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The Promise of Extending IUD Access to All Women

A new IUD was made expressly to break down cost and trust barriers. Will it succeed?

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IUD. (Photo: +mara/Shutterstock)

Half of all pregnancies in the United States are unintended. What would happen to this number if most American women had access to a form of birth control that was over 99 percent effective? From 2007-11, researchers at Washington University in St. Louis embarked on a groundbreaking study, the Contraceptive CHOICE <u>project</u>. The study's goal was to examine what would happen to unintended pregnancy rates in the St. Louis area if clinical providers educated women about all of their birth control options, and offered such options for free.

Five years later, the results were in. Published in *Obstetrics and Gynecology*, CHOICE researchers found that the group's abortion rate was half that of the St. Louis population at large; and the teen pregnancy birth rate was lower still, at 6.3 births per 1,000 people, compared to the national rate of 34.3 per 1,000. Seventy-five percent of the 9,256 teenage girls and women who had enrolled had chosen a long-acting reversible contraceptive (LARC) method, which include the IUD and the implant. Only 7.2 percent of women aged 15 to 44 <u>used IUDs</u> from 2011-13, compared to 28 percent of women who use the birth control pill and 16 percent who rely on condoms.

Ten percent of American women practicing contraception were using the IUD in the 1970s, according to David Hubacher, an epidemiologist <u>writing</u> in *Perspectives on Sexual and*

Reproductive Health. IUDs experienced a major setback in the U.S. in that same decade, when women using the Dalkon Shield began experiencing major complications en masse. As a result, IUD use decreased to less than one percent of the U.S. female population by the early 2000s.

Today, IUDs are becoming popular again, with the 7.2 percent figure cited earlier representing a peak in IUD use in the U.S. Many women choose this method because it is the most effective in preventing pregnancy, and because you can "set it and forget," says Dr. David Eisenberg, a researcher in the Contraceptive CHOICE study. And while this form of contraception is longacting, it's also reversible (hence the LARC acronym); once a woman wants to get pregnant, she can get it removed, with no effect on her reproductive health.

While women were counseled on all Food and Drug Administration-approved contraceptive methods they were offered long-acting reversible contraceptives like IUDs first as the most effective option. "We made sure that the clinical providers in the CHOICE project understood what many big public health and medical organizations have said, which is that long-acting reversible contraceptives should be the first line contraceptive method for all women and teenagers if that's what they choose," Eisenberg says. That, combined with taking away the cost barrier, led women to choose an IUD or implant in astonishingly large numbers.

The Contraceptive CHOICE project points to the need for affordable LARCs in the U.S. Unlike condoms or the pill, LARCs are over 99-percent effective in preventing pregnancy, with hormonal IUDs having a 0.2 percent failure rate. Currently, the upfront cost for an IUD is around \$1,000, making them unaffordable for many women, even with the Affordable Care Act mandating complete birth control coverage for new private insurance plans. Yet even if they can afford a LARC, women still have to wade through misinformation, including whether they're safe, or whether they're suitable for women who are not monogamous, or who have never had children.

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This is where Liletta comes in. Available since April 13, Liletta is a hormonal IUD being offered at reduced cost to public health clinics across the country; it was FDA approved based on what researchers call the largest hormonal IUD trial conducted in U.S. history. Besides enrolling 1,751 women, this trial included women of diverse racial, age, and health backgrounds to counter myths that this method doesn't work for certain women.

"We wanted to develop an IUD for the sole purpose of expanding access to all women," says Pamela Weir, the COO of Medicines 360, a hybrid non-profit, social enterprise, and pharmaceutical company, as it describes itself, responsible for Liletta. This is a story about how Medicines 360 hopes to do this, even in the current reproductive health landscape of high costs and lack of information.



In 2010, Wagatwe Wanjuki was unemployed and writing about feminist issues. Her precarious financial situation made it difficult for her to use oral contraception as her birth control of choice:

"I would be sexually active and then I would stop, and then I would have to rush to go back on the pill," she says. "And my life was all over the place in terms of whether I had health coverage or how much it cost because of whatever legislation passed or wasn't renewed."

Wanjuki had qualified for a free year of health care at Planned Parenthood that was almost up. She made an appointment to get an IUD. "This was in the days way before Obamacare," she says. "So I said, 'Let me take advantage of getting free birth control and I will be all set until I'm almost 30."

That same year, the Affordable Care Act went into effect, requiring new private insurance plans to cover birth control without a co-pay. Yet there are <u>many exceptions</u> to this rule, with plans only required to cover one brand of each type of birth control, and with other plans grandfathered in and not having to fulfill this requirement at all.

And even in the era of required health insurance, many people still can't afford it. When Alison Turkos quit her non-profit job to become an abortion counselor in 2013, she gave up a higher salary and her employer's health insurance plan. This year, the clinic Turkos frequented offered three LARC insertions for uninsured women. So she filled out the paperwork to get a Mirena IUD free of charge. On the day of, however, the clinic asked her for a \$100 co-pay.

"My income level is not one where I could pay \$100 without some advanced budgetary notice," Turkos says. "So they were able to set me up a sliding scale of benefits, so my IUD was 100 percent free."

Turkos' story speaks to the need for affordable IUDs, especially when costs concerning consultations and insertions can add up. The federal government helps somewhat with this under the Title X grant program, under which clinics that see patients from underserved populations qualify for reduced-price drugs and products as part of the 340b program. This includes family-planning devices like hormonal IUDs Mirena and Skyla and the copper Paragard IUD. Costs can decrease from \$1,000 to as low as \$250.

Medicines 360 hopes to sell Liletta to such clinics for as little as \$50, which would go a long way toward fulfilling its stated goal. "Speaking as someone who works at a university medical center and is the medical director of a local Planned Parenthood affiliate," says Eisenberg, who ran the St. Louis site for the Liletta trial, "if it costs the clinical provider and the physical clinics less for a drug product, they're gonna pass those savings onto their patients, hands down."

This low price point could incentivize some clinics to actually stock IUDs instead of ordering them when a patient asks for one. "The reason same-day placement is important is because patients don't come back," says Patty Cason, a nurse practitioner at Planned Parenthood Los Angeles who also trains other providers in placing and discussing Liletta and other IUDS with patients. "Even if you can't provide it for them when they want it, then they don't come back, or if they do come back, they're pregnant, which is quite dispiriting for everyone involved."

Dr. David Noya says that his clinic—the South Central Family Health Center in Los Angeles—gets reimbursed for IUDs under California's Medi-cal insurance and Family PACT program for

low-income patients. Yet fronting these costs, even at 340b prices, puts significant strain on the clinic's budget.

"Having an IUD that is just as effective at a lower cost benefits not only our organization but health care costs in general," Noya writes in an email. "If [there are] evidence-based studies from clinical trials that the Liletta IUD is just as effective and as easy to insert as its competitors we would definitely consider switching over to the low-cost product."



Krissy Leahy is the program coordinator for "Get Smart b4u Get Sexy," an <u>initiative</u> of Black Women for Wellness, based in Los Angeles, that provides comprehensive sex education to young black women.

Recently, Leahy <u>posted</u> on Black Women for Wellness' Facebook page, asking users what they think of IUDs. Many of the messages were negative: "The fuq.. [sic] I heard its been causing bad side effects. The best birth control...Abstinence/Celibacy. If you're not engaging in sex you have nothing to worry about," wrote one visitor.

"Remember the Delkon [sic] shield. It made women unable to carry full term...," wrote another.

The Dalkon Shield IUD was aggressively marketed in the 1970s until thousands of women filed a class action lawsuit against the manufacturer for severe complications such as pelvic infections, ectopic pregnancies, and even death. Distrust over providers who recommend the IUD also comes from the Tuskegee syphilis experiments, Henrietta Lacks' stem cells being used without her family's knowledge and permission, and sterilizations forced on women of color throughout history, Leahy explains.

"Many people question IUDs because of its history, and I think for women of color that history is stronger, just because birth control methods, particularly long-acting reversible contraceptives have been used to control women in poverty, and control women based on their race also in terms of when they can or can't reproduce," she says. To back this up, Leahy discusses Dorothy Roberts' *Killing the Black Body*, which <u>details</u> the history of policymakers trying to control the reproductive health of women of color, including when it comes to LARC insertion.

The Liletta clinical trial, also known as the Access IUS <u>study</u>, explicitly deals with IUD misconceptions and shows that it's suitable for many different types of women. To deal with the notion that the device is unsuitable for women who had never had children, 57.7 percent of women in the Liletta trial fit this criteria. The trial also included overweight and obese women and teenagers as young as 16. And study enrollees' racial breakdown "<u>parallel the 2010 census</u>" when it comes to the proportion of Caucasian, African-American, and Hispanic women researchers enrolled, as the study says.

The question is whether a diverse range of women will seek out this information, and trust it. Turkos and Wanjuki were empowered to do so because of their proximity to reproductive health and feminist activism. Turkos herself also grew up in a household that was open about sex,

which makes her comfortable, she says, in discussing IUDs and other forms of birth control with everyone from her parents to her partners and to the public through her Twitter account.

* * *

Chrishaun Bradford grew up in a low-income neighborhood in Oakland, California, where many of her peers were unexposed to sex education and were unable to afford adequate health care. Teen pregnancy was a looming reality in her life, with her mother having Bradford a day after her 16th birthday, and with a friend also giving birth to a baby in high school.

This friend got an IUD after having this baby, so when Bradford decided to consider one, she asked her for advice. "I was using her for reassurance, 'cause I had to feel good about getting it, or that it was actually effective," she says. "She said it was fine, that she hardly ever thought about the fact that she had it."

Bradford's mother also had an IUD, and had made sexual protection an open topic from day one in their household: "Of course she encouraged me not to have sex, and the things that could happen if you do have sex," Bradford says. "But even though she didn't want me to do it, she taught me about protecting myself, and I think that's what ultimately allowed me to make the decision on my own that that what I wanted."

She got her Mirena IUD at the Kaiser Permanente facility where her mother works as a nurse. Her mother's health insurance covered the whole thing. She praises the Mirena for fulfilling its purpose ("I feel like it was pretty effective in its goal of preventing children, you know, *babies*," she says). She says she experienced noticeable side effects while on it, however, including debilitating cramps during her period. During a routine check up a year ago, Bradford asked her provider to check on her IUD, but he couldn't find it, even after doing an ultrasound.

Less than five percent of Mirena users have <u>experienced</u> an IUD expulsion like Bradford's. Three-and-a-half percent of Access IUS participants experienced such an adverse event, while 1.5 percent experienced bleeding issues and 1.3 percent had mood swings. Even more rare were serious side effects like uterine perforation.

Bradford is still trying to make sense of how her expulsion may have happened ("Maybe it was inserted wrong, maybe it moved around after a couple of years," she says). Yet she would consider getting another IUD if she can build up trust in it again. "Maybe I would wait until it's been used a while, this new one that you were talking about," she says. "So that I would know from others who experienced it how it affected them."

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