disease, then clinicians could refer the patient to a physician who specializes in this population.

• Identify risk factors. "Sometimes, we can identify risk factors that can be modified and lower the risk of having complications with pregnancy," Lindley says. "Once she becomes pregnant, it's recommended for moderate- to high-risk women with cardiovascular disease to be managed in a collaborative fashion with maternal fetal medicine and a cardiovascular specialist. They can develop a multidisciplinary plan for monitoring women during pregnancy."

Depending on a patient's risk factors, providers might want to help the patient select an appropriate time of delivery and mode of delivery. "We need to reduce risks and quickly recognize and treat those complications should they occur," she adds.

• Be aware of disparities. "There are a lot of reasons for disparities. For Black women, it's quite striking and not solely related to income and education level," Lindley says. "Almost certainly, some disparities are related to underlying, systemic bias and racism."

The problem is a failure to recognize the disease in women of color, and failure to promptly treat them and educate them on the risk, she explains. Reproductive health providers need to talk with all patients with cardiac disease and risk factors about how to recognize their symptoms.

"Educate all patients, but particularly women who have risk factors of maternal morbidity, including obesity, Black race, advanced maternal age, and hypertension," Lindley says. "Educate them on what the risks and symptoms are so they can recognize the symptoms."

Another step is for reproductive health providers to be part of the solution in working on the larger systemic issues that contribute to racial and other disparities among women seeking contraceptive and pregnancy care. "Pregnant women of color often have a higher burden of underlying cardio risk factors," Lindley says. "We should continue to address racial bias and improve access to care."

This means providers should be part of community-based solutions to barriers such as lack of transportation or child care.

• Discuss emergency contraception. Emergency contraception is not a long-term solution, but it is important for women with high risk factors for morbidity and mortality in pregnancy to know there is an option should they have intercourse without optimal contraceptive protection.

"Women are more likely to use emergency contraception if their physician has talked to them about it and prescribed it for them," Lindley says. "It can be their back-up contraception, which is safe, but

shouldn't be used as their primary contraception." ■

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Positive Contraceptive Outcomes Seen in Teen Pregnancy Prevention Program

A comprehensive intervention for preventing unintended pregnancies among teens led to greater use of long-acting reversible contraception (LARC), fewer incidences of unprotected sex, and a big reduction in unintended pregnancies, results of a new study revealed.[1]

The 18-month Teen Options to Prevent Pregnancy (TOPP) intervention was given to a population of youths, ages 19 years and younger, who were at least 28 weeks pregnant or less than nine weeks postpartum. They also had to be enrolled in Medicaid. They were recruited from seven OhioHealth women's clinics and the postpartum units of OhioHealth hospitals.

"They were adolescent mothers, and we looked at what we could do to prevent repeat unintended pregnancy," says **Dara Lee Luca**, PhD, former senior researcher at Mathematica Policy Research in Cambridge, MA. "Most of their first pregnancies were unintended, and we were mainly focused on reducing rapid repeat pregnancies, such as having a second pregnancy within 24 months of the initial pregnancy."

Research shows rapid repeat pregnancies among adolescents lead to enduring emotional, psychological, and educational challenges.[2]

About one-third of recently pregnant adolescents experience a repeat pregnancy within two years of a previous birth or abortion. Enrollment in the TOPP study began in 2011 and continued until 2014.[1]

"We did a baseline survey at enrollment and a survey 18 months after enrollment, asking them the same questions and looking at whether they had a new pregnancy," Luca says.

The intervention was compared with a control group with access to existing standard-of-care services provided through their local healthcare organizations, home visiting programs, and community-based organizations. "If you were in the control group and not randomized for the intervention, then it would be business-as-usual services in their area," Luca says.

TOPP reduced rapid repeat pregnancies and led to significant reductions in unprotected sex. About 21% of women in the TOPP intervention group reported a repeat pregnancy at the 18-month survey, compared with 38% reporting a repeat pregnancy among the control group, Luca says.

In the intervention group, 22.4% of participants reported having sex without an effective contraceptive method in the past three months, compared to 34% of the control group. Both groups had a similar number of sexual partners.

LARC use also was significantly higher among the TOPP group than the control group, and rates of intercourse without a condom were lower.

"Around 40% of treatment group members reported using LARC in the past few months, at time of the survey, compared to 26% of control members," Luca says. "This is a stark difference. A lot more people were using LARC, and this also was accompanied by a drop in repeat pregnancy."

TOPP uses phone calls and promotes healthy birth spacing along with effective contraceptive use. Since its population of adolescent mothers is relatively transient, phone communication is easier to schedule and bypasses the need for convenient transportation. It also allows nurses to have a higher caseload than they would have with a home visiting program.

TOPP includes three parts, led by trained nurse educators.

• **Contraceptive counseling.** "This is personalized counseling on

contraceptive use with motivational interviewing techniques," Luca says. "It's a collaborative style of communication designed to strengthen personalization and specific goals."

The participants explore their own goals for change.

The nurse educators were trained extensively on motivational interviewing. First, they met at a two-day retreat. Then, for the first year, they received additional training with a consultant on a weekly basis. After the first year, nurses met with the consultant every other month, Luca explains. At the training sessions, nurses might discuss with the consultant how to troubleshoot challenges in conducting interviews.

While receiving ongoing training, nurse educators connected with the study's participants at least once a month, making an average of eight connections over 18 months, with a maximum of 24 connections. "This wide range depended on the participant's needs," Luca says. "Some people talked to the nurse a lot, and some chose not to use that service a lot."

Motivational interviewing is a technique of guiding and empowering people through respectful, nonjudgmental listening and giving information. Nurse educators individualized their client-centered, collaborative counseling style with the goal of promoting behavior change, but without sounding paternalistic or authoritative.

"They used motivational interviewing to elicit information about the person's past experiences and to encourage them to examine their own knowledge base on contraception," Luca explains. "Based on the goals, they worked collaboratively with participants to provide individualized plans."

The nurses were cautious and tried to not appear coercive, but the goal was to guide the participants to birth control methods they could use consistently, if that was part of their plan.

• **Contraceptive services.** "This part was to reduce logistical barriers to contraception use," Luca says. "It could be transportation barriers or not having access to a provider."

Barriers to effective contraception include lack of knowledge and difficulty finding a provider and scheduling an appointment. "TOPP provided access to program clinics and free transportation services. There was a board-certified OB/GYN who provides a wide range of contraceptive services," she says. "If [the participants] needed to reach a healthcare provider, they could get this free van service."

A program clinic was available for free if a participant did not have a regular provider. "All of the women were on Medicaid, and they already had access to contraceptive services, but we were trying to address these nonfinancial barriers, like how to find a provider and what type of contraceptive service to use," Luca explains.

• **Social support services.** A social worker helped participants with social determinants of health barriers.

The social worker provided an initial psychosocial assessment and needs assessment, looking at each person's risks. Based on the assessment, the social worker would offer support and referrals to various social services, including housing, child care, employment, and mental healthcare. "Some people were referred to employment agencies, and some were interested in continuing education," she adds. "The role of the social worker was to give the correct referrals."

The social support piece is to address the types of barriers that might prevent someone from using contraceptives. These include stress from poverty or unstable housing, where it is hard to adhere to a consistent birth control plan. The social worker did not provide follow-up to see if the women contacted the referral sources.

"Social work was less emphasis on that part and more like an initial assessment and then giving referrals," Luca says.

The investigators received federal funding for the resource-intensive study. It included salaries for a social worker, registered nurse, administrative staff, an OB/GYN, and funds for various contraceptives. "The nurses are registered nurses, and their time is expensive," Luca says.

A cost-effectiveness analysis showed the program was effective, but it would be difficult to justify its implementation in a setting with limited resources. TOPP cost about $1.7 million to treat 297 participants. This is compared to the public cost of an unintended pregnancy of $24,619 over a five-year period.

"We don't quite offset the cost, but most of it is offset by the reduced public cost of supporting unintentional births, and there are other benefits," Luca says. "There are long-term benefits to the labor market that are not captured in the 18-month survey." ■

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Biden Administration Proposes New Title X Rule

In April, the U.S. Department of Health and Human Services (HHS) proposed a new Title X rule to ensure access to quality family planning services. The proposed changes would revise the Trump administration's 2019 rules that Title X advocates say are harmful to women served by these public health services.

"Those rules have undermined the public health of the population the program is meant to serve," HHS wrote. "The department proposes to revise the 2019 rules by readopting the 2000 regulations (65 FR 41270) with several modifications needed to strengthen the program and ensure access to equitable, affordable, client-centered, quality family planning services for all clients, especially for low-income clients."[1]

The Trump administration changed Title X, prohibiting program clinicians and staff from giving patients any information about abortion services. It also made it logistically impossible for Title X clinics to offer abortion services at the same site, even though those services were not funded by Title X. *(For more information, see the story in the October 2020 issue of* Contraceptive Technology Update*.)*

The 2019 gag rule affected 4 million patients, including 40% who received care at Planned Parenthood facilities. After the gag rule, patients who received Title X services had to find new providers or stop receiving care.[2]

President Biden's administration is beginning to return integrity to Title X, says **Julie Rabinovitz**, MPH, president and chief executive officer of Essential Access Health in Berkeley, CA.

"Even the wording in the proposal truly reflects the administration's strong dedication to ensuring access to affordable, quality family planning services throughout the country," she says. "We believe they are committed to making this a program about access, quality, and equity."

The National Family Planning & Reproductive Health Association (NFPRHA) said it is relieved by the proposed rule for Title X. "Across the country, at least 1,300 health centers have withdrawn from the program since July 2019, leaving more than 1.5 million people without access to Title X-funded care," said **Clare Coleman**, president and chief executive officer of NFPRHA.[3]

Planned Parenthood Federation of America also applauded President Biden for moving to end the Title X gag rule. "In less than two years, the gag rule has forced providers out of the program and decimated patients' access to affordable birth control, STI testing, cancer screenings, and more," said **Alexis McGill Johnson**, president and chief executive officer of Planned Parenthood.[2]

In the proposed rule, HHS cited some of the negative effects of the 2019 rule:

- After the 2019 final rule was implemented, 19 Title X grantees out of 90 grantees, along with 231 subrecipients and 945 service sites, withdrew from the Title X program. This meant that one in four Title X-funded sites were no longer available, and six states no longer offered these services.
- In California, the largest Title X project nationally, 36% of Title X service sites withdrew from the program, leaving more than 700,000 patients without access to this care.
- While close to 4 million clients were served by Title X programs in 2018, that number plummeted to 3 million clients served in 2019.
- The 2019 rule also decreased access for low-income, uninsured, and racial and ethnic minorities' access to Title X family planning services, increasing health inequities.
- Because of the 2019 rule, 225,688 fewer clients received oral contraceptives, 49,803 fewer clients received hormonal implants, and 86,008 fewer clients received intrauterine devices.
- There also were 90,386 fewer Pap tests, and 188,920 fewer clinical breast exams. Sexually transmitted infection (STI) testing decreased by 625,802 for gonorrhea, 256,523 for chlamydia, and 77,524 for syphilis.[4]

According to HHS, the 2019 rule undermined the mission of the Title X program by helping fewer individuals in planning and spacing births, providing fewer preventive services, and delivering fewer STI screenings. The new rule will reverse these trends. "This will remove the 2019 Final Rule requirements for strict physical and financial separation, allow Title X providers to provide nondirective options counseling, and allow Title X providers to refer their patients for all family planning-related services desired by the client, including abortion services," the rule stated.[4]

But the proposed rule — with its 30-day comment period that ended in mid-May — still did not go far enough, according to both Coleman and Rabinovitz.

"Unfortunately, the administration's proposal lacks a true sense of urgency, and it fails to make the promise of greater access a reality for the millions who rely on this," Rabinovitz says. "Title X patients need immediate relief."

Every day the Trump-era regulations remain in effect, millions of low-income and rural women and people

of color receive a lower level of care. "They're denying them complete and unbiased information about their pregnancy options, and this leaves a lot of gaps nationwide," she adds. "We're calling on the Biden administration to do what the Clinton administration did in 1993 and call for the suspension of the Trump rules, while they go through the proposed rulemaking [process]."

NFPRHA implored HHS to suspend the 2019 Title X rule through separate rulemaking, Coleman says. "Unlike the Clinton administration actions suspending the domestic gag rule while proposing new rules, this proposed rulemaking leaves more than 2,600 health centers subject to program rules that the Biden administration and the provider network find untenable. Our field deserves relief now."

Waiting for the proposed rule to be made final could take months or years. "We're thrilled about the new regulations, which take us back to the 2000 regulations and adds meat around access, quality, equity, and team-friendly services, which are all critical components of the Title X Family Planning Program," Rabinovitz says. "But at the same time, the administration needs to suspend the Trump regulations right now, while they're going through the rulemaking process." ■

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FDA Makes Medication Abortion Available Via Telehealth

In April, the Food and Drug Administration (FDA) enabled reproductive health providers to prescribe mifepristone, the abortion medication, via telemedicine — at least through the duration of the pandemic.

"The FDA removed the onerous and unnecessary restrictions on accessing mifepristone during the pandemic, and this decision protects the health and safety of patients and clinicians," says **Julie Rabinovitz**, MPH, president and chief executive officer of Essential Access Health in Berkeley, CA. "It means patients will no longer have to travel to receive medication for abortion care, and it closes inequitable gaps in time-sensitive abortion access. Now, the Biden administration must move quickly to make this policy change permanent. It should not just remain during the pandemic, but it should remain long-term."

On April 12, the FDA wrote a letter to Maureen G. Phipps, MD, MPH, FACOG, chief executive officer of the American College of Obstetricians and Gynecologists (ACOG). In April 2020, ACOG had asked former FDA Commissioner Stephen Hahn to lift in-person dispensing requirements for certain prescription drugs during the public health emergency.

The letter stated the FDA's Center for Drug Evaluation and Research had reviewed data on expanding telemedicine abortion services and found no increases in serious safety concerns, such as hemorrhage, ectopic pregnancy, or surgical interventions.[1]

"The FDA will exercise enforcement discretion about in-person [prescriptions]," Rabinovitz says.

As long as other requirements of the mifepristone Risk Evaluation and Mitigation Strategy are met, the FDA approved lifting the requirement of in-person dispensing of mifepristone, since the COVID-19 pandemic presents additional COVID-related risks to patients and healthcare personnel when patients visit a clinic solely to receive a prescription of mifepristone, said the letter, signed by FDA Acting Commissioner Janet Woodcock, MD.[1]

Within a few days of the FDA's letter on telemedicine mifepristone, a physician from Seattle launched an online platform called Abortion on Demand. Women can make virtual appointments to obtain the abortion pills through a mail-order pharmacy.[2,3]

Women complete a secure questionnaire to make an online appointment. The medication is mailed in a discreet package. They follow instructions for the pills, then they receive a follow-up text message. If they experience any problems, 24/7 physician support is available. The service costs

$239 and requires clients to produce a photo ID, a positive pregnancy test, and to be less than eight weeks since their last period. They also must be at least 18 years of age and live in one of the 20 participating states, and Washington, DC, eligible for the service. Georgia is the only eligible Southern state, and Illinois is the only eligible Midwestern state, although the website notes that Michigan and Pennsylvania will be eligible soon.[3]

According to the physician who founded Abortion on Demand, **Jamie Phifer**, MD, the first women to use the service live in places where they cannot easily access abortion providers, or they have child care issues that make traveling to a provider challenging.[2]

The FDA's action is temporary, depending on the length of the pandemic and whether the Biden administration lifts the in-person requirement permanently. "Clearly, this administration is committed to evidence-based medicine and science," Rabinovitz says. "But there's no scientific or medical justification for requiring women to travel to a hospital, clinic, or medical office to pick up their medications."

Extensive evidence and expert analyses have shown that mifepristone is safe when prescribed through telemedicine. "This decision is welcome. It's definitely long overdue, and needs to be permanent," Rabinovitz says. "The harm of these regulations falls hardest on people of color, those who live in rural areas, and those who are struggling to make ends meet. We believe the administration has an opportunity and obligation to ensure individuals across the country have access to the early abortion care they need, without delay."

One potential obstacle to continuing these prescriptions is the Jan. 12 U.S. Supreme Court decision in *FDA v. American College of Obstetricians and Gynecologists*, in which the court ruled in favor of requiring the abortion pill to be picked up in person, even during the pandemic, according to a recent perspective paper. The authors noted the actual ruling is moot because the FDA's April 12 action nullifies it, but that the court's decision includes troubling stealth logic.[4]

As the paper notes, when the pandemic made it difficult for people to pick up medications at pharmacies, the FDA waived the in-person pickup requirements for controlled substances, including methadone and fentanyl, but did not waive this requirement for mifepristone. Abortion medication was the only self-administered drug that patients could not obtain by mail or a pharmacy drive-through window.[4]

A federal court had ordered the FDA to exempt mifepristone because patients had to decide between COVID-19 risk or delaying abortions.

The decision's trap is that it decided the lower court should have deferred to the FDA's expertise to assess public health, which sets a precedent for courts siding with politicized agencies, such as federal agencies with political appointees, over evidence-based and scientific expertise. The three dissenting liberal justices called the decision a "callous response."[4] ■

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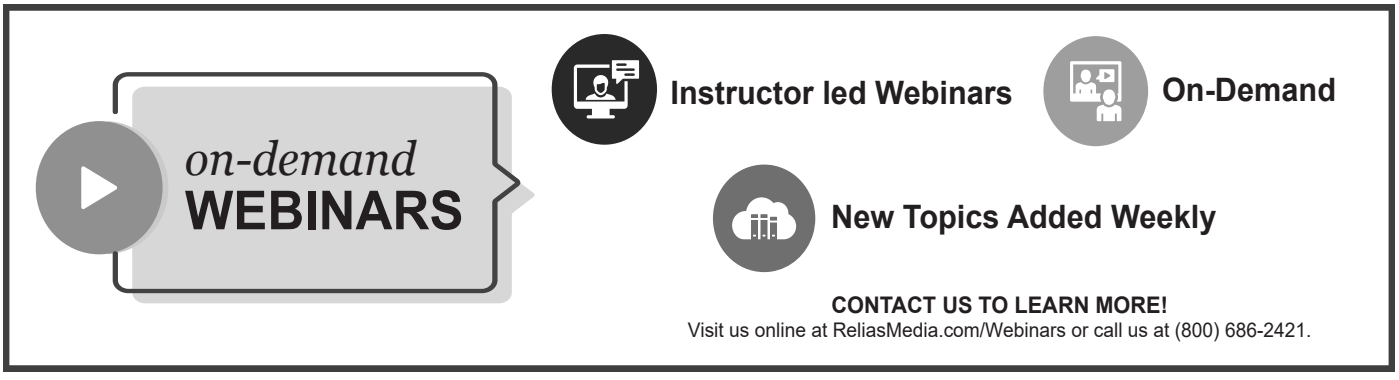

Study: Abortions Do Not Lead to Mental Health Problems

The results of a large body of research suggest abortions do not have a negative effect on women's mental health, despite claims from anti-abortion groups and state legislatures.[1]

The authors of a new paper noted the reasons why women decide to undergo an abortion include many mental health risk factors, such as poverty, lack of social supports, domestic violence, rape, incest, pre-existing mental illness, and lack of education. But post-abortion, women's mental health status does not deteriorate, although stress levels might increase if they experience barriers in obtaining the abortion.[1]

"The main gist of the paper is, 'Don't believe anyone who tells you that abortion causes mental illness or impairs anybody's psychiatric well-being,'" says **Nada Stotland**, MD, MPH, professor of psychiatry at Rush Medical College in Chicago. Stotland researches psychiatric issues surrounding abortion. She also is the former (2008-2009) president of the American Psychiatric Association. "There is evidence, going back decades, that having an abortion in and of itself does not cause anybody to have a psychiatric illness, and rarely causes anybody to even have any significant prolonged negative psychological outcome."

For women who have undergone an abortion, the most common reaction is relief, Stotland says. "Some people may feel guilty. Some people may feel sad, but not clinically depressed. I've said in some hearings that if 50% of marriages end in divorce, I think there are a lot more people regretting getting married than having abortions. Are you going to make it harder for people to get married?"

While there are people who will say they are sorry for their abortion, if they are asked if they would still have obtained an abortion if in the same circumstances and could do it over, they say they would do it again. "Maybe they wish they had a child now that they have education, income, and steady support of their living situation," Stotland says. "But when you say, 'Was that the wrong decision at the time?' they say, 'No, that was the best decision I could do at the time,' and there's no evidence of traumatic, lasting regrets."

In the 1980s, Surgeon General Everett Koop reported extensive research into legalized abortion, finding that the risk of a woman dying was 25 times greater with giving birth than with abortion.[2]

According to 2013 reports (after Koop's death), Koop had refused to prepare a report that detailed negative mental health effects of abortions, despite pressure from President Reagan. Koop had written to Reagan that scientific experts and evidence suggested the negative health effects were not as conclusive as Reagan hoped.[3]

"Reagan appointed Koop as surgeon general and ordered him to report on the impact of abortion on women in America," Stotland says. "He was expected to write a kill report. But it turned out that Dr. Koop could have been very against abortion, but was not a liar."

Stotland, who was a committee chair with the American Psychiatric Association in the 1980s, was asked to review literature and speak at a hearing, held by Koop, on abortion. After the hearing, Koop refused to write a report that made unsubstantiated claims about abortion's mental health effect on women, she explains.

Despite the lack of solid, evidence-based data on causative links between abortion and mental illness, some states require abortion providers to tell patients of the risk of depression, suicide, substance use, and other issues. "There is no other medical procedure in which the state tells doctors and providers which words they have to tell patients about the procedure," Stotland says.

There also are no parallels to how some states require providers to take an ultrasound of the woman's embryo and make her look at it, she adds.

"I was a psychiatric consultant in OB/GYN and psychiatric medicine, and there's no other similar situation," Stotland says. "It is much more important for women's mental health to be able to get abortions when they need them, and it's deleterious to their mental health to put barriers in their way. All the obstacles only increase the stress on your patient. You can reassure the patient that once she decides this is what she has to do with her life, she can rest assured that [having an abortion] will not increase any psychiatric condition." ■

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CME/CE QUESTIONS

1. **Which type of contraception is safest for all underlying cardiovascular conditions?**

   a. The vaginal ring
   b. Combined hormonal pill
   c. The patch
   d. Long-acting reversible contraceptive (LARC)

2. **Teen Options to Prevent Pregnancy (TOPP), an 18-month intervention studied in a population of Medicaid-enrolled youth who either were pregnant or had recently given birth, made a significant positive change by:**

   a. increasing use of LARC, decreasing unprotected sex, and reducing unintended pregnancies.
   b. increasing use of birth control pills.
   c. decreasing low-birth weight deliveries.
   d. increasing social media messages among the adolescents about use of contraceptives.

3. **Which group is least likely to know their HIV status, according to Emily Murphy, MD?**

   a. Women over age 40
   b. Men who have sex with men
   c. Adolescents
   d. All reproductive age women

4. **On April 12, the Food and Drug Administration (FDA) notified the American College of Obstetricians and Gynecologists that the agency had made which change regarding mifepristone?**

   a. FDA allowed advanced practice providers to prescribe it.
   b. FDA said providers could prescribe mifepristone via telemedicine, through the pandemic.
   c. FDA made telemedicine abortion permanent.
   d. FDA approved use of a second abortion medication in the event mifepristone was unavailable.

STI QUARTERLY™

A SUPPLEMENT TO CONTRACEPTIVE TECHNOLOGY UPDATE

Fewer Tests, Possible Increases in Sexually Transmitted Infections During Pandemic

High STI rates before COVID-19

Public health officials still do not know the full effect of the pandemic on the incidence of sexually transmitted infections (STIs) in the United States.

The COVID-19 pandemic disrupted STI testing. It is unknown if people engaged in risky behavior during various regional and national shutdowns.[1]

"The big message is we're not really sure what is happening," says **Philip A. Chan**, MD, MS, infectious diseases physician and associate professor at Warren Alpert Medical School and School of Public Health at Brown University. "When we talk about sexually transmitted disease cases, those are based on medical diagnoses and people testing positive. The way the pandemic impacted healthcare is people didn't present to doctors, so there was a decline in diagnosed STI cases."

But that could be an illusion. "None of us think there is a true decrease because we're not sure," says Chan, an attending physician at The Miriam Hospital Immunology Center in Providence, RI. "The word on the street is people are having fewer sexual partners. We're not sure what's happening with STIs in the pandemic. As things reopen, there's a huge concern that we may see things spike."

This interim period — post-vaccine and before the end of the pandemic — is an important time for public health agencies and reproductive health providers. "It's a critical time to encourage people to get tested, stay vigilant, and stay engaged with education about sexually transmitted infections and health," Chan says. "In the last decade, we've seen exponential increases in chlamydia, gonorrhea, and syphilis, and then the pandemic hit. We [may be] still on an upward trend."

The Centers for Disease Control and Prevention (CDC) reported in 2019 that the United States saw the highest-ever recorded rates of chlamydial, gonococcal, and syphilis infections. Young women, ages 15 to 24 years, had the highest rates of chlamydia. Adolescents also had the highest gonorrhea rates.[2]

But STI testing was disrupted in 2020 because of the redirection of scarce public health resources to accommodate widespread testing of SARS-CoV-2, says **Fareeda Haamid**, DO, pediatrician in the division of adolescent medicine at The Ohio State University College of Medicine. The shift to accommodate COVID-19 testing led to a scarcity in STI testing materials, especially laboratory supplies and testing kits.

"This had an impact globally, was far-reaching, and was mostly concentrated around chlamydia and gonorrhea testing," Haamid explains. "Our microbiology colleagues in the lab ordered these supplies in advance, and noticed a dwindling supply and it not being replenished."

The CDC wrote a letter on Sept. 8, 2020, encouraging continued screening of asymptomatic, sexually active females younger than age 25 years, as well as men who have sex with men, when STI diagnostic tests experienced only moderate shortages. The letter also suggested judicious use of diagnostic testing within the adolescent population, with decisions guided by local shortages and supply limitations.[2]

"They were aiming to test and treat as many infected people as possible and prioritize the potential for STI complications," Haamid says.

There are several potential causes of the pre-pandemic trend of rising STIs cases. "There are issues with access to

STI prevention and treatment due to poverty, stigma, drug use, and unstable housing, which all impact access to care," Haamid explains. "There also has been a decline in condom use among young people, who are the most vulnerable."

Funding to pay for STI programs has been cut at the state and local levels."We've seen in recent years that almost half of local programs had budgetary cuts and clinics closing, resulting in reduced patient follow-up and diminished screening capacity," she says. "It's these three things: access issues, decline in condom use, and budgetary cuts."

More research is needed to determine the reason for the decline in condom use, but one theory is that as young people increasingly use long-acting reversible contraceptives, they are less likely to use condoms, Haamid says.

It also is possible that people have more sex partners, which could contribute to asymptomatic spread of STIs. "We think network spread is how some of these STIs spread," Chan says.

For example, chlamydia is asymptomatic in 80% to 90% of the people with the STI, Chan says.

Access also is an issue. "There may be a lack of access to condoms; the verdict's still out on all of the 'whys' that this is happening," Haamid says.

The solution is for providers to offer STI tests, when available, to everyone, especially young women, letting patients know about how infections can be asymptomatic. "The reason for the focus on women is for the risk of complications," Chan notes. "Complications include infertility, chronic pelvic pain, and pelvic inflammatory disease, which is when it infects the ovaries and causes abscesses and serious infection."

Providers also should consider the possibility of infections of areas other than the vagina and urethra. "Over the last 10 years, we've realized that people who perform oral sex or have receptive anal sex can get gonorrhea or chlamydia in the throat or rectum, and that would not be picked up if you just have the urine test," Chan says.

Men who have sex with men, and heterosexual men and women could become infected in those areas. Clinics should test with swabs for the throat and rectum. "A lot of clinics have people do it themselves, giving them a swab and great instructions on doing it," he says. "We make it more acceptable to patients by having them do it themselves."

Reproductive health providers also could stress harm reduction strategies. "Find creative, flexible ways to reach adolescents, and know the population you are serving," Haamid adds. ■

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Intervention Reduces Positive STI Tests and Increases Condom Use

A culturally tailored intervention for a particularly vulnerable group of Black women has reduced the odds of testing positive for a sexually transmitted infection (STI) and increased condom use in vaginal or anal intercourse, the authors of a recent study found.[1]

The five-session, group-based intervention, called Empowering African American Women on the Road to Health (E-WORTH), was created in 2015. More than 350 Black women were recruited from community supervision programs for the study. Participants had a history of drug use, but were in drug treatment. They also were on probation, parole, or in an alternative-to-incarceration program in New York City. They had risk factors for HIV or STIs, and/or they were HIV positive. The women were randomized to receive E-WORTH or an HIV testing control condition.[1]

"The intervention was designed by Black women for Black women," says **Louisa Gilbert**, PhD, associate professor and co-director of the Social Intervention Group, the Global Health Research Center of Central Asia, and CHOSEN (Columbia Center for Healing of Opioid and Other Substance Use Disorders — Intervention Development and Implementation) at Columbia University School of Social Work in New York City.

For example, a group of Black women who helped design E-WORTH tweaked the characters created for various scenarios and

examples in the group sessions. The women would say that a particular scenario or verbal exchange was not realistic, and the content then was changed, Gilbert says.

"We used words that were in their everyday language, in terms of the way we'd introduced activities," she adds. "These examples in scenarios and vignettes would resonate with them."

The intervention featured trained counselors or case managers, who also were Black women, to deliver both E-WORTH and the control condition. Women who received the E-WORTH intervention had 54% lower odds of a positive STI test in the 12-month follow-up when compared with the control group. Their rates of sex without condoms dropped 38%.

The four 90-minute group sessions were designed to gain trust and engagement among the target population. For instance, they featured scenarios with Black women characters, whose narratives were designed by Black women who helped create the program.

"They gave motivational pieces on how to stay safe and addressed sexual communication and negotiation skills," Gilbert explains. "It addresses how to stay safe in certain sexual situations, and also in social support enhancement in reducing risks and identifying needs."

Part of the cultural aspect of the intervention involved talking with women about the effect of race on their circumstances, including laws and policing that landed these women under community supervision in the first place. "It's the new Jim Crow system, and we acknowledged that their partners are in and out of prison because of the same radicalized drug laws," she explains. "There are huge disparities in legal reaction to drugs."

E-WORTH raised awareness of systemic racism and what Black women face. It also suggested they needed to band together to protect themselves from STIs and HIV, she adds.

The sessions included 45 minutes of computerized activities and time for social support enhancement and group interactions. This included discussions about drug treatment, sexual health, and how intimate partner violence can affect reproductive health decisions.

"Often, women in abusive relationships have trouble negotiating safer sex," Gilbert says. "As a group, they talk about the challenges they're having, what their goals are for the following week, and how they will achieve them."

These group sessions promoted bonding and provided support, she notes.

Because so much of healthcare and research participation has moved to electronic versions over the past year, Gilbert says E-WORTH also could be adapted to a virtual intervention. "Half of the intervention was computerized self-paced modules, and there is potential for a virtual group, as well."

An essential feature is how it is culturally tailored for its audience. "It's consistent with other culturally tailored interventions for African Americans," she explains. "Those interventions tend to do better than non-culturally tailored interventions."

One of the factors that makes this population particularly challenging for a health-related intervention is the propensity for medical distrust. "African American mortality rates and STI rates are higher [than other groups]," Gilbert says. "We have to openly acknowledge the medical distrust and huge racial disparities in terms of reproductive health and outcomes."

For instance, Black women are two to three times more likely to die from pregnancy-related causes than are white women, according to data from the Centers for Disease Control and Prevention.[2]

E-WORTH, while designed for at-risk Black women, could be tailored to other populations such as Latinas and adolescents. "It primarily targeted women in community supervision, their life experiences, and challenges of reproductive health and negotiating safer sex, which could be universally applied to a lot of women," Gilbert says. "There is broader applicability, and there are options to tweak it to whatever population you'll deliver it to." Culturally tailored interventions work in whichever population is being served, she adds.

Disseminating the intervention is the next step. "Now that we know it works, we're looking at how we can scale it up in different settings," Gilbert says. "I'd like to see it used in family planning, in addition to community supervision settings to reach African American women at risk." ■

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Study: STIs Can Affect State Medicaid Budgets

Screening and treatment of sexually transmitted infections (STIs) can cost states tens of millions of dollars in Medicaid budgets, but public health activities to prevent STIs can help reduce these costs, according to a new study.[1]

Contraceptive Technology Update asked researcher **Melinda A. Merrell**, PhD, MPH, research assistant professor in the Rural & Minority Health Research Center at the University of South Carolina, to discuss her study's findings and implications. This interview has been edited lightly for length and clarity:

CTU: What do your findings suggest about the cost of diagnosing and treating STIs? How might it compare to the cost of investing in public health prevention efforts?

Merrell: Our findings suggest that diagnosis and treatment of the most commonly reported STIs does financially impact individual state Medicaid programs. While we were unable to provide a direct cost comparison between expenditures for Medicaid programs vs. public health prevention activities, we know that primary prevention and improved access to STI services can reduce the burden of these diseases, thus reducing costs overall.

CTU: Which STIs were included in the analysis? How common are those infections in the states you studied, and in the United States?

Merrell: Chlamydia, gonorrhea, and syphilis were chosen for this study due to their overall prevalence in the United States as well as increasing trends in cases since 2014. As of 2018, the national prevalence of chlamydia was 1.8 million cases (a 14% increase since 2014); gonorrhea, 583,405 cases (63% increase); and primary and secondary syphilis, 35,063 cases (71% increase). By state in 2018, Maryland had 35,482 chlamydia cases, 10,305 gonorrhea cases, and 2,536 syphilis cases. South Carolina had 33,910 chlamydia cases, 13,801 gonorrhea cases, and 1,152 syphilis cases.[2-4]

CTU: Why did you choose to compare South Carolina with Maryland? What difference in Medicaid expenditures for STI care did you find between these two states?

> "WE KNOW THAT PRIMARY PREVENTION AND IMPROVED ACCESS TO STI SERVICES CAN REDUCE THE BURDEN OF THESE DISEASES, THUS REDUCING COSTS OVERALL."

Merrell: We wanted to examine differences in Medicaid expenditures between two states. Currently, one of the biggest differences we can observe in Medicaid programs is whether access to coverage was expanded to people with incomes up to 138% of the federal poverty line as a result of the Patient Protection and Affordable Care Act (ACA). Maryland and South Carolina had similar rates of Medicaid participation and STI prevalence but differed on Medicaid expansion, which made them ideal for this comparison. Maryland expanded Medicaid eligibility under the ACA in 2014; South Carolina has not yet exercised this option.

We found that STI screening and treatment in Maryland was performed in higher numbers and at a higher total expenditure to the Medicaid program as compared to South Carolina. This was in spite of the observation that most services provided for STI care in South Carolina occurred in a high-cost setting (the emergency department).

Maryland Medicaid spent $41.5 million in state fiscal year (SFY) 2016 and $45.4 million in SFY 2017, while South Carolina Medicaid expenditures were $22 million in SFY 2016 and $22.6 million in SFY 2017. The highest cost setting for Maryland Medicaid was the outpatient hospital setting ($26.4 million in SFY 2016 and $27.4 million in SFY 2016).[1]

These findings suggested that differences in Medicaid eligibility between the two states as well as the design of the healthcare delivery system in Maryland, among other factors, may have increased access to STI services for Maryland Medicaid participants. ■

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