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Intrauterine Devices (IUDs): Access for Women in the U.S.

Intrauterine devices (IUDs) are one of the most effective forms of reversible contraception. IUDs, along with implants, are known as long-acting reversible contraception (LARCs) because they can be used to prevent pregnancy for several years. IUDs have been used in the U.S. for decades, but a safety controversy in the 1970s prompted the removal of all but one IUD from the U.S. market by 1986. The first new generation IUD was introduced to the U.S. market in 1988, following revised Food and Drug Administration (FDA) safety and manufacturing requirements.[1] Recent controversies have focused on the mechanism of action of IUDs, the high upfront costs for the device, and variability in insurance coverage and access. This fact sheet reviews the various IUDs approved by the FDA, awareness, use, and availability of IUDs, and key issues in insurance coverage and financing of IUDs in the U.S.

WHAT IS AN IUD?

IUDs are small devices placed into the uterus through the cervix by a trained medical provider to prevent pregnancy. A follow up visit is recommended post-insertion to confirm placement, and a visit to the provider is required for removal.[2] IUDs are effective for 3 to 10 years, depending on the type of IUD. There are two major categories of IUDs - copper and hormonal- and within those categories, there are currently five IUDs approved by the FDA (**Table 1**). IUDs work by affecting the ovum and sperm to prevent fertilization and are more than 99% effective at preventing pregnancy. They do not protect against HIV and other sexually transmitted infections (STIs). IUDs do not affect an established pregnancy and do not act as an abortifacient.

NON-HORMONAL COPPER-T INTRAUTERINE DEVICE

The copper IUD is a hormone-free T-shaped device wrapped in copper wire and is effective for up to 10 years.[3]

- Marketed under the brand name **ParaGard** by Teva Women's Health Pharmaceuticals, the copper IUD was approved by the FDA in 1984 and has been available in the US since 1988.[4,5]
- The copper IUD begins working immediately after insertion and consequently does not require a woman to use a backup method of contraception after insertion.[6] Because of this, the copper-IUD can also be used as emergency contraception within 5 days of unprotected intercourse or method failure and is more effective at preventing pregnancy than emergency contraceptive pills.[7,8] Unlike Plan B emergency contraceptive pills, the effectiveness of IUDs does not vary based on a woman's weight.
- Many women who receive an IUD for emergency contraception retain the IUD as their primary form of contraception. One study found almost 95% of women who received an IUD as emergency contraception were still using this method 12 months later.[9]
- Prior theories that the copper IUD damages fertilized embryos or prevents implantation are not supported by current evidence.[10]

Hormonal Intrauterine Devices (LNG-IUD)

There are currently four hormonal IUDs available on the US market, also known as LNG-IUDs because they contain the progestin hormone levonorgestrel, which is released in small amounts each day. Today, most women who use IUDs use one of the hormonal products. Hormonal IUDs are not effective as emergency contraception.

- **Mirena,** manufactured by Bayer Healthcare Pharmaceuticals, is the hormonal IUD that has been on the market longest and is most commonly used.[11] In addition to preventing pregnancy, the FDA approved use of Mirena in women using this IUD as contraception to treat heavy menstrual bleeding. Mirena, as well as the copper IUD, are not FDA approved for women who have not had children (nulliparous),[12] but research has found that they can be provided safely and effectively to these women.[13]
- **Skyla,** also manufactured by Bayer, is slightly smaller than the Mirena, making it a better candidate for nulliparous women.[14]
- **Liletta** was approved in 2015. Actavis in conjunction with Medicines360, a non-profit women's pharmaceutical company, developed Liletta specifically to be low cost and available to public health clinics enrolled in the national 340B Drug Pricing Program, which provides reduced cost pharmaceuticals to providers that serve low-income populations.[15]
- **Kyleena,** the newest IUD, was approved by the FDA in September 2016, and became available in October 2016.[16] It's also manufactured by Bayer, and contains lower hormone levels than Mirena.

Table 1: Types of IUDs

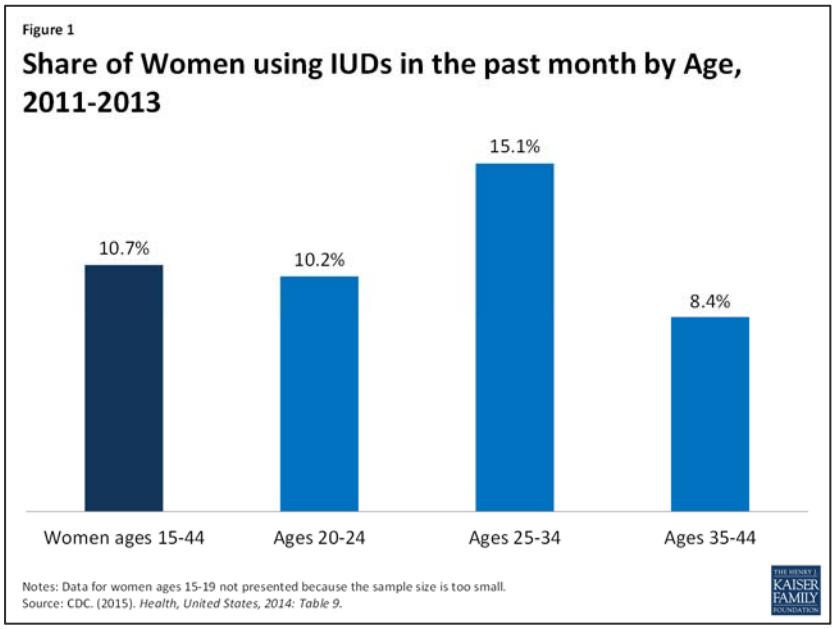
Copper IUD	Available Since	Years Effective	Use and FDA Approval	Possible side effects
Copper IUD (Paragard)	1988	10 years	Approved only in parous women, but available to all women regardless of parity. Can be used as Emergency Contraception when inserted within 5 days.	• Abnormal menstrual bleeding. • Higher frequency or intensity of cramps/ pain.
Hormonal IUDs	**Available Since**	**Years Effective**	**FDA Approval**	**Possible side effects**
Mirena	2001	5 years	Approved only in parous women, but available to all women regardless of parity.	• Inter-menstrual spotting in the early months. • Reduces menstrual blood loss significantly. • Hormone-related: headaches, nausea, breast tenderness, depression, cyst formation.
Skyla	2013	3 years	Approved for women regardless of parity.	
Liletta	2015	3 years	Approved for women regardless of parity.	
Kyleena	2016	5 years	Approved for women regardless of parity.	

Use, Awareness, and Availability of IUDs

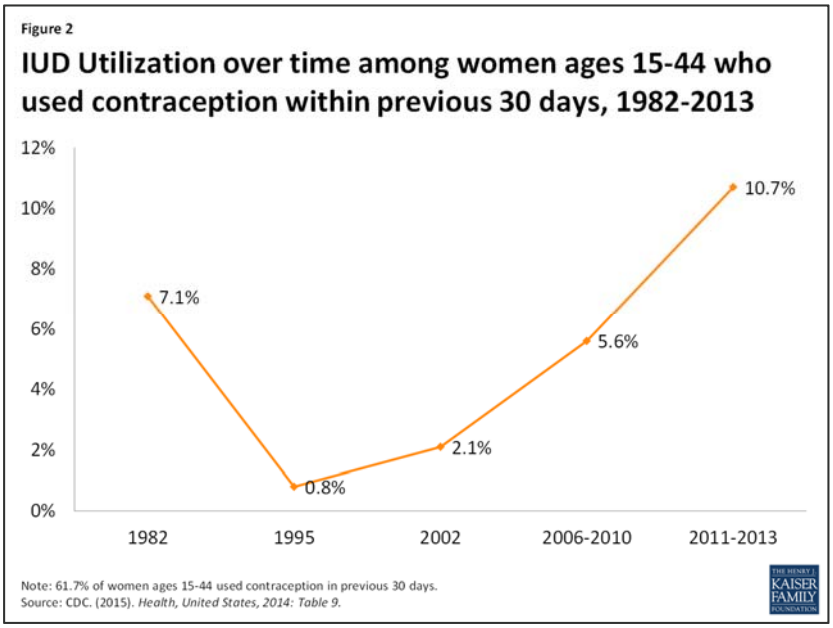
Use of IUDs in the U.S. has been increasing substantially since the early 2000s, but is still lower than other methods. Attitudes regarding safety of IUDs are beginning to shift and interest is growing, especially among younger providers and younger women who have less knowledge of the IUD controversies of the past.[17]

Use

- Recent data from the CDC estimates 10.7% of women who use contraception ages 15 to 44 used an IUD in 2011-2013.[18] Use is highest among women ages 25 to 34, 50% higher than the use rate among women ages 20 to 24 (**Figure 1**). While women with children report higher use of IUDs, this trend may be changing as newer IUDs are marketed to nulliparous women.[19]



- IUDs usage varies significantly between countries, but is higher in many other countries than in the U.S., especially western Europe where the Dalkon Shield, one of the products that resulted in harm to women in the U.S. in the 1970s, was never available.[20]
- Multiple provider groups including the American College of Obstetricians and Gynecologists (ACOG)[21] and the American Academy of Pediatrics (AAP)[22] have recommended the use of IUDs for all women, since the FDA approved IUDs for younger women and those who have not had children. Utilization among all women, but especially younger women, has risen (**Figure 2**).



Awareness

- Almost all obstetricians and gynecologists (ob/gyns) provide IUDs in their practice (95.8%).[23] However, there are some barriers stemming from physician beliefs that have limited access for women. A 2013 survey found that two-thirds of ob/gyns who provide IUD services believe IUDs were

appropriate for nulliparous women and less than half believe IUDs were appropriate for adolescents. The study also found that approximately 1 in 7 ob/gyns believe pelvic inflammatory disease is a significant risk of IUD use, despite substantial research to the contrary.[24] These data may not reflect recent increases in provider education as well as approval of new IUDs targeted specifically towards younger women.

Post pregnancy

- Providing IUDs to women immediately following a delivery, miscarriage or abortion can be convenient and an effective strategy for averting unintended pregnancy.[25] Women may be particularly motivated to begin using contraception in the immediate post-partum period, and data indicate women are more likely to obtain an IUD in the immediate post-partum period compared to a follow-up visit.[26] Although expulsion rates of IUDs are higher for post-partum women, they are lower when the IUD is inserted approximately 10 minutes after the placental delivery than if the IUD is inserted up to four weeks after the birth.
- IUD insertion immediately post-partum is not common. Many providers are unaware IUD insertion post-pregnancy is safe and effective. Less than half of ob/gyns interviewed in a 2013 study (46%) said an IUD could be inserted immediately after birth and only one-fifth (20%) said IUDs could be inserted after an abortion or a miscarriage.[27] Women with IUDs have lower rates of repeat abortion than women who choose other methods.[28]

Availability

- Many deliveries are covered by insurers paying a global fee to clinicians to provide all necessary services from prenatal through post-partum care, so providers may not be separately reimbursed for the cost of a post-partum IUD.[29] Some state Medicaid programs are testing the impact of separate reimbursements to providers for IUD insertion immediately post-partum.[30]
- Currently, many physicians require two visits for a woman seeking an IUD: a consultation and the follow up visit for insertion.[31] Stocking IUDs onsite allows clinicians to provide same-day services to women, but some providers have been hesitant to stock IUDs because of the high upfront costs.
- Community health centers (CHCs) are an important source of care for many low-income and uninsured women of reproductive age. However, access to IUDs has been challenging for some CHCs due to a combination of reasons, including high upfront costs and limited training and staff capacity to provide IUDs. Approximately half (51%) of community health centers provide IUDs or implants as part of the family planning services they offer, meaning many women seeking services from clinics may not have immediate access to IUDs.[32]

Insurance Coverage and Financing of IUDs

The costs of IUDs have been a barrier to its use, for both patients and providers. Prices for an IUD typically range between $500 and $1,000, in addition to provider visits for insertion, removal and confirmation that the device was properly placed.[33] While many insurance plans have covered IUDs for years, prior to the passage of the Affordable Care Act (ACA), women were likely to have out-of-pocket charges for the product as well as the associated visits. The ACA has eliminated these costs for many women.

Private Insurance

- The ACA includes a requirement that most private insurance plans must cover at least one type of all 18 FDA-approved contraceptive methods for women as prescribed without cost sharing. This means that most private plans (small and large group, self-funded, and individually purchased plans) must cover the copper IUD and at least one hormonal IUD at no cost to policy holders.[34] Research has found two-thirds of women (62%) with private insurance paid $0 in out of pocket costs for an IUD in Spring 2014, compared to 45% of women in Fall 2012.[35] Another study found a 68% decline in average out-of-pocket spending on IUDs among women covered by one large insurer in the first year of the requirement.[36]
- Although insurers are required to cover at least one hormonal IUD, the plan determines which hormonal IUD is covered. Plans must cover an alternate hormonal IUD if medically necessary.
- Insurers are able to use medical management to help control costs and encourage beneficiaries to choose more affordable contraceptive methods. While insurers can require step therapy and prior authorization, federal guidance prohibits insurers from categorically restricting access to a method. Insurers can choose to cover generic contraceptives only while charging cost-sharing for the brand-name version, but since IUDs do not have a generic equivalent, the brand name version must be covered without cost sharing.

Medicaid

- Federal law requires Medicaid programs to cover family planning services and supplies without cost-sharing, but there are variations in coverage between states and between different Medicaid populations. For women enrolled in traditional Medicaid programs that were in place prior to the passage of the ACA, coverage of IUDs is determined by each state program.[37] States policies may limit coverage to only certain brands or types or apply medical management protocols to restrict availability.
- Women who qualify for Medicaid under the ACA's expansion of the program must receive coverage for both the copper and at least one hormonal IUDs because the ACA requires these expansion programs to cover all FDA approved methods for women without cost-sharing, which is the same as the requirement for private insurance plans.[38]
- Public insurance coverage of IUDs and other highly effective methods has been shown to save money for states.[39]
- Currently, 28 states extend Medicaid coverage for family planning services, including contraception, to some uninsured women who do not qualify for full scope Medicaid.[40] States retain the flexibility to decide whether and which IUDs are covered by these programs.

Uninsured

- The federal Title X National Family Planning Program funds a network of clinics to provide family planning care to millions of low-income and uninsured women at reduced or no cost. The national program has emphasized provision of LARCs, especially to teens, in recent years by providing additional training for providers and clinics. The Liletta IUD was developed specifically to be low cost and is available to many clinics enrolled in the federal 340B Drug Pricing Program, which includes health centers and clinics that receive Title X funding.[41]

- Some manufacturers operate programs that offer reduced price or fully subsidized IUDs for some low-income women.[42] IUD manufacturers may also offer installment plans for women who purchase IUDs directly and have no other coverage.[43]
- Recent studies have found young women are very likely to choose the most effective methods of contraception when cost barriers are removed. The Contraceptive CHOICE Project offered young women seeking care at Title X clinics in Colorado and at Washington University in St. Louis, contraception without cost-sharing. More than half of women chose an IUD as their method of contraception.[44, 45] Continuation rates among participants who chose IUDs (77-79%) were significantly higher than non-LARC users (41%) 24 months after choosing their method.[46] High continuation rates among IUD users have been documented in other studies looking at national claims data.[47]

Conclusion

IUDs are one of the most effective forms of reversible contraception and interest in them is growing among women and their providers. While use of IUDs is still relatively low, the ACA's requirement for coverage of contraceptive services and supplies without cost-sharing removes cost barriers for millions of women with private coverage. The elimination of the cost related barriers along with greater awareness and acceptance of IUDs among providers and women will likely increase the use of one of the most effective methods of contraceptive available to women with the potential to reduce unintended pregnancies in the U.S.

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