

**Tennessee Initiative for Perinatal Quality Care
Maternal Quality Improvement**

Immediate Postpartum Long Acting Reversible Contraception



Nikki Zite, MD, MPH
TIPOC Maternal Medical Director

Suzanne McMurtry Baird, DNP, RN
TIPOC Maternal Quality Improvement Specialist

Brenda Barker, MEd, MBA, TIPOC
TIPOC Executive Director

Theresa Scott, MS
TIPOC Data Manager

TIPOC would like to thank other states who have shared and/or published their LARC QI toolkits. We have learned from your efforts and initiatives and have adapted portions from each state toolkit. All state initiatives that we have reviewed are included in the "Additional Resources" section of this toolkit. Together, we can make a difference!

February 26, 2018

Dear colleagues:

I applaud the efforts of TIPQC and their partners in decreasing barriers to timely access to contraception. As we know, unintended pregnancies often lead to poor outcomes for both women and children. Accessing contraception is especially challenging for new mothers that are facing many additional responsibilities of caring for a newborn; and often the mother's needs may go unmet. Contraceptive counseling and management is critical in the prenatal and immediate postpartum period to avoid short-interval pregnancies that have additional risks beyond that of other unintended pregnancies.

It is my hope that every birth hospital will think through its own unintended barriers to contraception of all types in the immediate postpartum period and then commit to work with the TIPQC community of practice with the goal of better serving women's reproductive health needs. It our mutual goal that contraception counseling will begin in the prenatal period and that all options would be available to women at the time of delivery. We firmly believe that appropriate counseling is critical in this endeavor. It must be non-coercive and client centered and should include advantages, risks, contraindications and alternatives to allow for informed decision making. A woman should fully understand her options and that her decision to receive a method is completely voluntary. Recognizing the importance of language in the contraception conversation, the Tennessee Department of Health has further stressed the importance of "voluntary" by referring to Long Acting Reversible Contraception (LARCs) as Voluntary Reversible Long Acting Contraceptives (VRLACs). We welcome you to consider the use of that language in your own practice as well.

The Tennessee Department of Health applauds the work of TIPQC and partnering facilities, providers, payers in expanding the scope of contraception options available to families. We are proud of the collaborative work that has made this project a reality, and we welcome you to this shared quality improvement opportunity.

Sincerely,

John J. Dreyzehner, MD, MPH, FACOEM
Commissioner, Tennessee Department of Health

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Note: disclaimer adapted from the Indiana LARC toolkit.

Executive Summary

Prior to November 2017 reimbursement was a critical factor limiting access to voluntary long acting reversible contraceptives (LARC) during a delivery hospital admission in Tennessee. Through the efforts of TennCare, Manage Care Organizations, Tennessee Department of Health, Tennessee Hospital Association, and TIPQC the insertion fees for immediate postpartum LARC have been unbundled from the global reimbursement for a delivery and now is an option for TennCare recipients. This Executive Summary will include the 5 W's for the TIPQC Immediate Postpartum Voluntary Long Acting Reversible Contraception (LARC) quality improvement project.

Why: Over one-half (57.5%) of Tennessee women giving birth in 2013 reported that they had not been trying to get pregnant and less than half (43.3%) had been using birth control. In addition, in 2014, 22.7% of women had short birth interval deliveries – defined as infants born less than 24 months apart. (TDH Data, 2016) Planned, well-spaced pregnancies are healthier pregnancies. Immediate postpartum LARC can help better space pregnancies. If LARC is not available at a delivering institution, a key opportunity to offer contraceptive access is missed.

What: Providing a woman access to contraception allows her to optimize health by treating modifiable risk factors prior to a planned pregnancy and assists in preventing undesired pregnancies. Data demonstrates that preventing undesired pregnancies with appropriate spacing between pregnancies decreases preterm birth and other causes of maternal and infant morbidity and mortality. (DeFranco, Seske, Greenberg & Muglia, 2015; Mayer, 1997; Orr et al, 2000) Likely, use of LARC decreases Neonatal Abstinence Syndrome (NAS). LARC/VRLAC is an effective reversible contraceptive that includes intrauterine devices (IUDs) and implants (placed in the arm). The efficacy of LARC compares to permanent sterilization, but offers the option of future fertility if the women desires. Immediate postpartum LARC is a safe and convenient procedure during the delivery hospitalization.

Who: All members of the obstetric care team plan, coordinate, and offer immediate postpartum LARC to desiring and qualified women delivering at a participating institution. Hospital administrative support for LARC is essential to provide team leadership, process development, implementation oversight, and quality measurement. Procurement and inventory of devices is implemented based on institution systems and processes, which may include Pharmacy or Supply Chain. Providers are educated on benefits and risks of LARC in order to counsel women, ensure the woman is an appropriate candidate, and properly place the device. Nursing and operating room team members assist providers in recognizing candidates to ensure that all women who meet criteria and desire LARC receive it, and assist the provider during placement. Lactation consultants understand the impact of LARC on breastfeeding and encourage women to choose the best option for them and their family.

Where: LARC contraceptive placement occurs during delivery hospitalization in Labor and Delivery, the Operating Room, or on Post-partum/Mother-Baby unit.

When: IUD placement occurs immediately post-delivery when the woman is either in the labor and delivery suite/birthing room or operating room. Implants are typically placed prior to discharge from the institution.

AIM: To improve the health of infants as well as eligible, desiring mothers in Tennessee by increasing access to contraception through systematically promoting and supporting immediate postpartum LARC in the birth setting in Tennessee, thus reducing unplanned pregnancies, improving pregnancy spacing, and potentially reducing NAS births.

IMMEDIATE AIM: To increase access to immediate postpartum LARC to 50 % of participating institutions by March 2019. Once an institution's supporting structure is complete, to increase placement in *eligible women desiring* immediate postpartum LARC to 70% by March 2019.

BACKGROUND

Overview and United States (U.S.) Data

- 61.4% of all women use some form of contraception. (Kavanaugh & Jerman, 2018)
- 89.6% of women at risk of unintended pregnancy use a method of contraception. (Kavanaugh & Jerman, 2018)
- LARC use is growing in the U.S. In 2014 (latest U.S. data), 14.3% of all women used a LARC method, an increase from 2008 use of 6.0%. (Kavanaugh & Jerman, 2018)
- 4% of teens use IUDs and 6% use implants. (Kavanaugh & Jerman, 2018)
- The most effective contraceptives are long-acting reversible contraceptive devices (LARC). Making these devices available to women would prevent the incidence of unintended pregnancies. (ACOG, 2015)
- Fewer than 1 in 100 women using an intrauterine device (IUD) or contraceptive implant will get pregnant within one year. Compared to typical use of birth control pills and male condoms, 9 out of 100 and 18 out of 100 women will get pregnant within one year, respectively. The number is higher if not used correctly and consistently. (Guttmacher Institute, 2016)
- Birth spacing of less than 18 months is associated with delayed prenatal care and adverse birth outcomes, including: (DeFranco, Seske, Greenberg & Muglia, 2015; Mayer, 1997; Orr et al, 2000)
 - Preterm birth
 - Neonatal morbidity
 - Low birth weight
- Adverse birth outcomes associated with birth spacing of less than 18 months are associated with: (IOM, 2007)
 - Developmental delay
 - Asthma
 - Vision and hearing loss

Unintended Pregnancy

- Approximately 45% of all pregnancies and 75% of U.S. teen pregnancies are unintended.
- 95% of unintended pregnancies occur among women who either use their contraceptive method incorrectly, inconsistently, or use no method. (Sonfield, Hasstedt, & Gold, 2016)
- Unintended pregnancies are higher in women who are: (Mosher, Jones, Abma, 2012)
 - Aged 18-24
 - Unmarried (particularly cohabitating women)
 - Not high school graduates
 - Ethnic or racial minorities
 - Low income

- 40% of women do not return for their 6-week postpartum visit and an estimated 40-57% of woman have unprotected intercourse before their scheduled postpartum check-up. (ACOG, 2016a; Brito, Ferriani, Quintana, Yazlle, Silva de Sa, Vierira, 2009; Connolly, Thorp, Pahel, 2005)

Incidence and Outcomes of Unintended Pregnancy in Tennessee (TDH Data, 2016)

- Over one-half (57.5%) of Tennessee women giving birth in 2013 reported that they had not been trying to get pregnant at the time that they became pregnant. Of these women, less than half (43.3%) had been using birth control.
- Among women who had not been trying to get pregnant, there was not a statistically significant change in contraceptive use between 2008 and 2013.
- In 2014, the mean birth interval in Tennessee was 50.0 months. However, 22.7% of women had a short birth interval.

Advantages of LARC Methods (ACOG, 2015):

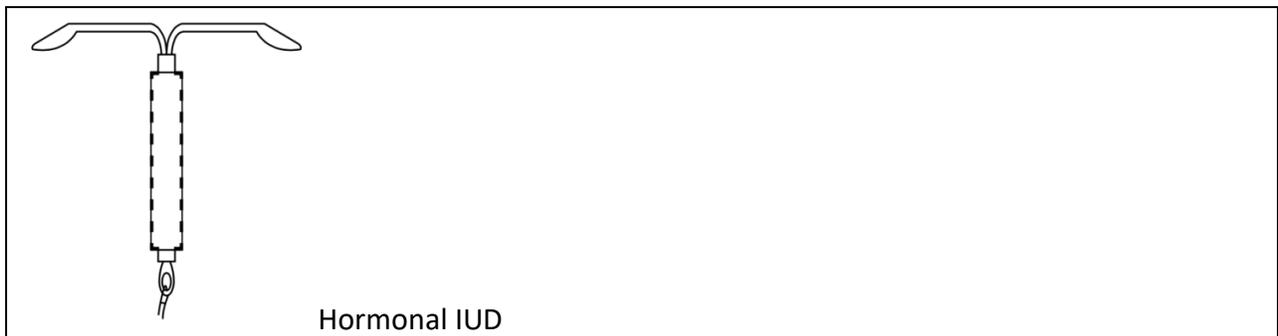
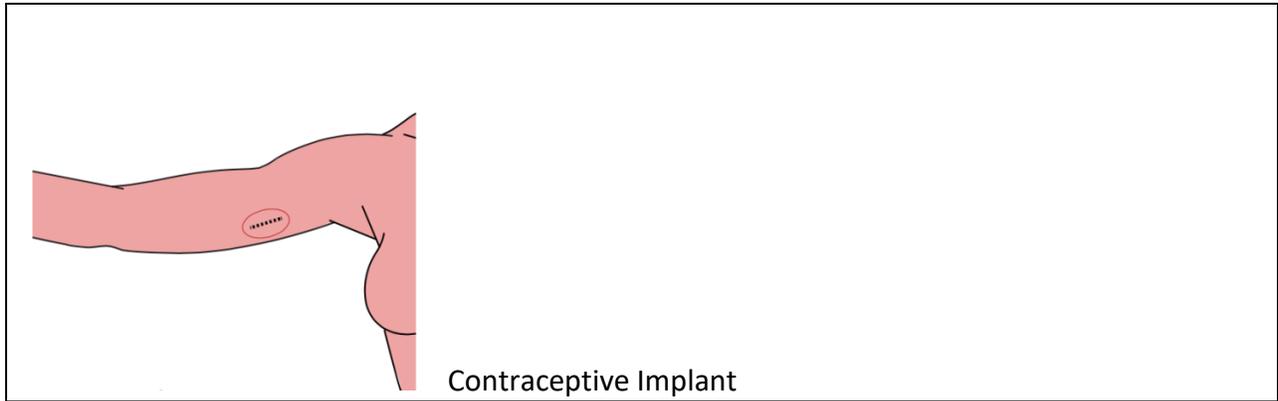
- Effectiveness independent from coitus, user motivation, and adherence
- Highest effectiveness, continuation rates, and user satisfaction of all reversible methods
- No requirement for frequent provider visits for resupply
- No requirement for additional funding for consistent use once placed
- Highly cost effective
- Reversible, with a rapid return to fertility after removal
- Few contraindications

Offering LARC methods in the immediate post-partum period for appropriate women may help lower unintended pregnancy rates because gaps in use and discontinuation of shorter acting methods are associated with unintended pregnancy rates in high-risk women. Even though there is an increased risk of expulsion if placed immediate postpartum, women during this time are highly motivated, pregnancy status is known, and it is convenient for placement. Given women have numerous challenges returning for their postpartum visit, evidence shows even despite the high expulsion rates, at 6 months, women that had LARC placed immediate postpartum are more likely to be contracepted. (Levi, Stuart, Zerden, Garrett, Bryant, 2015) In addition, even if they present for their post-partum visit, 45% of women report unprotected sex within 6 weeks of birth, prior to this appointment. (Bruto et al, 2009)

Summary of LARC Methods

Method	Available Since	Years Effective	Use	Possible Side Effects
Copper IUD				
ParaGard Copper T 380A	1984	10 years	<ul style="list-style-type: none"> Approved for women regardless of parity Can be used as emergency contraception. 	<ul style="list-style-type: none"> Abnormal, heavier menstrual bleeding Higher frequency or intensity of cramps/pain
Hormonal IUDs				
<i>Note: all currently available hormonal IUDs use levonorgestrel (LNG) and have the same possible side effect profile</i>				
Mirena	2000	5 years	<ul style="list-style-type: none"> Approved only in parous women, but available to all women regardless of parity.* Approved for treatment of anemia in women desiring contraception 	<ul style="list-style-type: none"> Inter-menstrual spotting in the early months. Reduces menstrual blood loss significantly. Hormone related: Headaches, nausea, breast tenderness, depression, ovarian cyst formation – all rare.
Skyla	2013	3 years	<ul style="list-style-type: none"> Approved for women regardless of parity. Smaller “T” and insertor than Mirena and Liletta 	
Liletta	2015	4 years	<ul style="list-style-type: none"> Approved for women regardless of parity. 	
Kyleena	2017	5 years	<ul style="list-style-type: none"> Approved for women regardless of parity. Smaller “T” and insertor than Mirena or Liletta Less LNG daily dose than Mirena and Liletta 	
Implants				
Nexplanon	2011	3 years	<ul style="list-style-type: none"> Approved for women regardless of parity 	<ul style="list-style-type: none"> Inter-menstrual spotting in the early months. Hormone-related: headaches, nausea, breast tenderness, depression, ovarian cyst formation.

*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 (ACOG, 2011). Adapted from: Kaiser Family Foundation, 2016 (see additional resources section)

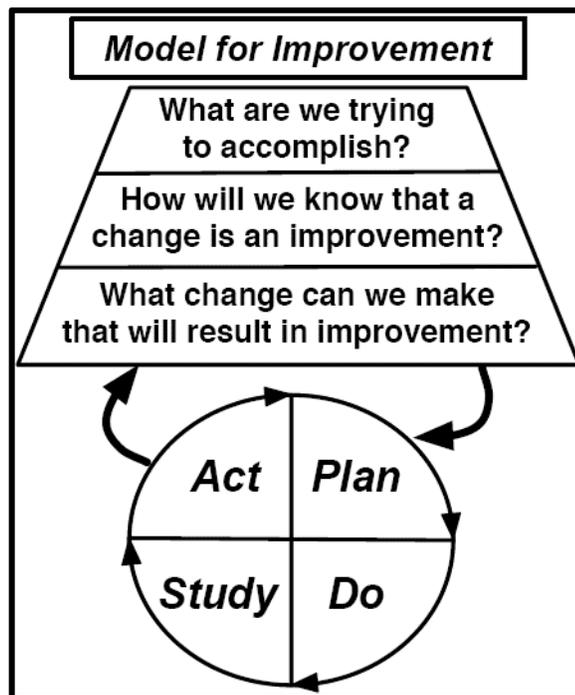


<http://www.astho.org/Maternal-and-Child-Health/Increasing-Access-to-Contraception/West-Virginia-Postpartum-LARC-Toolkit/>

The Tennessee Initiative for Perinatal Quality Care (TIPOC) thanks the West Virginia Department of Health and Human Resources, Bureau for Public Health, Office of Maternal, Child and Family Health for use of the West Virginia Postpartum LARC toolkit for use as a guide in the development of the Tennessee LARC toolkit.

QUALITY IMPROVEMENT OVERVIEW

This Quality Improvement (QI) Tool Kit is based on a set of clinical practices that have the potential to improve the outcomes of maternal and neonatal care, known as *Potentially Better Practices* (PBP's). They are labeled 'potentially better' rather than 'better' or 'best' because until the practices are evaluated, customized, and tested in your own institution, you will not know whether they are truly 'better' or 'best' (or 'worse'). Depending on the circumstances in your facility, you may have to implement other practices or modify existing ones to successfully improve maternal and infant outcomes. The PBP's in this collection are not necessarily the only ones required to achieve the improved outcomes targeted. Thus, this list of PBP's is not exhaustive, exclusive, or all inclusive. Changes in practice, guided by these PBPs, will require testing and adaptation to your circumstances and context to achieve measured improvements in outcomes. As you test and implement these PBP's, you should monitor the results closely to ensure that you are obtaining the desired results, that no harm is being done, and that no unanticipated results are seen. In addition to the suggested measures, you should track balancing measures. Your team can implement as many of the PBP's in this Tool Kit as you wish, based on an assessment of your unit's priorities, and based on availability of resources, time, and individuals with quality improvement skills.



TIPQC Immediate Postpartum Long Acting Reversible Contraception (PPLARC) Project Toolkit

This toolkit is a collection of evidence based practices based on a review of the literature and immediate postpartum LARC programs across the United States (U.S.). Any success realized from this toolkit is in part due to the generosity and collaborative spirit of the practices that participated in the TIPQC pilot project and toolkits from states that have successfully implemented immediate postpartum LARC as well as American College of Obstetricians and Gynecologists Post-Partum Contraceptive Access Initiative (ACOG PCAI).

This toolkit is intended for application in conjunction with a series of statewide learning sessions and webinars. This toolkit is presented as a “menu” of potential changes for participating institutions to consider in the context of local needs, culture, and resources. As with any bundle, the toolkit should be implemented with all interventions undertaken simultaneously. However, individualized institutional policy and ground work will be required as with any system process implantation and change. The TIPQC office is available to discuss local implementation strategies with project leaders and teams as needed.

To facilitate quantitative, data-driven improvement, this project utilizes a web-based data entry system through REDCap. REDCap data entry will help each participating institution organize data entry so that only the minimum essential data is collected, and in turn, provide easily generated, on-demand run charts and control charts from your project data. Additionally, as all teams participate, automated on-demand comparison to the most current project-wide aggregate data will be possible in order to facilitate rapid PDSA cycles as your team works to improve your system. Balancing the cost vs. value of data collection in a QI effort is challenging and the TIPQC office is available for consultation to assist project leaders and improvement teams in selecting the optimal approach for their institution.

Charter

The *TIPQC Immediate Postpartum Long Acting Reversible Contraction (PPLARC)* Project was selected by an inter-professional team of Tennessee obstetric providers. Institutions representing multiple Tennessee perinatal regions indicated their willingness to fully participate in the project if implemented on a statewide basis. By completing the project application, each participating institution agrees to the following fully implement the project as designed, collect and submit the required monthly data in a timely manner, and participate in monthly webinars and statewide face-to-face meetings.

PROJECT AIM: To improve the health of infants as well as eligible, desiring mothers in Tennessee by increasing access to contraception through systematically promoting and supporting immediate postpartum LARC in the birth setting in Tennessee, thus reducing unplanned pregnancies, improving pregnancy spacing, and potentially reducing NAS births.

Immediate AIM: To increase access to immediate postpartum LARC to 50 % of participating institutions by March 2019. Once an institution’s supporting structure is complete, to increase placement in ***eligible women desiring*** immediate postpartum LARC to 70% by March 2019.

Target Population

All women who are eligible and desire postpartum LARC after giving birth and/or terminating pregnancy in Tennessee institutions.

Eligibility Criteria (ACOG, 2016b)

- Healthy women of any reproductive age, desiring highly effective and reversible contraception
- If placing an intrauterine device (IUD), the woman:
 - Has not been ruptured for greater than 18 hours
 - Has no evidence of Triple I or other uterine infections
 - Has normal anatomic uterine cavity (same criteria as when placed unrelated to pregnancy)

Contraindications for Immediate Postpartum LARC placement (ACOG, 2016b)

- **If placing an IUD:**
 - Triple I diagnosis at time of birth, endometritis, and/or puerperal sepsis
 - Uncontrolled postpartum hemorrhage (defined as greater than 1000 mL blood loss for vaginal or Cesarean birth with risk of continued bleeding)
- **If placing contraceptive implant:** contraindications are the same as when unrelated to pregnancy

Definitions

- **Birth spacing:** the time from one child’s birth until the next pregnancy (also known as interpregnancy interval) (March of Dimes)
- **Chorioamnionitis:** See definition for Triple I
- **Eligible:** see above defined eligibility criteria
- **Golden Hour:** first hour of postnatal life
- **Immediate postpartum period:** during the delivery “hospitalization”.

- **Intended pregnancy:** pregnancy that was desired at the time it occurred or sooner. (Guttenmacher, 2016)
- **Long Acting Reversible Contraceptive:** Long-acting reversible contraception (LARC) methods include the *intrauterine device (IUD)* and the *birth control implant*. Both methods are highly effective in preventing pregnancy, last for several years, and are easy to use. Both are reversible.
<http://www.acog.org/Patients/FAQs/Long-Acting-Reversible-Contraception-LARC-IUD-and-Implant>
- **Preterm birth:** birth that occurs before the start of the 37th week gestation.
- **Rapid Repeat Pregnancy:** repeat pregnancy within 2 years of previous birth.
- **Triple I:** a term that used for intrauterine inflammation, infection or both; diagnostic criterial includes a maternal fever and one or more of the following: (Higgins et al, 2016)
 - Fetal tachycardia (greater than 160 beats per minute for 10 minutes or longer)
 - Maternal white blood count (WBC) greater than 15,000 in the absence of corticosteroids
 - Purulent fluid from the cervical os (cloudy or yellowish thick discharge confirmed visually on speculum examination to be coming from the cervical os)
 - Biochemical or microbiologic amniotic fluid results consistent with microbial invasion of the amniotic cavity.
- **Unintended pregnancy:** pregnancy that was either mistimed (occurred earlier than desired) or unwanted (occurred when no children, or no more children were desired).

MEASURES

Note: Reported monthly through REDCap

A. Outcome measures

1. Whether institution provides the option of LARC placement in the immediate postpartum period (Yes / No)
 - “Immediate postpartum period” is defined as during the delivery “hospitalization”.
 - If Yes, what specific LARC device(s) (Hormonal IUD, Copper IUD, Implants)?
2. Number of LARCs (IUDs and/or implants) placed
 - Only collected once institution is providing the option of LARC placement in the immediate postpartum period
 - For each type of LARC device (Hormonal IUDs; Copper IUDs; Implants):
 - i. Numerator = Number of devices placed
 - ii. Denominator = Number of women eligible (as of postpartum) for device placement, who desired immediate postpartum LARC placement
 - NOTE: There is the intent to capture & report the number of women who desired LARC, met criteria, but did not receive LARC

B. Structure/Process measures

1. Policy and Procedure

- Have policies, procedures, and/or guidelines been implemented to support immediate postpartum placement of LARC?
 - FIELD NOTE: Hospitals will be instructed to answer “No” until policies, procedures, and/or guidelines have been implemented – that is, not while they are being drafted and/or approved.
2. Availability of LARC for immediate postpartum placement
- For each type of LARC device (Hormonal IUDs; Copper IUDs; Implants):
 - i. Has the device been added to the institutional formulary/supply chain? (N / Y / Not applicable)
 - ii. Is the device and ancillary equipment available for all delivery suites? (N / Y / Not applicable)
 - iii. Is the device and ancillary equipment available for all OB ORs? (N / Y / Not applicable)
 - iv. Is the device and ancillary equipment available for all postpartum/mother-baby units? (N / Y / Not applicable)
 - If “No” to any of the above, what are the barriers?
3. Documentation revisions
- Have EMR and/or paper chart revisions been completed to assure adequate data collection, tracking, and documentation? Specifically,
 - i. EMR or paper chart for consent?
 - ii. EMR or paper chart for contraception choice counseling?
 - iii. EMR or paper chart order sets?
 - iv. Pharmacy system?
 - v. Billing system?
 - vi. Tracking tools?
4. Provider education
- Percentage of eligible providers (physicians, certified nurse midwives, and/or nurse practitioners) who have completed education and training program (0, $\frac{1}{4}$, $\frac{1}{2}$, $\frac{3}{4}$, All)
5. Nursing education
- Percentage of eligible nurses and/or surgical technicians who have completed education and training program (0, $\frac{1}{4}$, $\frac{1}{2}$, $\frac{3}{4}$, All)
6. Lactation consultant education
- Percentage of eligible lactation consultants who have completed education and training program (0, $\frac{1}{4}$, $\frac{1}{2}$, $\frac{3}{4}$, All)
 - *NOTE: some institutions may not have lactation consultants – will have field to capture “Not available”*
7. Patient education and counseling
- Prior to birth admission:
 - i. Numerator = number of women educated and counseled prior to birth admission
 - ii. Denominator = number of women who present in term labor

- iii. should not include preterm (prior to 30 weeks gestation), referrals/transport, or women with no prenatal care
- Prior to discharge:
 - i. Numerator = number of women educated and counseled prior to discharge
 - ii. Denominator = number of women who deliver

8. Balancing measures

1. Hospital Expenses
 - Total number of devices placed that were not fully reimbursed
 - Number of devices placed that were not fully reimburses due to insurance coverage / self-pay
 - Number of devices placed that were not fully reimburses because they were opened and not used
2. Number of women with expulsion after placement of immediate postpartum LARC IUD
 - For each type of IUD (Hormonal; Copper) and route of birth (C-section; vaginal birth)
 - *NOTE: TIPQC will provide an outline for institutions to explore as to when the IUD was expelled if they so choose.*
3. Number of institution triage/Emergency Department visits related to immediate postpartum LARC
 - For each type of LARC device (Hormonal IUDs; Copper IUDs; Implants)
 - *NOTE: TIPQC will provide an outline for institutions to explore presenting signs and symptoms if the woman returns to triage or Emergency Department if they so choose.*

GETTING STARTED

- Form a team (refer to TIPQC Just in Time Modules for more information)
- Complete the TIPQC project application
- Ensure facility has current Data User Agreement (DUA) with TIPQC; if not current, complete DUA
- Complete Tennessee Department of Health required data access forms
- Research and determine current system and needs for project implementation (e.g. Pharmacy, coding, reimbursement, training)
- Assign team members to data collection roles; notify TIPQC and TIPQC will set up REDCap User accounts and grant appropriate access
- Review TIPQC tool kit for immediate postpartum LARC
- Begin prioritizing action items with Plan, Do, Study, Act (PDSA) cycles
- Attend Kick off & Data Training
- Gather any baseline data available, find data sources, define data workflow

- Team meeting times, PDSA cycles
- Attend monthly huddles

DATA ENTRY, SYSTEM ACCESS, AND REPORT RECEIPT

Automated, on-demand run-charts and control charts of local data will be available again through the REDCap system. These analyses will reflect the data that has been entered by your institution at the time the report is generated. Similarly, the state aggregate report will reflect the aggregate of all participating centers based on currently available data. Accordingly, TIPQC will monitor the currency of data entry. Centers that are unable to enter their monthly data in a timely manner risk being removed from active participation as data entry lags reduce the value of the state aggregate report for all the remaining institutions who have entered their data on time. Institutions are highly encouraged to contact the TIPQC office if they find they are having difficulty meeting the data entry due dates/times.

POTENTIALLY BETTER PRACTICES

Potentially Better Practice #1: Establish a Policy and/or Procedure for Immediate Postpartum LARC Placement

Rationale: Formulating an evidence based practice policy and/or procedure for immediate postpartum LARC will provide consistency in practice and optimize opportunities for women who desire placement. Policy should cover placement of intrauterine devices and implants.

Implementation Strategies

1. Establish an inter-professional team (including representatives of all key sectors) to develop policy, practice, and process; include staff nurse and surgical technician representatives
2. Review scientific evidence re. immediate postpartum LARC
3. Review concepts re. change theory
4. Utilize “lessons learned” from other institutions who are implementing immediate postpartum LARC.
Note: several other state quality improvement teams are implementing immediate postpartum LARC (see resource section of this document)
5. Consider a survey of women who desire immediate postpartum LARC to determine patient perspective needs.
6. Consider impact on patient satisfaction.
7. Consider patient confidentiality issues that may arise if the woman does not desire others to know that LARC placement is to occur.
8. Determine how women will be counseled and offered immediate postpartum LARC. Optimally, women will be counseled prior to admission for birth. However, some women may present for birth desiring a long acting reversible contraceptive following birth having not received prior counseling.
9. Determine if the institution has provisions for teenage consent; is there a need for parental consent for LARC placement?
10. Determine how the provider will obtain informed consent for LARC placement. Informed consent is a process of providing oral and/or written communication regarding the risks, benefits, and alternatives to the procedure. Informed consent can only be provided and obtained by the provider (physician, CNM, WHNP). All core elements should be included and based on patient choice and safety.
11. Include contraindications for immediate postpartum IUD placement in policy language.
12. Determine how insertion pain/discomfort will be managed in women without ongoing anesthesia (e.g. pretreatment with nonsteroidal anti-inflammatory medications, paracervical block).
13. Determine equipment and supply needs for placement (e.g. Kelly or ring forceps, mechanical dilators, ultrasound for IUD placement).

14. Determine timing of placement in Labor and Delivery following vaginal birth and in the operating room following Cesarean birth. Best practice for placement is within 10 minutes following the delivery of the placenta. (ACOG, 2016)
15. Determine process if IUD expulsion occurs (e.g. replacement cost).
16. Determine clinical documentation requirements.
17. Consider simulation prior to implementation to determine effectiveness of policy, procedure, and process.
18. Determine required changes to policy, procedure, process prior to implementation (based on feedback, simulation data).
19. Communicate and educate all staff and providers that will be involved in LARC counseling and placement.

Potential Challenges

- Resistance to new policies and practices
- Lack of support from key stakeholders (e.g. administrative, medical, nursing, etc.)
- Lack of champions to help to establish policy and practice process for facility
- Lack of “buy-in” from providers and staff
- Concern re. cost and reimbursement
- Disagreement re. safety, validity, or importance
- Lack of quality monitoring to indicate if practice is consistent with policy
- Lack of communication and education for orientation of providers and staff to new policy or new hires to existing policies
- Perception of lack in patient interest
- Time constraints for training and implementation
- Informed consent not provided and/or obtained
- Staffing concerns during the time of planned placement
- Mother delivers preterm or without prenatal care and has not received previous counseling on immediate postpartum LARC
- Concerns re. immediate postpartum care, which includes but is not limited to: skin-to-skin interaction between mother and newborn, initiation of breastfeeding within the first hour of life, inability to perform maternal assessment requirements and/or interventions, newborn assessment requirements and medication administration
- Concern re. maintaining sterility in operating room
- Concern re. complications during IUD insertion, such as:
 - Maternal vasovagal reaction
 - Pain/discomfort
 - Uterine perforation (rate 0.3-2.6 per 1000 insertions of hormonal IUDs and 0.3-2.2 per 1000 copper IUD insertions) (Heinemann et al, 2015); note – 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, 2015)
- Concern re. IUD expulsion

- Concern re. interference with woman's desire to breastfeed (production of breastmilk)
- Persistence of myths that IUDs are harmful or not appropriate for the majority of women.
- Adherence to outdated eligibility criteria and clinical protocols.

WHO: Team composed of unit Administrator, Labor and Delivery and Mother/Baby Nurse Managers and staff; surgical technicians; Nurse Educators; Providers

Potentially Better Practice #2: Availability of Immediate Postpartum LARC IUDs for Placement in Labor and Delivery/Birthing or the Obstetric Operative Suite

Rationale: Having IUDs in stock and readily available streamlines the process and facilitates immediate postpartum placement. Infrastructure systems should be in place to ensure that women who desire LARC can receive it following vaginal or cesarean birth, and/or post-abortion.

Implementation Strategies

1. Determine types of IUDs that will be utilized for immediate postpartum LARC
2. Follow institutional processes for obtaining a new product contract
3. Pharmacy to address formulary changes as indicated
4. Determine costs of device and/or placement kit (e.g., device, local anesthetic, instruments)
5. Determine number of IUDs to have in inventory
6. Determine where to stock devices (e.g., Pharmacy, Supply Chain)
7. Follow institutional processes for stocking IUDs
8. Map process for obtaining an IUD in Labor and Delivery and/or obstetric operating room
9. Roles and responsibilities of the provider and nurse should be discussed and determined.
10. Consider use of a procedure checklist for insertions.
11. Monitor use of IUDs following implementation to make sure stock is not depleted
12. Determine reorder based on usage (Note: this may change as implementation occurs and more women desire placement)

Potential Challenges

- Inability to come to consensus re. types of IUDs to stock
- IUDs not stocked in areas where placement will occur
- Inability to timely obtain an IUD for placement
- Providers and staff not educated re. IUD stock and placement procedures
- More devices needed than stocked
- Devices not stocked; therefore, IUDs not placed
- Up-front costs of stocking IUDs.
- Staffing concerns during time of planned placement
- Timing from prescription for device to placement
- Concern regarding prolonging OR time

WHO: Pharmacy and/or Supply chain, unit administrator(s)

Potentially Better Practice #3: Availability of Immediate Postpartum LARC Implants

Rationale: Having implants in stock and readily available streamlines the process, prevents delays, and facilitates placement. Infrastructure systems should be in place to ensure that women who desire LARC implants can receive it following vaginal or cesarean birth, and/or post-abortion.

Implementation Strategies

1. Determine types of implants that will be utilized for immediate postpartum LARC
2. Follow institutional processes for obtaining a new product contracts
3. Pharmacy to address formulary changes as indicated
4. Determine number of implants to have in inventory
5. Determine costs of implant and/or placement kit
6. Determine where to stock implants (e.g., Pharmacy, Supply Chain)
7. Follow institutional processes for stocking implants
8. Map process for obtaining an implant on the postpartum/Mother-Baby unit
9. Roles and responsibilities of the provider and nurse should be discussed and determined.
10. Consider use of a procedure checklist for insertions.
11. Monitor use of implants following implementation to make sure stock is not depleted
12. Determine reorder based on usage (Note: this may change as implementation occurs and more women desire placement)

Potential Challenges

- Inability to come to consensus re. types of implants to stock
- Implants not stocked in areas of placement
- Inability to timely obtain an implant for placement; therefore, implant not placed
- Providers and staff not educated re. implant stock and placement procedures
- More implants needed than stocked
- Implants not stocked; therefore, implants not placed
- Up-front costs related to stocking implants
- Placement of implant may delay discharge from institution; postpartum/Mother-Baby bed needed
- Staffing concerns
- Timing of prescription for implant to placement
- Concerns regarding breastfeeding

WHO: Pharmacy and/or Supply chain, unit administrator(s), postpartum/Mother-Baby staff

Potentially Better Practice #4: Provide Education and Training for Providers, Nursing, Operative Staff, and Lactation Consultants

Rationale: Provider education and confidence prescribing of LARC are major factors related to access. Evidence-based education and training is recommended prior an institution offering immediate postpartum LARC. (ACOG, 2016) When providers lack full knowledge of the benefits and risks of contraceptive methods (including LARC), a woman may not be able to get her preferred method of contraception – or end up with no method of contraception. Education and training improve provider skills, confidence, and teamwork for providing LARC as an option during delivery hospitalization. In addition, all team members need to understand the process of LARC placement in order to provide patient education and answer questions. Integrated education programs may be included into new resident (teaching institutions) or midwife curriculum.

Implementation Strategies

1. Determine institutional systems and processes for immediate postpartum LARC prior to education.
2. Use an existing education program (e.g. ACOG resources, FDA training for implants)
 - <https://www.acog.org/About-ACOG/ACOG-Departments/Long-Acting-Reversible-Contraception>
 - See “Additional Resources” section for training links
3. Ensure budgetary funding for training and education.
4. Determine who will be training providers, nurses, surgical technicians/assistants, and lactation consultants.
5. Determine time, dates, and location for training that will allow the highest number of attendees.
6. Consider on-line or E-learning modules for training to increase participation and provide flexibility in training.
7. Provide tools and resources needed for training. These may include, but are not limited to simulation and use of mannequins.
8. Provide participants with evidence-based information on immediate postpartum LARC. Content may include, but is not limited to:
 - a. Benefits and advantages of immediate postpartum LARC placement
 - b. Importance and value of offering postpartum LARC as an option for contraception.
 - c. Candidates for immediate postpartum LARC placement
 - d. Risks of IUD and implants based on the method
 - e. Benefits of reducing unintended pregnancy and lengthening interpregnancy intervals
 - f. Contraindications of immediate postpartum IUD placement
 - g. Counseling and patient education
 - h. Placement techniques and best practices recommendations

- i. Assessment for complications
 - j. Nursing assessment following placement
 - k. Appropriate billing procedure
9. Provide feedback during and after training.
 10. Allow time for questions and answers following education and training.
 11. Ensure that participants have a pathway for follow up education and training as needed.
 12. Determine if institutional “credentialing” is required for providers prior to placement.
 13. Address any participant theoretical concerns re. breast milk production with placement of hormonal IUDs or implants. Lovonorgestrel IUD and implants are categorized as Medical Eligibility Criteria (MEC) Category 2 for women who are breastfeeding.

Potential Challenges

- Funding/ in kind donation for training time away from patient care
- Inability to get all providers, staff, or lactation consultants trained prior to implementation
- Inability of providers to reach agreement on best practices
- Provider attitude that risks outweigh benefits of immediate postpartum LARC placement
- Lack of consideration for the woman’s choice of contraception

WHO: providers (physicians, CNMs), staff (Labor and Delivery, operating room, postpartum/Mother-Baby, lactation consultants), educators

Potentially Better Practice #5: Patient Education and Counseling

Rationale: All women need full and accurate information regarding contraception options, including LARC methods. When providers are unprepared to offer patient focused counseling of contraceptive methods (including LARC), a woman may not be able to get her preferred method of contraception – or end up with no method of contraception. Providers should seek to ensure that counseling is provided in a consistent and respectful manner that neither denies access nor coerces a woman into using a specific method of birth control. Ideally, patient education and counseling regarding the woman’s desire for postpartum contraception is completed during the prenatal period and prior to birth. However, some women may present to the delivering facility without prior education and counseling. Therefore, a unified approach to the provision of consistent information is recommended. Standard components of LARC patient education may include, but is not limited to risks, signs of IUD expulsion, anticipated changes to menstrual bleeding, and theoretical issues related to breast milk production and successful breastfeeding.

Implementation Strategies

1. Establish and maintain rapport with woman
2. Develop culturally sensitive educational materials and shared decision making practice processes re. the availability of postpartum LARC as a contraception option during delivery hospitalization.
3. Assure that documentation systems are updated to include postpartum LARC counseling and education.
4. Have an inter-professional team review patient education materials for relevance, clarity, and accuracy.
5. Ensure that patient education materials are written using understandable terminology for all patient educational levels.
6. Have LARC samples available for demonstration
7. Determine the process for non-English speaking women to obtain counseling and education materials.
8. Outline risks and benefits of immediate postpartum LARC placement.
9. Map contraceptive choices for women who do not want placement of immediate postpartum LARC.
10. Consider and explore potential barriers to using LARC methods of contraception
11. Consider how a woman’s experiences may influence her responses to contraception counseling, particularly in relation to race and income.
12. Provide post-placement patient educational materials.
13. Confirm the woman’s understanding of LARC method by asking her to repeat information provided
14. Encourage questions
15. Consider talking points such as:
 - a. Effective – more effective than the pill, patch, or ring

- b. Low or no hormones
- c. Safe – safe, easy to remove, and won't affect future fertility
- d. Easy to use – don't have to remember to do anything for them to work
- e. Reversible – can be removed anytime; can get pregnancy right away after removal
- f. Long lasting – are effective for 3, 5, or 10 years

Potential Challenges

- There is no current validated patient education tool specific to immediate postpartum LARC.
- Inability for the woman to understand education presented and/or materials provided.
- Education not provided
- Education and materials are not effective
- Mother gives birth prior to education and counseling (preterm birth, no prenatal care, precipitous birth)

WHO: Medicine, nursing, nursing educator or clinical nurse specialist, lactation consultants, pharmacist

<p>Potentially Better Practice #6: Coding, Billing, Reimbursement</p>
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Rationale: Delivering institutions will be reimbursed for LARC devices (IUDs and implants) in addition to labor and birth charges. In addition, providers will receive reimbursement for the insertion procedure. All institutions should have an established billing procedure to include the proper billing codes, identified mechanisms to reconcile reimbursements with patient accounts, and a system to monitor and resolve denials.

Implementation Strategies

1. Buy in from institutional leadership
2. Determine appropriate billing codes and requirements for reimbursement.
3. Test billing codes and processes to assure adequate and timely reimbursement.
4. Ensure that all IT systems and/or paper charts are modified to document coding, billing, and reimbursement.
5. Track reimbursement of LARC devices and implants.
6. Determine process for opened – but not used – devices and implants.
7. Create provider order sets or add to billing forms (determined by institutional processes). Order sets should include the contraceptive device and local anesthetic.

Potential Challenges

- Use of inaccurate billing codes resulting in ineffective billing and reimbursement
- Lack of reimbursement
- Up front cost of stocking devices too expensive
- Patient cost
- Lack of private insurance plan coverage for LARC method desired by the woman
- Lack of private insurance plan coverage for all types of contraception
- Patient does not have insurance or Medicaid coverage
- Parental consent for teenager
- Lack of insurance coverage for removal of LARC device

WHO: Patient billing, Patient coding, Informatics

Information related to Tennessee Billing and Coding: https://www.acog.org/-/media/Departments/LARC/TN_PP-VRLAC-PublicMemo.pdf?dmc=1&ts=20180119T1544232070

Code Description	HCPCS Code
Intrauterine copper contraceptive (ParaGard™)	J7300
Levonorgestrel-releasing intrauterine contraceptive system (SKYLA™), 13.5 mg	J7301
Levonorgestrel-releasing intrauterine contraceptive system (Mirena™), 52 mg	J7298
Levonorgestrel-releasing intrauterine contraceptive system (Kyleena™), 19.5 mg	Q9984
Levonorgestrel-releasing intrauterine contraceptive system (Liletta™), 52 mg	J7297
Levonorgestrel implant system, including implants and supplies	J7306
Etonogestrel implant system (Nexplanon™), 68 mg	J7307

Code Description	CPT Code
Insertion of intrauterine device (IUD)	58300
Insertion, non-biodegradable drug delivery implant	11981

Code Description	ICD-10-CM Codes
Encounter for initial prescription of IUD	Z30.014
Encounter for initial prescription of implantable subdermal contraceptive	Z30.017
Encounter for insertion of IUD	Z30.430

Code Description	ICD-10-PCS Codes
Insertion of contraceptive device into uterus, via natural or artificial opening	0UH97HZ
Insertion of contraceptive device into right upper arm subcutaneous tissue and fascia, percutaneous approach	0JHD3HZ
Insertion of contraceptive device into left upper arm subcutaneous tissue and fascia, percutaneous approach	0JHF3HZ

EXAMPLE IMPLEMENTATION AND EVALUATION CHECKLIST FOR FACILITY USE

Steps	Specifics
1. Stakeholder Partnerships	<ul style="list-style-type: none"> ○ Administration <ul style="list-style-type: none"> <input type="checkbox"/> Education and buy-in <input type="checkbox"/> Approval as indicated ○ Provider (physicians, CNMs, NPs) <ul style="list-style-type: none"> <input type="checkbox"/> Education and buy-in <input type="checkbox"/> Informed Consent process defined ○ Nursing <ul style="list-style-type: none"> <input type="checkbox"/> Education and buy-in <input type="checkbox"/> Determining processes/practices for insertion of immediate postpartum LARC (e.g., environment, unit) <input type="checkbox"/> Policy, guidelines, procedure development <input type="checkbox"/> Supplies list ○ Quality Improvement Team (if applicable) ○ Risk Management Team (if applicable in your institution) ○ Pharmacy or Supply Chain <ul style="list-style-type: none"> <input type="checkbox"/> Vendor contracts <input type="checkbox"/> Inventory for estimated use <input type="checkbox"/> Distribution plan <input type="checkbox"/> Device stocking <input type="checkbox"/> Restocking process ○ Billing/Finance <ul style="list-style-type: none"> <input type="checkbox"/> Determine billing submission process <input type="checkbox"/> Determine appropriate codes for inpatient insertion <input type="checkbox"/> Charge documentation process ○ Computer Technology <ul style="list-style-type: none"> <input type="checkbox"/> Clinical documentation in electronic medical record – determine required changes <input type="checkbox"/> Charge capture process ○ Patient education materials available and distributed
2. Implementation	Go Live Date: _____
3. Process Improvements (as indicated)	○ As determined by monthly analysis of data and participating facility feedback
4. Project Evaluation	<ul style="list-style-type: none"> ○ Data collection (ongoing throughout the project) ○ Analysis of data <ul style="list-style-type: none"> - Monthly - Following completion of project ○ Post project debrief

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ADDITIONAL RESOURCES



ACOG Clinical Training Opportunities

All health care providers performing LARC insertions must complete appropriate training. Providers performing implant insertions and removals must complete manufacturer training. ACOG's LARC Program provides a list of clinical training for each of these devices.

For information on training sessions, visit: <https://pcainitiative.org/>

Family Planning National Clinical Training Center

- For a list of training opportunities, visit <http://www.ctcfp.org/larc/>
- For more information, contact Kimberly Carlson at 1-866-91-CTCFP (1-866-912-8237) or carlsonkim@umkc.edu

Method-Specific Training Opportunities

- Liletta® (LNG IUS)—Medicines360
 - To watch an online insertion and removal video, visit <https://liletta.biodigital.com/#/>
 - To request a training, visit: <https://www.lilettahcp.com/resources/insertion>
 - For more information, call 1-415-951-8700 or visit: <http://medicines360.org/connect>
- Mirena® (LNG IUS)—Bayer HealthCare Pharmaceuticals
 - To request a training, call 1-888-84-BAYER (1-888-842-2937)
 - For more information, visit: <http://hcp.mirena-us.com/who-is-right-for-mirena/>
- Nexplanon® (Contraceptive implant)—Merck & Co., Inc.
 - To request a training, call 1-877-467-5266
 - For more information, visit: <http://www.nexplanon-usa.com/en/hcp/services-and-support/request-training/request-form/index.asp>
- ParaGard® (Copper IUD)—Teva Women's Health, Inc.
 - To request a training, call 1-877-PARAGARD (727-2427)
 - For more information, visit: <http://hcp.paragard.com/>
- Skyla® (LNG IUS)—Bayer HealthCare Pharmaceuticals
 - To request a training, call 1-888-84-BAYER (1-888-842-2937)
 - For more information, visit: <http://hcp.skyla-us.com/contact-us/>
- Kyleena – Bayer Health Care Pharmaceuticals
 - To request a training, call 1-888-84-BAYER (1-888-842-2937)
 - For more information, visit: <https://www.kyleena-us.com/>
- University of California, San Francisco (UCSF) Bixby Center for Global Reproductive Health

The Beyond the Pill program partners with health care providers, researchers, and educators to improve women's access to effective contraception and reproductive health care. This training program is designed to increase provider knowledge and skills for IUDs and implants, and improve women's access to these methods of birth control.

 - To view an online training, visit: <http://beyondthepill.ucsf.edu/online-training>

- To request an on-site training, contact Jennifer Grand at 1-415-502-0331 or Jennifer.Grand@ucsf.edu
- For more information, visit: <http://beyondthepill.ucsf.edu>
- Upstream USASM provides onsite, comprehensive consulting and technical training to health centers so that they can provide the full range of contraceptive methods, same day, including IUDs and implants. This training includes CME/CE accredited content for clinicians such as IUD and Nexplanon placement skills. In addition, it offers counseling tips for health educators, counselors, and medical assistants as well as in depth revenue cycle management assistance and/or coding review for billing and financial staff.
 - To request a training, email Peter Belden at peter@upstream.org
 - For more information, visit: <http://www.upstream.org>

NOTE: This ACOG resource was last updated on February 19, 2016. Please email Mica Bumpus, LARC Program Manager, at MBumpus@ACOG.org with suggestions or comments. The resources listed above are for information purposes only. Referral to these sources and sites does not imply the endorsement of ACOG. Further, ACOG does not endorse any commercial products that may be advertised or available from these organizations or on these web sites. These lists are not meant to be comprehensive. The exclusion of a source or site does not reflect the quality of that source or site. Please note that sites and URLs are subject to change without notice.

INTERESTED IN INSERTING LARC POSTPARTUM? Go to online instruction at:
<http://www.cardeaservices.org/resourcecenter/inserting-long-acting-reversible-contraception-larc-immediately-after-childbirth> OR

[Immediate Postpartum Intrauterine Device Insertion Training Workshop](#) is a video-based workshop, created at Stanford and University of Colorado, Denver that combines video-based learning with simulation, including instructions on how to build the simulation model used in the video.

The ACOG LARC Program’s Immediate Postpartum Webinars - Immediate Postpartum Initiation of LARC Methods:
https://live.blueskybroadcast.com/bsb/client/CL_DEFAULT.asp?Client=490885&PCAT=2791&CAT=8604

- **State Quality Improvement Project Websites**
 - Delaware Toolkit: <http://www.upstream.org/delawarecan/>
 - Florida Toolkit: <http://health.usf.edu/~media/Files/Public%20Health/Chiles%20Center/FPQC/Access%20LARC%20Application%20Guide.ashx>
 - Indiana Toolkit: <https://www.ihaconnect.org/Documents/LARC%20Tool%20Kit.pdf>
 - Ohio Toolkit:
 - South Carolina Toolkit: <http://www.choosewellsc.org>; http://static.nichq.org/prevention-toolkit/resources/postpartum_larc_toolkit.pdf
 - West Virginia Toolkit: <http://www.astho.org/Maternal-and-Child-Health/Increasing-Access-to-Contraception/West-Virginia-Postpartum-LARC-Toolkit/>

- **Association of State and Territorial Health Officials (ASTHO)**
<http://www.astho.org/MCH/LARC/LARC-8-Strategies-for-Success/>
 ASTHO: state monitoring tool: <http://www.astho.org/Maternal-and-Child-Health/Increasing-Access-to-Contraception-Resources-from-States-Partners-and-ASTHO/?terms=LARC>
 1. Facility billing
 2. Coverage
 3. Uptake
 4. IUD removals
 5. Implant removals

- **Centers for Disease Control (CDC)**

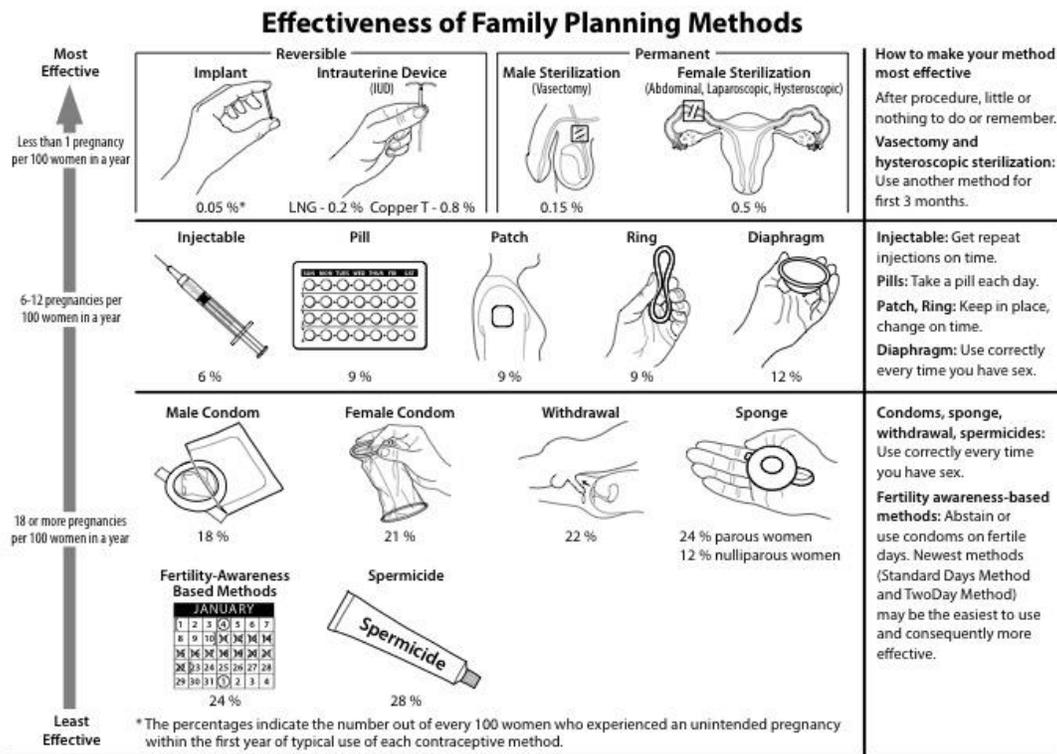
<https://www.cdc.gov/sixteen/docs/6-18-evidence-summary-pregnancy.pdf>

U.S. Medical Eligibility Criteria (US MEC) for Contraceptive Use
<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>

Categories of medical eligibility criteria for contraceptive use

Category 1	A condition for which there is no restriction for the use of the contraception method.
Category 2	A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
Category 3	A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
Category 4	A condition that represents an unacceptable health risk if the contraceptive method is used.

Source: Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. Medical Eligibility Criteria for Contraceptive Use. MMWR 2016;65(No. RR-3)



CS 242797



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CONDOMS SHOULD ALWAYS BE USED TO REDUCE THE RISK OF SEXUALLY TRANSMITTED INFECTIONS.

Other Methods of Contraception

Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.

Emergency Contraception: Emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy.

Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO, 2011; and Trussell J. Contraceptive failure in the United States. *Contraception* 2011;83:397-404.

- **Centers for Medicare and Medicaid Services**
<https://www.medicaid.gov/federal-policy-guidance/downloads/sho16008.pdf>
- **Jacob's Institute of Women's Health: Bridging the Divide**
<https://publichealth.gwu.edu/projects/jiwh/bridging-divide>
- **Kaiser Family Foundation: Medicaid Coverage of Family Planning Benefits: Results from a State Survey**
<https://www.kff.org/report-section/medicaid-coverage-of-family-planning-benefits-results-from-a-state-survey-reversible-contraception/>
- **LARC FIRST:** <http://www.larcfirst.com/index.html>
- **National Women's Law Center Issue – Birth Control**
<https://nwlc.org/issue/birth-control/>

- **National Institute for Children’s Health Quality (NICHQ): Strategies to Increase Access in Long-Acting Reversible Contraception (LARC) in Medicaid**
<http://www.nichq.org/resource/strategies-increase-access-long-acting-reversible-contraception-larc-medicaid>
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