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Implementation of Immediate Postpartum Long Acting Reversible Contraception Programs in Hospitals across Georgia, United States of America: A Qualitative Study

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ABSTRACT

Implementation of Immediate Postpartum Long Acting Reversible Contraception Programs in Hospitals across Georgia, United States of America: A Qualitative Study

By Barwani Khaura Msiska

Objective: To understand how hospitals implement steps to offer Long Acting Reversible Contraception (LARC) devices in the immediate postpartum period within the state of Georgia and identify barriers to and facilitators of immediate postpartum LARC implementation programs.

Methods: We conducted focus group discussions with 8 immediate postpartum LARC hospital implementation teams across the state of Georgia. Grounded theory principles were applied to data collection and analysis stages. We used the Immediate Postpartum LARC Implementation Guide stage-based approach developed by Hofler (2017) to understand hospitals execution of implementation steps and validated it.

Results: The study demonstrated that implementation of immediate postpartum LARC programs is cyclical and requires multidisciplinary coordination to execute individual steps. Hospital immediate postpartum LARC implementation teams identified four essential themes for successful implementation and sustainability of immediate postpartum LARC programs: (1) early multidisciplinary buy-in and establishment of a hospital implementation team; (2) continuous training of key stakeholders including the hospital implementation team and patient education; (3) payer preparedness for sustaining and expanding LARC programs, including establishment of a functional reimbursement system and monitoring of the implementation process; and (4) engaging stakeholders beyond the hospital. Hospital implementation teams' feedback also revealed key areas for improvement of Georgia's Immediate Postpartum LARC toolkit. Recommendations for the revision of the toolkit were made to reflect these findings including identified anticipated barriers.

Conclusion: Application of our findings in the revision of the toolkit will allow us to: improve anticipatory guidance provided to states and hospitals considering implementation and sustainability of their programs. A holistic framework may facilitate sustainability of immediate postpartum LARC programs by analyzing the interaction of the enabling environment, supply side, and demand side of each stage in the implementation process.

Implementation of Immediate Postpartum Long Acting Reversible Contraception Programs in Hospitals across Georgia, United States of America: A Qualitative Study

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A thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
in partial fulfillment of the requirements for the degree of
Master of Public Health in Global Health.
2017

ACKNOWLEDGEMENTS

First, I would like to thank God for guiding me through this thesis process.

Second, I would like to thank my thesis advisor Kate Winskell, PhD. Your constant support, patience, insights and your nuanced approach were invaluable to the development of this thesis and my experience at Rollins.

Third, I would also like to thank my committee member Melissa Kottke, MD, MPH, MBA. I am grateful for the opportunity to learn from you and be part of the Implementation of Immediate Postpartum Long Acting Reversible Contraception Programs research team under Jane Fonda Center, Emory University School of Medicine. Your passion, dedication, expertise and gentle guidance kept me aligned with the aims of the study.

Special thanks to Lisa Hofler, MD, MPH, MBA, who conducted the first phase of the study. Your dedication in translating policy into actionable processes was critical to this process. Thank you for letting me be part of your journey. Thanks also to Sarah Cordes, MPH, who conducted the follow-on focus group discussions with me. Thank you for making this a fun learning process; I learnt a lot from you.

I would also like to thank all the members of hospital implementation teams for taking the time to share your experiences in implementing immediate postpartum long acting reversible contraception programs. This thesis project would not exist without your insights and tremendous work. I hope these thesis results and recommendations make a valuable impact on implementation of immediate postpartum long acting reversible contraception programs in Georgia.

Lastly, I would like to thank my sister and mum for their support during this project and my time at Rollins.

The study was supported by a grant from the Society of Family Planning Research Fund.

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CHAPTER 1: INTRODUCTION

Introduction and Rationale

United States of America

In 2006, approximately half of all pregnancies in the United States of America (U.S.A.) were unintended, giving the U.S.A. the highest rate of unintended pregnancies among all high-income countries at 49%. Pregnancy was most likely to be unintended among younger teens 15 years and below, with 98% of pregnancies in this age group being unintended [1]. Nearly 1 in every 5 teen births is a repeat birth [2]. Women and girls with higher rates of unintended pregnancies are characterized by low socio-economic status, younger age, low education status, cohabitation with partners, and/ or minority group background. Unintended pregnancy is recognized as one of the key challenges and priority areas for public health; it is one of the priorities in Healthy People 2020 under the family planning goals [1, 2].

Multiple studies (e.g. [3, 4]) have demonstrated that unintended pregnancies reduce the interpregnancy interval. The World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) recommend an interpregnancy interval of more than or equal to 27 months [5]. Interpregnancy interval is the timing between a live birth and the next pregnancy. An interpregnancy interval below 18 months' increases risk of adverse birth outcomes, such as low birthweight, small gestational age, preterm birth, maternal anemia, third trimester bleeding, maternal mortality, and neonatal death. Additionally, high health care costs for girls and women are associated with rapid repeat pregnancy [6, 7].

Low access to and incorrect use of effective contraception methods are the main contributors to unintended pregnancy [1, 8]. Low access to contraception is due to the cost of contraception methods, high out of pocket costs, insertion and removal procedure for long acting reversible contraception (LARC) methods, limited over the counter contraception options, low comprehensive sexuality information and limited access to reproductive health services. Not all women who want to use a contraception method to meet their reproductive health intentions are currently using any method [8, 9]. The National Survey of Family Growth shows that 61.7% of all women between the ages of 15– 44 years use a form of contraception: 16% oral pills, 9.4% male condoms, 15.5% female sterilization, and 7.2% LARC. However, the majority of women and their partners continue to rely on short acting contraception methods, which comprise oral pills, condoms, vaginal rings, and injectable contraception [10]. Short acting contraception methods are the least effective contraception methods and have low continuation rates. Additionally, these contraception methods are user-dependent, which requires that the user remembers to consistently take and refill prescriptions to maintain effectiveness of the contraception method. Among all women and men using contraception, the method mix share is: 25.9% pills, 25.1% female sterilization, 15.3% male condom, 11.6% long acting reversible contraception (intrauterine device and contraceptive implant), 8.2% male sterilization, 4.8 % withdrawal, 4.5% the injectable contraceptive, 2.6% contraceptive ring, and 2.0 % other methods [11]. Women between the ages of 25-34 were twice as likely to use LARC at 11% in comparison to younger women aged 15-24 years at 5.0% and older women aged 35- 44 years at 5.3% [8, 9]. To date, oral contraceptive pills, female sterilization, and male condoms have remained the most popular contraception methods and their utilization trends from 2006-2010 and from 2011-2013 have been similar [9].

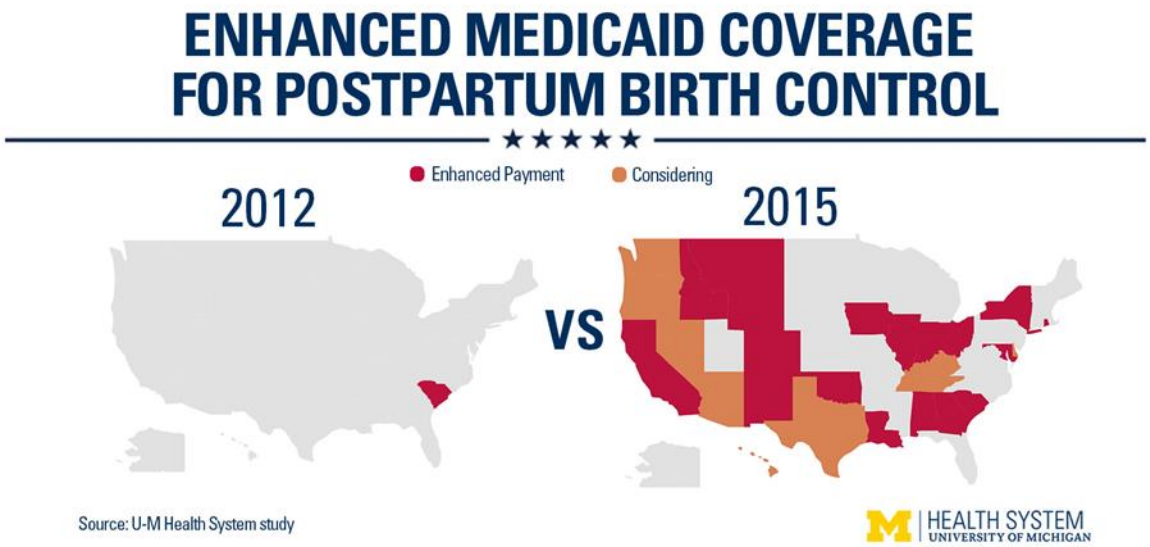
Total government birth-related expenditure in 2010 was $40.8 billion; half of the costs were attributed to prenatal care, delivery and postpartum care due to unintended pregnancies, including miscarriages, abortions and births [12]. The Guttmacher Institute in 2015 estimated that public expenditure on unintended pregnancies would have been 75% higher in 2010 without the publicly funded family planning programs [12]. A 2016 report by Kaiser Family Health estimates that half of all births were covered by Medicaid in 2016 compared to 45% in 2008 [6]. This provides an opportunity for Medicaid agencies to expand and implement policies that aim to provide affordable and accessible contraception services to improve maternal and neonatal health outcomes by reducing unintended pregnancy. Additionally, a dollar invested in a publicly funded contraception services program saves almost $6 of health care costs, reducing health care system expenditure [13]. Contraceptive methods offer the most effective approach to reducing unintended pregnancy, increasing interpregnancy interval, and facilitating cost savings.

The American Congress of Obstetricians and Gynecologists (ACOG), the CDC and the WHO support offering the full range of affordable and accessible contraceptives to reduce unintended pregnancies [5, 14]. Male sterilization, female sterilization and LARC, which includes the intrauterine devices and contraceptive implants, are the most effective contraceptive methods; after the procedure or insertion of the device the user doesn't have to do anything to maintain effectiveness of the method. Less than 1% of women using these methods get pregnant after a year of typical use; the implant has the lowest failure rate at 0.05%. The following contraception methods require a refill of prescription, and/or proper and consistent use by the user to maintain method effectiveness: the pill, injectable, vaginal ring, patch and diaphragm. Within the first year of typical use between 6-12% of women using these methods can experience an unintended pregnancy; the diaphragm has the highest failure rate among this group at 12%. Furthermore,

LARC methods have the highest 12-month continuation rates at 86.2% compared to non-LARC methods at 57%. LARC methods are reversible and the most effective contraception methods. ACOG, CDC and WHO recommend that LARC be offered to all adolescents and women who meet the medical eligibility criteria for optimal effectiveness of contraception use reducing the probability of unintended pregnancy. These methods can be used by nulliparous and multiparous women [15]. However, short acting methods remain popular in the U.S.A. due to cost and access barriers associated with LARC.

The government increased its efforts to offer a full range of contraceptive methods and remove barriers for potential contraception users in 2010 through the passing of the Affordable Care Act (ACA). ACA's mandate for contraception coverage and the family planning goals in Healthy People 2020 aim to increase the proportion of pregnancies that are wanted and increase the number of publicly funded clinics with Food and Drug Administration (FDA) approved contraception methods. This facilitated Medicaid agencies approving coverage for immediate postpartum LARC placement outside of the global fee for delivery since 2011. The aim of the policy was to increase access and remove financial barriers for hospitals to offer immediate postpartum LARC placement [16]. Figure 1 shows the 2012 and 2015 status of Medicaid agencies with and considering payment coverage for LARC in the immediate postpartum period developed by University of Michigan, Health System Study [17].

Figure 1. **Enhanced Medicaid Coverage for Postpartum Birth Control**



This reimbursement policy expands access to the most effective contraception to all women of reproductive age especially those who experience high rates of unintended pregnancy and are eligible for Medicaid benefits due to their socio-economic status. The immediate postpartum period is recognized as a safe time and indeed the perfect time for LARC insertion as the hospital setting and resources required for the procedure are convenient for the patient and the provider. Furthermore, the provider is certain that the woman is not pregnant and frequently women are more motivated to avoid unintended pregnancy at this time. Immediate postpartum LARC methods are recommended for breastfeeding women and reduce missed opportunities for contraception use as ovulation for most women resumes between 6-7 weeks after delivery and 60-70% of women

are sexually active by 6 weeks postpartum. Use of immediate postpartum LARC is associated with reduced rapid repeat pregnancy and increased interpregnancy interval [3, 18].

Georgia

The state of Georgia has poor maternal and child health outcomes which are attributed to the high rate of unintended pregnancies. The Guttmacher Institute reported that 60% of all pregnancies in Georgia were unintended in 2010; 58% of unintended pregnancy resulted in births, 28% in abortion and the rest in miscarriage. In 2010, the state's expenditure on unintended pregnancies was $ 917.4 million. In 2011, Georgia's maternal mortality ratio was 28.7 per 100,000 live births, which was higher than the nation's maternal mortality ratio of 15.9 per 100,000 live births [19, 20]. Pregnant women and girls in Georgia have the poorest prenatal care across all states, which is made evident by 15.95% of birth data missing a prenatal care measure in 2016 [19]. Prenatal care promotes healthy lifestyle through regular medical checkups to assess fetal development and the pregnant women's health, management of discomfort and potential health problems during pregnancy. Poor prenatal care is associated with high rates of premature births and infant mortality. In the state of Georgia in 2016, 10.8% of births were premature and infant mortality was 7.2 per 1000 live births of children under one year of age [19, 21].

Teens aged 15-19 years in Georgia are more likely to be mothers compared to other states; Georgia was ranked 14 out of 51 states on high teen birthrate in 2011 [22]. However, the teen birth rate seems to be on the decline with 25.6 births per 1,000 girls in 2015, a -10% change in teen birth rate from 2014. Furthermore, Georgia teen childbearing expenditure was $395 million in 2010. The decline in the teen birth rate over time saved the state of Georgia $492 million in teen related

pregnancy costs in 2015. However, 18% of all teen births were to teens who already had a child. A short interpregnancy interval is associated with poor perinatal outcomes; teenagers are more likely to have preterm births and infants with low birth weight [23].

In order to address the high rate of unintended pregnancy and high rapid repeat pregnancy rates as key contributors to poor maternal and child health outcomes, Georgia's Department of Community Health approved a Medicaid waiver in April 2014 for reimbursement of immediate postpartum LARC placement for hospitals and physicians fees separately from the global fee for delivery [24]. This policy aimed to remove hospital financial barriers in the provision of LARC and thereby to improve access for women [25]. Additionally, Medicaid covered all birth related costs for 54% of births in Georgia in 2015 and 60% in 2014. The policy provided an opportunity to expand access to the most effective contraception methods at the optimal window, in the immediate postpartum period [26].

Georgia Perinatal Quality Collaborative

Georgia Perinatal Quality Collaborative (GAPQC) is a collaborative effort to identify and implement quality improvement strategies for maternal and neonatal outcomes in Georgia that was launched in November 2012. Neonatologists, obstetricians, midwives, public health professionals and other stakeholders were prompted by Georgia's poor performance nationally on maternal and infant health indicators. Representation from the Georgia Hospital Association, the Georgia Chapter of March of Dimes and the United Way of Greater Atlanta make up part of the group. Current initiatives include: Newborn Screening for Critical Congenital Heart Defects, and LARC for Immediate Postpartum Use. The LARC initiative focuses on increasing the interpregnancy

interval to greater than 24 months with a goal of improving maternal and neonatal outcomes. This quality improvement initiative seeks to increase the number of women whose birth costs are covered by Medicaid that receive LARC in the postpartum period by 15% [27]. Members of the collaborative identified a gap in LARC knowledge, competence in device placement of LARC, and a need for guidance on how to institute LARC programs within the hospital. The initiative in collaboration with Emory's Department of Gynecology and Obstetrics developed Georgia's Immediate Postpartum LARC Toolkit which includes: immediate postpartum LARC sample consent forms, billing and coding examples, the provider resource guide, and other documents. The initiative supports the state by providing anticipatory guidance and capacity building for immediate postpartum LARC programs through trainings and monthly monitoring phone calls with hospitals across the state.

Jane Fonda Center - Emory University School of Medicine, Department of Gynecology and Obstetrics

The Jane Fonda Center is a key stakeholder in immediate postpartum LARC implementation in Georgia. The center seeks to advance scientific knowledge on adolescent reproductive health and the dissemination of information and strategies for healthy transition to adulthood. This center is housed under the Emory School of Medicine, Department of Gynecology and Obstetrics, Family Planning Division. The center's areas of interest include: social and institutional change, adolescent reproductive health, family planning, teen pregnancy and parenthood, health disparities, and use of technology to improve health service delivery, among others. The center has implemented a research project on immediate postpartum LARC in Georgia since 2013 designed to explore, characterize and understand the steps in the immediate postpartum

LARC implementation process. The project also seeks to document individual hospital experiences with an emphasis on facilitators and, barriers and iterative adaptation of the process for sustainability [28]. Hofler (2017), highlights findings from the first phase of the research project which was conducted between 2014-2015 by means of interviews with key stakeholders involved in the immediate postpartum LARC programs in Georgia [29]. The study characterized the immediate postpartum period by a stage-based approach. Implementation was grouped into three stages: exploration stage, installation stage, and implementation and sustainability stage. This resulted in the development of an Immediate Postpartum LARC Program Implementation Guide, an accompanying write up describing all the steps involved, key barriers and facilitators for each stage of the implementation process. However, most of these interviews were conducted when hospitals were initiating the implementation process and further understanding of how steps were executed is required as the process progresses. The second phase of study, which culminated into this thesis, was conducted between 2016 and 2017.

Problem Statement

Medicaid agencies in 26 states have immediate postpartum LARC reimbursement policies while 10 agencies are exploring introducing reimbursement policies. Current evidence on implementation of immediate postpartum LARC is limited to programs and studies focusing on implant devices in hospital settings, state agencies' roles and experiences, and key individual hospital stakeholders [29-31]. However, the scaling up and adaptation of immediate postpartum LARC programs in Georgia will only be facilitated by understanding how hospitals are implementing and meeting requirements of each implementation stage. The multi-disciplinary nature of LARC implementation involves inter-departmental coordination and team work among

key stakeholders in the hospital setting, an area which is not well explored. As health departments across the U.S.A. work to improve quality and availability of immediate postpartum services, understanding the implementation process is critical. We sought to expand on Hofler's study [29] by conducting follow up interviews with multi-disciplinary hospital teams on their implementation experiences in order to understand the diverse and comprehensive nature of implementation in each stage. Furthermore, we sought to recommend application of the findings to the revision of Georgia's Immediate Postpartum LARC Toolkit in order to provide anticipatory guidance to hospitals initiating and implementing LARC programs.

Purpose Statement

The purpose of this special studies thesis was to further explore how steps to offer LARC devices in the immediate postpartum period in hospitals across the state of Georgia were executed. Understanding how the steps identified in the first phase of the study translate into different hospitals' experiences, especially in the implementation and sustainability stage, is essential for refining implementation of immediate postpartum LARC programs in Georgia. Additionally, hospital teams' feedback on the steps characterized in the implementation guide and anticipated next steps will facilitate development of policies and revision of Georgia's Immediate Postpartum LARC Toolkit, ensuring that it is responsive, grounded in the hospitals' experiences and adaptive to the implementation facilitators, barriers and hospital needs identified with each stage.

Objective 1: To validate and understand how steps were implemented to offer LARC devices in the immediate postpartum period in different hospitals within the state of Georgia

Objective 2: To identify barriers to and facilitators of immediate postpartum LARC implementation programs in different hospitals within the state of Georgia

Objective 3: To solicit suggestions on the revision of the Immediate Postpartum LARC Toolkit

Significance Statement

The results of this study and their application in the revision of Georgia's Immediate Postpartum LARC Toolkit will provide comprehensive anticipatory guidance to hospitals exploring implementation of the immediate postpartum LARC process and integrating immediate postpartum LARC in their women and children services in Georgia and other states. Furthermore, it will provide insights for payer preparedness before immediate postpartum reimbursement policies are rolled out. It will also inform how Medicaid agencies can support further adaptation of the process, engage appropriate stakeholders within and beyond the health sector to sustain the programs.

Definition of Terms

Long Acting Reversible Contraception Methods (LARC): these are methods of birth control that are highly effective in preventing pregnancy for 3 to 12 years and are not user-dependent. These reversible methods include intrauterine device (IUD) and contraception implant; the user can remove them to get pregnant or to discontinue use [14].

Immediate Postpartum Long Acting Reversible Contraception: long acting reversible contraception methods that can be placed within 48 hours of delivery [14].

Liletta ® Intrauterine Device: is a sterile, levonorgestrel-releasing intrauterine system that prevents pregnancy for up to 3 years. It is a small, T-shaped piece of plastic inserted into the uterus to provide birth control [14].

Mirena Intrauterine Device: is a small, T-shaped plastic frame levonorgestrel-releasing intrauterine system, a hormone realizing IUD that prevents pregnancy for up to 5 years, inserted into the uterus for long-term birth control (contraception) [14].

Nexplanon: is a hormone-releasing birth control implant for use by women to prevent pregnancy for up to 3 years. The implant is a flexible plastic rod about the size of a matchstick that contains a progestin hormone called etonogestrel and it is inserted under the skin of the inner side of the upper arm [14].

ParaGard Intrauterine Device: is a non-hormonal intrauterine device (IUD) which is a small, t-shaped piece of plastic inserted into the uterus to provide birth control. This is a copper IUD

which lasts up to 12 years, and can serve as emergency contraception if inserted within 5 days after unprotected sex [14].

Postpartum period: is the period beginning immediately after the birth of a child and extending for about six weeks [14].

Pyxis: The Pyxis MedStation™ ES system is an automated medication dispensing system supporting decentralized medication management. It helps clinicians safely and efficiently dispense medications while offering ready system integration.

Skyla Intrauterine Device: is a (levonorgestrel-releasing intrauterine system) hormone-releasing IUD that prevents pregnancy for up to 3 years. It is a small, T-shaped piece of plastic inserted into the uterus to provide birth control and it is smaller than Mirena [14].

Acronyms

ACOG: American College of Obstetricians & Gynecologists

CDC: Centers for Disease Control and Prevention

EHR: Electronic Health records

GAPQC: Georgia Perinatal Quality Collaborative

IUD: Intrauterine device

LARC: Long acting reversible contraception

Key words

Long Acting Reversible Contraception, Immediate Postpartum LARC, Reimbursement, postpartum, LARC, IPPLARC

CHAPTER 2: LITERATURE REVIEW

The following literature review was conducted to provide the context and status of the immediate postpartum LARC process across health institutions in the U.S.A. The majority of studies on LARC have focused on the postpartum period, patient needs and provider attitudes, and efficacy of the LARC devices in the immediate postpartum period [14, 32]. However, many factors affect the implementation of immediate postpartum LARC programs, including the needs of health institutions, the interdisciplinary nature of the process, and stakeholders within and beyond the hospital. This review builds on the first phase of this study conducted between 2014–2015 with hospitals and key stakeholders across the state of Georgia [29]. The review seeks to better understand key components, barriers and facilitators of immediate postpartum LARC programs, and how anticipatory guidance can sustain rollout of the process to health institutions and maintain implementation as part and parcel of maternal and child health programs.

Barriers

Cost

Cost of LARC devices (IUD and contraceptive implant) and reimbursement of provider fees have been identified as a key barrier to timely and comprehensive LARC access and provision, especially in the immediate postpartum period. This barrier is exacerbated by: (1) institutional costs for insertion and removal of LARC, (2) low reimbursement payment rate, (3) indirect medical cost, (4) high out-of-pocket costs, and (5) extent of coverage by insurance companies [8, 14, 33].

Cost and Comprehensive Counseling as a Barrier and Opportunity

The contraceptive CHOICE project [8], a prospective cohort study, showed that provision of LARC free of cost to women of child-bearing age 14–45 years who are willing to initiate a new method of contraception increases uptake of LARC. Out of the 10,000 enrolled women, 67% chose LARC, 57 % chose IUD and 11% chose contraceptive implant, while 33% chose short acting methods as their first option. This study demonstrated that women and girls choose and use the most effective methods in delaying pregnancy if financial barriers are removed and comprehensive individualized contraception counseling with LARC as first option is promoted. Furthermore, same day insertion of LARC methods was associated with high willingness and use of LARC methods [8, 34]. The diversity of study participants suggests that any woman of reproductive age

can select and utilize LARC methods if comprehensive contraceptive counseling on the full range of methods and barriers to access are removed, increasing acceptability and use of LARC among women of reproductive age. These findings are significant to justifying state approval for placement of LARC devices in the immediate postpartum period. However, a study conducted with hospitals to understand their needs and processes in implementing LARC programs would provide greater comprehension of outcomes that can influence implementation of immediate postpartum LARC programs further.

A 2013 literature review by Eisenberg et al. identified cost as a major barrier to adolescents accessing LARC, especially the high upfront costs. The review assessed the impact of various payment (private insurance, government funded, self-pay) and financing approaches on LARC uptake among women and adolescents. It found that upfront direct costs such as device price, insertion costs, and indirect medical costs such as transportation to doctor's office are prohibitive [35]. This review of literature provided a framework to analyze how insurance coverage and social factors impact LARC access for adolescents. Further investigation of women's insurance type, preference of contraception method, and trends in LARC use since the implementation of the reimbursement policy would allow assessment of the policy impact.

The Guttmacher Institute explored LARC coverage among private insurance companies across states and found that coverage was guaranteed for methods with high upfront costs when state mandatory coverage was in place. Women were 11 times more likely to obtain an IUD if the out of pocket costs were less than $50 [36]. In a 2014 survey of 250 benefit managers responsible for employee insurance programs, Darroch et al. demonstrated how varied insurance coverage can affect adolescents' and women's ability to access LARC. In this study, 40% of companies covered IUD cost, 42% covered insertion costs, 35% covered removal costs whereas 81% covered oral

contraceptives, and some states required all Food and Drug Administration approved drugs and devices to be covered [6,7]. An analysis of the California family planning program cost saving on averted pregnancies and subsequent births demonstrated that LARC had the most cost saving per dollar spent for levonorgestrel implant at $15.90 and IUD at $7.24 [8]. Benefits of state mandatory coverage for contraception might be intensified for women and girls of low socio-economic status with private and public insurance. Increasing access at the immediate postpartum period might improve cost savings observed in the California family planning programs for the state of Georgia; savings can be reinvested to improve hospitals' capacity to offer LARC.

Facilitators

Reproductive Health Justice

Higgins (2014) argues that with the rise in interest and prioritization of LARC programs across states, clients' rights and choice must remain central to reproductive health programs [8, 37]. She warns of overstating LARC benefits for pregnancy prevention and maternal and child health outcomes without considering the social determinants of health. She proposes the application of a reproductive health justice approach to LARC programs for holistic family planning programs that engages patients as equal partners in their health with special focus on patients' needs, patient education, and provider training. However, she does not offer steps in applying this model, therefore stakeholders cannot operationalize the approach in their programs. However, this study will assess how hospitals are integrating rights based approaches to the provision of services.

The London Family Planning Summit in 2012 stimulated collective political commitment and renewed investment in family planning with a goal of increasing access to contraception for 120 million more girls and women globally by 2020. The summit noted that to achieve the set goal, a client oriented approach to offering contraception methods must be revisited to ensure that patients' consent is not compromised in an attempt to increase access [38]. This facilitated the development of a new conceptual framework for voluntary, human rights based family planning which builds on the International Conference on Population and Development human rights centered approach to sexual and reproductive health. The framework offers an integrated view of family planning programs through the program cycle at various levels from individual to policy, outlining the interconnectedness and complimentary benefits of a human rights approach to a public health issue. The framework also emphasizes multidisciplinary implementation of contraception programs and local ownership and resourcing of programs as key to fulfilling the reproductive intentions of their population. While the framework has great potential to impact the design, implementation and monitoring of family planning 2020 commitments, its adoption and application has been minimal [39].

Implementation and Efficacy

Recent studies have tried to characterize the implementation of Medicaid's immediate postpartum LARC policies. These studies have been limited to payer experiences and roles, individual hospital stakeholders' early steps of initiating the process in hospitals, and clinical provider specific competencies [17, 30, 31]. In a 2015 qualitative study, Moniz et al. identified Medicaid agencies providing immediate postpartum LARC reimbursement, and assessed barriers and facilitators of immediate postpartum LARC uptake at policy level. Reimbursement policy allows for payment of

immediate postpartum LARC device and procedure for Medicaid beneficiaries outside of the labor and delivery global fee, thereby reducing financial barrier to LARC immediately postpartum [17]. The study demonstrated that evidence on improved maternal and child health outcomes and cost savings motivated decision making of Medicaid agencies to roll out the reimbursement policy. However, lack of LARC awareness, misconceptions and buy-in from providers acted as barriers for states to roll out Medicaid's reimbursement policy. At the time of the interviews among forty Medicaid agencies, fifteen were providing separate or increased bundled payment. A bundled payment is a claim for insertion of a LARC device which prompts additional payment for all device placement delivery related care into a single payment. In contrast, nine Medicaid agencies were considering providing enhanced payment and in-patient LARC coverage and sixteen were not considering enhanced payment [17]. In a follow-up publication Moniz et al. assessed experiences of states in implementation of Medicaid immediate postpartum LARC reimbursement policy through qualitative interviews with forty Medicaid representatives; fifteen were implementing the reimbursement policy. The study identified three integral components Medicaid administrators experience with implementation of the reimbursement policy: payer preparedness, monitoring and evaluation of the policy implementation, and health institutions' needs and buy-in. The study highlighted the need for Medicaid agencies to operationalize and maintain billing and reimbursement processes among health institutions. The study also proposed that billing and reimbursement processes in program implementation must include functional charge capture that initiates internal processing of claims at the payer level before and during roll out of the program. She also proposed that the payer review competencies and facilitate training on immediate postpartum LARC implementation and billing procedures for clinical, pharmacy, billing, revenue staff and administrators. Additionally, the study emphasized that the payer must monitor and

evaluate health outcomes related to policy implementation with key clinical and programmatic indicators in collaboration with academic institutions. Moniz et al. suggested that the payer should consider a multi-stakeholder framework to the implementation of the reimbursement policy [31]. Although Moniz et. al proposed actions that payers can take to increase their preparedness and responsiveness towards hospitals, experiences of hospitals with the payer in establishing their implementation process is needed to gain a deeper understanding of the immediate postpartum LARC implementation process.

Multiple cohort and randomized pilot studies [40-42] demonstrate that providers and health institutions with buy-in on the provision of a full range of contraception methods, especially LARC, have significantly higher odds of achieving optimal interpregnancy interval among their clients compared to health institutions with low buy-in. Additionally, the expansion of insertion of LARC devices at different postpartum time periods facilitates use and does not affect breastfeeding patterns [43]. Therefore, hospitals implementing immediate postpartum LARC programs can use these studies to create buy-in among hospital and community stakeholders. A 2014 cohort study of 117,644 women with a second or higher order birth who were Medicaid beneficiaries with a contraceptive claim for 18 months after delivery found that the odds of attaining optimal interpregnancy interval was 3.89 times greater for women using LARC compared to short acting methods and 0.66 times the odds for women not using any contraception method. Each additional month of short-acting contraceptive use increased the odds of achieving optimal interpregnancy interval by 8% [44].

Furthermore, a randomized study of 46 women who desired a contraception method demonstrated that hormonal IUD insertion in the immediate postpartum group (within 10 minutes of placenta delivery), in the early postpartum group (10 minutes to 48 hours postpartum) had

significantly higher expulsion rates compared to interval insertion (at 6 weeks or more). An IUD expulsion rate is expressed in reference to time elapsed since implantation of an IUD, it is the rate of spontaneous rejection of intrauterine contraceptive device in the group of women who use them. The study estimated expulsion rates of 3%-6% during interval placement and between 8%-51% during immediate postpartum placement; breastfeeding patterns were similar among the women with different IUD insertion times [40]. This study can be leveraged especially among lactation consultants and patients during the prenatal period to demonstrate that LARC placement does not affect milk production. However, understanding the perceptions and experiences of lactation consultants would improve the impact of sharing clinical evidence among hospital immediate postpartum LARC implementation teams. There is need to monitor expulsion rates as the reimbursement policies become more established to assess how provider competencies affect insertion techniques.

Tocce et al. (2012) found high continuation rates of immediate postpartum implant among adolescents, 96.9% at 6 months and 86.3% at 12 months. This prospective observational study of adolescents in a prenatal-postnatal program also found that 18.6% of participants not receiving immediate postpartum insertion had become pregnant compared to 2.6% in the intervention group. Adolescents not receiving immediate postpartum insertion had 8 times higher odds of experiencing a repeat pregnancy compared to adolescents receiving the implant immediately postpartum [41]. Furthermore, adolescents' comprehension and preference for immediate postpartum contraception was identified as a key factor in the high continuation rates of the study. This demonstrates that offering immediate postpartum insertion of Nexplanon mitigates against social stressors and addresses limited access to LARC for adolescents. Understanding how best this can be

operationalized with providers through the state's immediate postpartum LARC program will facilitate a decline in teen pregnancy and in rapid repeat pregnancy.

Prager et al. assessed the insertion of intrauterine devices immediately postpartum, specifically looking at efficacy versus timing (immediate versus delayed postpartum insertion of IUD), and makes a case for promoting the IUD to women seeking to delay their next pregnancy through informed choice [42]. The study reaffirmed existing evidence that immediate postpartum placement of IUD is associated with increased expulsion as compared with interval and delayed insertion, however, patient health outcome should determine the risk benefit calculation [40, 42, 43]. The commentary provides a case for copper and hormonal IUD during the postpartum period as safe, long acting, and effective without user-dependence, and cost saving for both the provider, patient and health institution. Furthermore, it explores and challenges clinical misconceptions of postpartum IUDs by providing a detailed step by step insertion procedure for IUD with an eligibility checklist for providers. Clinician competencies in placing immediate postpartum LARC are identified as a key barrier and facilitator in initiating LARC programs [29, 42]. This checklist can be refined by hospitals developing protocols for IUD placement during the immediate postpartum LARC period. However, the study did not explore how the clinicians applied the checklist in placement of IUDs.

Anticipatory Guidance

The South Carolina Postpartum LARC Toolkit is a clinical resource guide which characterizes immediate postpartum LARC implementation in health institutions. The toolkit makes a case for postpartum LARC services in South Carolina, demonstrating reduction of

financial barriers to access to most effective contraception and improved health outcomes with increased patient informed choice. It offers strategies to improve LARC access, which are provider and client centered. A timeline for implementation among multidisciplinary stakeholders, which include clinical staff, billers, pharmacists, and administrators at a health institution, is presented step by step with efficacy and operational research on immediate postpartum LARC devices. Furthermore, prenatal contraceptive counseling is emphasized as a process from the first prenatal visit to ensure patients' reproductive intentions are honored. Patient and hospital procedures are detailed, providing guidance and maintaining standard of care across hospitals. This toolkit provides strategies to mitigate the challenges of the billing and reimbursement system which includes all the billing codes, claim submission, type of billing system to bill accurately at hospital level, and resources for in-patient hospital reimbursement [30]. The toolkit builds on experiences of three hospitals and service providers in those hospitals only. The barriers and facilitators identified are for insertion and removal of the contraceptive implant, which is not as time sensitive and does not require comprehensive development of supportive protocols and procedures for different birth deliveries. Additionally, the toolkit does not explore how hospital implementation teams drive LARC programs and steps. Characterization of the implementation process was limited to training, getting the device in the hospital, documentation, and charting.

This literature identifies facilitators and barriers to implementation of immediate postpartum programs, however, how hospitals execute and sustain LARC placement has not been well documented. Using emic perspectives of hospital immediate postpartum LARC teams, this study will assess if steps characterized by previous studies and insights on how hospitals can implement this process align. Additionally, the study will offer further guidance on how hospitals

at different stages of implementation can easily navigate multidisciplinary steps to move the process forward.

CHAPTER 3: METHODS

This qualitative study was a follow-on study to Hofler (2017), which conducted interviews and site visits between 2014-2015 with key stakeholders within 10 hospitals across the state of Georgia. The purpose of the study was to describe steps taken by hospitals to implement immediate postpartum LARC programs after the roll out of the reimbursement policy. A stage-based approach to immediate postpartum LARC implementation was developed from hospital experiences. However, hospitals were in different stages of implementation at completion of the study [29]. There was an identified need to refine our understanding of the implementation process and provide anticipatory guidance for institutions planning to initiate and maintain LARC programs.

The current study builds on Hofler (2017) and is part of a long-term program under the Jane Fonda Center to explore Implementation of Immediate Postpartum LARC Programs in Georgia. The qualitative study used a semi-structured focus group discussion guide to gain an in-depth understanding of the immediate postpartum LARC implementation process in Georgia hospitals. The focus group discussion guide was divided into three parts based on the application of implementation science to LARC programs using the Promoting Action on Research Implementation in Health Services (PARIHS) framework, similar to Hofler (2017) [29]. PARIHS framework is well-suited for applying the immediate postpartum LARC reimbursement policy into hospital programs; it examines interactions between evidence, context, and facilitation for knowledge translation [45, 46]. The three sections of the focus group discussion guide explored were: hospital status in relation to immediate postpartum LARC implementation, validation of the immediate postpartum LARC guide, and suggestions for comprehensive anticipatory guidance to support implementation team and hospital efforts.

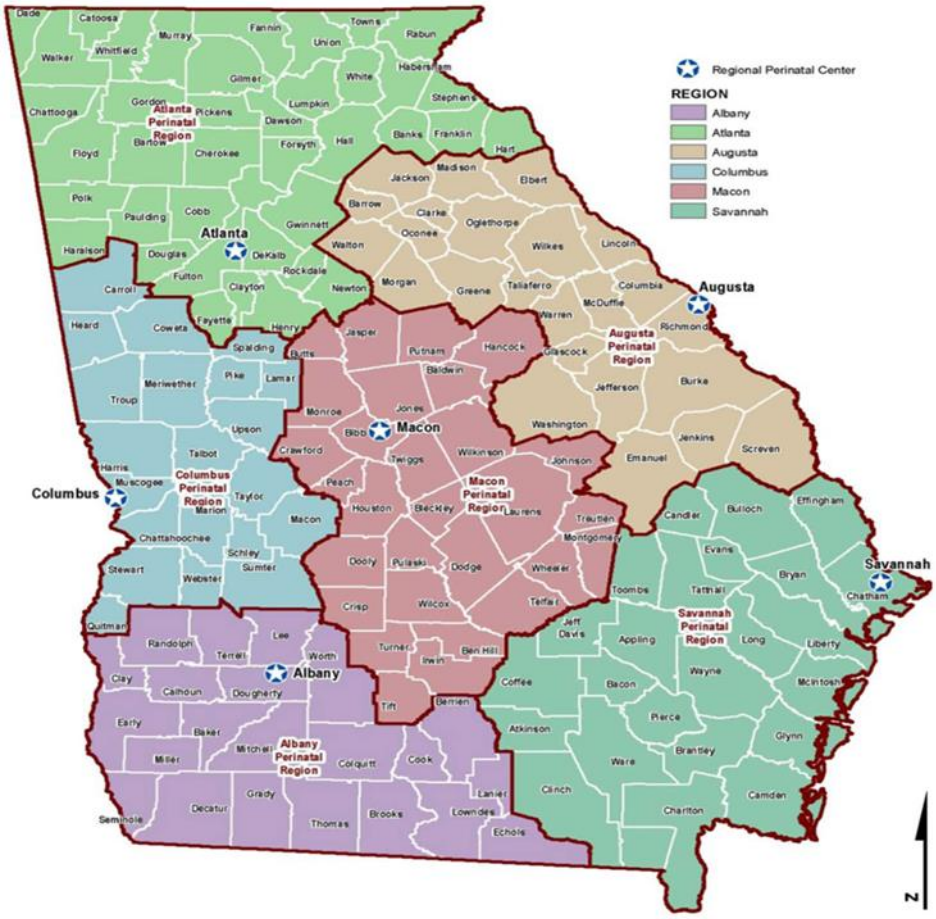
The study was approved by Emory University Institutional Review Board. The guide was piloted with the research team and staff members that were familiar with implementation of immediate postpartum LARC programs. The study had eight sites which included teaching hospitals and regional perinatal centers. These centers are identified by the Georgia Department of Public Health as providing comprehensive perinatal health care for pregnant women, their fetuses and infants of all risk categories. Figure 2 shows a map of Georgia's Regional Perinatal Centers and Perinatal Regions as developed by Georgia Department of Public health [47]. The study sites were maintained from Hofler (2017) to ensure validity of findings, comparison, and comprehensive analysis of implementation progress. Two sites from the previous study were excluded as one did not respond to the request for a follow up visit on time and the other had not begun implementing the program. Study participants were identified through key hospital stakeholders, immediate postpartum LARC hospital champions, and recruited through emails. Eligible individuals were members of the hospital implementation teams from different departments across the hospital. Data were collected between July-August 2016 in hospitals across the state of Georgia. All interviews were conducted face to face, except one which was a telephone call based on team member's availability. Data were collected by two members of the research team. The interviews were recorded after informed consent was obtained from participants. Notes of key issues were taken during each discussion which lasted about 40 minutes. Verbatim transcripts were developed from recordings by a transcription company. The transcripts were checked for completeness and accuracy and the data was de-identified.

The transcripts were read several times and memos were applied to promote immersion in the participants' worlds. A codebook was developed from the memos and based on questions on the focus group discussion guide; twenty-seven deductive, inductive, and in Vivo codes were

developed from the transcripts. The codebook was reviewed by the research team facilitating revision and validation of the codebook. Data were uploaded in MAXQDA version 12 (VERBI Software, Berlin, Germany). Grounded theory was applied to the data to further explore it through description, comparison, categorization of concepts, themes and conceptualization of the data[48, 49].

Data were analyzed per the three-stage approach suggested by the National Implementation Research Network's Stages of Implementation framework and approach applied in the first phase of the study by Hofler (2017). The three stages were exploration stage, installation stage, and implementation and sustainability stage. These three implementation stages are visually depicted in Figure 3 [29, 46]. The stage-based approach was used to validate the draft Immediate Postpartum LARC Program Implementation Guide. Furthermore, stages were used to understand hospital implementation of LARC program and hospital needs for each stage. Figure 4 shows Immediate Postpartum LARC Program Implementation Guide adapted from Hofler (2017): key steps are grouped by stages, starting with exploration, installation, and implementation and sustainability. Steps are organized by stakeholder group: clinical champions, pharmacy champions, financial champions, and IT/medical health records stakeholders [29].

Figure 2. **Georgia Regional Perinatal Centers and Perinatal Regions**



Source: Georgia Department of Public Health. Regional Perinatal Centers [map]. May 2016.

Figure 3. **Stages of Implementation**

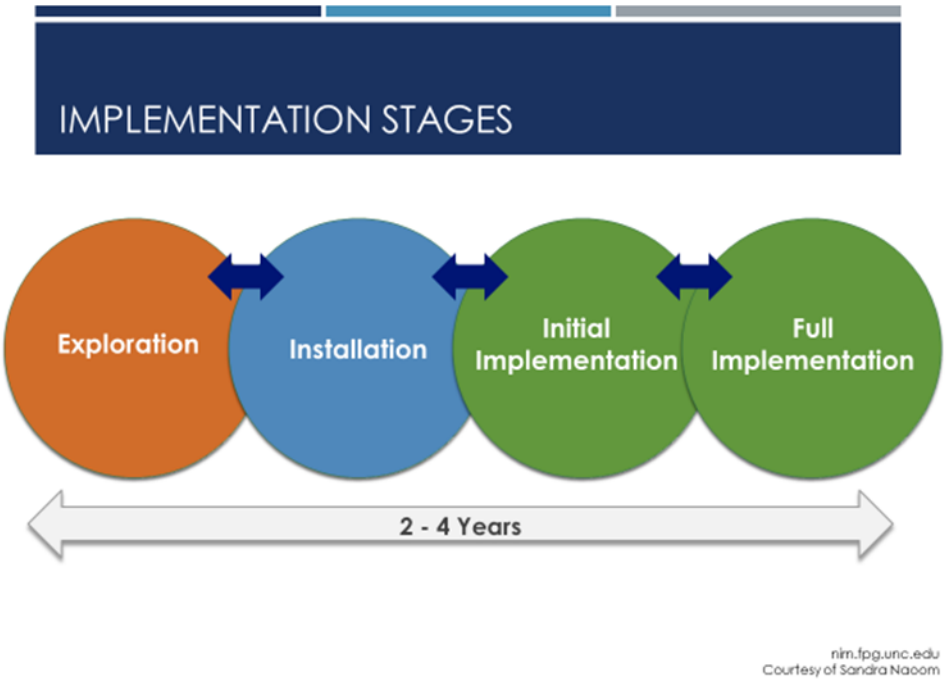
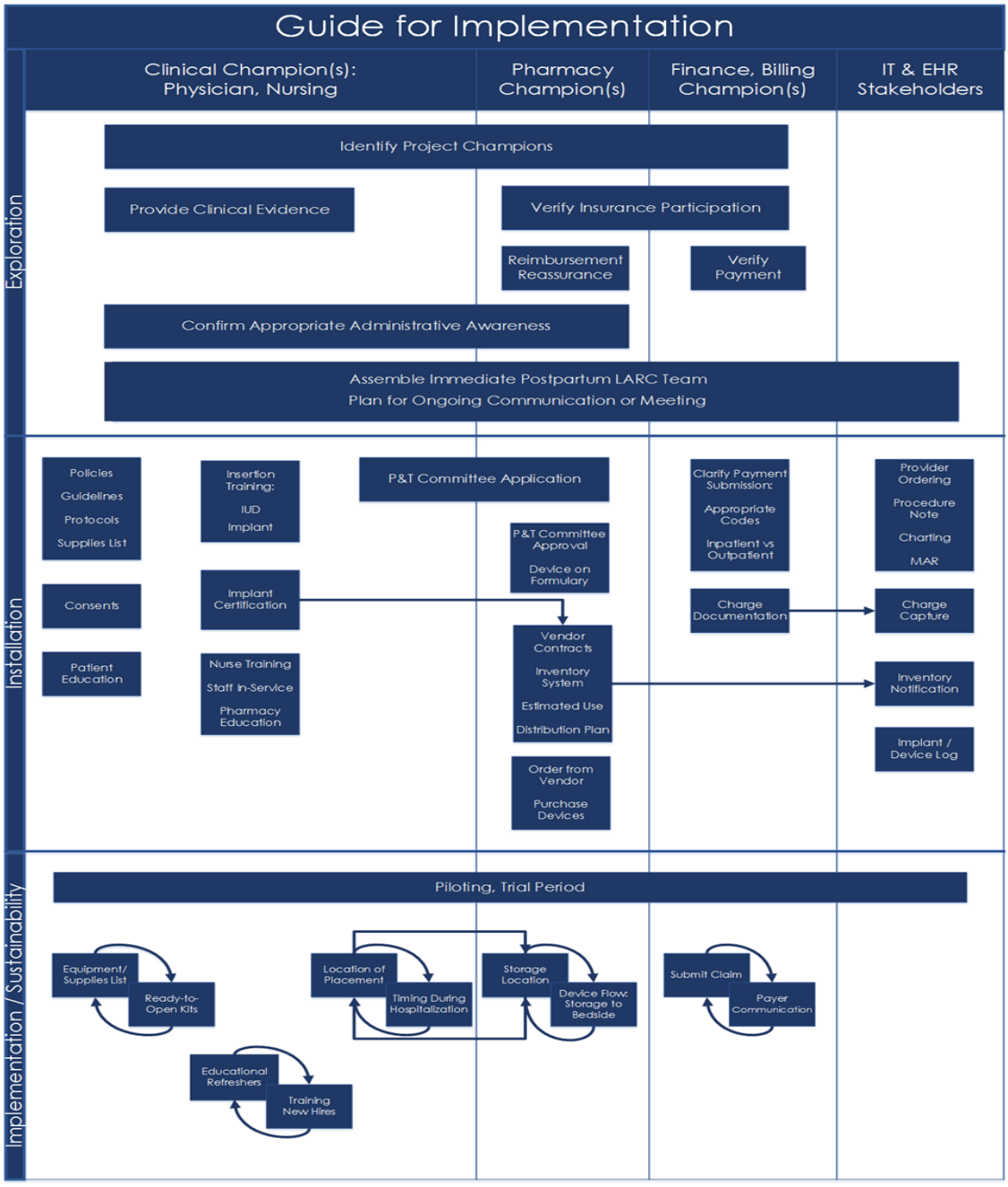


Figure 4. **Immediate Postpartum Long Acting Reversible Contraception (LARC) Program Implementation Guide:**



CHAPTER 4: RESULTS

Study Population

Thirty-four members of immediate postpartum LARC hospital implementation teams were interviewed for this study. These teams were multidisciplinary consisting of nurses, lactation consultants, physicians, pharmacists, administrators, a data manager, and billing and revenue personnel. Most of the study sites were teaching hospitals; six were regional perinatal centers, seven were referral hospitals, and five had obstetrics and gynecology residency programs. Many of the hospitals had a high Medicaid patient population characterized by poor prenatal care. At the time of the interviews all the hospitals were placing immediate postpartum LARC devices, although one was barely placing any devices due to delayed reimbursement by the payer. Three of the eight hospitals were exploring expanding the type of devices offered from one to two. Most of the hospitals were planning to go through the immediate postpartum LARC implementation process again to stimulate greater buy-in and sustainability of the program at their institutions with a focus on identifying a champion from another department, generating greater pharmacy buy-in for the installation stage, the finance and billing steps, the EHR steps for the installation stage, and refinement of the steps in the implementation and sustainability stage. Table 1 shows the characteristics of study participants and hospitals.

Table 1. Characteristics of Study Participants and Hospitals

Participants (n= 34) and Hospital (n= 8) Characteristics	
Professional role	
Physician	9
Nursing	14
Lactation consulting	1
Administration	2
Finance and billing	4
Pharmacy	3
Electronic health records	1
Type of hospital	
Referral hospital	7
Regional perinatal center	6
OBGYN residency programs	5
Implementation of immediate postpartum LARC program	
< 18 months	3
2 years	1
> 2 years	4
LARC devices offered	
Hormonal IUD	5
Copper IUD	2
Implant	8

LARC – Long acting reversible contraception

Stages for Implementation

Exploration stage

This stage involved a health institution assessing the immediate postpartum LARC project and identifying resources to initiate the program. The immediate postpartum LARC program implementation guide has seven distinct exploration steps detailed in Figure 4 [29]. Overall, hospitals reported that the guide was a true reflection of their experiences, although most of the steps happened concurrently and execution was varied across hospitals. All the hospitals had a self-motivated and self-identified project champion, most frequently an OBGYN. As one of the physician champions stated, “So I can say [overall Project Champion/physician] has cleared the way, she’s the machete through the jungle for us (hospital implementation team)”. However, in most of the hospitals project champions across other key stakeholder groups were not identified to compliment the clinical champion as the installation stage progressed, which was in contrast to the guide.

In three hospitals, the project champions were directors of women and children services who were also physicians. In contrast, two hospitals had nursing champions, while the others had attending physicians as champions. The champion usually organized a big meeting to raise awareness of immediate postpartum LARC benefit and the reimbursement policy on immediate postpartum LARC to members of the women and children services. This would be followed by smaller and one-on-one meetings with key stakeholders in the women and children services department. Furthermore, champions used existing meetings such as OBGYN or labor and

delivery weekly review meetings to make a case for immediate postpartum LARC in-patient services. The project champions identified meetings as a platform to assess awareness of and to follow up on the process tasks to initiate and institute the program.

The clinical champions who were mostly OBGYN physicians expressed frustration at getting key hospital stakeholders together for consensus building. For example: a physician champion stated, “There is always the same players at departmental meetings. It’s never who you want, it’s always who already knows what’s going on.” Most of the champions would share the ACOG committee opinion on immediate postpartum LARC and practice bulletin on LARC, Medicaid bulletin and clinical evidence on immediate postpartum LARC with other clinicians, hospital administration, pharmacy and billing personnel, thereby making a case for LARC’s future cost savings and improved health outcomes.

The majority of hospitals did not have scheduled immediate postpartum LARC meetings. They meet on need basis or informally: A clinical champion elaborated on the pattern of the meetings, “We talk with nursing and we talk at our department (OBGYN) meeting or executive committee meeting”. Three hospital teams reported engaging pharmacy and billing stakeholders on limited occasions and close to the end of the exploration stage to verify insurance participation and reimbursement for hospital administration buy-in. Prompting by the hospital administration to show the payer financial reassurance drove most project champions to engage with pharmacy, billing and finance. Although hospitals, which had nurses and physicians as champions engaged their heads of department to make a case for LARC with pharmacy, billing and hospital administration. At one hospital, the director of labor, delivery and perinatal services requested pharmacy to start carrying LARC for in-patient services.

> Prior to bringing them (immediate postpartum LARC devices) here, I (pharmacy champion) would say there wasn't a whole lot of resistance…it was something the medical director had requested from pharmacy for the patients and the rationale was good and we were under the impression that it was going to be for a pretty specific population. ….it was physician demand that really kind of drove it.

Four of the hospitals piloted the submission of claims to the payer, to assess application of appropriate codes and test the billing infrastructure. One hospital had a brief discussion with pharmacy and did not engage them further after initial verification of financial assurance, instead the nursing department facilitated all other pharmacy related steps. The rest of the hospitals through their billing personnel confirmed the institution's insurance participation and payer guarantee of adequate reimbursement of physician and hospital fees.

Implementation teams reported that there were no clear written responsibilities for identified key multidisciplinary stakeholders. However, over time each team member had a general understanding of their role based on their department, for example, a clinical champion said, "pharmacy is responsible for ordering and stocking of devices". Furthermore, identification of the implementation team was based on anticipated needs of the process including department specific steps for full hospital administration buy-in.

The majority of the teams regretted that they had not engaged pharmacy, billing and finance, and EHR key stakeholders earlier in the process. They felt they should have included these stakeholders in all initial meetings and identifying a champion after department buy-in. A nursing champion expressed that, "They (billing and finance, pharmacy and EHR stakeholders) are an important part of the team and moving forward".

Furthermore, all teams identified billing steps as key to hospital administration buy-in, a physician champion stated, “There is need to emphasize the finance and billing steps in exploration stage because hospitals (administration) will not say yes if they don’t see the money (reimbursement assurance and charge documentation)”.

Similar to Hofler (2017), interviews with stakeholders and hospital teams identified Medicaid reimbursement and project champions as key facilitators in this stage [29], complemented by the Georgia immediate postpartum LARC kickoff meeting, clinical evidence and GAPQC monthly conference calls. Barriers included: slow buy-in from pharmacy and billing stakeholders, limited comprehension of LARC among hospital stakeholders, and limited multidisciplinary communication and coordination. As one physician champion stated, “Getting everybody on board and making sure everybody has the same goal and everybody knows the plan. I think that’s key”.

Installation Stage

In this stage, hospitals were getting ready to offer immediate postpartum LARC. The steps taken in this stage varied with hospital size and prior experience with LARC and maternal child health quality improvement programs. Pace of implementing the installation stage in two hospitals that had started going through management changes in between their exploration stage and installation stage was slower compared to other hospitals. A clinical champion stated that, “Our hospital has gone through some changes in the last year so pushing all that through was a little bit slow”. The majority of the hospitals noted that the steps they took were more organic and fewer than those reflected in the implementation guide. Overall, the steps in this stage were described as

essential by participants although time consuming as compared to exploration stage steps. Consistent communication and collaboration between key stakeholders was required to build consensus.

All teams identified training on immediate postpartum LARC that was facilitated by GAPQC and a state clinical medical liaison as key in rolling out the installation stage. Participants noted that the trainings were an opportunity to bridge the gap between hospital buy-in and building clinician competences in placement of LARC devices. Trainings were described as didactic, hands on, focused on IUD insertion and removal practice, sharing lessons learnt from other states, and Georgia hospitals that were placing devices. These trainings were done as part of grand rounds geared towards physicians with attending privileges, OBGYN residents and at times nurses. One of the hospitals that was already placing LARC devices did not have a GAPQC facilitated training. The service providers were aware of LARC and had capacity to place and remove devices. However, the hospital felt that a training focused on benefits, implications and risks of LARC would have promoted greater physician and support staff buy-in for the program. Another hospital which was also implementing a LARC grant before the reimbursement policy approval had policies, procedures and trained clinicians available to offer inpatient LARC services when their hospital administration approved their participation in the program. However, the hospital noted the need for getting all OBGYN trained to offer immediate postpartum LARC as trained physicians were limited to those who directly supported the LARC grant. Most hospitals were not aware of Nexplanon certification requirement for all physicians and felt blindsided when pharmacy informed clinical champions that ordering of device was allowable only under a Nexplanon certified physician. All hospitals had in-person implant trainings facilitated by a Merck Nexplanon trainer. Teams reported that separate trainings on implant and IUD caused delays in their execution

of the clinical steps in installation stage. After implementing physician focused trainings, hospitals realized the need for nursing and support staff training as nurses' roles became more evident; nurses manage medical administrations record that track devices taken out of the Pyxis for a procedure, prepare the delivery room and support placement of devices.

Development and adaptation of the policies and protocols for placing LARC occurred simultaneously with the education and training steps. Training facilitators shared samples of documents for clinical steps (see Figure 1). One of the hospitals that were not placing LARC immediately postpartum before the policy implementation noted that, "It took a while to train the people, get polices and stuff written". Implementation teams reported that they spent less time adapting protocols for in-patient insertion of implants compared to IUDs, which included separate protocol for type of delivery, different insertion techniques, and considerations for safety. Team members noted that the project champion would develop an order set. Then it was shared with pharmacy and billing stakeholders as a first step to facilitate bundled billing for immediate postpartum LARC procedures. Furthermore, to ensure that appropriate codes were applied between the medication administration records managed by the nursing and physician administration records, pharmacy and billing personnel assessed if the systems were documenting the codes as they were inputted. Three institutions created order sets while two institutions created a separate billing procedure for LARC using a brief operative note.

Most hospitals adapted patient education materials while others used materials supplied by the manufacturer of devices. Patient education step usually preceded establishing consent process step; all hospitals either adapted their existing consent forms or used samples shared through GAPQC to suit their needs. The consent step involved mapping out clinicians' considerations and patients' LARC preferences form. Some of the hospitals included a contraception counseling

component to it, which was more detailed for nurses than physicians. All hospital teams perceived patient education as a process that must be initiated in the prenatal period. One physician champion stated, “I mean, when you’re here to deliver is not really the time to discuss LARC”.

On completion of steps that were deemed clinical, clinicians led by the project champion engaged pharmacy to get LARC devices in the hospitals. A nursing champion noted that, “It took a while to get pharmacy to have what we need”. Pharmacy stakeholders informed the project champion and other hospital stakeholders on the need to apply to the Pharmaceutical and Therapeutics (P&T) committee so that the device could be put on formulary. A pharmaceutical and therapeutics committee provides a multidisciplinary forum to implement principles of drug management to minimize waste, improve quality and cost of therapeutics care. Some hospitals noted that the P&T committee buy-in was slow because the membership is diverse, most times wanted proof of guaranteed reimbursement, and preparation of full documentation for the P&T committee was time consuming. One of the participants who was a pharmacy champion stated, “We (pharmacy) brought the device application through P&T committee. There was a lot of back and forth between us (pharmacy) and finance and department of community health because there was a big lag between when that (Medicaid bulletin) was put out and when it was implemented”. When P&T approved the application, device or devices were put on formulary, the hospital’s list of prescription drugs. However, one hospital did not apply to the P&T committee, all the pharmacy steps highlighted in the guide were refined for nursing who ordered and tracked the inventory for the devices in coordination with the clinical department.

Team members were dismayed by the time expended on negotiating and having a vendor contract in place. Teams stated that they would have preferred being forewarned by the payer or

GAPQC on who would be eligible to sign the vendor contract. A clinical champion further elaborated on this,

> The lead into this was that you have somebody who's going to be the medical person to sign on the dotted line and that is not your clinical operations officer, that's one of your physicians and most organizations don't have medical directors. So, they're going to have somebody who's going to be willing to take that on and those conversations need to start to start earlier as opposed to later.

Another clinical champion stated, "I would say if you know a specific LARC require certain things from vendor side, you put it in the toolkit and give people a head up that would be helpful". "I can tell you in our organization getting a contract signed takes a three-month process, just to get in the system".

The majority of the hospitals concurrently undertook pharmacy, finance and billing and EHR steps which were initiated with clinical trainings. The team worked together with pharmacy and EHR after the signing of the vendor contract to set up LARC device inventory systems which initiated submission of electronic purchase orders to device manufacturers systems and accepts response from manufacturers system. This required refining existing information technology infrastructure to immediate postpartum LARC. Completion of this stage included negotiations between the team on expected use and order to be placed. One of the clinical champions stated, "the pharmacy didn't want to stock them (LARC devices) unless we were going to use them, it was the chicken and egg thing and we finally convinced them we would use them. They stocked them". The pharmacy then worked together with the team to come up with a distribution plan to maintain a constant supply of devices which was refined continuously to suit the labor and delivery floor and pharmacy workflow. In this stage, almost all of the hospitals were storing their devices

within a locked room in pharmacy, which created delays and missed opportunities in placing devices especially IUDs, after vaginal and caesarian section deliveries. Pharmacy stakeholders completed steps for ordering and purchasing devices from vendors.

Development of an order list by clinicians facilitated coordination between clinicians, finance and billing step in this stage. In most of the hospitals the project champion shared the Medicaid bulletin with pharmacy and finance and billing, which was followed by the drug policy pharmacist setting up the drug information piece. The finance and billing used that information to get in touch with the payer to confirm that codes shared in the Medicaid bulletin were accurate and functional to facilitate charge submission. Some hospitals were given a short demonstration of how the codes were to be applied for in-patient LARC placement by the clinical (physician and nursing), pharmacy, finance and billing and HER to have a completed charge submission. A clinical champion commented, “When we first got started I think doctors in Atlanta, they gave us whatever we needed and we turned it over to our billers and coders and per them, there’s not an issue”. Then finance and billing personnel worked with information technology team members to ensure that completed charge submission was being documented and captured in the hospital system, thereby making sure that the charge submission process was complete. Team members expressed the need for guidance on how steps in the installation stage can be initiated earlier and inform EHR personnel of needed refinement to the system for immediate postpartum LARC.

Team members across all the hospitals agreed that information technology stakeholders were critical to full operationalization of the program, as they provide the link between charge submission and charge capture. For clinical documentation one of the clinical champions elaborated on the steps their implementation team took, “We have a brief operative note and basically what we’ve done is when we do our delivery, like if we’re to place a LARC, we just do

a whole another separate one so it actually ends up being a whole separate procedure in itself. … we've found our own way around doing it that way". Teams suggested that provision of templates on clinical documentation would provide a base for these steps. One of the clinical champion stated, "I don't know if you (Jane Fonda Center) have a templated operative note for that kind of thing, but that would be something, we talked about it, but we (implementation team) decided to leave it like it was". The clinical champion further elaborated on the complexities of hospital systems and development of templates that can easily be adapted by hospitals, "As far as the documentation, everybody has such a unique system it's really hard to make it where one size fits all". Hospitals' order sets for immediate postpartum LARC were integrated in the information technology system to interface with the medical administration records which involved registered nurse charting. This was coordinated with provider ordering, one of the nursing champions stated, "the nurse is responsible for documenting devices taken from the electronic medication system while the doctors place the device order and input device placement information". Participants acknowledged that these steps ensure completion of documentation with regards to LARC placement for charge submission and charge capture to be guaranteed.

All hospitals had inventory notification to track LARC use, maintain adequate levels of supply; this involved refining of the inventory system developed by pharmacy. Other hospitals developed their inventory notification as pharmacy was initiating its steps. However, teams refined the system per needs and anticipated LARC use. Some of the hospitals found having implant / device log numbers was helpful in refining charge documentation and capture, but this was mostly used to track individual use of devices with the view that it would assist with following up on reimbursement if individual claims were missing.

Barriers included: half of the hospitals had delays in getting the vendor contracts signed ("finding the right person to sign and getting comprehensive information from pharmaceutical companies took over four months"). Hospital teams had no sample documents that P&T committee would require. Pharmacy was hesitant to stock devices as costly as LARC with no projections on use.

Facilitators included: coordination among multidisciplinary team members towards a common goal of initiating and setting systems in place for immediate postpartum LARC, onsite immediate postpartum LARC training and monitoring calls by GAPQC.

Implementation and Sustainability Stage

In this stage hospital teams worked together to refine the process which is ongoing. This comprised of piloting, review and adaptation of steps and systems (Hofler, 2017). One of the clinical champions described the implementation and sustainability stage as, "Finding the best fit for the hospital and the process". Hospital teams acknowledged that the guide's depiction of their piloting and trial period was close to their past and present experiences.

All the hospital teams had tried alternative approaches to manage workflow for optimal immediate postpartum program implementation: first, on labor and delivery floor: second, between labor and delivery floor and pharmacy; and third, with finance and billing, and EHR departments. These alternative approaches involved clinicians, nursing, billing and finance, pharmacy and EHR personnel.

The most commonly described step in this stage was related to the assessment of placement and storage of devices for timing during delivery. Initially, all hospitals had their devices under

lock and key in the pharmacy. One of the nursing champions stated, “The pharmacy wanted to keep them downstairs. They locked them so tight in someone’s office. When we needed one we couldn’t get to it (LARC device) fast enough. Missed opportunity there. That was a big problem. So, they changed their process downstairs (pharmacy)”. Through continuous negotiation and discussion between team members and pharmacy, LARC devices were approved to be kept in the medication dispenser (Pyxis) on labor and delivery floor addressing barriers observed by the clinical personnel. Most hospitals maintained three LARC devices in the medical dispenser, the number increased if the hospital has more than one device on formulary. In contrast, two hospitals still had their LARC devices stored in pharmacy, a nursing champion from one of these hospitals stated, “In fact we still don’t have them in our Pyxis. They will not put them on the floor (labor and delivery). It is a cost issue. But that is still a bit of the puzzle that causes delay. If the physician does not notify us (nursing) upfront that we’re going to do this, we don’t start the ball rolling in time, we may miss the window, because of our internal issue”. A clinical champion from the same hospital commented, “This is optimal workflow for us, nurses know to coordinate to have it (LARC device) in the room before the placenta is out”.

All the hospital teams identified this step as critical to continued placement of devices and potential delay in placement of devices. Hospital teams reported instituting routine trainings for clinicians, residents, and new hires, as one nursing champion stated, “I have the education packet that I use to educate the others [new hires, part time staff]” and members of the support teams. The need to institute training for nursing personnel was emphasized by all hospital teams. A physician champion noted, “We need to train more nurse navigators in LARC as patients trust them”. The hospitals also included refresher trainings for trained clinicians in case of guidelines and clinical evidence update and continuously addressing concerns of lactation consultants. Furthermore, on

adapting patient education and LARC awareness activities to hospital's patient population, one physician champion noted, "The biggest hurdle that we face is actually communicating because we have a large Hispanic population and Hispanic women do not do IUDs and birth control hardly at all". As the process becomes more established, teams identified patient education as a core component in championing informed choice and expanding access to services. Almost all the hospitals were assessing how best to support pharmacy, finance and billing, and EHR personnel through brief refresher trainings and the hospital team in its coordination role. As one physician champion commented, "we (implementation team) got busy in our little pieces and forgot that we're all on the same team and we must bring that team together".

To operationalize claim submission, all hospital teams had checked that their claims were being captured right, identified an individual from revenue/billing to follow up on the submitted claims, and had meetings with Medicaid representatives to validate the codes used. Emphasizing reviewing of claims submission, a physician champion commented, "Rechecking that this is happening [clarifying payment submission, charge documentation and inventory notification] just kind of making sure that it is iterative". Three hospitals reported having stopped placement of devices for a period of four months at most to verify appropriate codes, refine charge documentation and charge capture across key stakeholders. The three hospitals resumed placement after resolving inaccuracies noted in the system with the Payer, that had affected clinical documentation and claim submission. At the time of the interview the state did not capture most of the claims submitted. Only two hospitals were being reimbursed, one of which was only for physician fees. Teams were frustrated by the seemingly limited payer preparedness demonstrated by the lack of reimbursement, misleading payer communication and assurance on claims processing. All teams noted that it would be difficult for their institutions to place devices in the

future if reimbursement hiccups were not resolved by the payer. As one revenue champion stated, "I decide from the business side, if it's not resolved, this program is in complete risk because we'll have to say we can't keep furnishing $ 700 drugs free of charge". Furthermore, hospital teams indicated that this was hindering planned expansion of device type offered, as one physician champion stated, "other hospitals are waiting to see if we get reimbursed to roll out this process". GAPQC was leading efforts to review other health conditions billing and reimbursement systems that would be adapted effectively for this process with the payer. Hospital teams suggested other systems that could be adapted to immediate postpartum LARC.

Furthermore, teams were also exploring how to audit performance of clinicians for quality assurance and monitor the process. As one physician champion commented,

> We haven't had anybody who is willing to do vaginal placement of LARC. We're still trying to figure out why. We don't know the barrier behind it and I think it is in terms of afterhours given, is divvied up between different providers and a lot are uncomfortable I think placing. I think it is an educational thing as well.

Teams stated that there are no standardized indicators and a monitoring matrix to capture trends and progress of immediate postpartum LARC programs. One of the physician champion noted, "likely to have a loop in this stage [as part of the implementation and sustainability] for monitoring indicators and process". EHR personnel noted that if they were notified of reporting needs during the installation stage they would have created commands to generate specific reports on a routine interval.

Most the hospitals indicated that they would want to go through the stages of implementation again while focusing on specific steps. One hospital that had not engaged pharmacy emphasized that implementing of installations steps for pharmacy would assist with generating pharmacy buy-in and expansion of the LARC program. Two hospitals wanted to use the re-implementation phase to identify a new overall champion to share responsibilities with the main project champion and make a case for LARC with other hospital stakeholders. For two hospitals that had gone through management transitions, they identified re-implementing steps as key to generating hospital administration buy-in and increasing number of LARC devices on formulary. However, all hospitals noted that this re-implementation depends on reimbursement being established in Georgia.

Facilitators for this stage included: early adoption of LARC placement by clinicians, buy-in from pharmacy personnel, engagement of nursing department in patient education, communication and coordination of roles among members of the implementation team, one of the nursing champion stated, “The revenue integrity director is phenomenal to work with and when we sit down and realize we’re not getting a charge she’s like a hound dog”. Additionally, having an OBGYN residency program was identified as a facilitator, as one physician champion commented, “We have residents here, but just family practice residents, they are not OB residency, it would be easy. So, they don’t place them routinely at all”.

Other Findings

Teams identified barriers and facilitators that overlapped all the stages. Most hospitals identified that engagement of pharmaceutical companies would ease vendor contract negotiation and procurement (negotiated device prices). As one of the physician champions stated, "Vendors ought to be behind this. They (vendors) ought to be going into the offices talking to the OBGYNs and the education piece. They ought to be in there talking about LARC". Only one hospital was continually engaged by pharmaceutical companies throughout the process which facilitated bringing new devices, buy-in of hospital administration and pharmacy. Pharmaceutical companies/vendors made a compelling case for devices rooted in efficacy studies and provided provider and patient education materials. One participant who was a physician champion described how vendors engaged their hospital to offer different types of devices, "ParaGard found out what we were doing and stepped in like wait a minute we want to do this too…then the Nexplanon dude comes in and he's like wait a minute". Participants also highlighted how in-patient services of LARC has increased demand for out-patient LARC placement. One of the physician champions commented, "But you know the funny thing is, what actually happened (placement of LARC in-patient) it's made our out-patient placement of these things (LARC) skyrocket". A physician champion furthermore elaborated the impact negotiated drug pricing had on management, "They (hospital administration and revenue office) are gang ho about it because reimbursement for us is really good we get the 340 B and we get that cost and so we you know, making money which is a first for that kind of thing. It has been very helpful". However, five hospitals had not been engaged by pharmaceutical companies while two were engaged for a limited period during the exploration stage.

Three hospitals teams were exploring how best to leverage stakeholders beyond the hospitals in the immediate postpartum LARC process. Hospitals were considering working with their department of community health and community level health actors to increase awareness of contraception options, especially immediate postpartum LARC among the hospital's patient population.

With each stage, team members reported exploring how to balance excitement for LARC expressed by clinicians, especially residents, and their perception of what is best for the patient with the patient's informed consent. As one of the physician champions commented, "The goal here should be working towards that everybody gets the method they wanted. If I find out 80 percent of people are getting LARC, I'm gonna worry". Clinicians who were part of the team spoke of raising awareness on the labor and delivery floor about use of consent forms (LARC preference) and patient education as a process during the prenatal period and inclusion of informed consent as a core principle of immediate postpartum LARC during staff training and meetings on the process. Almost all hospitals expressed a perception that teenagers and women of low-socioeconomic status or with poor health outcomes were LARC worthier patients than women who did not have these demographic characteristics.

Teams expressed lack of preparedness and confusion on how to address LARC preferences for patients with private insurance during the immediate postpartum period. For example, a physician champion explained how members of the implementation team determine which patients access immediate postpartum LARC by insurance type to guarantee reimbursement on claims. The physician champion commented, "There is a bit of review because we (the team) communicate to our staff, is this patient self -pay, that they're going to be using the health department, but if they were Medicaid, they were going to use, they could get them (LARC device) placed here. Then

private insurance; that where it gets a bit iffy". Only one hospital had all their private insurance patients' physician and hospital fees reimbursed. Another hospital had the clinical champion check insurance coverage before scheduled deliveries for reimbursement assurance. The rest of the hospitals decided not to place devices in patients with private insurance.

Application of Results – Recommendations for Revision of Georgia's Immediate Postpartum Long Acting Reversible Contraception (LARC) Toolkit

Common themes acknowledged by hospital teams include: step and stage specific anticipatory guidance, project champion and team members' roles and responsibilities, multidisciplinary communication and coordination, payer preparedness and delayed reimbursement, importance of informed choice for patient education and device uptake, and awareness of LARC by hospital administration and clinicians.

The toolkit was developed as Georgia rolled out the reimbursement policy. Thus, revisions are needed to reflect the state's status for institutions planning to initiate and for those implementing immediate postpartum LARC programs. The toolkit consists of: (1) provider's resource guide, (2) a presentation on billing and coding for immediate postpartum LARC, (3) job aids on LARC insertion steps for post placental delivery, (4) postpartum birth control options, (5) Georgia Medicaid banner message on immediate postpartum LARC, (6) Cochrane review of postpartum IUD, (7) EPIC procedure notes and Pharmaceutical and Therapeutic committee instructions, (8) a presentation on immediate postpartum LARC nursing education, (9) postpartum LARC evidence reference list – adapted from ACOG immediate postpartum LARC resource digest, (10) sample consent language, (11) GAPQC implementation checklist, (12) U.S. medical

eligibility criteria for contraceptive use, (13) U.S selected practice recommendations for contraceptive use, 2013, and (14) Immediate postpartum LARC in Georgia, study draft protocol.

Hospital teams emphasized the need to revise the toolkit while keeping it brief but comprehensive and exploring the steps involved in the implementation process. Teams also stressed that revisions to the toolkit must highlight key barriers and facilitators. As one of the physician champions stated, "Don't let people be surprised. I think the Nexplanon certification and vendor contract comes under that (being surprised)". Teams noted that existing resources for counseling and patient education for specific patient populations and key stakeholders' resources such as nurse, clinicians, pharmacy, finance and billing, EHR can be added to the provider resource guide. The teams proposed adding a brief description of the resources offered by a hyperlinked website and how it can be applied in the implementation process, "Making it easy and direct to use", as elaborated on by a physician champion.

Suggested revisions for the provider resource guide include: (1) mapping the status of hospitals implementing immediate postpartum LARC in Georgia, a visual depiction of LARC programs implementation status across the state of Georgia; (2) updating the case for immediate postpartum LARC – updating maternal and child outcomes including teen pregnancy for the state as new statistics are available and incorporating preliminary data from implementing hospitals and other states experiences; (3) key principles of informed consent, such as bullet points on why informed consent is central to provision of immediate postpartum LARC; (4) update patient and provider resources to include ACOG LARC program and LARC first project tools that will assist hospital teams to adapt material for patients and team members; (5) move insertion policies and detailed step by step guidance to appendix; (6) bullet points of essential tips for initiating, installing and sustaining immediate postpartum LARC programs; (7) updating the

documentation consideration and implementation steps section; (8) include billing and finance considerations; (9) consideration of next steps after the implementation piloting steps; and (10) revising the layout of the document.

Suggested revisions to the implementation guide: (1) exploration stage to include: piloting of appropriate codes, charge documentation, and charge capture; (2) installation stage to include: training of the implementation team in LARC program management and coordination. Also, add program indicators under IT & EHR stakeholder steps; make bold all the billing and finance and EHR steps; (3) implementation and sustainability stage: in the education/training loop include nurse navigators and patient education. Add a monitoring indicators and matrix loop; (4) add a box at the bottom of the stage with stakeholder engagement; vendors, community organizations included in it. In order to prompt implementation teams to think beyond the health institution for program implementation and sustainability; (5) overall have arrows that show that though the guide is a stage-based approach it is cyclical and mutually inclusive. The arrows will also show that once the process is completed hospital can reinitiate the process to improve on challenges noted in certain steps to improve process effectiveness.

Suggested revisions and inclusion to the toolkit: (1) Hofler (2017) - implementation of immediate postpartum LARC programs article and the implementation guide; this is a stage-based approach characterizing the steps involved in the immediate postpartum LARC implementation process based on experiences from Georgia hospitals; (2) adapt the immediate postpartum LARC protocol to reflect 2016 amendments; (3) a one pager describing Higgins' proposed reproductive health justice approach. Higgins makes a case for informed choice and its application to LARC programs; (4) one pager EngenderHealth SEED model for holistic family planning as it supports "program leads and staff [to] determine strengths and weakness

in family planning programs by identifying programmatic gaps that require further investment or more in-depth assessment" McGinn & Connor, 2011, p. 2). [50], this facilitates comprehensive analysis of determinants of health in synergic family planning interventions; (5) draft indicators for immediate postpartum LARC program and monitoring matrix; (6) update the EPIC and P&T committee presentation to have more screenshots of the documentation and steps to follow, including vendor contract considerations; (7) considerations for private insurance for immediate postpartum LARC placement.

CHAPTER 5: DISCUSSION AND CONCLUSION

Immediate postpartum LARC is increasingly receiving attention from state agencies and hospitals across the country. However, there is a gap in the literature on how health institutions can initiate and sustain immediate postpartum LARC programs. This study validated the Immediate Postpartum LARC Implementation Guide with minor suggestions for revisions. Furthermore, individual hospital experiences in implementing the exploration stage, installation stage, implementation and sustainability stage were used to suggest revisions for Georgia's Immediate Postpartum LARC Toolkit. Key concepts for successful initiation and sustainability of the process based on hospital experiences were: (1) having a self-motivated champion to organize key stakeholders for immediate postpartum LARC; (2) strong multidisciplinary buy-in and teams, such hospital teams harness collective action across different departments to complete each step; (3) assurance of reimbursement, use of appropriate codes and documentation between nursing, physician, EHR, pharmacy and billing enabled accurate ordering and follow up on claims submitted; (4) payer preparedness for sustaining and expanding LARC programs, establishment of a functional reimbursement system that provides adequate provider and hospital fees for placement of immediate postpartum LARC; (5) situating all the stages within a reproductive justice approach to manage provider expectations of LARC and increase patients' informed choice; (6) training as a continuous process overlapping each stage and stakeholders including the hospital implementation teams.

Overall, the study demonstrated the need for a reproductive justice approach in LARC programs. Although all hospitals had consent forms and a consent policy; team experiences suggest that providers' perceptions of LARC benefits for patients with limited prenatal care might

compromise informed choice. Deliberate actions to promote and monitor the consent process must be adapted within each stage. These findings validate caution voiced by Higgins (2014), that increased attention to LARC must be used to expand access to sexual reproductive health services for all and patient education through a reproductive justice approach. She emphasizes that contraception programs are based on principles of volunteerism and informed choice and that women reserve the final decision to use LARC or not [37]. These perspectives are critical especially with the history of coercion linked with contraception uptake among women of color and low socioeconomic status, who are the main beneficiaries of the reimbursement policy. As such we suggest that a checklist [dos and don'ts for informed consent] for providers and implementation teams to ensure that the consent process is prioritized in all the stages of implementation. These should include: (1) developing and adapting consent policies and forms; (2) initiating conversation about immediate postpartum LARC during prenatal care; (3) providing comprehensive contraception counseling and offering LARC to all women that fit the medical eligibility criteria; (4) filling in the preferred contraception choice on their form; and (5) requiring that patients sign the consent and release form before LARC device placement. Additionally, the possibility of including informed consent as a topic in grand rounds, departmental meetings and LARC trainings especially for new hires and residents is proposed as an ongoing component of quality control. We suggest an addition of a one pager of Higgins' proposed areas to initiate integration of a reproductive justice framework to LARC, to provide a structure for teams to ground their experiences and serve as a reminder for next steps to be viewed through reproductive justice lens. This framework also outlines the benefits for implementing a justice based approach in reproductive health for the provider and patient; these can be used to advocate for the integration of a reproductive justice lens into LARC programs.

Stages of Implementation

Exploration stage

We identified three factors as critical facilitators for hospitals consideration of the immediate postpartum LARC program: Georgia's coverage of immediate postpartum LARC outside of the global fee for delivery, GAPQC LARC initiative, and ACOG practice bulletin on LARC and committee opinion on immediate postpartum LARC. These facilitators enabled hospital stakeholders to make a case for LARC with assurance of anticipatory guidance for the process if they decided to implement the program. Additionally, the launch of Georgia's immediate postpartum LARC initiative was a platform for clinical stakeholders to increase understanding of LARC, provide in-patient training and address concerns before in-patient roll out. Although the implementation of reimbursement policy by states is key in encouraging hospitals to offer immediate postpartum LARC, the provision of anticipatory guidance and monitoring calls by GAPQC was critical in moving hospitals in Georgia from one stage to the next. States should consider having a partner organization to support hospitals in operationalizing the process.

Similar to findings of previous studies [17, 29], we identified the following as critical to initiating the process:

- First, a project champion who makes a case for providing immediate postpartum LARC in health institutions by raising awareness among hospital personnel and administration. The initial project champion is often self-appointed and driven by previous LARC experience,

perceptions of cost savings and LARC health benefits. The project champion targets key stakeholders in the hospitals, bringing them together to assess introduction of immediate postpartum LARC at the hospital. Literature on LARC safety, efficacy, other states' experiences and in state hospital experience through the Ryan LARC program were shared as part of consensus building on immediate postpartum LARC benefits and risks.

- Second, engagement of multidisciplinary stakeholder's key in the immediate postpartum LARC implementation process. This can be driven by a clear shared goal and complementary responsibilities to demonstrate that adoption of immediate postpartum LARC placement could be possible in their hospital through collective action thereby initiating hospital buy-in. Setting up of a multidisciplinary team is time consuming and challenging but necessary for project implementation and sustainability. The study demonstrated that hospitals that initially did not include pharmacy in their process faced prolonged resistance in ordering, storing devices and in consideration for expanding device type offered.
- Third, basic training on LARC. This can be done concurrently with either of the previous steps. The study identified a gap in basic understanding of LARC, implications of immediate postpartum LARC on patient, hospital outcomes and steps engaged in the process. Hospital administrators and stakeholder buy-in is influenced by perceptions of financial implications and health benefits of LARC.
- Four, verification of insurance participation and reimbursement assurance. These are key to gaining hospital administration, pharmacy, billing and finance buy-in.

The study revealed that health institutions had early buy-in and coordinated easily if they were either smaller in size or had an existing outpatient LARC program. One would expect that

department heads and personnel of smaller hospitals would work closely together with fewer hierarchies compared to larger hospitals. The study also suggests that project champions leveraged existing communication channels and success from quality improvement programs such as baby friendly to garner support for immediate postpartum LARC program. Therefore, there is need for hospitals to review existing processes and programs that can be leveraged to support the immediate postpartum program in their institution. We suggest inclusion of a brief paragraph before the implementation steps section in the provider resource guide outlining steps and questions hospitals should consider before rolling out the immediate postpartum LARC program. Questions such as: (1) how do members in different hospital departments communicate? (2) what existing processes can immediate postpartum LARC implementation be initiated through (high risk OBGYN clinic)? (3) who are the influential individual stakeholders among clinicians, nursing, pharmacy, billing, revenue, and EHR personnel?

Installation Stage

Our findings suggest that the installation stage steps for billing must be incorporated in the exploration stage as pilot and trial documentation steps to ease implementation of the installation stage. Furthermore, review requirements for EHR clinical documentation steps during exploration stage for the installation stage. This is critical as hospital administration buy-in was driven by verification of payment. However, with delays in reimbursement we anticipate that management teams will demand proof of claims submission and reimbursement before the hospital undertakes further steps. We recommend that hospitals work with the payer billing and EHR liaison to adapt the documentation system and provide proof of concept for reimbursement. We also recommend highlighting the billing and EHR steps in the installation stage and an inclusion of a footnote in

the guide for hospital teams to conduct those steps for a few devices in partnership with the state to demonstrate that the billing and coding system is functional and payment processing is occurring.

This study demonstrates that hospitals in the installation stage require adequate anticipatory guidance as key barriers and delays in the implementation process were identified in this stage. The ACOG LARC program and Association of State and Territorial Health Offices (ASTHO) LARC learning community has resources and webinars tailored to clinicians, pharmacists, billing and finance, EHR and other key stakeholders. Hospitals should utilize these resources to prepare for the intricacies of setting up the framework for the program. States that have rolled out the reimbursement policies have templates for consent, patient education, protocols and guidelines that can be adapted to individual hospitals in the installation stage. Efforts to promote understanding of immediate postpartum LARC and the process of implementation through trainings should extend beyond the clinical stakeholders. This study found that usually a state liaison and a GAPQC member would conduct in-service trainings, followed by a big meeting with clinicians to increase hospital LARC awareness and buy-in. As such, ownership of the program seems tied to clinical personnel although the installation stage requires equal efforts from different departments. We also identified the concept of "LARC worthy" populations among the multidisciplinary teams. This corresponds to a perception that immediate postpartum LARC placement must occur in a specific category of women. These women and girls were usually described as having a high chance of a rapid repeat pregnancy and with a high number of children. The contraceptive choice project [8] showed that all women and girls are potential users of LARC when barriers to access are removed; trainings on immediate postpartum LARC should be all encompassing to dispel misconceptions of LARC. Under the training section of the provider

resource guide we suggest adding: links to ACOG and ASTHO stakeholder specific trainings for billing and coding, pharmacy, EHR, insertion and removal of devices. Screenshots of documents needed for the pharmacy and therapeutic (P&T) committee meeting and putting the device on formulary must be added to the appendix. Delays in getting device on formulary were attributed to not developing necessary documentation in advance to make a case for LARC. The P&T committee is most of the time overburdened with requests and requires systematic documentation; presenting sample templates could ease these barriers. We recommend inclusion of a timeline indicating the duration of anticipated steps in the toolkit, this should be supported by the immediate postpartum LARC implementation guide that characterizes each step [29]. Additionally, we recommend including a step for finance and billing education to supplement the codes given by the state and ease the submission of claims and charge documentation in the implementation guide. Inclusion of a footnote on the implementation guide for teams during the installation stage to remind teams to agree on measures they will use to monitor the program enabling EHR to create appropriate infrastructure together with the clinical documentation, charge capture and inventory notification.

Implementation and Sustainability Stage

OBGYN residency programs in teaching hospitals may provide a resource pool to ease the burden of service provision and work flow management for clinical staff. The study demonstrated that implementation teams in teaching hospitals relied on residents to provide services in line with the standard of care and in order to maintain momentum of the LARC program. States and hospitals starting to place devices should invest in building knowledge of LARC placement procedures among residents through continued training and oversight. The Payer

should consider partnering with teaching hospitals to pilot and refine roll out of the reimbursement process before launching state wide. Similar to our findings, the ASTHO LARC learning community identified teaching hospitals as a driver for innovation, serving as a platform to adapt and test policies for quality improvement and tools development for state wide health polices [51].

Although not every hospital offered all FDA approved LARC methods, we identified a critical interaction between provider competencies and policies for device placement. It seems hospitals with limited LARC experience and low buy-in across departments were more likely to offer implants due to ease of placement with any type of delivery in contrast with IUDs. We recommend that after completing all the stages of the implementation process, hospitals can explore replacing or adding new devices on formulary based on demand, device efficacy and pricing. We also recommend inclusion of a next steps section in the provider resource guide; these are supportive of the implementation guide stages emphasizing maintenance and integration of the program LARC in hospital programs. This includes running through specific process steps to raise awareness of LARC and reduce potential barriers in the installation stage especially the billing and coding steps.

Our findings suggest that increasing involvement of nursing staff in the implementation process would improve LARC awareness and knowledge among patients. One of nurses' principal roles is to educate patients on health behaviors and available services, thereby providing interface between patients and the hospital. Nurses also work with physicians and other departments to ensure that all necessary delivery and LARC insertion equipment are available on the labor and delivery floor. McCone (2014) demonstrated that patients develop trusting relationships with nurses through prolonged interface, especially during the prenatal period. This interface was

associated with high levels of provider influence on patients' decision making to seek services [52]. Hospitals should define clear roles and responsibilities of nursing staff in this process and engage them in each step. We recommend that this be done by coopting a champion in the nursing department. We also recommend including the engagement of the nursing department in the next steps section of the resource guide, highlighting the opportunity that exists to reduce missed opportunities for LARC placement, and development of training materials for affiliated nursing groups.

Moniz (2016) highlighted three key areas for payer preparedness from her study with state agencies' program administrators [31]. Our study contributes to further understating of the payer's role and preparedness by identifying complementary areas from hospital experiences. First, provision of appropriate codes to hospitals with brief details on how codes should be used and reported by different hospital personnel to guarantee reimbursement. These codes allow pharmacy personnel to add on benefits not included in the diagnostic related group such as in-patient postpartum insertion codes, supply codes and diagnosis codes among others. Second, provide an outline for LARC documentation steps for pharmacy, billing, coding, and EHR systems. Third, automated notification confirming claim submission by the hospital. This would serve a twofold purpose: verifying that codes used were appropriate, and that the payer can capture claims submitted by hospitals. It would also allow stakeholders and the payer to identify any claims associated bottlenecks in the system. Fourth, consistent adequate reimbursement of claims that includes provider and hospital fees, thereby meeting the hospitals' financial burden of offering LARC immediately postpartum. Furthermore, the payer should engage pharmaceutical companies on behalf of hospitals to facilitate hospital stakeholder buy-in by negotiating 340B drug pricing for LARC devices, distribution of patient education material, guidance in completing vendor

contracts and ordering devices. Setting clear program indicators and goals that feed into a monitoring matrix at state level would allow the systematic review and refinement of the process based on hospitals performance. Projections of trends in LARC use could serve as a basis for making a cost benefit analysis and cost effectiveness case for the project and integration into standard of practice at delivery. We recommend that state agencies partner with academic institutions to explore the implementation process and sharing of lessons among hospitals. Successful implementation of the process relies on guidance provided; academic institutions can leverage their resources for research and application.

The study suggests that there is a need to focus on developing an integrated monitoring matrix for hospitals and the payer. A matrix that offers a comprehensive status of immediate postpartum LARC programs will serve as a basis to assess performance of the program and offer comparison with sites not implementing the project. A monitoring matrix would enable states to review trends and outcomes related to immediate postpartum LARC. Hospital teams can work with EHR personnel to set commands in the system to generate reports that capture the following: demographic characteristics of users, IUD expulsions, LARC removal, device type, proportion of teen pregnancy, and rapid repeat pregnancy. We recommend inclusion of a monitoring template in the toolkit; consistent data collection across hospitals will facilitate maintenance of program benchmarks for implementation and projections on future outcomes. The template will be based on Rankin (2016) and ASTHO LARC learning community proposed key components for LARC programs, which should assess implementation and the decision-making process of hospital teams [53]. The template will serve as a guide for hospitals to adapt to suit their needs while measuring similar outputs and outcomes overtime. We recommend that the monitoring and evaluation loop be included in the trial and pilot period of the implementation and sustainability stage.

The review suggests that there is need for hospitals that have implemented the process to cascade immediate postpartum LARC implementation to affiliated health institutions. The hospitals' experiences will serve as the pilot phase that can be refined before smaller hospitals assess the project for possible implementation. Hospitals' success in the health district might increase stakeholder awareness and buy in of the immediate postpartum LARC project.

Our study demonstrates the need to invest in long-term immediate postpartum LARC training needs of hospitals and implementation team. Continuous training of clinicians, key stakeholders and support staff in immediate postpartum LARC is essential in maintaining standard of care in delivery with new evidence, new hires, residents and staff not formerly engaged in the LARC process might have different understanding for the process. Furthermore, rapport and critical thinking building among implementation team members leads to better communication and coordination on shared goal. We recommend editing the training section of the resource guide to highlight the need for hands on case based training for the implementation team. Team members will have a chance through case studies and vignettes included in the toolkit to analyze a complex scenario and develop a plan of action. The training will strengthen and develop problem solving skills for complex and interdepartmental steps by the implementation team members. Routine trainings of hospital personnel especially residents can be instituted through grand rounds and multidisciplinary meetings.

Although all the hospitals had a project champion and had completed all the stages of implementation by the time of the interviews, we identified a need to improve execution of the implementation stages and responsibility of leading the implementation team. Identification of a new lead project champion from a different department could create greater buy-in and address their department's needs in the project explicitly. This serves as an opportunity for quality

improvement by hospitals going through the implementation cycle again; reviewing and adjusting steps in various stages. In the next steps section, we recommend including identification of new champions to provide clarity and lead in application of lessons learnt in stages of implementation. Since the implementation process is cyclical in nature, steps are mutually inclusive and refinement is continuous using past experiences as anticipatory guidance for future immediate steps.

With hospitals increasingly implementing immediate postpartum LARC programs, our findings identified two implications for hospital administration and health outcomes. First, in-patient placement of LARC devices increases outpatient placement. Therefore, hospitals planning to implement LARC programs must anticipate outpatient increased demand for LARC. Second, the reimbursement policy is explicitly for Medicaid holders, however women with private insurances are demanding LARC placement at delivery with increased patient awareness of immediate postpartum LARC. Where possible hospitals should identify a team member that will verify insurance participation and reimbursement when women state their contraception preference during the prenatal period. We recommend adding a step for private insurance reimbursement participation and assurance under the finance and billing steps. Over time, state agencies and hospitals can develop a comprehensive list of which private insurers cover LARC placement immediately postpartum including provider and hospital fees. Reimbursement is a financial incentive for providers and hospitals to offer LARC to women regardless of insurance provider, thereby expanding services and access to all women of reproductive age.

Limitations

Focus group discussions (FDG) were used to allow optimal engagement with team members and diverse feedback on their implementation process. It was not possible to have all members of the team present as the hospital departments' work flow would otherwise have been compromised. To mitigate this limitation, we made sure that team members from different departments were present to capture a range of ideas and experiences. To minimize social desirability bias and deferment to hierarchy during our discussions, an activity was embedded in the FDG guide to build rapport and allow each of the team member to contribute. The use of grounded theory allowed the emic perspective of participants to guide data collection and analysis and offer credibility to interpretation of findings. Similar to Hofler (2017), some of the study limitations included: members of the implementation teams were also part of GAPQC leadership and membership. Additionally, all hospitals involved had guidance and resources to sustain implementation even with delayed reimbursement, not all hospitals and states will have adequate resources to maintain implementation [29].

Strengths

The study included hospitals across the state of Georgia with different geographical and hospital settings. These hospital profiles are similar to health institutions across Georgia and other states; this will enable other hospitals and states to use these findings and the revised Georgia Immediate Postpartum LARC Toolkit to inform their programs. Previous studies [29-31] on the implementation process focused on either individual stakeholders or state agencies. However, the implementation process is complex and requires stakeholder collaboration within different hospital

departments and beyond. This study conducted discussions with members of the hospital implementation teams to understand how steps taken in various departments lead to implementation of each stage. This facilitated gathering of rich diverse views from team members, including ranking of barriers and facilitators for each stage by the team. Additionally, it allowed further exploration of the payer's role and responsibility during each stage of the implementation process. Unlike previous studies [30], hospital sites offered different LARC devices, with a minimum of one and maximum of three device type. By the time of the interviews for this study, all the hospitals had implemented all the stages and were exploring sustainability of the program in contrast to Hofler (2017), majority of hospital were in exploration and installation stages of implementation [29]. Hospital teams validated the steps characterized and grouped into stages by Hofler (2017) from their experiences as a true reflection of their implementation process, although execution of steps was varied across health institution. The hospital teams' emic perspectives drove the recommendation for revision of Georgia's Immediate Postpartum LARC Toolkit per the identified needs, facilitating responsive anticipatory guidance for initiating and sustaining postpartum LARC programs among hospitals, states and other supporting actors.

Conclusion

A holistic framework for implementing immediate postpartum LARC programs as a quality improvement intervention in maternal and child health services may facilitate sustainability of state wide LARC programs. The cyclical and multidisciplinary nature of the immediate postpartum LARC programs require understanding the complexities of the enabling environment, the supply side and the demand side of the implementation process to facilitate adoption and maintenance. This study demonstrated that the following are essential components to initiating and maintaining the gains of the immediate postpartum LARC reimbursement policy: payer preparedness and dynamics of hospital implementation team, early engagement of pharmacy, billing and finance, EHR personnel, and anticipatory guidance. As hospitals continue to implement immediate postpartum LARC programs, more studies investigating the implementation process must be conducted to provide evidence based practices in rolling out, sustaining LARC programs in and beyond the hospital context. Tools developed for the implementation process should be assessed and revised for relevance and optimal use as the programs become well established. Academic institutions have a role to play in conducting research and in quality improvement of immediate postpartum LARC programs. Hospital administration and the payer must be responsive to emerging steps in the implementation process as the program is integrated in core labor and delivery services. Success of implementing immediate postpartum LARC programs rests on each stakeholder, public and private in fulfilling their role.

CHAPTER 6: POLICY IMPLICATIONS/RECOMMENDATIONS

- States must provide adequate reimbursement for provider and hospital fees to stimulate hospital interest in provision of immediate postpartum LARC. However, sustainability of the programs depends on engagement of multidisciplinary stakeholders' action at different levels. Immediate postpartum LARC programs should not be implemented as siloed interventions.
- Application of hospitals' experiences in implementation of immediate postpartum LARC programs to the revision of Georgia's Immediate Postpartum Toolkit will strengthen anticipatory guidance to hospitals. Furthermore, increase hospital buy in and ownership of the program. The toolkit will be refined to align with the needs and anticipated barriers identified by hospital teams. Georgia's experience will serve as a lesson for new states considering roll out of the reimbursement policy.
- States and academic institutions must partner to conduct research on the implementation process; there is need for further assessment of the process as more hospitals reach implementation state and others consider initiating it. A gap still exists in understanding how programs can be: sustained and integrated within hospital infrastructure with wider multidisciplinary buy in. Additionally, quantitative research must be conducted to investigate hospital expenditures and observed health outcomes with implementation of the immediate postpartum LARC process. This will serve to justify continued state and federal funding for immediate postpartum LARC programs.
- States and hospital implementation teams must take deliberate actions to ensure that all key stakeholders are involved in the process as it is being initiated: clinical, pharmacy, billing

and finance and EHR personnel. Additionally, states must invest in establishing functional implementation teams to guide and champion the process in their health institution. However, there is need to understanding how the implementation team can be leveraged for effective execution of stages in the implementation process.

- The payer must conduct stakeholder and resource mapping before implementing immediate postpartum LARC programs. Additionally, the payer must consider a step wedge design to program roll out that may include: (1) find a partner teaching hospital where possible to pilot the full implementation systems and adapt tools for implementation; (2) establish a functional reimbursement and monitoring system; (3) establish relationships with vendors and community stakeholder for negotiated 340B drug discount pricing and patients awareness; (4) pilot in selected hospitals across the state that have diverse workflow and system; and (5) refine the implementation process and scale up the program implementation to all health institutions. All these steps are integral to the success and continued implementation of the program.

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APPENDIX

Appendix 1: Implementation of Immediate Postpartum LARC in Georgia Presentation and Focus Group Discussion Guide

Slide 1

Thank you for being here today. I'm ……...

Interviewer 2:
And I'm …….

Interviewer 1:

We're from Emory's Division of Family Planning and are working with Dr. Hofler to follow up on the interviews that she did with some of you and your colleagues about a year ago. The interviews were about getting LARC devices into hospitals around Georgia.

Today, we're going to check in with you all about how postpartum LARC implementation is going here, then we'll present some of the findings from Dr. Hofler's initial interviews, and then we're going to ask for some feedback from you about our results.

The Roadmap in front of you is the main product so far from the interviews and we'll be going through all the boxes and asking you all what you think about it, how we could improve upon it, and how we can expand it.

As we go through everything, please feel free to interrupt with any questions or comments. Do you have any questions so far?

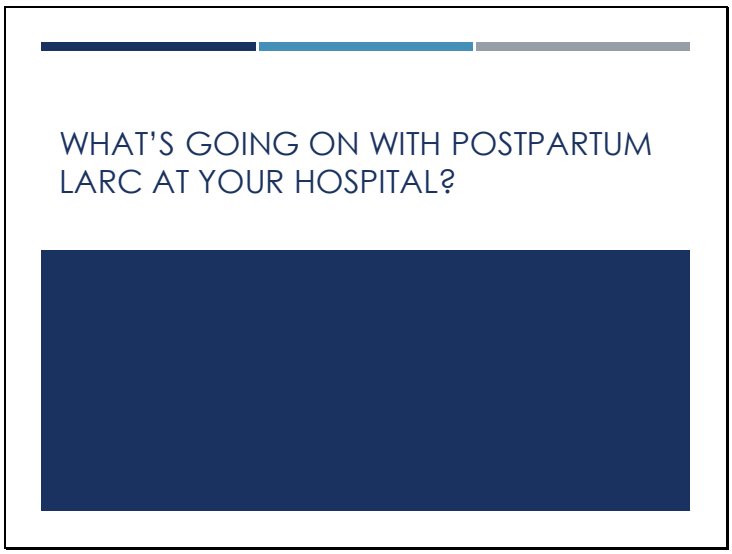
[HAND OUT INFO SHEETS]
This is an information sheet about the research that we're doing. We'd like to record our meeting today so that we don't miss anything. We'll have the recording transcribed and then will take out anything identifying from the typed copy and will then delete the recording. You don't need to sign this and you're welcome to keep it or give it back. Go ahead and take your time to review the info sheet.

Is it ok with everyone if we record this discussion? (check that all consent to the recording)

[START RECORDING]

Can you go around the table and introduce yourselves? Just your name and your title. Again, I'm Interviewer 1 and this is Interviewer 2 (point to next person to introduce themselves)

Slide 2



Interviewer 1:

1. Could you tell us what the status of postpartum LARC is here?

2. Can you talk a little about who's worked on bringing postpartum LARC here?
[what is your plan for getting people together to start working on brining postpartum LARCs here?]
    Probes:
    How were these people identified?
    Do you have regular meetings, calls or updates?

3. Do the people working on bringing postpartum LARCs have specific responsibilities?
    Probe:
    How do they communicate with internal and external stakeholders?

4. What has worked well?
    Probes:
    What pushed the project forward here?
    Which stakeholders were key?
    What are the next steps you will take to sustain this progress?

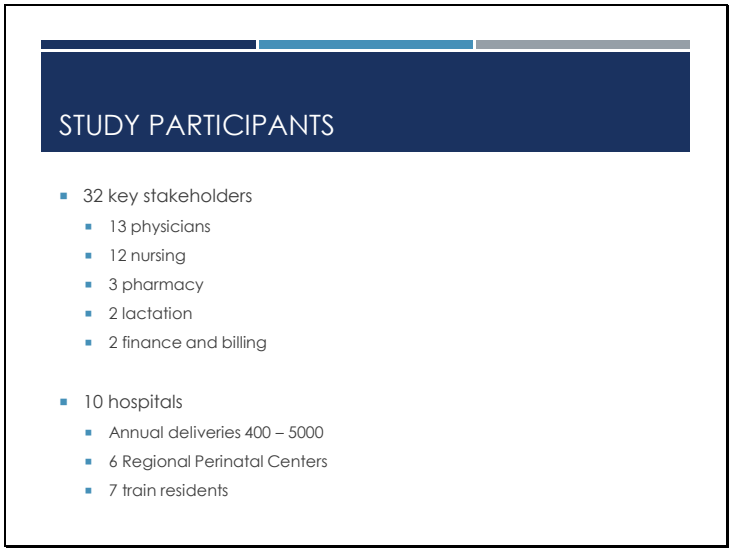
5.What challenges have come up so far when working on this project?
    Probes:
    How did you overcome these challenges?
    Do you anticipate any other issues coming up?

What would be/would've been helpful to overcome those challenges?

Alternate: Can you walk us through the process of an antepartum patient selecting a postpartum LARC to receiving the device?

6. How do you/ the hospital bill and code for immediate postpartum LARC? OR what is your plan for billing and coding for immediate postpartum LARC in this hospital?
Probe: ordering, documentation after insertion, follow up on reimbursement, communication between billing, pharmacy and clinical staff

Slide 3



Interviewer 1:

Thanks so much for getting us up to speed so that we understand where you all are with postpartum LARC. Now I'm going to tell you a little bit about our interview results and then we'll dive into the Roadmap in front of you.

We visited10 hospitals across Georgia to evaluate the status of LARC implementation.

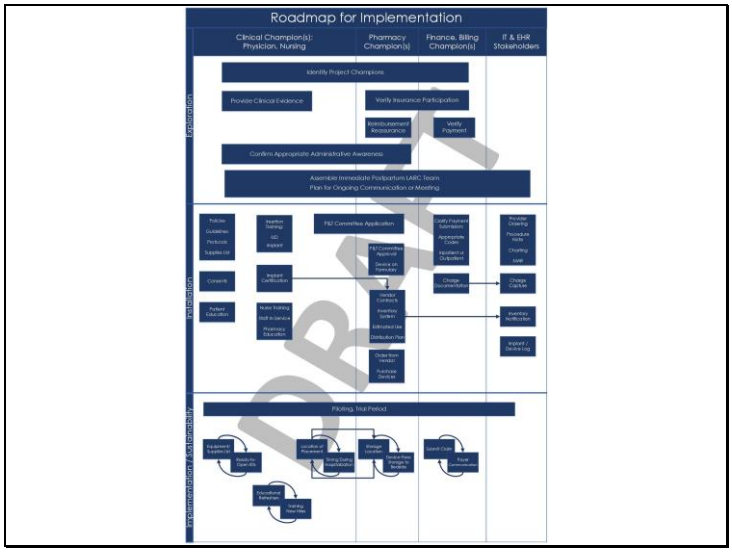
The objective of the study was to characterize the steps taken to offer immediate postpartum LARC. You can see that characterization on the Roadmap. We also wanted to identify the barriers, facilitators and institutional needs for implementing postpartum LARC.

In addition to physicians and nursing administrators, key stakeholders that we interviewed included pharmacists, billing personnel, and lactation consultants.

Of the 10 institutions, we visited, the median number of deliveries was 3000 per year. 6 were Regional Perinatal Centers, and 7 of the 10 provided resident training.

Most the study participants reported no formal LARC training, highlighting the importance of guidelines and education while getting ready to bring postpartum LARC to a hospital and make the project sustainable. This also shows how far everyone has come and what great work is being done!

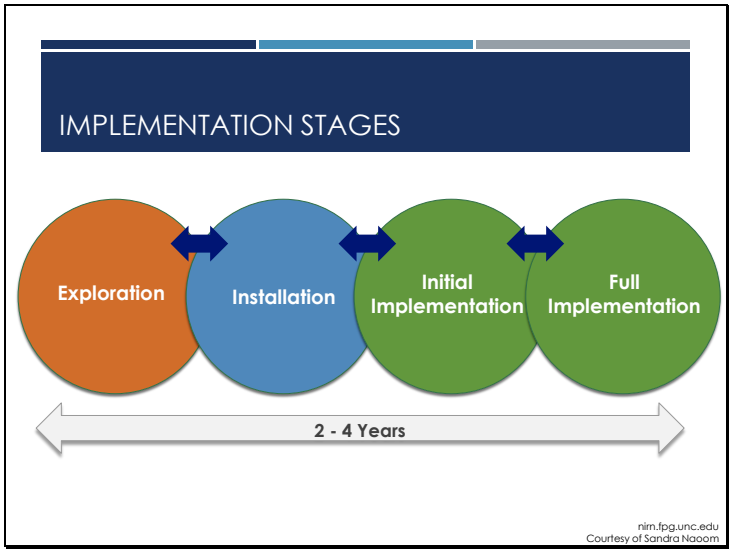
Slide 4



Interviewer 1:

Again, this is what you have in front of you. Interviewer 2 will go through everything in detail before we ask for feedback, but please interrupt us if you have comments or questions. We created the Roadmap using feedback from all the original interviews, so it's an ongoing collaborative effort. This may not exactly reflect what your process was here, but that's why we're getting feedback. We'll collect all the materials before we leave, but feel free to take notes or highlight as we go along.

Slide 5



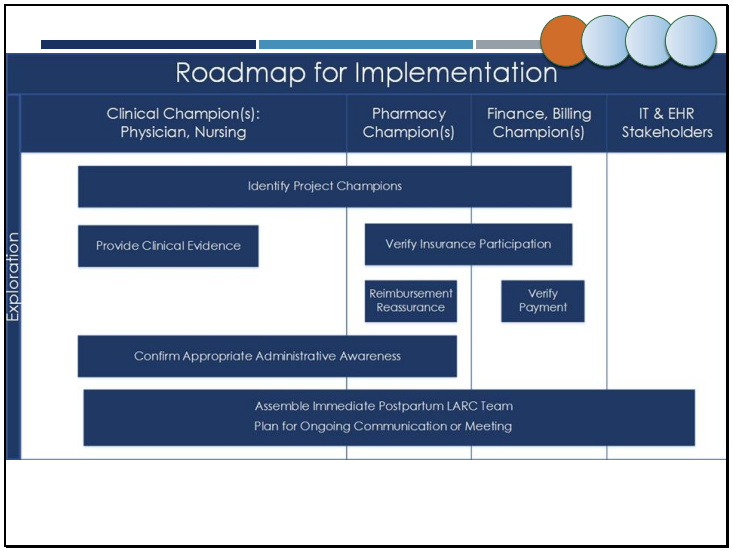
Interviewer 2:

Implementation science has identified four stages of active implementation: exploration;

installation, or the process of getting ready;

and initial and full implementation. We used these stages to organize the information you provided to us into key steps for immediate postpartum LARC implementation.

Slide 6



Interviewer 2:

Some of the steps and stages overlapped with GaPQC LARC trainings and Regional Perinatal Centers follow up phone calls and guidance on immediate postpartum LARC implementation.

We grouped the key steps by stage, starting with exploration.

Steps are organized by stakeholder group. We identified the groups as: clinical champions, pharmacy champions, financial champions, and IT/medical records stakeholders.

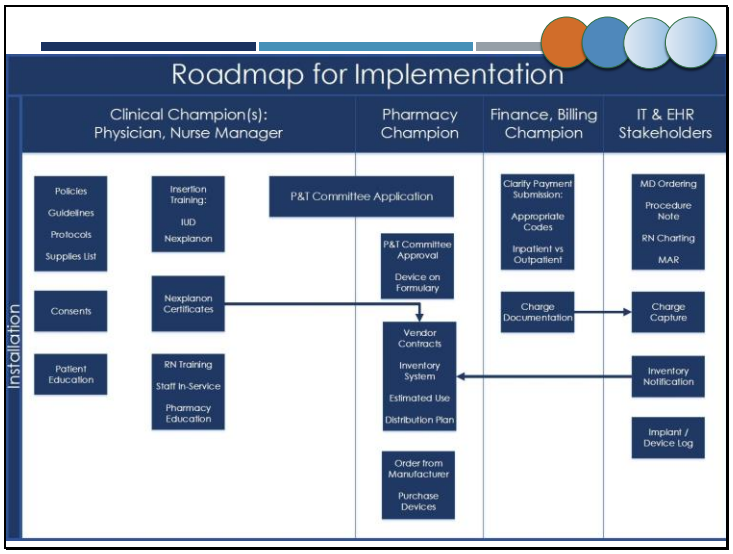
Bringing key stakeholders together first drives the project forward. You can see that many of the stakeholders worked together during this stage.

Some of the steps here address verification, like verifying insurance participation, reimbursement, and payment.

Other steps involve information gathering like providing clinical evidence whether to inform other stakeholders or hospital administration to get their buy-in.

Finally, establishing a plan for communication with everyone that is working on the project is key to moving forward. Sometimes this means regular monthly meetings, and sometimes it means starting with a big group of all possible stakeholders and scheduling smaller meetings as necessary.

Slide 7



Interviewer 2:

The next stage, the installation stage, which is getting the hospital physically ready for postpartum LARC.

We'll break it down by stakeholders –

Clinician champions typically gather and develop documents like policies, hospital protocols, consents (from a template or a new consent) and patient education materials like pharmaceutical brochures or custom info sheets.

The clinical champions also oversee training for both staff and physicians. This also can include Implant Certification.

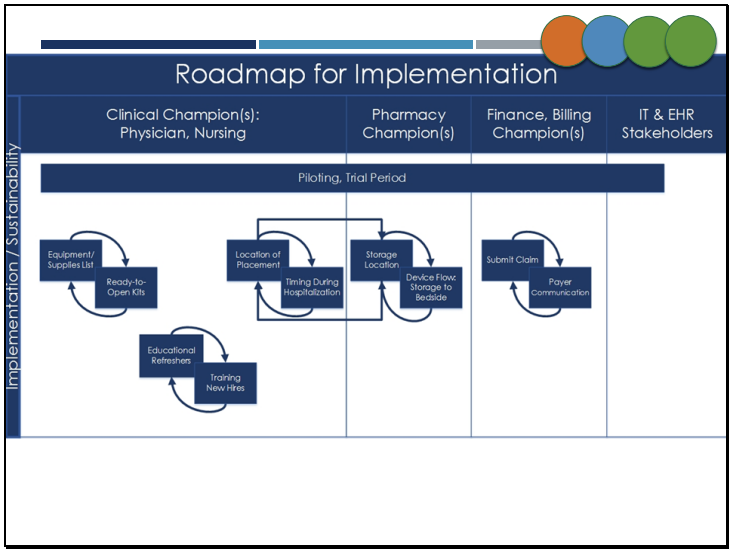
Clinical champions and the pharmacy worked together to bring LARC devices into the hospital. This typically includes applying to the Pharmaceutical and Therapeutics Committee so that the device can be put on the formulary.

Once that is done, the pharmacy can take over and create contracts, make a distribution plan, and purchase the devices.

Financial and billing champions can clarify the appropriate codes to use and proper charge documentation during this stage.

The IT and EMR stakeholders, with input from other stakeholders, can work on creating infrastructure in the EMR for ordering, note writing, charting, charge capture, and inventory notification.

Slide 8



Interviewer 2:

Before the project is fully implemented, most hospitals will go through a pilot or trial period. This may be only using one device at first or only placing devices in a few patients and seeing how that goes before offering them more widely.

This phase may also include several feedback loops that may help refine each hospital's process.

For example, educational refreshers and a plan for training new hires (staff, residents, technology updates) may be an ongoing process that changes as more staff and physicians are familiar with postpartum LARC.

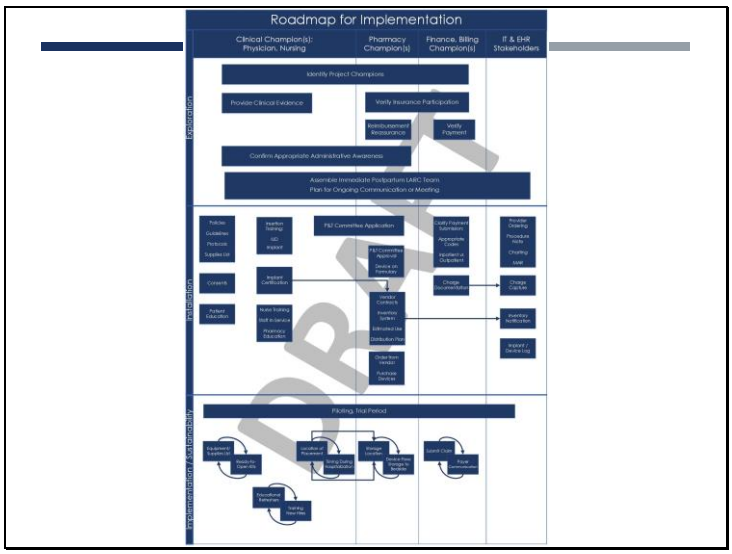
Also, troubleshooting the best location for LARC storage and placement as well as the timing during the patient's hospitalization may help to prevent missed placement opportunities due to time and storage location.

Submitting claims and following up with the payer may also be an ongoing process until postpartum LARC reimbursement is well established in Georgia.

Slide 9

Thank you!

Slide 10



Interviewer 2:

Do you have any questions or comments?

Now we will get your feedback on the draft roadmap and use it to build on available resources for immediate postpartum LARC implementation.

Now the group will conduct an activity to provide feedback on the draft immediate postpartum LARC implementation guide. The participants will each be provided with a copy of the roadmap, pieces of paper highlighting each step and sticky notes.

Activity Aim

The purpose of the activity is to (1) to explore if the draft roadmap is a true reflection of hospitals implementation process of immediate postpartum LARC, (2) to understand how the roadmap can be modified to support coordinating teams and hospital efforts, (3) to gain a deeper understanding in how hospitals implemented/ are implementing their exploration, installation and pilot stages.

The semi structured and open format of the activity eliminates defined preconceived notions by the researchers about hospitals implementation of IPPLARC. The moderator will inform the group that they will conduct an activity to provide feedback on the draft roadmap for immediate postpartum LARC implementation process. The moderator with the help of the assistant will place a flip chart paper in the middle of the group then pass out sticky notes and markers to each participant. Then the activity will be conducted.

Note to moderator: ask participants to remove steps they feel are not necessary. Then tell them to write the steps they feel are missing on the sticky notes and add them where appropriate in the process and rearrange to closely reflect their implementation process on one flip chart paper together

Please use any of the supplies that you'd like to make notes.

Interviewer 1/Interviewer 2:

- What steps do you think are missing from the Roadmap?
- What steps did you not need at this hospital?
- Are there any steps that you would rearrange?

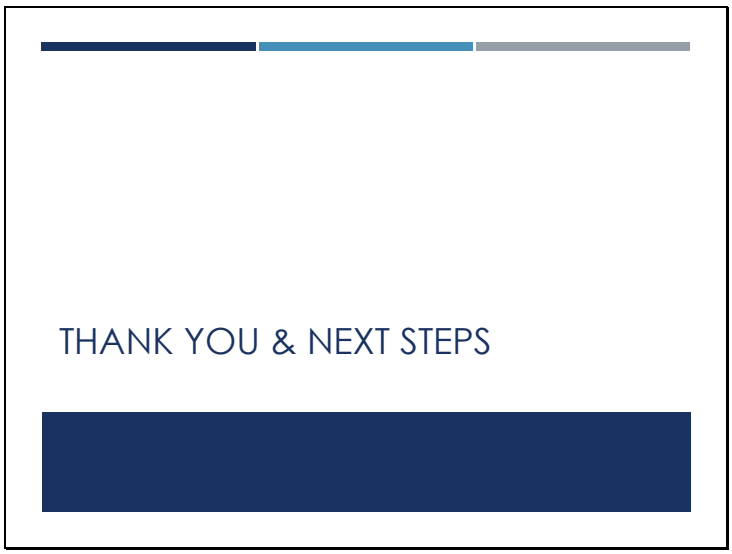
///
Why did you remove the other steps?
Why did you include new steps?
Why did you place step …… in a different stage?
What are all the things you considered when assessing these steps?

How can the roadmap be improved?
(Probe: detailed steps, case studies)

What type of support would be/ has been most helpful at each stage of the roadmap?
Probe:
At exploration stage?
At installation stage?
At implementation stage?
External support? (state, community services)
(patient education, mentorship, orientation to LARCs and billing and coding)

Do you have any suggestions for a resource guide on immediate postpartum LARC?
(Probe: topics, themes, flow)

Slide 11



Interviewer 1:

Thanks so much for going through the Roadmap with us.

Our next steps after these meetings are:
- Refining the roadmap using your feedback
- Developing a more comprehensive guide to immediate postpartum LARC implementation for Georgia hospitals and possibly other states
- Publishing our results in a research journal
- Distributing the roadmap and guide back to you all

Does anyone have any further comments or questions? Here's my card, please don't hesitate to contact us if anything comes up. Thanks again for participating!

We'll stop recording now.