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Bridging the Divide White Paper: Long-Acting Reversible Contraception (LARC) in the United States

Julia Strasser
George Washington University

Liz Borkowski
George Washington University

Megan Couillard
George Washington University

Amy Allina
George Washington University

Susan Wood
George Washington University

Jacobs Institute
of Women's Health
THE GEORGE WASHINGTON UNIVERSITY

LONG-ACTING REVERSIBLE CONTRACEPTION

Overview of Research & Policy in the United States

Julia Strasser, MPH
Liz Borkowski, MPH
Megan Couillard, BS
Amy Allina, BA
Susan Wood, PhD

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INTRODUCTION

Unintended pregnancy rates in the US – long considered a public health challenge – have recently started to decline, along with abortion and teen pregnancy rates. Recent data suggest that unintended pregnancy rates are at their lowest levels in the last several decades (Finer & Zolna, 2016). Researchers attribute this drop to several different factors, including increased access to and use of more effective methods of contraception. Only 5% of unintended pregnancies occur among consistent users of contraception, while 54% occur due to non-use and 41% to inconsistent use (Sonfield, Hasstedt, & Gold, 2014).

Long-acting reversible contraceptive (LARC) methods demonstrate great potential in reducing unintended pregnancy, as they require virtually no user adherence and can therefore contribute to the percentage of consistent contraceptive users. LARC methods include two types of contraceptives: intrauterine devices (IUDs) [1] and subcutaneous hormone-releasing implants. Although LARC methods have had a rocky history in the US, newer LARC products have recently gained in popularity, potentially due to their lower rates of side effects, greater effectiveness, and broader acceptability among different populations of women.

This paper summarizes current knowledge on LARC methods, from mechanism of action to access barriers to emerging policy concerns in the US. Other contraceptive methods – such as the birth control pill, patch, or ring, or the contraceptive shot – are considered short-acting contraceptives and are not discussed in this paper.

[1] These methods are also sometimes referred to as intrauterine systems (IUSs) or intrauterine contraceptives (IUCs); this paper uses the term IUD to include all types of intrauterine contraceptives.

Overview of LARC Methods

Four types of IUDs are currently licensed for use in the US: Mirena (sold by Bayer), Skyla (Bayer), Liletta (Allergan), and ParaGard (Teva). All four are inserted into the uterus by a clinician. Mirena, Skyla, and Liletta work by releasing the hormone levonorgestrel into the uterus and are generally called levonorgestrel-releasing (LNG) IUDs or hormonal IUDs. ParaGard is a non-hormonal, copper-containing method and is known more generally as a copper IUD (or Cu IUD). Mirena is effective for up to five years, Skyla and Liletta for three, and ParaGard for ten.

Nexplanon (sold by Merck) is the only type of implant currently available in the US. It is inserted under the skin on the arm by a clinician and works by releasing the hormone etonogestrel into the arm. It is effective for up to three years. Nexplanon's predecessor (Implanon) functioned very similarly but was not radio-opaque, meaning it could not be viewed on an X-ray. Some women may have existing Implanon implants that were placed before Nexplanon became available, but providers are no longer offering Implanon to new implant patients.

All forms of LARC can be removed by an appropriately trained provider at the request of the patient. Increasingly providers, especially those in obstetrics and gynecology (OB/GYN) programs, receive training on IUD insertion and removal during residency, but a provider must go through a formal training session created by the manufacturer before providing Nexplanon to patients. *Table 1. Summary of LARC Methods* (page 4) shows an overview of the types of methods, including their US Food and Drug Administration (FDA) approval dates.

Current Usage

Worldwide, LARC methods are the second most common method of contraception, after female sterilization. Fourteen percent of married or in-union women use LARC methods worldwide, compared with 19% who use female sterilization and 9% who use contraceptive pills (United Nations, 2015; Xu, Macaluso, Ouyang, Kulczycki, & Grosse, 2012). Rates of LARC usage tend to be higher worldwide than in the US, where a small but growing proportion of women use a LARC method. Based on the most recent data from the Centers for Disease Control and Prevention (CDC), approximately 7.2% of all US women ages 15-44 use a LARC method (Branum & Jones, 2015). This usage rate represents a dramatic growth in use from 2002, when only 1.5% of US women used a LARC method (Branum & Jones, 2015). Among women who use any method of contraception, 11.6% use a LARC method, up from 2.4% in 2002 (Kavanaugh, Jerman, & Finer, 2015). In the population with private insurance coverage, IUD insertion rates increased six-fold from 2002 to 2008 (Xu et al., 2012).

Current use of LARC methods is higher among women ages 25-34, compared with women ages 15-24, and rates of use are three times higher in women who have had at least one child (parous women), compared with women who have not (nulliparous women). However, in recent years,

LARC method use has increased almost ten-fold in women with no previous births (Branum & Jones, 2015).

Data suggest that sexually active teens are at an especially high risk for inconsistent use of user-dependent methods (such as condoms or oral contraceptive pills) (Gavin et al., 2013) and that LARC methods may therefore be a good option for this population. However, only 4.3% of teens who use contraception use a LARC method (Kavanaugh et al., 2015). Among teens who receive contraceptive care at health centers funded through the federal Title X program (see *Box 1. Publicly Funded Family Planning*, page 27), these numbers appear to be increasing in recent years. In 2005, only 0.4% of teens ages 15-19 at Title X health centers used LARC methods, compared with 7.1% in 2013 (Romero et al., 2015).

Table 1. Summary of LARC Methods

	Available Since	Years Effective	Use	Possible Side Effects	Dosage
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.	Abnormal menstrual bleeding. Higher frequency or intensity of cramps/ pain.	n/a
Hormonal IUDs					
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.	Initial: 20 mcg/day Before removal: 10 mcg/day
Skyla	2013	3 years	Approved for women regardless of parity.		Initial: 14 mcg/day Before removal: 5-6 mcg/day
Liletta	2015	3 years	Approved for women regardless of parity.		Initial: 18.6 mcg/day Before removal: 12.6 mcg/day
Implants					
Nexplanon	2011	3 years	Approved for women regardless of parity.	Inter-menstrual spotting in the early months. Hormone-related: headaches, nausea, breast tenderness, depression, cyst formation.	Initial:60-70 mcg/day Before removal: 25-30 mcg/day

*In 2005, the package label for the ParaGard IUD changed. The new label no longer contains language that suggests the IUD is appropriate only for women with one or more children. However, the Mirena label has not yet undergone a similar change (American College of Obstetricians and Gynecologists, 2011).

Source: Kaiser Family Foundation, 2015

History of LARC Methods in the US

The IUDs and implant available today were preceded by earlier versions that left a problematic legacy for both patients and providers. Although many of the problems associated with earlier methods have since been addressed, the history of these two categories of methods continues to have an impact on LARC provision and use today.

IUD History

First Generation IUDs: Initial Uptake, Challenges, and Rapid Decline

The first generation of IUDs, available in the United States starting in 1968, were made out of a variety of different materials, including plastic and copper, and were manufactured in a variety of different shapes. Some of the more common types of IUDs in the first generation were the Lippes Loop, the Copper-7, and the Copper-T. Within a few years, more than 10% of US women who used contraception were using an IUD (Sonfield, 2007).

The Dalkon Shield came on the market in the United States in 1971, and during the four years that it was available, more than two million women used this IUD. It was a distinctively shaped plastic IUD, and it was the only IUD with a tail made out of a multifilament thread rather than monofilament tail. Ultimately, this tail string was identified as a significant design flaw (see "Sexually Transmitted Infections and Pelvic Inflammatory Disease," page 18). Although initial clinical trials reported a pregnancy rate of only 1.1% and an expulsion rate of 2.3%, a study conducted soon after introduction raised questions about the developer's claims, finding a pregnancy rate for the device of 4.7 per 100 woman-years[2] (Davis, 1970; Jones, Parker, & Elstein, 1973). The pregnancy rate would develop particular importance because risks associated with continuing pregnancy in Dalkon Shield users were later identified as another significant problem with this product.

Despite IUDs' initial popularity, use of the method began to decline rapidly as serious health problems associated with their use came to light. These problems included high rates of pelvic inflammatory disease (PID) – which, when not treated effectively, can lead to infertility and even death – and high rates of septic miscarriages in cases when the IUD failed to prevent pregnancy. By 1973, there was enough concern about IUD-associated infections that Congress held hearings where two physicians testified about the hazards the devices posed to women's health (Boonstra et al., 2000; Sonfield, 2007). Simultaneously, the CDC began conducting a survey about IUD-related complications that physicians had observed among their patients, which identified more than 3,500 unduplicated case reports of hospitalizations associated with an IUD in the first six months of 1973.

[2] For differences in reported pregnancy rates (percentage, number per woman-years, etc.) of current methods, see *Table 2. Measures of Contraceptive Efficacy and Failure*, page 15.

Applying these estimates to national data yielded estimates of 7,900 IUD-associated hospitalizations, and five IUD-associated fatalities (Centers for Disease Control and Prevention, 1997). However, these numbers represent estimates from only a single, limited time period, and the total number of infections and deaths associated with IUD use during the 1960s and 1970s has not been definitively established.

The survey also found a relative excess of Dalkon Shield users among those suffering from IUD-associated complications, including complicated pregnancies among these users. The original report concluded that the association might be explained "by an elevated rate of pregnancy with this device, by an increased rate of complications once a pregnancy is established, or by a combination of these postulated factors" (Centers for Disease Control and Prevention, 1997). After publication of the survey, the CDC continued to monitor the problem, publishing an analysis that concluded death from miscarriage was three times more likely among Dalkon Shield than other IUD users (Cates, Ory, Rochat, & Tyler, 1976) and later reporting that Dalkon Shield users were at greater risk for PID than users of other IUDs or people not using IUDs at all (Centers for Disease Control and Prevention, 1983).

The manufacturer (the A.H. Robins Company) suspended US sales of the Dalkon Shield in 1974, although it continued to distribute the device globally (Mintz, 1986). In the United States, women brought hundreds of thousands of lawsuits against the company, resulting in $24 million in jury awards, more than $375 million in payments to dispose of cases, and more than $100 million in legal expenses. In 1985, the company declared bankruptcy, and the Dalkon Shield has not been offered since (Mintz, 1986).

NEW REGULATION OF MEDICAL DEVICES

The scale of the damage done by the Dalkon Shield and the enormous public attention it drew led to major changes in US regulation of medical devices (Rados, 2006). Up until 1976, FDA had very little authority over medical devices – device manufacturers were not required to provide evidence of safety or efficacy for their products before marketing them, and the agency had only limited authority to address problems that emerged afterward. Then, in 1976, the Medical Device Amendments were enacted, requiring device makers to register with the agency and follow quality control procedures. The law gives FDA the ability to subject some devices to pre-market review and approval, and authorizes the agency to ban a device that presents a substantial deception or substantial unreasonable risk of injury or illness (Food and Drug Administration, 2014). The standards for device approval are still, however, significantly less stringent than for drugs; for example, manufacturers are not always required to provide FDA with data from clinical trials for devices before selling them in the United States.

FIRST GENERATION IUDS: LEGACY/IMPACT ON CURRENT UPTAKE

Although the Dalkon Shield has not been sold in the United States since 1974, the high level of public awareness of the problems associated with it created enormous doubt about the safety of all IUDs. Additionally, a 1976 CDC study identified a health risk associated with IUDs that was not limited to Dalkon shield users. That analysis concluded that when an IUD user became pregnant, the risk of death from miscarriage was more than 50 times greater for women with an IUD in place who continued their pregnancies than for those without an IUD. The authors of that study wrote that while "the Dalkon Shield carried an increased risk of death, as compared to other devices, […] pregnant women with either a loop or a coil [IUD] in place also had a higher risk of dying from spontaneous abortion than those without any device" (Cates et al., 1976).

Despite the accumulation of data showing the association between early IUDs and infection, almost 2.2 million US women continued using IUDs through the early 1980s, making up more than 7% of contraceptive users in the country (Forrest, 1986). The rate of IUD use dropped again when the manufacturers of the Lippes Loop (with 31% of the US IUD market) and of the Copper-7 and Copper-T (with a combined 66% of the US market) stopped providing devices in this country (Forrest, 1986). Starting in 1986, there was just one IUD available to US women – Progestasert, a hormone-releasing device that had to be replaced annually – and it was not widely used. By 1995, fewer than 1% of US contraceptive users were using an IUD (Piccinino & Mosher, 1998).

This history of IUDs, while unknown to many contraceptive users and even healthcare providers today (Sonfield, 2007), appears to have had a lasting effect on IUD use in the United States. When redesigned IUDs were later brought back to the US market, they faced an unreceptive climate. A new copper IUD (ParaGard) was introduced in 1988, and a new hormone-releasing IUD (Mirena) was approved in 2000, but uptake of both devices was negligible for many years. Contraceptive experts attribute this in great part to the facts that both contraceptive users and healthcare providers in this country had little or no direct experience with IUDs, and what they knew about them was mostly negative (Sonfield, 2007).

By contrast, IUD use was significantly greater in Europe, where sale and use of copper IUDs continued uninterrupted throughout the 1980s and 1990s, and where the Dalkon Shield was rarely used. The level of IUD use varies in Europe from country to country but for many years has dwarfed use in the United States. A study conducted in 2006 by the manufacturer of one IUD found that 27% of contraceptive users in Norway were using IUDs; 21% in Sweden; and about 10% in the Czech Republic, Germany, and the United Kingdom (Sonfield, 2007).

In the United States, perceptions about the risks of the method continue to be shaped by its history in this country, even while knowledge of the historical facts has begun to fade. The association with serious infection and consequent infertility, in particular, may have suppressed use by young women and women who had not had children (Whitaker, Dude, Neustadt, & Gilliam, 2010). The FDA labels for both ParaGard and Mirena at the time of approval stated that users should have had at

least one child and should be in a mutually monogamous relationship (Teal & Romer, 2013). ParaGard's manufacturer publicly stated that the company was taking a "conservative approach" when it introduced the product in the United States, believing that this would reduce the likelihood that a woman using an IUD would be harmed and sue the company (Roan, 1993). The restrictions were taken off the label for the copper IUD in 2005, but many contraceptive users and healthcare providers still had significant doubt that the method was safe for young women.

Unlike in Europe where IUDs had continuity of use over the same time period, re-uptake of IUDs in the US has proceeded slowly. Recent surveys of reproductive age women have shown that many women do not know about the method or whether it would be safe and appropriate for them (Kaye, Suellentrop, & Sloup, 2009; Stanwood & Bradley, 2006); see "Women's Perspectives on LARC Methods," page 26. Until recently, high upfront costs have also compounded these barriers, making it difficult for some women who want an IUD to get one (Sonfield, 2007). Furthermore, studies among healthcare providers suggest that many providers still believe that IUDs are not appropriate for adolescents or for women without children (Harper, Blum, Thiel de Bocanegra, et al., 2008; Tyler et al., 2012); see "Providers and LARC Methods," page 32.

Implant History

The history of implanted contraceptives in the United States is quite different from that of IUDs, but it also created a backdrop that affects how current methods are viewed and approached by both healthcare providers and contraceptive users today. Unlike Dalkon Shield users, the health problems women experienced with the first implant marketed in the United States were not typically life-threatening, but there was significant negative public attention to the method as a result of both clinical problems and policy controversies.

First Generation Implant: Initial Uptake, Challenges, and Rapid Decline

Norplant, the first contraceptive implant available in the United States, went on the market in 1991. It consisted of six plastic capsules, which were implanted under the skin of a woman's arm. Each capsule contained 36 mg of levonorgestrel, released gradually, and the device could prevent pregnancy for up to five years. Norplant was hailed as a major advance that offered a new way to deliver contraceptive hormones, eliminating the possibility of missed doses. Studies showed that after five years of use, the cumulative pregnancy rate for Norplant users was approximately 1%. Additionally, the return to fertility was fast, with the hormones disappearing from circulation within a week after device removal (Fraser et al., 1998). A reversible contraceptive method with such high efficacy was seen as potentially revolutionary in the field. In the headline on the front page, one major, national newspaper called it "as perfect a method as you can have" (Painter, 1990).

In Norplant's first year in the United States, the manufacturer (Wyeth Ayerst) reported that about 100,000 women received the Norplant implants; by the end of the second year there were reports that the number had risen to 500,000; and by 1994, nearly one million US women were reported to be using Norplant. This rapid rise occurred in spite of its relatively high cost, with the device itself priced at $350 and provider insertion and removal fees of at least $150 each. Although the manufacturer did not make Norplant available at a discounted public sector price, as was done for all other contraceptive methods at the time, it did set up a foundation to distribute Norplant to low-income women who were uninsured and not eligible for publicly subsidized programs (Samuels & Smith, 1992a). Despite the cost challenges, demand grew so quickly that it outpaced the company's manufacturing capacity at the beginning. Family planning clinics put some women who wanted to get the implant on waiting lists (Boonstra et al., 2000), and state family planning programs implemented eligibility criteria to determine who would get the sought-after implants (Samuels & Smith, 1992a).

With its high public profile, Norplant also attracted significant interest from policy makers. Proposals to incorporate Norplant into social service programs proliferated; there were also cases where it was incorporated into criminal justice sentencing procedures. Both of these developments generated significant criticism and controversy (see "LARC Methods and Reproductive Injustice," page 29).

However, the fast rise of Norplant was followed by a precipitous fall. Women began to experience unpleasant side effects, including irregular menstrual bleeding, headaches, mood changes, breast tenderness, and weight changes. Irregular bleeding was particularly problematic, as more than half of women using the method experienced bleeding lasting more than eight days per month, which continued for 20% of women after three years (Fraser et al., 1998; Samuels & Smith, 1992b; Sivin, Mishell, Darney, Wan, & Christ, 1998). After five years, about 25% of users requested removal because of bleeding and another 15% requested removal because of headache or weight gain. (Fraser et al., 1998; Sivin et al., 1998). Although some of these side effects had been observed during the clinical trials, many women did not anticipate them, potentially due to inadequate counseling from providers.

IMPLANT: REMOVAL PROBLEMS

Some women also experienced problems with incorrect placement of the Norplant capsules, infection at the site, and difficulty with removal. When an implant was not placed correctly, it could be expelled or cause an infection. Implants that were placed too deeply or capsules implanted too far apart could be difficult and painful to remove. The procedure for inserting and removing the capsules sometimes caused keloid (overgrowth) scars to form, a problem more common among African-American women (Samuels & Smith, 1992b; Scott, 1992). Problems with insertion and removal were attributed in part to lack of adequate training for providers (Samuels & Smith, 1992b; Sivin et al., 1998). Experts reviewing the US Norplant experience noted that although 26,000

physicians had been trained on insertion, training in removal was significantly less common. They recommended allocation of resources to train providers in removal, particularly those who served poor women in rural areas and medically underserved communities (Samuels & Smith, 1992a).

Tens of thousands of lawsuits were filed in the late 1990s against Norplant's manufacturer, as well as against providers inserting and/or removing the contraceptive. Although the company made settlement payments to many women and even prevailed in some cases that went to court, it did not admit to being at fault. Views about Norplant within the reproductive health community remained sharply divided.

Norplant sales were suspended in the United States in 2002, due to manufacturing issues that raised concerns about the effectiveness of particular lots. A retrospective analysis of the US Norplant experience, published by the Institute of Medicine, attributed the downfall of this product to a combination of factors, including: women's discomfort with side effects; problems with insertion and removal of the device; lawsuits against the manufacturer; legislative and criminal justice efforts to use the implant to restrict child-bearing in ways that disproportionately affected women of color and low-income women; and negative publicity associated with all of the above (Boonstra et al., 2000; Harrison & Rosenfield, 1998). This experience made Norplant's manufacturers hesitant to sell another implant in the United States (Boonstra et al., 2000) even after second-generation implants, such as Jadelle, were developed and made available elsewhere. The single-rod implant (first branded as Implanon, now Nexplanon) made its US appearance in 2006, eight years after it was first introduced in other countries, and its slow uptake may be explained, at least in part, by lingering memories of Norplant.

Mechanism of Action

Pregnancy Prevention

In order to define how a contraceptive method works to prevent pregnancy, it is important to establish the definition of pregnancy. A consensus exists in the medical community on when pregnancy begins, namely, when implantation of a fertilized egg occurs (American Congress of Obstetricians and Gynecologists, 2014; Code of Federal Regulations, 2009; Gold, 2005). It is important to differentiate between implantation and fertilization, particularly with regard to LARC methods, because this difference determines whether a method acts as a contraceptive or as an abortifacient. A method that prevents fertilization or stops the fertilized egg from implanting is considered a contraceptive. A method that acts after implantation interrupts a pregnancy and is considered an abortifacient.

IUDs

COPPER IUD

Although several types of copper IUDs exist around the world, ParaGard (Copper T 380A) is the only copper IUD available in the US. ParaGard received FDA approval in 1984 and is currently distributed by Teva Women's Health.

ParaGard has a T-shaped, flexible plastic frame with copper wire coiled around the vertical stem and one copper collar around each arm of the T. The device measures 36 mm vertically by 32 mm horizontally (1.42 in by 1.26 in, or about the size of a half dollar coin) and weighs less than one gram (0.035 ounces, or half the weight of a dime). ParaGard must be inserted into the uterus by a medical professional, and is approved to stay in place for up to 10 years, although studies have shown it to remain effective through 12 years (Grimes, Lopez, Manion, & Schulz, 2007; O'Brien, Kulier, Helmerhorst, Usher-Patel, & d'Arcangues, 2008; United Nations Development Programme, 1997).

Copper IUDs work by releasing copper ions, which affect the reproductive tract in different ways to prevent pregnancy. Copper IUDs raise the concentration of copper in the cervical mucus (Hagenfeldt, 1972a), which reduces sperm motility and viability (Hefnawi et al., 1975; Knazická, Lukác, Grén, Formicki, & Massányi, 2012; Ortiz & Croxatto, 2007). High enough concentrations of copper ions may cause sperm death (Elstein & Ferrer, 1973; Hefnawi et al., 1975; Kesserü & Camacho-Ortega, 1972; Knazická et al., 2012). The presence of copper ions helps prevent fertilization of the egg, even when sperm are present, but copper IUDs do not stop ovulation (release of the egg) (Roblero, Guadarrama, Lopez, & Zegers-Hochschild, 1996). Copper IUDs may

also work by causing a chronic inflammatory response[3] in the uterus (Cuadros & Hirsch, 1972; Hagenfeldt, 1972b), which reduces sperm viability. They may also prevent implantation of a fertilized egg into the endometrial lining of the uterus (Savaris, Zettler, & Ferrari, 2000; Stanford & Mikolajczyk, 2002). Finally, the copper IUD may affect cell signaling in the endometrial lining, which can prevent implantation (Gemzell-Danielsson, Berger, & Lalitkumar, 2013; Hefnawi et al., 1975). These mechanisms of action on the endometrium may occur pre- or post-fertilization, but *always before implantation occurs* (American College of Obstetricians and Gynecologists, 2011; Stanford and Mikolajczyk, 2002).

Effective dosage of copper in an IUD is determined by total exposed copper surface area. The total exposed copper surface area of ParaGard is 357-403 mm^2 (0.55-0.62 square inches, or enough to cover a ladybug). Other copper IUDs have proven to be moderately effective with as little as 200 mm^2 exposed copper (0.31 square inches) (Farr & Amatya, 1994; Hefnawi et al., 1975; O'Brien et al., 2008).

THE COPPER IUD AS EMERGENCY CONTRACEPTION

The copper IUD also may be used as emergency contraception (EC) if inserted within five days of unprotected intercourse. The copper IUD is over 99% effective as EC (Liying & Bilian, 2001; Trussell, Ellertson, Stewart, Raymond, & Shochet, 2004; Wu et al., 2010), which is more effective than hormonal EC pills (Plan B or its generics, or Ella) (Duramed Pharmaceuticals, 2009; von Hertzen et al., 2002). Its effectiveness is not influenced by the timing of the menstrual cycle (Turok et al., 2013).

The copper IUD works in two ways as EC: primarily by preventing fertilization and also by reducing likelihood of implantation. As stated earlier, copper ions (1) cause sperm death and decreases in sperm motility and viability, which prevents fertilization, and (2) reduce endometrial receptivity. This latter effect reduces likelihood of implantation (Gemzell-Danielsson et al., 2013). Research has shown that inserting any IUD, even inert models (ones without copper or hormones), cause a local foreign body reaction that inhibits implantation, and thus may be used as EC (Guillebaud, Kubba, Rowlands, White, & Elder, 1983; Ortiz & Croxatto, 2007; Parr & Shirley, 1976). Emerging research suggests that hormonal IUDs, when used in combination with oral LNG (Plan B or its generics), can also serve as effective EC up to five days after unprotected sex (Turok et al., 2016).

Copper IUDs are offered or prescribed much less frequently than EC pills, despite their superior effectiveness (Harper, Blum, Thiel de Bocanegra, et al., 2008). The low rate of use for IUDs as EC may be due to physicians' lack of knowledge regarding acceptable IUD candidates, including

[3] The chronic inflammatory response is localized (occurs only in the uterus) and is characterized by the presence of white blood cells. This response is not the same as the extreme reaction from an acute inflammatory response, such as a bee sting or allergic reaction.

nulliparous women (Harper, Blum, Thiel de Bocanegra, et al., 2008; Harper, Raine, Thompson, Stratton, & Speidel, 2011), or to an unfounded concern about insertion mid-menstrual cycle, as an IUD can be inserted any time pregnancy can reasonably be excluded (American College of Obstetricians and Gynecologists, 2011). Greater provider knowledge and experience is linked to higher rates of counseling and provision (Gold, Schein, & Coupey, 1997; Harper, Blum, Thiel de Bocanegra, et al., 2008; Harper, Henderson, et al., 2012).

After seeking EC, women may be more motivated to use other contraceptive methods (Gainer et al., 2003), and providing the copper IUD would present an additional advantage for women who want to use a more effective method. Potential barriers include lack of patient knowledge about the method and cost (Turok et al., 2011), as well as limited availability of providers willing or able to schedule same-day IUD insertions (Harper, Speidel, et al., 2012). Additionally, EC pills are generally easy to acquire and are taken correctly without a provider present (Harper, Cheong, Rocca, Darney, & Raine, 2005), which may make the IUD less attractive in comparison.

HORMONAL IUDS

The first hormonal IUD to receive FDA approval was Mirena, in 2000. Two other types of hormonal IUDs are currently on the market in the US: Skyla and Liletta.

All hormonal IUDs have T-shaped plastic frames with hormonal reservoirs. Mirena and Liletta measure 32 mm by 32 mm (1.26in by 1.26 in), and Skyla is slightly smaller, measuring 30 mm vertically and 28 mm across (1.18in by 1.10 in). The flexible T-shaped frames include a drug reservoir containing levonorgestrel (LNG), a synthetic progestin, that is released through a rate-controlling membrane (Gold Standard, 2015; Lähteenmäki, Rauramo, & Backman, 2000). LNG is also used in the Plan B EC pills; another synthetic progestin, etonogestrel, is used in other hormonal birth control methods, including the Nexplanon implant, the Nuvaring, and oral contraceptive pills.

Although the dosage and duration of effect varies between the different hormonal IUDs, the human body uses the hormone from each the same way, with a mostly local effect at the uterus. The major mechanism is that the hormone released by the IUDs prevents fertilization by thickening cervical mucus to stop sperm from swimming up the cervix and fertilizing an egg (Bayer HealthCare Pharmaceuticals, 2009; Bayer HealthCare Pharmaceuticals, 2013; Kesseru, Camacho-Ortega, Laudahn, & Schopflin, 1975; Stanford & Mikolajczyk, 2002). The hormone also thins the endometrial lining of the uterus, which limits the ability of a fertilized egg (if one were fertilized) to implant (Sheppard, 1987); this same mechanism causes lighter menstrual periods. The IUD also creates an inhospitable environment in the uterus (Stanford & Mikolajczyk, 2002) and interferes with cell signaling necessary for implantation (Archer, DeSoto, & Baker, 1999). Similar to the copper IUD, the LNG IUD lowers the motility and viability of sperm within the uterus, but does not do so as effectively as the copper IUD (Mishell Jr, 1998). Hormonal IUDs may also inhibit ovulation, but do not consistently do so, as three out of four Mirena users still ovulate (Bayer HealthCare Pharmaceuticals, 2009).

Mirena and Liletta are nearly identical products, with the major difference being the length of time the device is approved to stay in place (five years for Mirena and three years for Liletta, based on the length of the clinical trials conducted by each manufacturer). However, Skyla is a bit smaller than Mirena and Liletta, and it is generally marketed toward nulliparous women. Clinical trials of both Skyla and Liletta specifically included nulliparous women and women with existing STIs, while the trials for Mirena did not. Mirena does not have an FDA-approved indication for use in women who have no children, but has nonetheless been widely used in this population successfully (Lyus, Lohr, & Prager, 2010; Prager & Darney, 2007).

There are differences in the dose of LNG and the rate of release over time for the different hormonal IUDs. Dosage information is provided in *Table 1. Summary of LARC Methods*, page 4. The lower release rate of Skyla is still effective in preventing pregnancy, but 2.5 times more Mirena users will stop getting their periods (i.e., experience amenorrhea) than Skyla users (Bayer HealthCare Pharmaceuticals, 2009; Bayer HealthCare Pharmaceuticals, 2013).

IMPLANT

Implanon, the oldest implant currently offered in the US, was approved in 2006 but has since been replaced by Nexplanon, which was approved in 2011.

Nexplanon is a thin, flexible rod measuring 4 cm by 2 mm (dimensions similar to a matchstick) and made of a polymer. It is packaged with a sterile, non-reusable applicator and placed subdermally on the inside of the patient's upper arm; labelling recommends insertion in the non-dominant arm. The skin of the upper arm is disinfected and numbed, and the implant is guided to the correct position under the skin with a needle. The implant is removed by numbing the skin, making a small incision where the rod ends, and grasping the implant with forceps. A new implant may be immediately reinserted in the same arm, without requiring a new incision.

The active ingredient in the implant is etonogestrel (ENG), another synthetic progestin. The ENG in the implants works primarily by preventing ovulation for up to three years while the implant is in place (Croxatto & Mäkäräinen, 1998; Croxatto, 2002). The ENG is released at a constant, small dose, which prevents the spikes of the two naturally occurring hormones that cause ovulation – luteinizing hormone and follicle stimulating hormone (Croxatto & Mäkäräinen, 1998; Croxatto, 2002). ENG also thickens cervical mucus and affects the endometrial lining, but these function as secondary effects of the implant in preventing pregnancy (Croxatto, 2002).

Each implant rod contains 68 mg ENG (Merck & Co., Inc, 2015a, 2015b). The release rate begins at initially 65 micrograms per day, and slows to 40 micrograms at the end of the first year, 35 at the end of the second, and 25-30 at the end of the third (Merck, Sharp & Dohme, 2015).

The implant is becoming more popular in recent years, nearly tripling from 0.3% of women age 15-44 using it in 2006-2010 to 0.8% in 2011-2013 (Branum & Jones, 2015).

Safety and Efficacy of LARC Methods

Decades of research have shown that current LARC methods are very safe and very effective. Side effects or adverse events do occur, but are rare and generally not serious.

LARC methods demonstrate strong potential in reducing unplanned pregnancy because of their exceptionally low failure rates and their virtual absence of user error. Most contraceptive methods have substantially lower effectiveness rates for typical use versus perfect use, but for LARC methods, the typical and perfect effectiveness rates are virtually identical. Healthcare providers insert the LARC method, and patients are only required to return to the clinic for removal at the end of three, five, or ten years, or whenever they choose to stop using the method. IUDs have yearly failure rates between 0.2% and 0.8%; implants have failure rates of 0.05%. By contrast, oral contraceptive pills and condoms have failure rates of 9% and 18%, respectively, with typical use (Wellisch & Chor, 2013). In one recent study, the risk of contraceptive failure for participants using a contraceptive pill, patch, or ring was 20 times the risk of failure for those using a LARC method (Winner et al., 2012).

IUDs

EFFICACY

Recent studies of all types of IUDs find failure rates of 0.3%, 0.6%, and 0.9% at years one, two, and three, respectively, with an overall failure rate of 0.27 per 100 participant-years (Winner et al., 2012).

Although ParaGard is the only copper IUD available in the US, over 30 types of copper IUDs are available in Europe and have been studied for the last several decades (Heinemann, Reed, Moehner, & Do Minh, 2015a). Studies have shown contraceptive failure rates of 0.1 to 2.2 per 100 woman-years for the copper IUD (American College of Obstetricians and Gynecologists, 2011; Heinemann et al., 2015a). In a recent, multinational, prospective, long-term cohort study in Europe, results from nearly 60,000 women showed an overall failure rate of 0.06 in the LNG cohort, as compared with 0.52 in the copper cohort. Rates of ectopic pregnancy were also low in both groups, at 0.02 per 100 woman-years in hormonal IUD users and 0.08 per 100 woman-years in copper IUD users (Heinemann et al., 2015a).

The hormone-releasing IUDs (Mirena, Skyla, and Liletta) exhibit very similar efficacy profiles. Estimates vary slightly by study, but the overall failure rates (i.e., pregnancy rates) are quite low. One literature review (Mansour, 2012) estimates a failure rate of 0.2% during the first 12 months of use, with 0.5 to 1.1 failures per 100 users at 5 years, for Mirena, the first LNG IUD to receive approval in the US. Efficacy is not adversely impacted by patient compliance or patient age (Mansour, 2012). Similarly, failure rates for Liletta – the newest LARC method to receive FDA approval – in a recent clinical trial were 0.15 (Pearl Index) through year one, 0.26 through year two, and 0.22 through year

three (Eisenberg et al., 2015). The successful placement rate was 98.7% of all women in the study, including both parous and nulliparous women (Eisenberg et al., 2015). The most common adverse events that led to discontinuation of the IUD were expulsion (3.5%), bleeding complaints (1.5%), acne (1.3%), and mood swings (1.3%). Expulsion occurred less frequently in nulliparous women (Eisenberg et al., 2015). More serious side effects/adverse events included ectopic pregnancy (rate: 0.12 per 100 woman-years through year three), uterine perforation (0.17% of participants), and pelvic infection (0.6% of participants); all pelvic infections resolved with antibiotic treatment (Eisenberg et al., 2015).

Table 2. Measures of Contraceptive Efficacy and Failure

Measure	Definition	Examples
Pearl Index	The number of failures of a contraceptive method per 100 woman-years of exposure (without using a backup method, like condoms). One woman-year is 13 menstrual cycles.	The implant has a Pearl Index of 0.38. In clinical studies, six contraceptive failures occurred over 20,648 menstrual cycles. The Yaz birth control pill has a Pearl Index of 1.41, because 12 contraceptive failures occurred over 11,480 menstrual cycles.
Typical Use Failure Rates	Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.	The implant has a typical use failure rate of 0.05%. Combined birth control pills (which contain estrogen and progestin) have a typical use failure rate of 9%.
Perfect Use Failure Rates	Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.	The implant has a perfect use failure rate of 0.05%. Combined birth control pills have a perfect use failure rate of 0.3%.

Sources: Bayer HealthCare Pharmaceuticals, 2012; Centers for Disease Control and Prevention, 2015; Merck & Co., 2015b; Trussell, 2011

RETURN TO FERTILITY

Once inserted, the continuation rates for hormonal IUDs are approximately 76% at one year and drop in later years, but rates vary significantly by study, from 33% to 85% at year five (Mansour, 2012). Following IUD removal, women return to fertility fairly quickly. One-year post-removal pregnancy rates range from 79% to 96%, depending on the specific sub-population; by comparison, one-year pregnancy rates for women practicing natural family planning methods are 92% (Mansour, 2012). Following the Liletta study, 70.6% of women who discontinued the method and were seeking to become pregnant conceived within six months, and 86.8% within twelve months, with a median time to conception of four months; these findings indicate a rapid return to fertility (Eisenberg et al., 2015).

OTHER BENEFITS

Additional, non-contraceptive benefits associated with hormonal IUDs include a reduction in heavy menstrual bleeding and protection against unchecked endometrial growth in menopausal women during estrogen therapy (Mansour, 2012). Women may effectively transition from using LNG IUDs for contraception to using them for hormone therapy for menopause (Mansour, 2012).

SAFETY

Side effects associated with IUDs are generally minor and can include nausea, depression, headache, breast tenderness, and acne (Mansour, 2012). Women with the copper IUD often experience heavier bleeding and cramping, while women with hormonal IUDs experience lighter menstrual bleeding and some spotting in between periods (American College of Obstetricians and Gynecologists, 2011). Providers consider these issues to be expected and do not require additional evaluation for them. However, some women choose to discontinue IUD use because of irregular bleeding or cramping (Foster et al., 2014).

Some serious outcomes associated with insertion and use of IUDs can occur, though these are rare. These include: uterine perforation, expulsion of the IUD, pelvic inflammatory disease (PID), ovarian cysts, and ectopic pregnancy. Recent studies find uterine perforation rates of 0.3 to 2.6 per 1000 insertions for hormonal IUDs and 0.3 to 2.2 per 1000 for copper IUDs (Heinemann, Reed, Moehner, & Do Minh, 2015b). In a large multinational European study, researchers found perforation rates of 1.4 per 1000 in hormonal IUD users and 1.1 per 1000 in copper IUD users, which aligns with results from previous studies (Heinemann et al., 2015b). Of the perforations, only 9% of the hormonal IUD perforations and 20% of the copper IUD perforations were diagnosed during or immediately after insertion (Heinemann et al., 2015b). These findings are not surprising, given results from other studies that suggest perforations may be completely asymptomatic and may go undetected for months; the mean time to detection in a separate European study was 306 days (Mansour, 2012). Women who were using an IUD for the first time had a higher risk of perforation than women who previously had an IUD. Other risk factors for perforation included breastfeeding

at the time of insertion and having recently delivered a baby (Heinemann et al., 2015b), which concurs with findings in other studies (Mansour, 2012).

Expulsion occurs in approximately 5-10% of patients and is most common in the first three months after insertion, with risks declining the longer the IUD is in place (Madden et al., 2014; Mansour, 2012). Functional ovarian cysts may occur with hormonal IUDs, as with other progestin-only contraceptive methods. In most women, these cysts are asymptomatic and disappear spontaneously within the first few months following diagnosis (Mansour, 2012).

Finally, ectopic pregnancy – which occurs when gestation takes place somewhere other than in the uterus, such as in the fallopian tube – is a potentially dangerous side effect of IUDs and can present with abdominal pain, fainting, and/or vaginal bleeding. In women using no contraceptive method, the rate of ectopic pregnancy is 1.4 per 100 pregnancies (Mansour, 2012). Estimates vary, but the risk of ectopic pregnancy is generally slightly higher in IUD users than in the general population if the IUD fails to prevent contraception. In one Finnish study of LNG IUD users, 52% of the pregnancies that occurred were ectopic; however, overall rates were still low, at 0.045 and 0.22 per 100 women at one and five years, respectively (Mansour, 2012). These findings echo other studies that show rates between 0.02 and 0.2 for hormonal IUD users and 0.1 and 0.8 in copper IUD users (Eisenberg et al., 2015). Other studies support the finding that IUDs do not increase the absolute risk of an ectopic pregnancy (since very few women will get pregnant), but among women who have IUDs and do become pregnant, there is a higher relative risk than in women who do not have IUDs (American College of Obstetricians and Gynecologists, 2011). Any woman who becomes pregnant when an IUD is in place should have the IUD removed, if possible (American College of Obstetricians and Gynecologists, 2011).

SEXUALLY TRANSMITTED INFECTIONS AND PELVIC INFLAMMATORY DISEASE

Neither IUDs nor implants provide protection against sexually transmitted infections (STIs). With IUDs, the potential for STIs to develop into pelvic inflammatory disease (PID) has been a particular concern due in large part to the historical association between the first-generation devices (particularly the Dalkon Shield) and PID during the 1970s.

Modern IUDs show either no or a very small increased risk of PID. Unlike the Dalkon Shield, they have solid (monofilament) strings, so bacteria cannot easily move into the uterus as they could with the multifilament strings of the Dalkon Shield (Bank, MacDonald, & Wiechert, 1984). The device itself does not increase risk of infection. Rather, there is a slight increase in risk of infection during the insertion process and the 20-day period immediately following insertion (Farley, Rowe, et al., 1992; Whitaker et al., 2008). In particular, the increased risk of PID occurs when women have pre-existing bacterial STIs (e.g., gonorrhea or chlamydia). The majority of PID cases are caused by sexually transmitted microorganisms, and when an IUD is inserted, any of these microorganisms

present in the endocervical canal could be transported into the uterine cavity, thus increasing the risk of PID (Meirik, 2007; Mohllajee, Curtis, & Peterson, 2006). In women at low risk of STIs, the risk of PID is less than 1 in 100 women (Mansour, 2012).

It is difficult to establish robust clinical evidence of the true impact of PID in users of the current generation of IUDs with pre-existing infections because no studies (to date) directly examine whether IUD use or insertion impacts risk of PID. The primary reason for this gap in the literature is that it is clinically unethical to leave STIs untreated and follow participants to see if their infections develop into PID (Mohllajee et al., 2006). Given the lack of primary studies, researchers conducted a systematic literature review, which found six studies of IUD use that also included measures of STIs. In these studies, a low prevalence of STIs and a low incidence of PID further complicated the findings, but all studies observed a greater risk of PID among women with STIs than among women without STIs (Mohllajee et al., 2006). However, it is impossible to determine from this study whether the increase in risk is the same as the increase in risk among women without IUDs. Thus, the researchers conclude that it is not currently known whether IUDs increase the risk of PID in women with STIs (Mohllajee et al., 2006); this echoes findings in other studies (American College of Obstetricians and Gynecologists, 2011). Other researchers suggest that IUD users may be on "heightened alert" for PID and may therefore seek a clinical evaluation, which in turn makes them more likely to be diagnosed with PID than users of other contraceptive methods, who are less likely to seek clinical evaluation and therefore less likely to be diagnosed (Hubacher, Grimes, & Gemzell-Danielsson, 2013). To avoid the potential for existing infections to develop into PID, some clinicians have advised that prophylactic antibiotics be given to women at the time of IUD insertion, but current evidence does not support this practice (American College of Obstetricians and Gynecologists, 2011).

INSERTION & REMOVAL

Most providers find both insertion and removal of IUDs to be fairly easy. Recent studies find that 72% to 87% of providers report "easy" insertion (Mansour, 2012). Many women experience pain during insertion and/or removal, but the pain is generally temporary. One survey reports that 9% of women consider the insertion procedure painless, compared with 72% who consider it moderately painful and 17% severely painful; nulliparous women are at higher risk for difficult or painful insertions (Mansour, 2012). Providers may rely on one or multiple techniques to assist with insertion, including cervical dilation, analgesics, or paracervical block using injection of local anesthesia. Similarly, some clinicians use misoprostol – a medication primarily used for medication abortion – due to its effects of stimulating uterine contractions and dilating the cervix. However, data suggest that these techniques actually have little or no effect on pain or ease of insertion (Lopez et al., 2015; Mansour, 2012; Mody et al., 2012).

Traditionally, clinicians have preferred or required patients to be actively menstruating during insertion, but there is little evidence to support the benefits of this practice, as long as pregnancy

can be reasonably ruled out through other means (American College of Obstetricians and Gynecologists, 2011). Regardless of the timing of insertion, no back-up pregnancy prevention method (e.g., condoms, spermicide, or abstinence) is required following insertion of the ParaGard IUD; backup methods are recommended for up to one week for both the hormonal IUDs and the implants (see *Table 3. CDC Guidance for LARC Initiation*, page 57) (American College of Obstetricians and Gynecologists, 2011; Centers for Disease Control and Prevention: Division of Reproductive Health, 2013).

Removal of IUDs is fairly straightforward for clinicians, and generally less painful for patients, than insertion. Nearly all (97%) providers in a recent study reported easy removal, and 42% of women described IUD removal as mild to moderately painful, and only 2% considered it severely painful (Mansour, 2012). Some women have expressed concerns about the need to have a clinician remove their IUD, with a portion of those women citing this particular reason not to choose an IUD as their contraceptive method. One qualitative study found that women discussed clinician removal as "constrain[ing] their control over their contraception" (Asker, Stokes-Lampard, Wilson, & Beavan, 2006).

To explore ways to address this concern, recent research has studied self-removal of IUDs (i.e., women removing the IUD themselves without the aid of a clinician). Self-removal is a relatively safe process for most women under most circumstances; women simply locate the IUD strings and pull until the IUD is removed. The main risk is syncope (fainting), which is expected to occur in about 0.01% of attempts at removal. A rarer, but more dangerous, risk occurs when an IUD is embedded in the uterine wall. This generally occurs long before removal, either during or after insertion; it can be painful and requires a clinician's assistance for removal (Foster, Karasek, Grossman, Darney, & Schwarz, 2012).

One study of self-removal offered participants who presented to the clinic for IUD removal the option to remove the IUD themselves or to have the clinician remove it. Most participants (59%) attempted IUD self-removal; of these, 19% successfully removed their own IUDs. The removal process took an average of 3.6 minutes for women who succeeded with self-removal (Foster et al., 2014). Women with longer IUD strings (also called "removal strings") were more likely to be successful – the odds of removal were 63% greater for every centimeter increase in string length (Foster et al., 2014). Women who were willing to attempt self-removal cited the following reasons for attempting it: "[to] see if I can do it" and "I liked the idea of removing the IUD myself" (Foster et al., 2014). Most women (58%) reported that they would recommend attempting IUD self-removal to a friend, and 54% reported that they would try self-removal in the future if they had another IUD and wanted to discontinue its use (Foster et al., 2014).

A separate study examined whether women without current IUDs would be more or less interested in obtaining one if self-removal were a possibility. The findings of this study were more mixed, with 25% reporting that they would be *more* likely to try an IUD, 31% reporting that it would not affect their likelihood of trying one, and 34% saying they would be *less* likely to try one (Foster et al., 2012).

Notably, 17% of women who had not previously considered an IUD reported that they would consider one if they could remove it themselves (Foster et al., 2012).

Further research is needed on self-removal, as there are few studies on this topic, and the results are not definitive. The current extent of women attempting self-removal at home is unknown, as women may not report to the clinic for any follow-up (Foster et al., 2014); further research could help describe current self-removal rates. Researchers also note that, if self-removal does become a clinically recommended option, women must also receive counseling that they cannot reinsert the device and that they can become pregnant immediately after removal, unless they switch to another method (Foster et al., 2012).

CONTRAINDICATIONS

While current evidence describes only a few contraindications for use of LARC methods, some providers still follow outdated guidelines that unnecessarily limit the women who are candidates for IUDs (see "Provider Knowledge," page 32). A prime example of this phenomenon is the use of IUDs in nulliparous women. Although having given birth was considered a requirement of the first few generations of IUDs, substantial evidence has supported removal of this limitation.

One reason that providers may prefer not to insert IUDs into nulliparous women is the difficulty associated with insertion in this population. One recent review notes: "Although nulliparity is not a contraindication for LNG-IUS use, nulliparous women were reported to have 1.6-fold higher relative risk for difficult insertions compared with parous women" (Mansour, 2012).

In immediately postpartum women, some concerns around the use of a hormone-releasing IUD and the potential impact on breastfeeding persist. However, recent studies have shown no difference between hormonal and copper IUD users in either breastfeeding itself or the growth and development of infants (American College of Obstetricians and Gynecologists, 2011; Mansour, 2012). Other plausible but generally unsupported contraindications include history of bone mineral density problems and history of cardiovascular disease (Mansour, 2012). Two of the few persistent and well-documented contraindications for hormonal IUD use are breast and uterine cancer; women with either a history or current diagnosis of either cancer are discouraged from obtaining a hormonal IUD (Mansour, 2012).

IMPLANT

EFFICACY

Nexplanon also shows an excellent safety and efficacy profile. As Implanon and Nexplanon use the same hormonal processes, studies describing the contraceptive efficacy of Implanon – which was

approved first and therefore has more research associated with its use – can be applied to the contraceptive efficacy of Nexplanon. A multicenter, open-label clinical trial whose results were released just prior to Implanon's FDA approval in the US found that no subjects (out of 330) became pregnant during the two-year study period (Funk et al., 2005). During the post-treatment period, 46 subjects did not use any contraceptive method, and of these, 11 became pregnant between one and 18 weeks after removal, demonstrating a rapid return to fertility after removal (Funk et al., 2005). These findings concur with other studies, which indicate that ovulation resumes in more than 90% of subjects within three weeks of removal (Funk et al., 2005).

SAFETY

As with IUDs, most side effects or risks associated with implants are minor, and serious adverse events are rare. In the clinical trial mentioned above, 85% of participants reported some type of minor adverse event. These included headache, vaginitis, acne, dysmenorrhea, mood swings, weight increase, depression, and urinary tract infection (Funk et al., 2005). Thirteen percent of study participants discontinued use of the implant because of bleeding irregularities, and two study participants (0.6%) reported serious adverse events (one ruptured ovarian follicle and one acute exacerbation of depression) (Funk et al., 2005). There were no clinically meaningful effects on physical or pelvic examinations, vital signs, or body mass index (BMI) during the study period (Funk et al., 2005). These findings are consistent with other findings in the literature, which suggest that adverse events are usually minor and may include those mentioned above, as well as weight gain and breast tenderness (American College of Obstetricians and Gynecologists, 2011).

INSERTION AND REMOVAL

Insertion of implants is generally even easier than insertion of IUDs, but removal can be more challenging than insertion. A clinical trial of Implanon found that the average insertion time was 0.5 minutes and that average removal time was 3.5 minutes (Funk et al., 2005). Some rare but possible side effects co-occurring with insertion include expulsion, hematoma (clotted blood under the skin), or swelling at the implant site. Pain and redness at the insertion site may also occur but are generally transient. Problems with removal tend to occur in rare cases when the implant breaks or is difficult to locate; fewer than 1% of women reported removal difficulties in the clinical trial (Funk et al., 2005). Self-removal is not a feasible option for implants.

POSTPARTUM AND POST-ABORTION LARC METHODS

The immediate postpartum period offers a uniquely favorable time for initiation of a LARC method. Women who have recently given birth are known not to be pregnant, may be particularly motivated to use contraception, are usually already in a hospital setting, and are at risk for rapid repeat pregnancy (American College of Obstetricians and Gynecologists, 2011). Women covered by Medicaid face a particularly high risk for rapid repeat pregnancy within 18 months of a prior birth

(Moniz et al., 2015). Rapid repeat pregnancies can have adverse effects for both mothers and children, including preterm birth and low birthweight infants, and lower income potential for mothers (Baldwin & Edelman, 2013; Partington, Steber, Blair, & Cisler, 2009). However, only 54%-65% of women who request a postpartum LARC method actually receive it, often because health-care delivery systems do not provide insertions without requiring the woman to return for another appointment, and new parents may not be able to do so (Moniz et al., 2015; Zerden et al., 2015).

It is important to note that the risk of expulsion of both copper and hormonal IUDs is higher in the six-month period following immediate postpartum insertion (within 10 minutes of delivery), at an estimated expulsion rate of 24% (American College of Obstetricians and Gynecologists, 2011; Grimes et al., 2007). While IUDs are generally acceptable for both breastfeeding and non-breastfeeding women immediately postpartum, the data on the safety of the implant in breastfeeding women is more mixed. Potential concerns include negative effects of the hormones from the implant on milk production and infant growth and development, but recent observational studies have shown no effect on these outcomes (American College of Obstetricians and Gynecologists, 2011). The CDC lists postpartum implants as Category 2 (advantages generally outweigh the risks) (Centers for Disease Control and Prevention, 2010), and the American College of Obstetricians and Gynecologists (ACOG) lists postpartum implants as Category 1 (safe at any time) for breastfeeding women (American College of Obstetricians and Gynecologists, 2011).

For many of the same reasons that that postpartum period represents an ideal time for initiation of LARC methods, the post-abortion period may also be a good time for LARC initiation. LARC methods are safe and effective in post-abortion cases – though IUDs should not be inserted after septic abortion – and lower the risk of rapid repeat pregnancies and abortion (American College of Obstetricians and Gynecologists, 2011). Most research on post-abortion (and postpartum) LARC insertion focuses on IUDs, rather than implants, as there are specific risks related to both childbirth and surgical abortion that are relevant for IUDs but not for implants because of where the insertion occurs for each method (intrauterine vs. subdermal). With IUDs, there is no increased risk of expulsion after a first trimester abortion, but there is an increased risk with a second trimester abortion (American College of Obstetricians and Gynecologists, 2015). Failure rates post-abortion are similar to failure rates in general; a recent literature review found that the failure rate for Mirena inserted post-abortion is 0.8 per 100 women at five years, compared with a range of 0.5 to 1.1 in non-post-abortion settings (Mansour, 2012).

Clinical Guidelines for LARC Method Use

Several clinical and professional societies make recommendations for the use of LARC methods, including the CDC, ACOG, the World Health Organization (WHO), and the American Academy of Pediatrics (AAP). ACOG notes that OB/GYNs may use overly restrictive criteria in identifying candidates for LARC methods, despite a lack of evidence to support these restrictions (Luchowski et al., 2014b).

The clinical guidelines issued by the CDC and WHO are provided in Tables 3-5 in the Appendix. ACOG's recommendations – which generally agree with the CDC and WHO recommendations – include: (1) providing counseling on all contraceptive options, including LARC methods, for all women at risk of unintended pregnancy (2) encouraging use of LARC methods for all appropriate candidates, including nulliparous women and teens, and (3) adopting best practices for LARC insertion. Best practices include offering LARC methods on the same day as requested if pregnancy can be "reasonably" excluded; offering LARC methods at the time of delivery, abortion, or miscarriage; screening for STIs at the time of insertion and treating any infections without removal of the IUD; and offering the copper IUD as emergency contraception (American College of Obstetricians and Gynecologists, 2015). It is important to note that offering LARC methods on the same day as requested may represent a change in practice for some providers who currently require separate visits for the consultation and the insertion (Kaiser Family Foundation, 2015).

Both ACOG and the AAP have recently issued recommendations for LARC methods to be considered first-line contraceptives for teens (American Academy of Pediatrics, 2014; American College of Obstetricians and Gynecologists, 2015). ACOG notes high rates of effectiveness, high rates of satisfaction and continuation, and no need for daily adherence as the key reasons in supporting the use of LARC methods among teens (American College of Obstetricians and Gynecologists, 2015).

Quality Family Planning (QFP) Guidelines

After a multi-stage process drawing on established procedures for developing clinical guidelines, CDC and the HHS Office of Population Affairs released a guidance document called "Providing Quality Family Planning Services" (QFP) in 2014. It is intended for all providers and potential providers of family planning services, including primary care providers. The QFP recommends a client-centered approach and delivering "high-quality care to all clients, including adolescents, LGBTQ persons, racial and ethnic minorities, clients with limited English proficiency, and persons living with disabilities." At patient encounters, it recommends that providers assess the primary reason for the client's visit, determine whether the client has another source of primary care, and then assess the client's reproductive life plan. For clients who are sexually active and do not want a child at this time, providers should offer contraceptive services (Gavin et al., 2014).

When providing contraceptive services, the QFP recommends that providers follow these steps: establish and maintain rapport with the client; obtain clinical and social information, including contraceptive experiences and preferences and a sexual health assessment; and "work with the client interactively to select the most effective and appropriate contraceptive method." The latter step involves educating the client, and the QFP suggests, "Providers are encouraged to present information on potential reversible methods of contraception by using a tiered approach (i.e., presenting information on the most effective methods first, before presenting information on less effective methods)." Then, providers should help clients consider potential barriers to using the methods they are considering. When warranted, providers should conduct physical assessments such as blood pressure readings; however, the recommendations warn, "Unnecessary medical procedures and tests might create logistical, emotional, or economic barriers to contraceptive access for some women." Finally, the QFP advises providers to provide the selected method along with instructions, and "help the client develop a plan for using the selected method and for follow-up, and confirm client understanding" (Gavin et al., 2014).

Factors Affecting LARC Use

Women need full and accurate information about all contraceptive options, including LARC methods, and should have ready access to all of them. When women or their providers lack full knowledge of the benefits and drawbacks of various contraceptive methods, or when providers are unprepared to offer client-focused counseling or same-day LARC insertion, a woman may not be able to get her preferred method of contraception – or may end up with no method at all.

In a 2015 survey, 104 researchers who recently published peer-reviewed research on LARC methods identified the top five factors they perceived as preventing US women from using LARC methods. The barrier they identified most commonly was the cost of the device for women, followed by women's knowledge of LARC method safety and acceptability, and their expectations about side effects and placements (Foster et al., 2015). Respondents also mentioned a shortage of trained providers, a lack of counseling, and "rationing," meaning "either providers withholding limited devices for only 'deserving' patients or insurance companies putting limits on how many LARC devices a woman can have within a 3- or 5-year period" (Foster et al., 2015).

Women's Perspectives on LARC Methods

Surveys and interviews with women often find a lack of information about LARC methods as well as concerns about method characteristics and side effects, and many of these are based on misinformation. Some women are not familiar with LARC methods (Burns et al., 2015; Gomez et al., 2015; Kay, Suellentrop, & Sloup, 2009; The National Campaign to Prevent Teen and Unplanned Pregnancy, 2015a; Spies et al., 2010; Whitaker et al., 2008; White et al., 2013), and many are not aware of how effectively LARC methods prevent pregnancy (Biggs & Foster, 2013; Callegari, Parisi, & Schwarz, 2013; Hladky et al., 2011), or that they are significantly more effective than other methods (The National Campaign to Prevent Teen and Unplanned Pregnancy, 2015b). They may not realize that LARC methods are suitable for women who have never given birth (Rocca & Harper, 2012), including adolescents (Hladky et al., 2011), or that a history of STIs or pelvic inflammatory disease does not rule out IUD insertion (Hladky et al., 2011). Despite strong evidence that IUDs are safe and fertility returns quickly after removal, many women fear that IUDs may increase the risk of infection (Callegari et al., 2013; Hladky et al., 2011; Spies et al., 2010), cancer (Hladky et al., 2011; Kay, Suellentrop, & Sloup, 2009), ectopic pregnancy (Hladky et al., 2011), or infertility (Gomez, Fuentes, & Allina, 2014; Hladky et al., 2011; Rocca & Harper, 2012; Spies et al., 2010).

Financial Barriers to LARC Methods

Cost is a major barrier to the uptake of LARC methods; the full price of a LARC device can range from $500 to more than $900 (Bedsider.org, 2016), and additional provider charges for insertion and follow-up visits can bring the total bill above $1,000 (Eisenberg, McNicholas, & Peipert, 2013).

Many insurers are now required by law to cover the full cost (see "Payment Policy," page 46), although the cost to providers of stocking LARC devices can also inhibit access. In a study involving more than 600 abortion patients at 17 reproductive health centers across the US, post-abortion LARC method initiation was far higher among women with public insurance than those without insurance, and was higher in states requiring private insurers to cover contraception (Rocca, Thompson, Goodman, Westhoff, & Harper, 2015). In interviews with 120 Latina women seeking sterilization in El Paso, Texas, approximately one-third said they would be interested in a LARC method if one were available for free or at low cost (White et al., 2013).

Box 1. Publicly Funded Family Planning

Publicly funded family planning consists of two major funding sources: Medicaid and the Title X Family Planning program. The majority of this funding (75%) comes from Medicaid reimbursements for services and supplies (Centers for Medicare and Medicaid Services, 2015; National Family Planning and Reproductive Health Association, 2015). Under Medicaid, family planning is a mandatory benefit, and states receive an enhanced Federal Matching Assistance Percentage (FMAP) of 90%; cost-sharing is not allowed. Medicaid also reequires that individuals have a choice of provider, meaning that states must allow Medicaid enrollees to receive services from any qualified and licensed entity (National Family Planning and Reproductive Health Association, 2015).

Title X of the Public Health Service Act (Title X) was enacted in 1970 and remains the only federal grant program dedicated solely to providing comprehensive family planning services (Office of Population Affairs, 2014). Administered by the Office of Population Affairs (OPA) in the US Department of Health and Human Services, the Title X program funds a network of over 4,000 family planning centers across the country – including state health departments, federally qualified health centers, and specialized family planning clinics – and provides services to millions of men and women (Office of Population Affairs, 2014). Title X is a safety net program that provides coverage for low-income men and women who do not have another source of coverage, such as private insurance or Medicaid.

The program requirements for Title X include the provisions that "Family planning services are to be provided solely on a voluntary basis" and that "Clients cannot be coerced to accept services or to use or not use any particular method of family planning" (Office of Population Affairs, 2014). Title X providers must also provide services for adolescents and must ensure confidentiality for services; parental consent for family planning services and supplies are not required (Office of Population Affairs, 2014).

Costs can be especially problematic for adolescents who lack independent access to the funds needed to pay for services or who use their parents' insurance. Regulations on parental consent for teens using private insurance for contraception vary by state, while federal regulations specify that adolescents may receive family planning services from Medicaid and Title X programs (Eisenberg

et al., 2013); see "Parental Consent Policies for Adolescents & Confidentiality of Care," page 53. Even if parental consent is not required, using a parent's insurance typically results in the policyholder receiving an explanation of benefits that lists the provider and service. This can be problematic for teens who do not want their parents to know they are (or are preparing to be) sexually active (Sedlander, Brindis, Bausch, & Tebb, 2015). Some states have implemented policies designed to prevent or reduce such confidentiality breaches (Tebb et al., 2014), and many Title X providers serve adolescent clients without charging them co-payments (English, Summers, Lewis, & Coleman, 2015; Lewis, Summers, English, & Coleman, 2015; Masselink et al., 2016).

Women's Preferences Regarding Contraceptive Characteristics

Other concerns about LARC methods stem not from misinformation, but from women's preferences. Different women prioritize different contraceptive attributes at different times in their lives. Some may select less-effective forms of contraception in order to ensure easy reversal or avoid certain side effects. Client-centered contraceptive counseling should address each woman's unique priorities and situation and provide her with information about methods that best meet her own specific needs.

In surveys and interviews, some women tell researchers that they prefer not to have devices inside their bodies (Borrero et al., 2011; Gomez et al., 2015; Potter, Rubin, & Sherman, 2014; Spies et al., 2010), or are concerned about long-term hormone use (Borrero et al., 2011). Some want to avoid insertion pain (Gomez et al., 2015; Hillard, 2013), the possibility of heavier or irregular bleeding (Spies et al., 2010; White et al., 2013), or other side effects (Whoops Proof Birth Control, 2015). The need to see a provider for both insertion and removal may pose concerns for some women, especially those with insecure access to insurance or healthcare (Foster et al., 2014; Gomez et al., 2014; Gomez et al., 2015). Even women with reliable access to care may find some providers reluctant to remove devices inserted recently. Interviews with women who considered elective IUD removal within nine months of insertion found many of the study participants "reported that their providers communicated a preference, explicitly or implicitly, for them to keep the IUD." Participants' comments suggest providers may have been concerned about patients' likely substitution of less-effective methods or may have predicted that side effects would subside after several months of use; even if these providers were considering their patients' long-term health, the study authors note "the need to improve prompt access to IUD removal" (Amico, Bennett, Karasz, & Gold, 2016). One survey of more than 600 women seeking abortions found 25% would be more willing to try an IUD if they could remove it themselves (Foster et al., 2012); also see "Insertion & Removal," page 19.

A survey of more than 500 women seeking abortions at six clinics in 2010 asked women about the contraceptive features they considered most important. For this group, who the authors note includes women at high risk of unintended pregnancy, the features deemed "extremely important" by the largest number of women were effectiveness, a lack of side effects, and affordability. For

91% of respondents, no existing method had all the features they considered extremely important, and LARC methods possessed fewer of these features than the ring, sponge, patch, and pill did. An oral contraceptive available without a prescription would have 71% of the extremely important features the surveyed women identified, while a self-removable IUD would have 61% of their desired features (Lessard et al., 2012). Even when women have accurate knowledge of LARC options, LARC methods do not fully meet the needs and preferences of a substantial portion of the population, suggesting that current options should be improved.

While a substantial group of women prefer non-LARC methods because they want to be able to stop them at any time without visiting a provider, LARC can be a more easily reversible alternative for women who might otherwise opt for sterilization. African-American women are more likely than white women to choose sterilization, but they are also less likely to have heard of IUDs, and post-sterilization regret is especially high among African-American women (Borrero et al., 2011). An analysis of 2006 - 2009 Pregnancy Risk Assessment Monitoring System data from 12 states found women with Medicaid-paid deliveries were more likely than those with private insurance to choose postpartum sterilization, and the authors suggest that one reason for the difference could be women with Medicaid coverage seeking to secure contraception before their coverage expired 60 days after delivery (White, Potter, & Zite, 2015). With Medicaid expanding in many states and postpartum LARC insertion availability increasing, women who might previously have selected postpartum sterilization may be able to consider LARC methods as an alternative.

LARC Methods and Reproductive Injustice

Women's attitudes toward LARC methods and their reactions to counseling that is built on tiered effectiveness must also be understood in the context Gomez and colleagues describe as "the long-standing devaluation of the fertility and childbearing of young women, low-income women and women of color in the United States, and the perception that these women have too many children" (Gomez et al., 2014). Unlike oral contraceptives or barrier methods that are under the control of the user, LARC methods are significantly provider-dependent. This has advantages, in reducing the opportunity for errors that lead to unintended pregnancy, but it also creates the potential for the method to be used in ways that are not fully voluntary, because the person using the contraceptive does not have independent control over starting and stopping use.

The history of reproductive injustice – denying some groups of women the control to make their own reproductive decisions – is long and not confined to the distant past. Through the 1970s, coercive sterilization was performed on welfare recipients, Native Americans, and Latinas from some states; in the 1990s the introduction of Norplant launched an outbreak of incidents using, or proposing use of, the method to undermine certain women's autonomy in contraceptive decision-making; and women in California prisons underwent coerced sterilization as recently as 2006 to 2009 (Gold, 2014). More recently, a number of states have adopted policies that create incentives or disincentives to limit childbearing by women receiving public assistance.

POLICIES TARGETING WOMEN RECEIVING PUBLIC ASSISTANCE OR INVOLVED IN THE JUSTICE SYSTEM

Public health experts considering the problem at the time of Norplant's introduction (see "Implant History," page 8) identified three distinct, though interrelated, ways the implants could be used coercively: within the judicial system, in sentencing or plea negotiation, or as a condition of parole or probation; in the policy and legislative arena, through incentives for use or disincentive plans to reduce childbearing by poor women; and in individual interactions between providers and patients where provider bias could lead to violations of informed consent, steering women inappropriately toward the method. Some proponents of these uses of Norplant, however, defended them on the grounds that, because the method allows a return to fertility after removal, it is not an ethical violation to mandate involuntary insertion or otherwise undermine fully voluntary choice of the method (Feringa, Iden, & Rosenfield, 1992; Gold, 2014).

In several court cases in the 1990s, women convicted of child abuse were offered reduced sentences if they agreed to use Norplant (Feringa et al., 1992). Only one state, Illinois, established a policy to prevent such judicial involvement in contraceptive decision-making, enacting a law that prohibits judges from making contraceptive use a condition of sentencing (Gold, 2014).

By 1994, legislation had been proposed in 13 states to establish financial incentives for Norplant use among "welfare mothers," as described in an editorial in the *Philadelphia Inquirer* (Philadelphia Inquirer, 1990a). The *Inquirer's* later apology for its editorial endorsement of this approach succinctly explained the problem with financial incentives, stating, "to dangle cash or some other benefit in front of a desperately poor woman is tantamount to coercion" (Philadelphia Inquirer, 1990b). Although none of these bills was enacted, analysts have noted that the concept they introduced informed later debates over family caps in welfare reform, which limit welfare payments to families that have additional children while receiving welfare benefits (Gold, 2014). Sixteen states currently limit total family benefits, reduce benefits, or do not provide additional benefits for additional children born while the family receives assistance (Covert, 2015). Such laws may create financial pressure to use forms of contraception that a woman might not have chosen in the absence of such policies. The California policy, for example, specifically exempts a woman who has an additional birth from the limitation if she provides written verification that she is using a long-acting reversible contraceptive method (Gold, 2014).

INDIVIDUAL ACTIONS, EXPERIENCES, AND CHOICES

Reproductive injustice can operate in more subtle ways, too. A randomized study in which more than 500 providers viewed videos of standardized patient requests for contraception advice found that providers were more likely to recommend IUDs to black and Latina women with low socioeconomic status (SES) than to white women with low SES (Dehlendorf, Ruskin, et al., 2010). Other studies have found black low-income women being more likely than white low-income women to report having been pressured by clinicians to use contraception (Becker & Tsui, 2008),

and Hispanic women more likely to have been counseled about sterilization (Borrero, Schwarz, Creinin, & Ibrahim, 2009). Interviews with African-American women found half reported experiencing discrimination when obtaining family planning services; this included experiences that reflected stereotypes, such as providers assuming they had multiple sexual partners (Thorburn & Bogart, 2005). One study found that compared to middle-class white women, low-income women of color were more likely to report having been advised to limit childbearing or to be discouraged from having more children (Downing, LaVeist, & Bullock, 2007). In a qualitative study involving Black and Hispanic women who received contraceptive counseling at a Medicaid-funded clinic, several reported feeling coerced or perceiving racially-based discrimination (Yee & Simon, 2011).

In this context, it is hardly surprising to find that the attitudes about and use of contraception by low-income women and women of color are different from those of white women and women with greater financial resources (McClain, 2015). In a survey of more than 600 women at risk of unintended pregnancy, black and Latina women had more than twice the odds of believing "the government encourages contraceptive use to limit minority populations" (Rocca & Harper, 2012). As part of a study on contraceptive choice, participants in focus groups with both white and black women raised the issue of reproductive coercion, particularly forced sterilization of women of color (Meier, Sundstrom, & DeMaria, 2015).

In a study that provided women requesting IUD removal with the opportunity to first attempt removing the devices themselves, "African American women had four times greater odds of reporting that the feature of self-removability makes them more likely to recommend the IUD to a friend" (Foster et al., 2014). A survey of women seeking services from abortion and family planning clinics in 11 states found that non-Hispanic black, Latina, and Asian Pacific Islander women were more likely to report that being able to stop using a method at any time was an "extremely" important contraception feature than were non-Hispanic white women (Jackson, Karasek, Dehlendorf, & Foster, 2015). An online survey that oversampled women of color found that 3% of participants reported IUDs had been misused against people in their communities, and 9% reported that to be the case for the contraceptive implant (Burns et al., 2015).

In an analysis of data from the National Survey on Family Growth, Kavanaugh and colleagues did not find poverty status to be associated with LARC method use. They did find black women were less likely than white women to use LARC methods. Among LARC users, black women were more likely to use implants than were white women, and women with incomes below 300% of the federal poverty level were more likely to use implants than were higher-income women. The authors note that these patterns could be due to either preferences or to inequitable access (Kavanaugh et al., 2015).

It is important for providers to consider how women's experiences may influence their responses to contraceptive counseling, particularly with regard to race and income. Higgins offers providers this reminder:

"Due to her social privilege, a white, middle class, fully insured, married woman will not have to wonder if her physician recommends LARC because of her race, her social class and/or the provider's concern about her potentially out-of-control fertility. In contrast, a poor woman of color may well feel sociodemographically targeted when a provider recommends LARC, especially given prior abuses such as coerced sterilizations, financial incentives for long-acting contraceptive use and other human rights abuses." (Higgins, 2014)

Providers and LARC Methods

PROVIDER KNOWLEDGE

Providers who offer family planning services should have up-to-date knowledge of the professional guidelines for LARC methods, but recent research has found that many providers have overly restrictive criteria for LARC candidates, which may prevent a woman in their care from getting the contraceptive method that best meets her needs and preferences. Provider surveys have found that many providers consider women to be poor candidates for either or both types of IUDs if they have a history of pelvic inflammatory disease (Biggs, Harper, Malvin, & Brindis, 2014; Harper, Henderson, et al., 2012; Luchowski et al., 2014b; Madden, Allsworth, Hladky, Secura, & Peipert, 2010; Vaaler, Kalanges, Fonseca, & Castrucci, 2012) or ectopic pregnancy (Biggs et al., 2014; Harper, Blum, Thiel de Bocanegra, et al., 2008; Harper, Henderson, et al., 2012; Kavanaugh, Frohwirth, Jerman, Popkin, & Ethier, 2013; Luchowski et al., 2014b; Philliber et al., 2014; Tyler et al., 2012), or if they are adolescents or have not had children (Biggs et al., 2014; Callegari et al., 2014; Luchowski et al., 2014b; Madden, Allsworth, Hladky, Secura, & Peipert, 2010). Some consider contraceptive implants to be inappropriate for women who smoke or have a history of hypertension (Biggs et al., 2014). Provision of the copper IUD as emergency contraception has remained low (Harper, Speidel, et al., 2012; Luchowski et al., 2014b).

Studies have identified several provider characteristics that are associated with more accurate knowledge of LARC methods. These include being involved with teaching residents or fellows (Callegari et al., 2014); receiving continuing education and reading ACOG publications (Luchowski et al., 2014b); and being an obstetrician-gynecologist as opposed to a family physician (Dehlendorf, Levy, Ruskin, & Steinauer, 2010). Offering on-site IUDs is also associated with greater knowledge of LARC methods (Dehlendorf, Levy, et al., 2010; Tyler et al., 2012). One survey of Texas providers found urban providers were more likely than their rural counterparts to recommend the contraceptive implant (Vaaler et al., 2012).

PROVIDER TRAINING

Not all providers of contraceptive care are trained to insert LARC devices, and a lack of provider training can also limit a woman's ability to get a LARC method, especially the contraceptive implant. Survey responses from more than 1200 Fellows of the American College of Obstetricians and

Gynecologists indicate that 96% provide IUDs, but only 51% offer the single-rod implant; relatedly, 92% reported residency training on IUDs, and 51% on implants. Thirty-two percent cited lack of insertion training as a barrier to offer implants, and recent continuing education was strongly associated with implant insertion. Physicians between the ages of 41 and 48 reported receiving the most training and experience with implant insertion during residency (Luchowski et al., 2014a). A survey of providers participating in California's Family PACT program for family planning found a similar gap: 67% reported offering the IUD on-site, while only 40% report offering the implant (Biggs et al., 2014). Factors that may help explain the discrepancy between offerings of IUDs and implants include the time gap in contraceptive implant availability between Norplant's withdrawal from the US market in 2002 and the later approval of the single-rod implant in 2006 (which likely affected residency training), and the fact that physicians must complete a three-hour, manufacturer-provided training in order to place implants (Luchowski et al., 2014a).

A variety of factors influence whether a clinician is trained in LARC insertion and comfortable offering those services. Philliber and colleagues (2014) found that, among clinicians at family planning clinics, those with 10-19 years of experience were less comfortable with insertion (of both IUDs and implants) than were those with one to nine years in practice or those with 20 or more years. Among the most recently licensed clinicians, 88% reported receiving training in IUD insertion, while 74% received it for the single-rod implant (Philliber et al., 2014). A survey of St. Louis-area clinicians who provide OB/GYN care found that 36% reported not being trained in IUD insertion during their residency or advanced-practice nurse training, and that clinicians who trained at Catholic institutions were less likely to have been trained than those who trained at secular institutions (Madden et al., 2010).

Providers may also lack specific training on providing postpartum LARC methods; in one study, obstetricians were more likely than midwives or family-medicine providers to report experience placing IUDs postpartum (Holland, Michelis, Sonalkar, & Curry, 2015). Others have identified insufficient training during family medicine residencies as one possible reason that family medicine physicians are less likely to provide IUDs than OB/GYNs are (Harper, Henderson, et al., 2012; Landry, Wei, & Frost, 2008; Rubin, Fletcher, Stein, Segall-Gutierrez, & Gold, 2011).

Health System Factors Affecting LARC Provision

In addition to training, there are other health system factors that affect the likelihood that a provider will offer LARC services. Studies of family medicine physicians have identified limited time for counseling during patient visits as a possible barrier (Harper, Henderson, et al., 2012; Schubert, Herbitter, Fletcher, & Gold, 2015). Investment by a particular health system may increase the likelihood that LARC methods will be available to its patients in comparison to patients of other providers in the same region. In California, Park and colleagues documented that Title X providers were more likely to offer LARC methods on-site than were providers not participating in the Title X program, and rural Title X providers were more likely to offer on-site LARC methods than were

their urban Title X counterparts (Park, Rodriguez, Hulett, Darney, & Thiel de Bocanegra, 2012). Similarly, a survey of more than 400 federally qualified health centers found that those receiving Title X funding were more likely to offer LARC methods on-site than those not receiving Title X funding (Beeson et al., 2014).

In this same survey, more than two-thirds of the health centers offered IUDs on-site, but only 36% reported on-site implants; the most commonly reported barriers to on-site LARC methods included stocking costs and insufficient staffing and training. The centers without on-site LARC will typically provide referrals or give women prescriptions for IUDs or implants, so a woman can purchase the device from a pharmacy and bring it back to the health center for insertion (Beeson et al., 2014). Updating facility guidelines, improving counseling for clients, and offering broader training for staff requires financial support as well as staff time (Kavanaugh, Jerman, Ethier, & Moskosky, 2013). Initiatives to provide LARC methods in primary care practices that were not previously offering them must consider clinical protocols, malpractice insurance, and device stocking as well as training for all involved staff (Pace, Dolan, Tishler, Gooding, & Bartz, 2016).

SAME-DAY LARC METHOD PLACEMENT

Requiring multiple office visits for LARC methods is a significant and unnecessary barrier. Women who select a LARC method at one visit may not be able to return for a separate insertion visit, especially if they live far from the provider (Bergin, Tristan, Terplan, Gilliam, & Whitaker, 2012). Providers who do not keep LARC methods in stock must order them, which creates a logistical barrier to same-day placement (Biggs, Harper, & Brindis, 2015). A survey of providers participating in California's Family PACT program found that nearly all Planned Parenthood practices reported providing IUDs and implants with a single visit, while nearly none of the private practices did (Biggs, Harper, & Brindis, 2015).

Because the risk of pelvic inflammatory disease is higher in women with an untreated STI at the time of IUD insertion (though still low overall), many providers prefer to administer STI tests and wait for the results before inserting IUDs. ACOG advises that data do not support pre-insertion routine STI screening for women at low risk of STIs. For women at high risk, they recommend screening for STIs and placing the IUD on the same day or when test results are available. While they advise treating women with known chlamydia or gonorrhea cervicitis before IUD insertion, antibiotic therapy can be administered while leaving the IUD in place for any women whose test results indicate chlamydia or gonorrhea infection after IUD insertion (American College of Obstetricians and Gynecologists, 2011). Recent studies found some providers require two visits because they allow time for STI test results to be completed; some also cite the difficulty of fitting both counseling and insertion into a single visit, or other aspects of clinic workflow (Biggs, Arons, Turner, & Brindis, 2013; Biggs, Rocca, Brindis, Hirsch, & Grossman, 2015).

Stocking of the devices is also a challenge for providers, as mentioned above. With IUDs and implants typically costing several hundred dollars, many providers cannot afford to keep them in

stock. Cost can be a particular issue with Title X providers, who charge their low-income clients fees on a sliding scale. Many of their clients are uninsured or prefer to pay a sliding-scale fee rather than using coverage that may compromise their confidentiality (e.g., a health plan shared by a parent or spouse). These low or zero dollar client payments do not come close to covering the cost of most LARC devices (English et al., 2015; Masselink et al., 2016). Other public sector providers, such as federally qualified health centers, also face stocking barriers (Beeson et al., 2014; Rosenbaum, Shin, Wood, & Sharac, 2015). Recent guidance from CMS proposes a model that state Medicaid programs might explore to address stocking barriers (see "Recent CMS Guidance for States," page 50).

Box 2. Zika and LARC

Current concerns about serious fetal anomalies caused by the Zika virus have brought a new urgency to efforts to deliver highly effective contraceptive services in regions where Zika is prevalent. In April 2016, scientists examined the growing evidence and concluded that prenatal Zika virus infection causes serious fetal brain anomalies, including microcephaly, in which the brain and skull are abnormally small (Rasmussen et al., 2016). The virus is transmitted by mosquitos and can also be spread via sexual contact; it can remain in the semen of infected men for an indeterminate amount of time, and researchers do not know if it can spread via other bodily fluids (CDC, 2016a). While noting that women are delivering apparently healthy infants in areas with active Zika transmission, CDC has advised women diagnosed with Zika to wait at least eight weeks after their symptoms' first appearance before trying to get pregnant, and men diagnosed with the illness to wait six months to have unprotected sex (CDC, 2016b). These recommendations are based on current understanding of how long Zika virus remains in blood and semen; however, data on viral persistence are still quite limited, and to minimize risk, the recommended times to wait extend well beyond any documented persistence.

For women and men living in areas with active Zika transmission, the agency states: "CDC recommends healthcare providers talk with their patients about their pregnancy plans during a Zika virus outbreak, the potential risks of Zika, and how they can prevent Zika virus infection. These are very complex, deeply personal decisions, and we are communicating the potential risks of Zika virus infection during pregnancy for people who live in areas with active transmission. We are encouraging health care providers to have conversations with women and their partners about pregnancy planning, their individual circumstances and strategies to prevent unintended pregnancies." (CDC, 2016b)

Local mosquito transmission of Zika is occurring in Puerto Rico, and CDC scientists worked with the Puerto Rico Department of Health and other partners to explore contraceptive needs and access there. They estimate that 138,000 women aged 15-44 in Puerto Rico are at risk of an unintended pregnancy — meaning, they are fertile and do not desire pregnancy, and they are not using one of the moderately or most effective methods of contraception (IUD, implant, injection, pills, ring, or patch). The authors conducted interviews with key stakeholders in Puerto Rico, who "identified the need for increased contraceptive supplies, family planning delivery sites, training for providers on LARC insertion, education for women and men on effective contraception to reduce unintended pregnancy, and decreased financial and administrative barriers for providers and patients" (Tepper et al., 2016).

Reducing Barriers While Preserving Autonomy

Women's access to LARC methods improves when providers: (1) have complete knowledge of these methods; (2) can provide comprehensive, client-centered counseling; (3) are trained to insert both IUDs and implants; and (4) have the financial and logistical capacity to offer them on the same day as contraceptive counseling, as well as immediately following delivery or abortion. LARC method use has increased in places where interventions have reduced cost and knowledge barriers. However, many advocates, providers, and researchers emphasize that the goal of such interventions should be increasing women's access to contraceptive services that support them in identifying and using the method that best meets their needs, rather than increasing LARC method use specifically.

Some have warned that using a tiered efficacy approach to education, with the most effective methods (i.e., LARCs) described first (as the QFP recommends; see "Quality Family Planning (QFP) Guidelines," page 24), has the potential to become too directive, as it assumes that effectiveness is the most important factor in the woman's decision. Providers must ensure that patient autonomy is paramount while providing accurate information about effectiveness (Stanback, Steiner, Dorflinger, Solo, & Cates, 2015). Indeed, this is consistent with the QFP's overall emphasis on taking a client-centered approach and assessing clients' preferences before beginning education.

Another factor complicating contraceptive decision-making is the complex nature of pregnancy intention in many women. One study found that 23% of women asked whether they were trying to or trying not to conceive responded that they were "okay either way" (McQuillan, Greil, & Shreffler, 2011). Qualitative studies involving low-income women have found that participants do not always think they have control over whether or when they get pregnant (Borrero et al., 2015; Hodgson, Collier, Hayes, Curry, & Fraenkel, 2013; Whoops Proof Birth Control, 2015), so they may not formulate specific pregnancy intentions (Borrero et al., 2015). Hodgson and colleagues found from focus groups, "Family planning was seen as a way to slow down an inevitable process that is ultimately in the control of God or fate" (2013). However, fatalism — believing events to be controlled by God or fate — is not necessarily at odds with feelings of agency or use of contraception (Jones, Frohwirth, & Blades, 2016). Jones and colleagues report, "some women using highly effective methods related that if they were to become pregnant, they would interpret it as a sign that the pregnancy was 'meant to happen'" (2016). Borrero and colleagues found that happiness over a pregnancy is distinct from intention, and women may express happiness about pregnancies even if they were not planning to get pregnant (2015). Aiken and colleagues report, "it is possible for women to express happiness at the idea of pregnancy while simultaneously earnestly trying to prevent conception" (Aiken, Dillaway, & Mevs-Korff, 2015).

Several advocates, researchers, and practitioners have advocated a reproductive justice approach to LARC methods. Aline Gubrium and colleagues describe it in this way:

> "A reproductive justice approach means reducing barriers to accessing LARC and making them readily available to all fully informed people who want them. However, it also means respecting the decision not to use these methods or to have these methods removed when they wish. The quality of contraceptive programs should be based not on how many LARC methods they distribute, how many adolescent pregnancies they prevent, or how much money taxpayers save, but by how many people feel truly respected and cared for when it comes to childbearing and family formation." (Gubrium et al., 2016)

Research suggests that in contraceptive counseling, women prefer to control the ultimate selection of the method and to receive providers' input in ways that prioritize and value their goals and preferences (Dehlendorf, Levy, Kelley, Grumbach, & Steinauer, 2013). While encouraging more research into evidence-based strategies for effective contraceptive counseling, Dehlendorf and colleagues conclude that the limited available research supports "a shared decision making approach that focuses on eliciting and responding to patient preferences and of specific task-oriented communication strategies to enhance the process of method selection, facilitate correct use of a chosen method, and meet women's overall reproductive health needs" (Dehlendorf, Krajewski, & Borrero, 2014).

Research on Reducing Cost and Knowledge Barriers

Efforts to improve LARC method access are making it easier for providers to offer IUDs and implants and for women who want them to get them. For instance, providers who completed the Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, a large training program that includes 64 OB/GYN departments in the US and Canada, had increased knowledge and self-assessed clinical competencies for IUDs and implants among residents (Steinauer, Turk, Fulton, Simonson, & Landy, 2013). ACOG provides resources to help providers update their knowledge on contraceptive options, share knowledge with colleagues, and launch or expand LARC method programs in their practices and facilities.

A randomized trial involving 40 Planned Parenthood clinics across the US included trainings at 20 of the clinics, with an emphasis on ethical issues and the importance of patient-centered counseling and LARC removal upon request. Trainings also included educational training for clinic staff, hands-on IUD insertion practicum for clinicians, counseling role-playing for health educators, and billing technical assistance for clinic managers. LARC method initiation was higher at the clinics where the trainings occurred compared to the other clinics. It was also higher at the clinics with Medicaid family planning expansion programs and among women with public health insurance compared to those who were privately insured (Thompson et al., 2016).

Online and phone tools could complement in-person counseling, and researchers are developing and testing several. A randomized trial of the "Plan A Birth Control" app, with patients randomly assigned to counseling with the app or a health educator, found both groups had similar LARC

knowledge and uptake (Sridhar, Chen, Forbes, & Glik, 2015). A pilot study found that a counseling app that clients can use in the waiting room increased participants' contraceptive knowledge and interest in the contraceptive implant (Gilliam, Martins, Bartlett, Mistretta, & Holl, 2014). A feasibility study of the "Get It and Forget It" online video about IUDs, offered in both English and Spanish, found increased knowledge of and interest in IUDs among women who viewed the video and completed surveys before and after doing so (Garbers et al., 2015).

Researchers have also evaluated websites and courses that may improve contraceptive knowledge. An exploratory study found providing contraceptive information through an interactive Facebook page to be an effective way to increase contraceptive knowledge (Kofinas et al., 2014). Surveys of students from four community colleges conducted before and after they completed three online lessons on contraception from the National Campaign to Prevent Teen and Unplanned Pregnancy found both women and men were more likely to report they would consider using a different method of birth control after completing the lessons (Antonishak & Connolly, 2014). In a qualitative study with patients and providers who explored the National Campaign's Besider.org online support tool, patients described the tool as trustworthy, accessible, and empowering, but providers expressed concerns about its legitimacy and accessibility to patients (Gressel et al., 2014). A randomized trial of Bedsider.org, in which women in the Bedsider group were introduced to the site via video and received quarterly emails with Bedsider content during a 12-month period, found women in the intervention group were significantly less likely to report unprotected sex or unintended pregnancies compared to the control group (Antonishak, Kaye, & Swiader, 2015). Additional research into these and other educational tools can extend knowledge about effective ways to augment the information women receive from providers.

Recent large-scale initiatives to reduce barriers to LARC methods for women in specific metropolitan areas and states demonstrate that when LARC methods become more accessible, large percentages of women seeking contraception choose them – and the result is falling rates of unintended pregnancy. In Iowa, a five-year initiative that provided extra funds for Title X and other family planning providers allowed for large jumps in the number of clients using LARC methods, and the state's abortion rate fell even as abortion care became more accessible. A multi-year study in St. Louis with more than 9,000 participants found that, when offered education on LARC options and no-cost insertion, thousands of women chose IUDs and implants, and sharp declines in teen pregnancy and abortion rates followed. After a Colorado initiative allowed Title X providers to offer same-day LARC method access, the state saw lower rates of teen pregnancy and abortion.

These three programs are described in more detail below.

IOWA INITIATIVE TO REDUCE UNINTENDED PREGNANCIES

In 2007, the privately funded Iowa Initiative to Reduce Unintended Pregnancies launched with the goals of reducing unintended pregnancies among Iowa women ages 18 to 30 and increasing support for publicly funded family planning. Funding allowed 17 Title X family planning agencies, which provided services at 81 clinical sites, to expand hours and locations; train clinic staff on client education and counseling; and purchase IUDs and implants, which they had previously been unable to afford to stock (Office of Population Affairs, 2012; Philliber Research Associates, 2012). After receiving Initiative funds, all Iowa Title X agencies offered the implant and both hormonal and copper IUDs (Philliber Research Associates, 2012).

The Iowa Initiative also involved a public marketing component. The Center for Social and Behavioral Research at the University of Northern Iowa conducted research and testing and, in 2010, launched the "Until You're Ready, Avoid the Stork" campaign, which was rolled out statewide after performing well in northwestern Iowa. Most of the Title X providers conducted marketing efforts, including making IUDs and contraceptive implants free for a limited time; when these promotions were not in effect, the usual Title X sliding-scale fees applied (Office of Population Affairs, 2012; Philliber Research Associates, 2012).

To evaluate the Initiative's performance, researchers from Philliber Research Associates and the Bixby Center for Global Reproductive Health at University of California San Francisco analyzed data from participating clinics and statewide statistics (Office of Population Affairs, 2012). From 2005 to 2012, the percentage of Iowa Title X reproductive-age clients using LARC methods increased from less than 1% to 15% (Biggs, Harper, & Brindis, 2015). During that time period, abortion access expanded in the state, with medication abortion via telemedicine becoming available in 2008; as a result, the number of abortion facilities in the state rose from nine in 2008 to 19 in 2009. Nonetheless, the number of abortions for Iowa residents dropped from 8.7 per 1,000 reproductive-age women in 2005 to 6.7 in 2012 (Biggs et al., 2015).

The Iowa Initiative also occurred in the context of the state's expansion of Medicaid coverage of family planning services for lower-income residents. In 2006, Iowa began providing Medicaid coverage for family planning services for women with household incomes of up to 200% of the federal poverty level, as well as those who would otherwise lose Medicaid coverage following delivery of a baby (Sonfield, Alrich, & Gold, 2008). An evaluation of this program reported that an average of 22,000 women enrolled each month between 2006 and 2010; the authors calculated that the program averted more than 4,000 births, and as a result produced more than $50 million in savings to Medicaid (Momany & Carter, 2011).

The Iowa Initiative's partner organizations advocated to expand this program, and in September 2010, the state made several changes. The state Medicaid program expanded access to family planning for both women and men up to age 54 with household incomes of up to 300% of the federal poverty level (Office of Population Affairs, 2012). Women with Medicaid coverage may not

be charged co-payments for family planning services, so out-of-pocket charges cease to be a barrier (although other costs, such as childcare and transportation, may remain challenging). Funding from the Initiative allowed Title X providers to stock LARC devices and take other steps to expand access to these highly effective forms of contraception. While the Iowa Initiative concluded as scheduled in 2012 (Office of Population Affairs, 2012), the expanded coverage and infrastructure remain.

CONTRACEPTIVE CHOICE PROJECT (ST. LOUIS, MISSOURI)

Also in 2007, researchers launched the Contraceptive CHOICE Project to study the contraception women choose when cost, education, and access barriers to LARC methods are reduced. The multi-year, privately funded study, based at Washington University in St. Louis and involving several community providers, enrolled over 9,000 St. Louis metro-area women ages 14-45. Participants had been sexually active in the last six months or anticipated being sexually active in the next six months, wanted to avoid pregnancy for at least a year, and were interested in starting a new form of reversible contraception (Birgisson, Zhao, Secura, Madden, & Peipert, 2015; Secura, Allsworth, Madden, Mullersman, & Peipert, 2010).

While determining potential participants' eligibility for the study, trained staff members read women a script describing LARC methods. Women who enrolled received contraceptive counseling that covered the range of available methods, as well as being screened for STIs. Once a clinician gave approval for each participant's selected method, she received it at no cost (Secura et al., 2010). Participants received their selected methods free for two to three years, and could change methods at any point during the study (Birgisson et al., 2015).

The Contraceptive CHOICE Project developed a structured, comprehensive contraceptive counseling program that aimed to "provide accurate, unbiased information about all contraceptive methods to help the woman assess her needs and make an informed decision" (Madden et al., 2013). The counseling framework was modeled after the GATHER counseling process, "a client-centered process focused on the woman, her expressed needs, situation, problems, issues and concerns" (Madden et al., 2013).

Participants enrolled in the Contraceptive CHOICE Project from August 2007 through September 2011. They completed questionnaires upon enrollment, phone interviews three and six months later, and phone interviews every six months after that. Researchers analyzed these responses as well as local and state statistics. In 2015, they reported that 75% of participants chose a LARC method (46% hormonal IUD, 12% copper IUD, 17% implant), and that LARC methods were 20 times more effective than non-LARC hormonal methods (pill, patch, and ring) (Birgisson et al., 2015).

The rate of teen pregnancy for women in the study was more than four times lower than the national rate: 34.0 pregnancies per 1000 teens in the CHOICE study, compared to 158.5 per 1000 sexually experienced US teens. The rates of teen births and abortions were correspondingly lower – 19.4 vs. 94.0 births per 1000 teens, and 9.7 vs. 41.5 abortions per 1000 teens (Secura, Madden, et al., 2014).

To investigate the potentially larger impacts in the St. Louis region, researchers examined the repeat abortion rates (i.e., out of women receiving abortions, what proportion had received an abortion previously) for women ages 15-44 in St. Louis city and county and in Kansas City, which is demographically similar. They found a significant decrease in the percent of repeat abortions in the St. Louis area from 2006 to 2010, while the percent of repeat abortions in Kansas City increased significantly over the same time period (Birgisson et al., 2015; Peipert, Madden, Allsworth, & Secura, 2012).

An analysis of responses from participants who completed surveys at baseline, six months, and 12 months found the median number of acts of intercourse reported for the past 30 days increased significantly. However, rates of chlamydia and gonorrhea infections were not significantly higher among the women whose surveys indicated an increase in acts of intercourse when compared to the women who reported the same or fewer acts (Secura, Adams, Buckel, Zhao, & Peipert, 2014).

COLORADO FAMILY PLANNING INITIATIVE

In 2009, the Colorado Department of Public Health and the Environment used foundation funds to launch the Colorado Family Planning Initiative (CFPI) to increase LARC method access for women at high risk of unintended pregnancy. For five years, CFPI provided funding to 28 Title X-funded agencies in the 37 Colorado counties where 95% of the state's population lived (Ricketts, Klingler, & Schwalberg, 2014). Before this initiative began, Colorado faced particularly high unintended pregnancy rates; in 2005, 61% of births to women 15-24 were reported to be unintended at the time of conception.

Like many of their fellow Title X providers, the Colorado clinics had provided a broad range of contraceptive options but had struggled to afford IUDs and implants. CFPI funding covered the costs of IUDs and implants, as well as contraceptive rings, and the Title X agencies then offered these options to all clients at no cost (Ricketts et al., 2014). (Under Title X guidelines, clients with incomes below the federal poverty level would pay nothing for any method, while others would have been charged on a sliding-fee scale.)

CFPI did not just cover device costs, though. It also funded provider and staff training on counseling and insertion techniques, expansion of clinic hours and sites, and technical assistance on coding, billing, and management. The number of women served in Colorado's Title X-funded clinics increased 23% from 2008 to 2011. Clients' demographic characteristics changed little in that time; in both years, the majority were white, under age 25, and had incomes below the federal poverty level (Ricketts et al., 2014).

Among the targeted age group (15-24), LARC method use quadrupled from fewer than 5% in 2008 to 19% in 2011. IUD use nearly tripled, and implant use was ten times greater in 2011 than in 2008. This increase was nearly matched by a decrease in the percentage of clients using birth-control pills

for contraception (Ricketts et al., 2014). Helping women switch from less-effective methods to more-effective methods can reduce unintended pregnancies, but the effect would likely be even more pronounced in women not using contraception at all but not desiring pregnancy who adopted highly effective methods (Lindo & Packham, 2015).

The decline in teen pregnancies following CFPI's launch was quick and striking. From 2009 to 2011, the birth rate for Colorado teens ages 15-19 declined 26% (Ricketts et al., 2014). Over a longer period, from 2008 to 2014, the Colorado teen birth and abortion rates both dropped by 48% (Wolk, 2015). Teen birth rates have declined nationwide in recent years, but Colorado saw the greatest percentage change in teen births from 2008 to 2013 (Cohen, 2015). In addition, researchers comparing data from 2008 and 2012 found a 12% drop in the odds of preterm birth, and the odds were significantly lower for women living in counties served by CFPI-funded Title X providers (Goldthwaite, Duca, Johnson, Ostendorf, & Sheeder, 2015).

A study of rapid repeat pregnancies in adolescents enrolled in a prenatal-postnatal program (and who expressed a desire to avoid pregnancy for at least a year after giving birth) found that 65% of those who chose to use immediate postpartum implants continued to use them for two years (Han, Teal, Sheeder, & Tocce, 2014). Two years after giving birth, only 31% of participants in the immediate postpartum implant group, including those who had their implants removed, became pregnant again within two years, compared with 41% of the comparison group, which included those who selected implants four or more weeks after delivery, chose other forms of contraception, or used no contraception (Han et al., 2014). Based on these findings, researchers calculated that a program that provided 1,000 women with immediate postpartum implants would result in savings that not only cover the costs of the devices and insertions, but avoid $2.5 million in prenatal care, delivery costs, and management of miscarriage and ectopic pregnancies (Han et al., 2014). The estimate does not include social and economic costs for adolescent mothers who experience rapid repeat pregnancies, though these can also be substantial.

Colorado's experience also provides cost and savings estimates that can help other states that may consider similar programs. The CFPI cost $27 million over seven years, while in its first three years alone it saved an estimated $79 million (Wolk, 2015). With private funding expiring, public health advocates have urged Colorado's legislature to fund the initiative's continuation. Lawmakers narrowly rejected the 2015 funding request, but approved $2.5 million in 2016 (LARC4CO, 2016).

DELAWARE CONTRACEPTIVE ACCESS NOW (CAN)

A new public-private partnership called Delaware Contraceptive Access Now (CAN) aims to change the high rate of unplanned pregnancies (57%) in the state (Rini, 2016). With philanthropic support and reallocated funds from the state's Division of Public Health budget, Delaware is working with Upstream USA, a nonprofit that helps health centers improve reproductive healthcare (Markell, 2016). At 60 Delaware clinics, Upstream will equip providers and staff to offer same-day LARC insertion. This includes: training providers in IUD placement with a simulator; role-playing

with staff who will ask women about their pregnancy plans and counsel them about contraceptive options; helping clinics join group purchasing arrangements for device discounts; and assisting with insurance billing procedures (Kliff, 2016). In a *New York Times* op-ed, Governor Jack Markell wrote "By the end of 2017, we will ensure that the nearly 200,000 women of reproductive age in our state have access to the full range of methods" (Markell, 2016).

Current Policy Issues

Performance Measures for LARC Method Use

Some research and clinical organizations have proposed performance measures for the use of LARC methods. Performance measures (also called quality measures) help assess whether clinical guidelines are being followed, or more broadly, whether the correct or accepted clinical processes are taking place in clinical settings. Clinics and clinic systems may wish to implement performance measures for a variety of reasons, including quality improvement, transparency, accreditation, funding, or other reasons (Health Resources and Services Administration, 2011). Many healthcare researchers and clinical organizations agree on the general need for valid and rigorous measures of clinical performance; these focus on the organization or health system, rather than on individual providers (Berenson, Pronovost, & Krumholz, 2013; Health Resources and Services Administration, 2011).

A recent report from the Institute of Medicine notes that "better measures are needed to provide a full assessment of unintended pregnancy" and suggests several alternative measures, including contraceptive use (Blumenthal, Malphrus, & McGinnis, 2015). In particular, the measure of contraceptive use "considers unintended pregnancy at any age, and could be useful for stakeholder groups that work with older populations or with a broader focus on women's health and health care" (Blumenthal et al., 2015).

Agreement does not yet exist about whether or how to employ performance measures to evaluate provision of LARCs. A recent survey of LARC clinicians and researchers found that many would be hesitant to employ any goals or benchmarks for two primary reasons: (1) populations served differ significantly regarding interest in LARC methods, reducing the meaning of comparisons across different healthcare settings, and (2) any incentives, particularly financial ones tied to patient uptake of LARC methods, might result in coercive practices that would ultimately reduce patient satisfaction and, in turn, reduce provider credibility (Foster et al., 2015). The second concern stems from a well-documented phenomenon of directive counseling, at the expense of patient autonomy – examples from the literature include clinicians bypassing informed consent for chlamydia testing, over-prescription of antibiotics, and disenrollment of noncompliant patients from practices (Dehlendorf, Bellanca, & Policar, 2015); also see "LARC Methods and Reproductive Injustice," page 29.

Some leading organizations have proposed performance measures that do not directly count the number or proportion of women using LARC methods but focus on other elements of the LARC process. For example, ACOG has proposed a performance measure of the "Percentage of eligible women seeking contraception who are **offered** LARC" (American College of Obstetricians and Gynecologists, 2011). In early 2016, the Office of Population Affairs (OPA) proposed a performance measure and submitted it to the National Quality Forum. The proposed measure is the percentage of women age 15-44 at risk for unintended pregnancy who receive a LARC method;

however, there is no specific benchmark percentage or target that providers are encouraged to meet. As OPA describes in the proposal to the National Quality Forum, the proposed measure is an *access* measure – not an *outcome* measure – that is designed to "ensure women have access to LARC methods given the many provider and system level barriers, yet to also ensure that they are offered in a client-centered, non-coercive manner" (personal communication, Loretta Gavin, 2016). To meet the second criterion, the OPA measure suggests focusing on settings with low rates, as they indicate the need for an assessment of possible barriers that may restrict access for women seeking LARC methods. High rates of LARC method usage may not be appropriate for all patient populations, so this measure allows for flexibility and shifts the emphasis from incentivizing any LARC use, whether clinically appropriate or not, to reducing barriers.

Another alternative, suggested by several participants of the survey mentioned above, is to provide financial incentives for training on LARC method provision and counseling but not solely for provision of LARC methods (Foster et al., 2015). These latter options have the potential to increase LARC method usage indirectly through improving physician training and awareness, while allowing patients to maintain autonomy in their contraceptive decision-making. Still other researchers and clinicians do not believe that a need exists for any performance measures, as LARC method usage has increased in recent years and may continue to do so in the future without implementation of performance measures (Foster et al., 2015).

Payment Policy

As LARC methods often have high upfront costs, LARC coverage policies play a large role in determining their accessibility. Despite high upfront costs, research suggests that LARC methods are actually cost-saving over time, with one study estimating a savings of $2.3 million over two years for every 1,000 Medicaid-eligible women; LARC device costs can reach up to $775, while the cost of a publicly funded birth is estimated at over $11,000 (Moniz et al., 2015). Some coverage of LARC methods exists under both private insurance plans and public coverage models, but there is a lack of uniformity within and across types of coverage. For example, LARC methods must be covered without cost-sharing for women who are Medicaid-eligible as a result of the Affordable Care Act (ACA)'s expansion of Medicaid, while women in states that did not expand Medicaid may or may not receive the same benefit, depending on the exact policies in their state.

PRIVATE INSURANCE

Before the passage of the ACA, private insurers were not subject to specific requirements for coverage of any contraception, including LARC methods. While 28 states had some pre-ACA requirement to cover all contraceptive methods, much of this coverage involved some type of cost-sharing with the patient (Sonfield, 2013). This resulted in higher out-of-pocket costs and often meant that women who wanted to choose a LARC method could not afford to do so. One study, conducted in 2008, found that, among women who expressed interest in an IUD and had private

insurance coverage, out-of-pocket expenses over $50 were significantly associated with failure to obtain an IUD (Gariepy, Simon, Patel, Creinin, & Schwarz, 2011).

The ACA's contraceptive coverage guarantee was designed to reduce or eliminate the barrier of cost-sharing for all FDA- approved contraceptive methods. Regulations implementing the ACA specify that all non-grandfathered health plans must cover all FDA-approved contraceptives without cost-sharing and apply to health plans sold in the individual or employer group market (Becker & Polsky, 2015; HealthCare.gov, 2016). Plans were first required to start covering these services in August 2012, with the full phase-in starting in 2013. To be considered grandfathered (and therefore exempt from this coverage requirement), a plan must have existed prior to passage of the ACA and cannot have made significant changes in premiums, benefits, terms of coverage, or cost-sharing. While many plans met these criteria immediately after passage of the ACA, the number of grandfathered plans has been diminishing in the years since; in 2012, 48% of covered workers received coverage through a grandfathered plan, compared with only 26% in 2014 (Sonfield, Tapales, Jones, & Finer, 2015).

While details of contraceptive coverage can vary somewhat from plan to plan, the ACA requirement means that non-exempt plans must cover at least one type of each FDA-approved method. For example, a plan may cover generic forms of birth control pills without charging a copay while requiring cost-sharing for brand name versions (Centers for Medicare and Medicaid Services, 2015). However, they cannot meet the requirement simply by covering birth control pills without cost-sharing while imposing cost-sharing for other methods, such as the ring or patch; each category of method must have at least one type of that particular method covered without cost-sharing. For the IUD, this means that plans must cover at least one copper IUD and at least one hormonal IUD; plans may determine which hormonal IUD(s) will be covered, although they must cover an alternate IUD if a provider deems it "medically necessary" for any individual patient (Centers for Medicare and Medicaid Services, 2015; Kaiser Family Foundation, 2015). Plans are allowed to employ "reasonable medical management" strategies, such as prior authorization or drug formularies, as long as they do not categorically restrict access to a particular method (Kaiser Family Foundation, 2015; Sonfield, 2013). They may also choose to cover services only within their provider network and may impose cost-sharing for out-of-network providers (Sonfield, 2013).

Recent evidence suggests that some plans are not complying with the coverage mandate by denying coverage, requiring cost-sharing, or otherwise restricting access. In one survey of 20 health plans in five states, researchers found that three plans offered no coverage for Nexplanon, three offered no coverage for Skyla, and one offered no coverage for ParaGard (Sobel, Salganicoff, & Kurani, 2015). Furthermore, only ten plans offered coverage without cost-sharing or medical management limitations for Nexplanon and Skyla, and only 14 for ParaGard (Sobel et al., 2015). Another report finds that "Fifty-six issuers in 13 states offer preventive services coverage that does not comply with the ACA" (National Women's Law Center, 2015).

Women whose plans do comply with the coverage requirement seem to be experiencing increased coverage and decreased cost-sharing for all contraceptive methods as ACA implementation continues. In 2012, 45% of IUD users in one national study reported no out-of-pocket costs for their IUDs, compared with 62% of users in 2013 and 2014 (Sonfield et al., 2015). The average price (to the consumer) for an IUD insertion fell from $293.28 in June 2012 to $145.24 in June 2013 (Becker & Polsky, 2015).

Questions have arisen as to whether employers that claim a religious objection to inclusion of some or all contraceptives under their health plans can be exempt from the requirement. In 2013 the United States Supreme Court ruled in Hobby Lobby v. Burwell that, without a reasonable accommodation, closely-held for-profit employers could claim an exemption because such corporations are covered by the Religious Freedom Restoration Act (RFRA) (Becker & Polsky, 2015; Burwell v. Hobby Lobby Stores, Inc., 2014).

In a separate case (Zubik v. Burwell), religious nonprofit organizations sought the type of complete exemption from the guarantee that churches receive, while rejecting the government's religious accommodation. Under the accommodation, employers with religious objections have the right to refuse to include contraceptives in their plans; at the same time, the accommodation ensures that employees receive coverage directly through their plan's insurer or third party administrator, which provides the coverage itself. On May 16, 2016, the Court instructed both sides to reach a negotiated settlement. This extraordinary resolution effectively leaves the accommodation rule in place and applicable to all employers while the settlement is being worked out. It remains unclear if this approach will protect women's access to coverage of all methods of contraception if they work for an employer that objects to this coverage.

MEDICAID

Family planning services and supplies, furnished without cost-sharing, are a coverage requirement for all Medicaid programs (Ranji, Bair, & Salganicoff, 2016). However, the Medicaid family planning reqirement, which dates to 1970, lacks the "approved FDA methods" coverage standard that applies to non-grandfathered health plans under the ACA, meaning that states have the flexibility to establish their own standards, applying reasonable coverage limits. Family planning is protected by special free-choice-of-provider rules that enable beneficiaries to obtain care from the provider of their choice, although states also may treat family planning services as a covered service under their comprehensive managed care contracts (Ranji et al., 2016). Most women of reproductive age who receive coverage through traditional Medicaid programs (77%) are enrolled in a managed care plan (Ranji et al., 2016). Although states' managed care contracts may specify that less than all methods and services will be covered, women remain entitled to coverage without cost-sharing and can seek care from the provider of their choice.

The entitlement to family planning coverage depends, of course, on being enrolled in Medicaid. As of May 2016, 31 states and the District of Columbia had opted to extend Medicaid to all non-elderly adults with incomes up to 138% of the federal poverty level ($16,242 for an individual in 2016); an estimated 4.7 million women of reproductive age qualify for coverage under this new low-income adult category because they were not previously eligible under one of Medicaid's traditional coverage categories, which include pregnancy, disability, or extreme impoverishment and parental status (Kaiser Family Foundation, 2016; Ranji et al., 2016). In addition, states have the option (either as a state plan amendment or via special demonstration authority under Section 1115 of the Social Security Act) to create a limited eligibility category consisting of individuals who are not pregnant and whose income meets state eligibility levels, with coverage limited to family planning and related services. Under either eligibility approach, eligibility is capped at the highest income level for pregnant women under a state's Medicaid or CHIP plan. Family planning waivers provided coverage for 3.5 million women in 2011 (Ranji et al., 2016).

Box 3. California's Family Planning State Plan Amendment

California's Family Planning Access Care and Treatment (PACT) Program operates under a Medicaid state plan amendment to provide reproductive health services to women and men with incomes under 200% of the federal poverty level. All contraceptives are available at no cost for those who qualify (Biggs et al., 2014). Between 2008 and 2010, the California Department of Health Care Services' Office of Family Planning disseminated LARC information and web-based trainings, and offered five in-person provider trainings on IUD insertion (Biggs et al., 2014). From the program's inception in 1997 through FY 2005-06, the proportion of female Family PACT clients receiving IUD services had been at around 5% every year, but by FY 2010-11, it was up to 10% (Bixby Center for Global Reproductive Health & University of California San Francisco, 2013).

A 2011 survey of Family PACT sites — which includes private practices participating in the program, as well as Title X and other clinics — found that 74% of respondents reported routinely discussing IUDs with their contraceptive patients, and 49% reported routinely discussing implants. A minority of providers still considered some groups of women, such as smokers or women with a history of pelvic inflammatory disease, to be poor candidates for LARC methods despite professional guidelines concluding that the devices are safe and effective for these groups (Biggs et al., 2014).

The same 2011 survey of Family PACT providers found that 67% of respondents reported offering an IUD on-site, and 40% reported offering the contraceptive implant on-site. Among those with on-site provision, 58% required two or more visits for IUD placement, and 47% required two or more visits for implant placement. The main reason for having two visits was to wait for STI test results, although some providers also considered it useful for women to have more time to be certain of their LARC method selection (Biggs, Harper, et al., 2015).

Because Medicaid beneficiaries who qualify for coverage on the basis of the ACA *expansion* category are entitled to all of the essential health benefits that are covered for people who purchase coverage through the insurance marketplace, they get the benefit of the ACA regulation's contraceptive coverage standard, which is incorporated into the regulatory definition of essential health benefits. Thus, in Medicaid ACA expansion states, women eligible on the basis of the expansion would be covered without co-payments for all FDA-approved contraceptive methods (Kaiser Family Foundation, 2015), regardless of the coverage standard used for the traditional Medicaid population. This means that they are entitled to coverage for the copper IUD, at least one hormonal IUD, and at least one implant without cost-sharing, as is the requirement for Marketplace plans subject to the essential health benefit standards (Kaiser Family Foundation, 2015). Whether states do in fact distinguish between traditional and expansion populations in terms of the contraceptive options they cover is not clear.

RECENT CMS GUIDANCE FOR STATES

In April 2016, CMS released an informational bulletin on different approaches to LARC coverage under state Medicaid programs, and in June 2016, the agency wrote to state health officials further elucidating federal requirements for coverage of family planning services and methods and offering recommendations for how to ensure Medicaid coverage of LARC methods (Centers for Medicare & Medicaid Services, 2016a; Centers for Medicare & Medicaid Services, 2016b). The bulletin describes existing state-level policies, within both fee-for-service and managed care systems, though it does not direct states to adopt these approaches. The letter to state health officials provides guidance to states on family planning services generally, including specific provisions relevant to LARC methods such as those clarifying that states are prohibited from imposing prior authorization policies or restrictions on removal that interfere with a Medicaid beneficiary's ability to freely choose a method of family planning. The letter also recommends that states better ensure access to family planning services by covering all FDA-approved contraceptive methods, including both prescription and non-prescription methods. It further encourages states to explore using available waivers to implement a proposed model for dealing with stocking problems that frequently create financial barriers for providers who want to offer LARC methods. The full informational bulletin can be found at: https://www.medicaid.gov/federal-policy-guidance/downloads/CIB040816.pdf, and the full state health official letter can be found at https://www.medicaid.gov/federal-policy-guidance/downloads/sho16008.pdf.

POSTPARTUM COVERAGE UNDER MEDICAID

Medicaid coverage for LARC methods provided immediately postpartum is particularly complicated due to the payment structure of obstetric services under both Medicaid and private insurance plans. Frequently, hospitals receive reimbursement for obstetric care through a "bundled" payment that may not cover the costs of LARC insertion or the device itself (Moniz et al., 2015; Ranji et al., 2016). Thus, providers may not wish to offer postpartum LARC methods to women covered by Medicaid

because they or their health system may lose money in the process. Several states have issued guidance for reimbursement of postpartum LARC provision, but there is no uniform coverage for it (American Congress of Obstetricians and Gynecologists, 2016).

Box 4. Reimbursement for Postpartum LARC in South Carolina

In 2012, South Carolina became the first US state to institute a Medicaid policy enabling hospitals and providers to receive full reimbursement for postpartum LARC method insertion. This effort is part of the South Carolina Birth Outcomes Initiative (SCBOI) to improve maternal and newborn health with the collaboration of over 100 stakeholders, including South Carolina's Department of Health and Human Services (SCDHHS), the South Carolina Hospital Association, March of Dimes, and Blue Cross Blue Shield of South Carolina (Heberlein, Billings, Mattison-Faye, & Giese, 2016).

To ensure that postpartum women with Medicaid coverage are able to receive LARC methods before being discharged from the hospital, all the managed care organizations that contract with South Carolina's Medicaid program adopted the reimbursement policy. Then, hospitals in the state had to plan and implement their own policies. Three hospitals that participated in preparing a toolkit to assist others reported that this process took approximately six months. Steps necessary for successful implementation include identifying a physician champion and nursing leader; building administrative support and infrastructure; working with physicians and nurses to develop an insertion process; training all clinical staff; and making adjustments based on regular review. In addition, the toolkit notes that contraceptive counseling should begin at the first prenatal visit, and that a shared decision making model is useful and keeps patient preferences at the forefront (Heberlein et al., 2016).

South Carolina is one of the states whose experience is informing the Immediate Postpartum LARC Learning Community, which is convened by the Association of State and Territorial Health Officials with support from the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, and the Office of Population Affairs (Association of State and Territorial Health Officials, 2014).

A recent study of Medicaid fee-for-service programs suggests that state Medicaid representatives' understanding of the health benefits of providing LARC methods postpartum and the costs associated with LARC provision vary with the state's policy regarding coverage for immediate postpartum LARC provision. Researchers identified three categories of state-level policy: (1) separate or bundled payment provided (2) considering (but not yet implemented) enhanced payment, or (3) not considering enhanced payment (Moniz et al., 2015). Among 40 states that responded to this survey, 15 fall into the first category, 9 into the second, and 16 into the third. When interviewed about this topic, Medicaid representatives for states in the first category emphasized the health benefits of postpartum LARC methods when discussing their state's policy, while those in states in the third category did so less frequently. Additionally, states in the third

category discussed concerns around upfront costs, while states in the first category viewed the policy as cost-saving in the long term (Moniz et al., 2015).

The researchers in this study conclude that there is an opportunity for advocacy around Medicaid policy for postpartum LARC methods. They note: "clinicians play a critical role as local champions for policy change, as our interviewees often described providers as uniquely well positioned to educate Medicaid agencies about the importance and benefits of immediate postpartum LARC. Such efforts may be most successful when clinician advocates seek to align immediate postpartum LARC with their local Medicaid agency's other stated priorities and goals." (Moniz et al., 2015). The CMS letter to state health official also proposes solutions to postpartum coverage barriers, encouraging states "to establish payment policies that, when a woman chooses, permit and encourage insertion of LARCs immediately following a vaginal delivery or surgical procedure as a separately identified service that is eligible for the [FMAP]" (Centers for Medicare & Medicaid Services, 2016b).

COVERAGE FOR REMOVAL

Both Medicaid and private insurance plans that are subject to the ACA requirement to cover contraceptive care without cost-sharing are required to cover LARC removal as well as insertion, also without cost-sharing. However, some plans have not been complying with this requirement and either denying reimbursement or requiring a medical justification for removal (Armstrong et al., 2015). For instance, South Dakota Medicaid's 2016 billing manual states, "The removal of an implant is only reimbursable by South Dakota Medicaid when due to infection, rejection or when determined medically necessary. South Dakota Medicaid will not reimburse for the removal of the implant if the intent is for the recipient to become pregnant" (South Dakota Department of Social Services, 2016). The June 2016 letter from CMS to state health officials explicitly instructs that state Medicaid programs must reimburse providers for both insertion and removal of the LARC method. Additionally, certain payers have established policies that "limit the number of IUDs that a woman can obtain within a certain timeframe" (Armstrong et al., 2015). The CMS letter to state health officials specifically addresses this in the context of Medicaid, stating that "States and managed care plans should avoid practices that […] impose medically inappropriate quantity limits, such as allowing only one long acting reversible contraceptive (LARC) insertion every five years, even when an earlier LARC was expelled or removed" (Centers for Medicare & Medicaid Services, 2016b). Providers may be able to help patients facing such limitations to obtain a replacement product from the manufacturer.

TITLE X AND 340B

Providers who receive Title X funding (see *Box 1. Publicly Funded Family Planning*, page 27) – as well as other non-profit providers, such as federally qualified health centers and Ryan White HIV/AIDS Program grantees – can purchase discounted drugs, including contraceptives, through the 340B

Drug Discount Program. Eligible covered entities register to participate in the 340B Program and once approved, may see savings of 25-50% on drug costs (Health Affairs, 2014; Health Resources and Services Administration, 2016). The 340B price for any given drug is determined by 340B statutory authority and is set as a ceiling price through the manufacturer. A special case with respect to LARC methods and 340B coverage is Liletta, which was developed specifically to be available to clinics enrolled in the 340B drug pricing program (Kaiser Family Foundation, 2015). The standard 340B price for Liletta is $50 (University of California, San Francisco, 2016). This cost can translate to significant savings to patients. While patients who receive coverage through a private insurance plan or Medicaid are not eligible for the 340B pricing, the Liletta manufacturer has developed a patient assistance program that allows insured women to pay no more than $75 out-of-pocket for the device (Actavis Lilettta Patient Savings Program, 2016).

Parental Consent Policies for Adolescents & Confidentiality of Care

There are two main policy issues with respect to parental consent and notification for LARC methods: consent for contraceptive services and confidentiality for contraceptive services through health plans.[4] As of early 2016, most states allow some or all minors to consent to their own contraceptive services. Twenty-six states allow all minors above the age of 11 to consent to contraceptive services, and another 20 states allow some categories of minors (e.g., those who have a specific health issue, who are married, etc.) to consent to contraceptive services (Guttmacher Institute, 2016). Four states have no policy or law in place; in these states, clinicians determine their own policies for requiring consent, such as providing care without parental consent to minors "they deem mature" (Guttmacher Institute, 2016).

Research suggests that policies requiring parental consent for services, particularly sensitive services such as contraceptive care, can adversely impact adolescents' access to these services. One study of adolescents seeking family planning services at a public clinic found that 46% of these patients would use an over-the-counter method of contraception (e.g., condoms), and 20% would switch to either withdrawal or no method if parental notification were required for contraception (Jones, Purcell, Singh, & Finer, 2005). Another study found that, if parents were informed that they were seeking prescription contraception, 59% of teens reported that they would stop using some or all healthcare services, including testing and treatment for STIs (Reddy, Fleming, & Swain, 2002). Although these studies took place before the rise in popularity of LARC methods, they still suggest that requiring an adolescent to obtain parental consent to receive services such as LARC insertion could be a barrier, leading teens to rely on less effective methods or to use no method at all.

[4] There are no LARC-specific parental consent or notification concerns, as of early 2016. All LARC-related consent issues fall more broadly under the issue of accessing contraceptive services and supplies without requiring parental notification or consent.

PRIVATE HEALTH PLANS AND EXPLANATIONS OF BENEFITS

Confidentiality for services billed to private health plans is a more complex issue. The Health Insurance Portability and Accountability Act (HIPAA) allows parents to access a minor's medical records, except when the minor is provided with confidentiality under state law or if the parent consents to allowing the minor's records to remain confidential (Committee On Adolescence, 2014). Parents may also inadvertently see records of their adolescent child's access to contraceptive care if an explanation of benefits (EOB) is provided by the health plan or if a practice's electronic medical record includes information for all family members in one location (Committee On Adolescence, 2014). This same concern also extends beyond teenagers and includes children up to age 26 covered on a parent's plan, as well as women covered by their spouse's plan.

The purpose of an EOB is to increase transparency between insurer and insured and to reduce fraud (Tebb et al., 2014). Individuals enrolled in Medicaid usually do not receive EOBs, especially for sensitive services (Tebb et al., 2014). Some plans will allow the EOB to be "suppressed" (i.e., not sent or filed electronically), but state policy on this issue varies widely across the country (Tebb et al., 2014). When patients are concerned about EOBs being shared with someone else, they may forgo coverage through their private plan and seek coverage through Medicaid (generally a family planning waiver, if this exception is allowed in their state) or through other safety net programs such as Title X. Unfortunately, this pattern can burden an already underfunded safety net system (Tebb et al., 2014). A June 2016 letter from CMS to state health officials reiterates the existing requirements under HIPAA that state Medicaid programs and managed care plans are required to comply with in order to protect the confidentiality of individuals seeking family planning services.

A recent report outlines potential solutions to address the problem of EOBs for sensitive services. These include: (1) not requiring health plans to send an EOB when no balance is due for services provided, (2) applying a generic current procedural terminology (CPT) code to sensitive services, (3) requiring plans to honor requests for confidential communications from all individuals obtaining sensitive services, (4) creating a CPT code to suppress EOBs for confidential services, (5) requiring health plans to communicate directly with adult patients (up to age 26) who are covered as dependents on their parents' plans, (6) educating parents so they can understand the importance of the provision of confidential care, and (7) engaging and educating adolescents about their rights to confidential health services (Tebb et al., 2014). Several states – including New York, Wisconsin, Massachusetts, Colorado, and California – have already begun to employ one or more of these approaches (Tebb et al., 2014).

The American Academy of Pediatrics has issued the following statement on confidentiality among adolescents:

> "In the setting of contraception and sexual health care, the American Academy of Pediatrics (AAP) believes that policies supporting adolescent consent and protecting adolescent confidentiality are in the best interests of adolescents. Accordingly, best practice guidelines recommend confidentiality around sexuality and sexually transmitted infections (STIs) and minor consent for contraception." (Committee On Adolescence, 2014)

Future Directions

Although a substantial body of research exists on safety and efficacy of LARC methods, as well as on certain barriers to LARC usage, gaps in the research persist. For example, some studies have identified interest from women in the possibility of self-removal of IUDs, and additional research in this area could inform development of future contraceptive technologies and clinical guidelines for women with IUDs. More research on patient experiences and preferences could also shed light on new or existing issues related to LARC provision. This research is especially important among younger populations, including teens, where LARC use is growing rapidly in recent years but where fears or inaccurate knowledge on the part of both patients and providers may present unnecessary barriers. While examining patient experiences is important, research from the provider perspective is equally important. This research could build upon existing literature on provider knowledge and activities and could evaluate training of both clinicians and clinic staff, who influence different parts of the patient experience of care. Additionally, research to identify health system barriers to LARC removal and to evaluate initiatives eliminating those barriers would contribute importantly to women's satisfaction and successful use of LARC methods as well as to providers' ability to incorporate LARC services into their practices.

As postpartum LARC provision continues to increase, future research also needs to examine key clinical aspects, such as reducing the risk of expulsion. Additionally, research into payments for postpartum LARC methods, particularly in the context of the ACA, can provide insight into potential barriers or facilitators for both the patients and providers.

Recent research suggests that, although use of LARC methods is increasing, condom use among the teen population is decreasing, which could increase risks for STI transmission. An analysis of the Youth Behavioral Risk Surveillance (YRBS) Survey found that, among the 1.8% of US teens using LARC methods, condom use is about 60% less likely than among oral contraceptive users; however, no differences were observed between LARC method users and users of the injectable, patch, or ring (Steiner, Liddon, Swartzendruber, Rasberry, & Sales, 2016). Research from the National Survey of Family Growth also found that condom use was lower for women relying on provider-dependent methods (including LARCs) than for women relying on user-dependent methods (e.g., the pill, patch, and ring) (Eisenberg, Allsworth, Zhao, & Peipert, 2011; Pazol, Kramer, & Hogue, 2010). While these studies can provide insight into the cross-sectional nature of condom use among LARC users, they cannot identify a causal link that would show LARC use is driving down condom use. Therefore, more research is needed to clarify the relationship between condom use and LARC method use, especially if LARC method use continues to rise in the coming years.

With implementation of the ACA well underway, several possible avenues for policy-related research emerge. First, some research exists on the impact of the contraceptive coverage mandate,

and this research suggests that women are in fact accessing contraception through their insurance policies and paying less for it. However, there are relatively few studies examining this question, and further research could further demonstrate the impact of the mandate. Second, much of the existing research has focused on IUDs or on all contraceptive types more broadly but has not focused specifically on implants or examined the category of LARC methods as compared to other methods. One reason for this gap is the low number of users for implants, but as these numbers begin to grow, additional research that includes implant users could help inform research and policy discussions. Furthermore, health law research will continue to play a key role as cases challenging the ACA and other statutory and regulatory coverage requirements are decided and potentially have an effect on contraception provision across the country. While LARC access is expanding in some areas, early evidence suggests this may be affected by state legislators' actions to stop sending Medicaid reimbursements or other public funds to Planned Parenthood or other providers that also offer abortion services (Stevenson et al., 2016). Additional research on the impacts of such policies can further elucidate how politics can affect women's access to contraception.

Finally, as LARC use increases and more information about LARC methods becomes available, messaging research can help both patients and providers receive the most relevant information about LARC methods, while avoiding the insufficiently nuanced suggestion that LARC methods could be a "silver bullet" to end unintended pregnancy.

CONCLUSION

This paper has explored some of the existing research on the access to and current policies regarding long-acting reversible contraception. It is not meant to be an exhaustive literature review but rather an overview of current evidence and its impact on policy. Exchange of accurate scientific and clinical information between researchers and policy-makers has the potential to help ensure that policies are grounded in science. Making the connection between policy and science is critical if we are to promote women's health through improved access to high-quality healthcare.

APPENDIX A. TABLES

Table 3. CDC Guidance for LARC Initiation

	Copper IUD	**Hormonal IUDs**	**Implant**
Timing of Initiation			
Any Time Pregnancy Can Be Reasonably Ruled Out	Can be inserted at any time	Can be inserted at any time Back-up method may be needed for up to 7 days post-insertion	Can be inserted at any time Back-up method may be needed for up to 7 days post-insertion
Postpartum	Can be inserted immediately postpartum Back-up method may be needed for up to 7 days post-insertion for women ≥21 days postpartum	Can be inserted immediately postpartum Back-up method may be needed for up to 7 days post-insertion for women ≥21 days postpartum	Can be inserted immediately postpartum Back-up method may be needed for up to 7 days post-insertion for women ≥21 days postpartum
Post-Abortion	Can be inserted within the first 7 days post-abortion	Can be inserted within the first 7 days post-abortion Should not be inserted after septic abortion	Can be inserted within the first 7 days post-abortion Back-up method may be needed for up to 7 days post-insertion, unless placed at the time of a surgical abortion

Source: Centers for Disease Control and Prevention: Division of Reproductive Health, 2013

Table 4. CDC Guidance for Pre-Insertion Procedures and Contraindications

	Copper IUD	Hormonal IUDs	Implant
Weight	Obese women can use Cu IUDs	Obese women can use LNG IUDs	Obese women can use implants
Bimanual (Pelvic) Exam & Cervical Exam	Necessary pre-insertion to assess uterine size and position and to detect any cervical or uterine abnormalities	Necessary pre-insertion to assess uterine size and position and to detect any cervical or uterine abnormalities	Not necessary
Screening for STIs & Provision of Prophylactic Antibiotics	Not needed if STI screening guidelines have been followed Prophylactic antibiotics generally not recommended Insertion should be delayed in women who have a very high individual likelihood of STI exposure	Not needed if STI screening guidelines have been followed Prophylactic antibiotics generally not recommended Insertion should be delayed in women who have a very high individual likelihood of STI exposure	Not needed
Breast Exam	Not necessary in any women Women with breast disease can use the Cu-IUD	Not necessary in asymptomatic women Women with current breast cancer should not use LNG IUDs	Not necessary in asymptomatic women Women with current breast cancer should not use implants
Cervical Cytology (e.g., Pap test)	Not necessary in asymptomatic women Women with cervical cancer should not use the Cu-IUD	Not necessary in asymptomatic women Women with cervical cancer should not use LNG IUDs	Not necessary in any women Women with cervical disease can generally use implants
HIV Screening & Acquired Immunodeficiency Syndrome (AIDS)	Not necessary Women with AIDS who are not clinically well should generally not undergo IUD insertion	Not necessary Women with AIDS who are not clinically well should generally not undergo IUD insertion	Not necessary Women with HIV infection can generally use implants

Source: Centers for Disease Control and Prevention: Division of Reproductive Health, 2013

Table 5. CDC Guidance for LARC Follow-Up Care

	Copper IUD	Hormonal IUDs	Implant
Routine Follow-Up	No routine follow-up visit required	No routine follow-up visit required	No routine follow-up visit required
Bleeding Irregularities	Unscheduled spotting or light bleeding, as well as heavy or prolonged bleeding, are common and generally not harmful, and decrease with continued use.	Unscheduled spotting, light bleeding, or amenorrhea are common and generally not harmful, and decrease with continued use.	Unscheduled spotting, light bleeding, or amenorrhea are common and generally not harmful, and might or might not decrease with continued use.
PID	Does not need to be removed immediately if the woman needs ongoing contraception. If no clinical improvement occurs 48-72 hours after treatment, continue antibiotics and consider removal of the IUD.	Does not need to be removed immediately if the woman needs ongoing contraception. If no clinical improvement occurs 48-72 hours after treatment, continue antibiotics and consider removal of the IUD.	N/A
Pregnancy	Provider should advise the woman that she has an increased risk for spontaneous abortion, septic abortion, and preterm delivery if the IUD is left in place. Provider should also evaluate for possible ectopic pregnancy.	Provider should advise the woman that she has an increased risk for spontaneous abortion, septic abortion, and preterm delivery if the IUD is left in place. Provider should also evaluate for possible ectopic pregnancy.	N/A*

* There are few documented risks to the woman or the fetus if the implant is left in place; there is no evidence that the risks associated with the hormones in implants are different from those of combination oral contraceptives. Providers may counsel patients to have the implant removed, (Bayer HealthCare Pharmaceuticals 2013).

Source: Centers for Disease Control and Prevention: Division of Reproductive Health, 2013

Appendix B. List of Acronyms

Acronym	Full Form
AAP	American Academy of Pediatrics
ACA	Affordable Care Act
ACOG	American College of Obstetricians and Gynecologists (or the College's companion organization, American Congress of Obstetricians and Gynecologists)
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
CPT	Current Procedural Terminology
EC	Emergency Contraception
ENG	Etonogestrel, the synthetic hormone used in implants
EOB	Explanation of Benefits
FDA	US Food and Drug Administration
HHS	Health and Human Services
HRSA	Health Resources and Services Administration
IUC	Intrauterine Contraceptive
IUD	Intrauterine Device
IUS	Intrauterine System
LARC	Long-Acting Reversible Contraception
LGBTQ	Lesbian, gay, bisexual, transgender, or queer
LNG	Levonorgestrel, the synthetic hormone used in IUDs
OPA	Office of Population Affairs
PID	Pelvic Inflammatory Disease
QFP	Quality Family Planning Guidelines
STI	Sexually Transmitted Infection; sometimes called Sexually Transmitted Diseases
WHO	World Health Organization

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