Current Research and Policy on Long-Acting Reversible Contraception (LARC): Key Points for Policymakers

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.[1] Researchers attribute this drop to several different factors, including increased access to and use of more effective methods of contraception.

Long-acting reversible contraceptive (LARC) methods demonstrate great potential in reducing unintended pregnancy, as they require virtually no user adherence. LARC methods[*] include two types of contraceptives: intrauterine devices (IUDs)[†] 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.

In June 2016, the Jacobs Institute of Women's Health published a white paper summarizing the scientific evidence and current policy related to LARC methods. The full white paper with complete references is available at http://ow.ly/l4WH301I9yn.

The following provides a summary of key points discussed in that white paper.

Overview of LARC Methods & Current Usage

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

[*] 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.
[†] 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.

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.

Increasingly, providers receive training on IUD insertion and removal during their residency training, but a provider must go through a formal training session created by the manufacturer before providing Nexplanon to patients. All forms of LARC can be removed by an appropriately trained provider at the request of the patient.

Worldwide, LARC methods are the second most common method of contraception, after female sterilization.[2,3] Rates of LARC usage tend to be higher worldwide than in the US, where approximately 7.2% of all US women ages 15-44 use a LARC method,[4] and 11.6% of women who use any contraceptive method use a LARC method. Current usage represents dramatic growth in use from 2002, when only 1.5% of all US women used a LARC method,[4] and 2.4% of women using any method of contraception used a LARC method.[5] Rates of use are lower among teens; only 4.3% of teens who use contraception use a LARC method,[5] although these rates appear to be increasing in recent years.

Mechanisms of Action

To understand 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). According to this clinical definition, all LARC methods act as contraceptives, preventing fertilization or stopping the fertilized egg from implanting rather than acting after implantation, which would interrupt a pregnancy and be considered an abortifacient. [6–8]

ParaGard (Copper T 380A) received FDA approval in 1984 and is approved to stay in place for up to 10 years, although studies have shown it to remain effective through 12 years.[9–11] Copper IUDs work by releasing copper ions, which affect the reproductive tract in different ways to prevent pregnancy, including: reducing sperm motility and viability;[12–14] causing sperm death;[12,14–16] preventing fertilization of the egg, without stopping ovulation[17]; or preventing implantation.[14,18] These mechanisms of action may occur pre- or post-fertilization, but always before implantation occurs.[19,20] The copper IUD also may be used as emergency contraception (EC), if inserted within five days of unprotected intercourse, and is over 99% effective in this context.[21–23]

The first hormonal IUD received FDA approval in 2000. All hormonal IUDs release levonorgestrel (LNG), a synthetic progestin, through a rate-controlling membrane.[24,25] LNG prevents fertilization by thickening cervical mucus to stop sperm from swimming up the cervix and fertilizing an egg.[20,26–28] The hormone also thins the endometrial lining of the uterus, which limits the ability of a fertilized egg (if one were fertilized) to implant;[29] this mechanism also causes lighter menstrual periods. 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.[30]

The Nexplanon implant is a thin, flexible rod that is placed subdermally on the inside of the patient's upper arm, and is approved to stay in place for up to three years. The active ingredient in the implant is etonogestrel (ENG), another synthetic progestin. The ENG in the implants works

primarily by preventing ovulation.[31,32] ENG also thickens cervical mucus and affects the endometrial lining, but these function as secondary effects of the implant in preventing pregnancy.[31]

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. Additional details about the history of LARC methods are available in "History of LARC in the United States" at http://ow.ly/ZtQ5302VMTE.

The first generation of IUDs became available in the United States starting in 1968, and within a few years, more than 10% of US women who used contraception were using an IUD.[33] In 1971, the Dalkon Shield IUD came on the market, and during the four years that it was available, more than two million women used this method. Despite IUDs' initial popularity, use declined rapidly as women began to report serious health problems associated with their use. Dalkon Shield users in particular seemed to suffer from IUD-associated complications; death from septic miscarriage was three times more likely among Dalkon Shield than other IUD users,[34] and other studies reported that Dalkon Shield users were at greater risk for pelvic inflammatory disease (PID) than users of other IUDs or people not using IUDs at all[35], due to a design flaw. In the United States, women brought hundreds of thousands of lawsuits against the company, and the manufacturer (the A.H. Robins Company) suspended US sales of the Dalkon Shield in 1974. In 1985, the company declared bankruptcy.[36]

By the 1980s, many fewer women – about 2.2 million – were using IUDs, and rates dropped again when the manufacturers of the Lippes Loop and of the Copper-7 and Copper-T 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. By 1995, fewer than 1% of US contraceptive users were using an IUD.[37]

When redesigned IUDs were later brought back to the US market, they faced an unreceptive climate. Contraceptive users and healthcare providers had little or no direct experience with IUDs, and what they knew about them was mostly negative.[33] The association with serious infection and consequent infertility, in particular, may have suppressed use by young women and women who had not had children.[38]

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, and the device could prevent pregnancy for up to five years. 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.[39] 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.[40,41]

Some women also experienced problems with incorrect placement of the Norplant capsules, infection at the site, and difficulty with removal. Problems with insertion and removal were attributed in part to lack of adequate training for providers.[40,42] 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. Norplant sales were suspended in the United States in 2002, due to manufacturing issues that raised concerns about the effectiveness of particular lots. This experience made Norplant's manufacturers hesitant to sell another implant in the United States[43] even after second-generation implants, such as Jadelle, were developed and made available elsewhere.

Safety and Efficacy of Modern LARC Methods

Decades of research, both in the US and Europe, 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. 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. Recent studies 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), and implants have failure rates of 0.05%.[44] By contrast, oral contraceptive pills and condoms have failure rates of 9% and 18%, respectively, with typical use.[44]

IUDs

Side effects associated with IUDs are generally minor and can include nausea, depression, headache, breast tenderness, and acne.[45] 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.[19] Although irregular bleeding and cramping are not dangerous, some women choose to discontinue IUD use because of these effects.[46]

More serious outcomes associated with insertion and use of IUDs include: uterine perforation, expulsion of the IUD, ectopic pregnancy, and pelvic inflammatory disease (PID). Rates of these events are generally low. 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.[47] Expulsion occurs in approximately 5-10% of patients and is most common in the first three months after insertion, with the risk declining the longer the IUD is in place.[45,48]

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. Most studies suggest 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.[19]

[‡] Typical use failure rates are defined as the percentage of typical couples who experience an accidental pregnancy during the first year of using a method, if they do not stop use for any other reason. Perfect use failure rates are defined as the percentage of couples who experience an accidental pregnancy during the first year of using a method perfectly (i.e., consistently and correctly), if they do not stop use for any other reason.[116,117]

With IUDs, there is a slight increase in risk of pelvic inflammatory disease (PID) during insertion and the 20-day period immediately following,[49,50] particularly when women have pre-existing sexually transmitted infections (STIs) like gonorrhea or chlamydia. It is difficult to establish robust clinical evidence of the true impact of PID in users of the current generation of IUDs because it is clinically unethical to leave STIs untreated and follow participants to see if their infections develop into PID.[51] 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.[19] Besides the increased risk of PID during insertion, there are few risks associated with the insertion and removal processes, and most providers find both insertion and removal of IUDs to be fairly easy.

Some women have expressed concerns about the need to have a clinician remove their IUD, with women in one study saying that clinician removal "constrain[s] their control over their contraception"[52] and a portion of women citing the need for clinician removal as a reason not to choose an IUD as their contraceptive method. 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.[53]

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%.[45]

Implant

Nexplanon also shows an excellent safety and efficacy profile. As with IUDs, most side effects or risks are minor, and serious adverse events are rare. Side effects may include headache, vaginitis, acne, dysmenorrhea, mood swings, weight increase, depression, and urinary tract infection.[54] As with IUDs, bleeding irregularities can occur and are non-serious, but women may choose to discontinue use of the methods because of these effects.[54]

Insertion of implants is generally even easier than insertion of IUDs, but removal can be more challenging than insertion. Problems with removal tend to occur in rare cases when the implant breaks or is difficult to locate.[54] Self-removal is not a feasible option for implants.

After implant removal, women can expect a rapid return to fertility. Within three weeks of removal, ovulation resumes in more than 90% of women.[54]

Clinical Guidelines for Providing LARC Methods

Several clinical and professional societies make recommendations for the use of LARC methods, including the American College of Obstetricians and Gynecologists (ACOG), the Centers for Disease Control and Prevention (CDC), 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.[55] ACOG recommends: encouraging use of LARC methods for all appropriate candidates, including for nulliparous women and teens; offering LARC methods on the same day as requested if pregnancy can be reasonably excluded; 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.[56]

ACOG also recommends offering LARC methods at the time of delivery, abortion, or miscarriage.[56] The immediate postpartum and post-abortion periods offer a uniquely favorable time for initiation of a LARC method. Women are known not to be pregnant, may be particularly motivated to use contraception, are usually already in a medical setting, and are at risk for rapid repeat pregnancy.[19] However, only 54%-65% of women who request a postpartum LARC method actually receive it.[57,58] A disadvantage associated with postpartum IUDs is increased risk of expulsion; there is also an increased expulsion risk after a second trimester abortion. The data on safety of the implant in breastfeeding women are mixed, and concerns persist about potential negative effects on milk production and infant growth and development due to the hormones, despite recent studies that show no effect on these outcomes.[19] The CDC lists postpartum implants as Category 2 (advantages generally outweigh the risks),[59] and ACOG lists postpartum implants as Category 1 (safe at any time) for breastfeeding women.[19]

In 2014, after a multi-stage process drawing on established procedures for developing clinical guidelines, the CDC and the HHS Office of Population Affairs released a key guidance document called "Providing Quality Family Planning Services" (QFP). It is intended for all providers and potential providers of family planning services, including primary care providers, and is available at: http://www.cdc.gov/reproductivehealth/unintendedpregnancy/qfp.htm. The QFP recommends a client-centered approach, as well as "a tiered approach (i.e., presenting information on the most effective methods first, before presenting information on less effective methods)."[60]

Factors Affecting LARC Use

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,[61] and additional provider charges for insertion and follow-up visits can bring the total bill above $1,000.[62]

Other barriers include lack of information about LARC methods, misinformation on LARC methods, and concerns about method characteristics and side effects. Some women are not familiar with the different LARC methods,[50,63–68] and many are not aware that they are significantly more effective than other methods.[69] Women may also have different priorities for contraception or may 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. A study from 2010 found that the contraceptive features deemed "extremely important" by the largest number of women were effectiveness, a lack of side effects, and affordability.[70]

Women's attitudes toward LARC methods must 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."[71] 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.[72] Sixteen states currently have policies

that create incentives or disincentives to limit childbearing by women receiving public 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 LARC method.[73]

These historical and current experiences of reproductive injustice impact patient-provider interactions today, particularly regarding LARC methods. In a recent survey, black and Latina women had more than twice the odds of believing "the government encourages contraceptive use to limit minority populations";[74] a separate survey that oversampled women of color found that 3% of participants reported IUDs had been misused against people in their communities and 9% believed that to be the case for the contraceptive implant.[63] Providers' personal or professional beliefs and biases may also have an effect. For example, 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.[75] Another 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.[76]

In addition to implicit (or explicit) racial and/or income-based biases, many providers continue to impose overly restrictive criteria for either LARC insertion or removal. For example, provider surveys have found that many providers consider women to be poor candidates for either or both types of IUDs if they are adolescents or have not had children,[55,77–79] although these restrictions run contrary to current clinical guidelines. In addition, some providers require two clinical visits because they administer STI testing before insertion and allow time for STI test results to be completed, even though current guidelines do not support pre-insertion routine STI screening for women at low risk of STIs.[80,81] For device removal, some women have reported provider-based barriers, in particular for 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."[82]

Another barrier to women seeking to obtain LARC methods, especially the contraceptive implant, may be lack of provider experience with the methods and limited availability of training, restricting providers' ability to offer the method.[83] Between 2002 and 2006, there was no contraceptive implant available in the US, and even today physicians must complete a three-hour, manufacturer-provided training in order to place implants. 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 implant.[83] 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.[77]

Health system factors may also affect the likelihood that a provider will offer LARC services. Some providers cite the difficulty of fitting both counseling and insertion into a single visit, or other aspects of clinic workflow, as potential barriers at the health system level.[80,81] Financial resources and on-site availability also play a role. The most commonly reported barriers to on-site LARC methods included stocking costs and insufficient staffing and training. 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, where patient payments fall far below the cost of most LARC devices.[84,85]

Health centers that cannot or do not stock LARC methods on-site must order them, 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.[86] However, all these practices create significant and unnecessary barriers to same-day placement,[87] requiring patients to make multiple office visits. 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's office.[88]

Reducing Barriers While Preserving Autonomy

LARC method use has increased in places where interventions have reduced cost and knowledge barriers, and there is substantial interest in replicating and expanding these interventions. 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 only a tiered efficacy approach to education, with the most effective methods (i.e., LARCs) described first, has the potential to become too directive, as it assumes that effectiveness is the most important factor in the woman's decision. 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 the woman's own goals and preferences.[89] While encouraging more research into evidence-based strategies for effective contraceptive counseling, Dehlendorf and colleagues suggest "a shared decision making approach that focuses on eliciting and responding to patient preferences."[90]

Improvements in provider training, as well as development of web-based and phone-based counseling tools, can also improve access to LARC methods. For instance, a 2016 randomized trial involving 40 Planned Parenthood clinics across the US found that LARC method initiation was higher at the clinics where LARC-based trainings occurred compared to the other clinics.[91] Online and phone tools could complement in-person counseling, and researchers are developing and testing several, including the "Plan A Birth Control" app[92] and the "Get It and Forget It" online video.[93]

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. Programs in Iowa, St. Louis, and Colorado have seen success in the form of increased rates of LARC method use and declines in each area's teen pregnancy and abortion rates; Delaware has also recently implemented a promising LARC initiative. For additional details on these initiatives, see "LARC: State-Level and Regional Research" at http://ow.ly/ZtQ5302VMTE.

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.[94] There are concerns, however, that performance measures that specifically assess LARC method use could produce unintended consequences, such as indirectly encouraging directive counseling at the expense of patient autonomy and ultimately reducing patient satisfaction and provider credibility (Foster et al., 2015).

To avoid this outcome, some 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, such as measuring the percentage of women who are offered a LARC method[19] or measuring the percentage of women who receive a LARC method, without identifying a specific benchmark percentage or target number.[95] These measures allow for flexibility and shift the emphasis from incentivizing any LARC use, whether clinically appropriate or not, to reducing barriers.

Current Policy Issues

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.[57] 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.

Before passage of the Affordable Care Act (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,[96] which often meant that women who wanted to choose a LARC method could not afford to do so. Regulations implementing the ACA specify that all non-grandfathered health plans must cover all FDA-approved contraceptives without cost-sharing.[97,98] While details of contraceptive coverage can vary somewhat from plan to plan, the ACA requirement means that non-exempt plans must cover the implant, at least one copper IUD, and at least one hormonal IUD.[99,100] However, recent evidence suggests that some plans are not complying with the coverage mandate by denying coverage, imposing cost-sharing, or otherwise maintaining financial barriers that restrict access.[101,102]

All Medicaid programs must furnish some family planning services and supplies without cost-sharing, but states can establish reasonable coverage limits, and inclusion of LARC methods is not required.[103] Medicaid beneficiaries who qualify for coverage on the basis of the ACA expansion category get the benefit of the ACA regulation's contraceptive coverage standard. However, it is not clear whether states do in fact distinguish between traditional and expansion populations in terms of the contraceptive options they cover.

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.[57,103] Thus, providers may not wish to offer postpartum LARC methods 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.[6]

Both Medicaid and private insurance plans that are subject to the ACA contraceptive coverage requirement are required to cover LARC removal as well as insertion, also without cost-sharing. However, some plans and Medicaid programs have not complied with this requirement – denying reimbursement or requiring a medical justification for removal.[104] For instance, South Dakota's Medicaid program issued a billing manual in January 2016 stating that it only allows reimbursement for implant removal "when due to infection, rejection or when determined medically necessary" but does not reimburse if "the intent is for the recipient to become pregnant."[105]

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.[106,107] The letter specifically clarifies provisions prohibiting states from imposing restrictions on removal that interfere with a Medicaid beneficiary's ability to freely choose a method of family planning. 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.

Finally, providers who receive Title X funding – 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 may see savings of 25-50% on drug costs,[108,109] and may pass these savings along to patients. 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.[100] The standard 340B price for Liletta is $50.[110] 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.[111]

Parental Consent Policies for Adolescents & Confidentiality of Care

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 parental consent or notification.

As of early 2016, 26 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.[112] Research suggests that policies

requiring parental consent for services could lead to choices that put adolescents at increased risk for unintended pregnancy, such as relying on less effective methods or using no method.[113]

While Medicaid and Title X programs generally do not send an explanation of benefits (EOB) detailing the services they provided after seeing an adolescent for family planning services,[114] a parent of an adolescent who receives coverage through a parent's private insurance plans may learn that their child sought or accessed contraceptive services or supplies when they receive an EOB.[115] Some private plans will allow the EOB to be "suppressed" (i.e., not sent or filed electronically), thus avoiding this concern. However, state policy on this issue varies widely across the country.[114]

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. Areas of future research include: potential for self-removal of IUDs; patient experiences and preferences surrounding LARCs, especially among younger and other vulnerable populations; provider knowledge and attitudes; health system barriers to LARC removal; reducing clinical risks, such as the risk of expulsion; and trends in condom use associated with trends in LARC use. Health law and health policy research are also key, especially as aspects of the ACA continue to be implemented at the state level and as state legislators attempt to cut public funds to Planned Parenthood or other providers that also offer abortion services. Finally, as LARC use increases and more information about LARC methods becomes available, communications 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.

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