Improving Contraception Use in the Postpartum Period

Monica Todd Horne

East Carolina University

Scholarly Project

Submitted to the faculty of the

Graduate School of East Carolina University

in partial fulfillment of the requirements

for the degree of

Doctor of Nursing Practice

July 2016

Greenville, NC

Signature page removed

Abstract

In the United States (U.S.) there are 6.4 million pregnancies per year, over half of which (51%) are unintended. At the time of hospital discharge many women do not have a postpartum contraception plan which puts them at risk for an unintended pregnancy. The consequences of unintended pregnancy for women, children, society and the healthcare system can be devastating. Healthy People 2020 recognized pregnancy and postpartum health behaviors as national objectives but did not include contraception. In 2015, the World Health Organization (WHO) reported an especially high-unmet need for contraception in postpartum women.

The purpose of this educational counseling intervention was to address contraception education and planning for the postpartum period using the Plan-Do-Study-Act Cycle as a conceptual framework. The target population was postpartum patients who received their antenatal care at East Carolina University Women's Physicians and Brody School of Medicine Outpatient Center (ECU OB/GYN). The methodology for this educational counseling intervention was to (a) perform a retrospective chart review to assess if postpartum contraception education was introduced prenatally and at hospital discharge, (b) implement an educational intervention for providers using the Diffusion of Innovations framework, and (c) perform a prospective chart review following implementation of the educational intervention at hospital discharge. The goal of this educational intervention was to formulate a plan to ensure all prenatal patients received standard education regarding postpartum contraception and were discharged after delivery with a well-defined plan for contraception.

ACKNOWLEDGEMENTS

My deepest gratitude is to my committee chair, Dr. Rebecca Bagley. Her patience, understanding, and support kept me going through this project. She served as an inspiration in times of crisis and gave me the courage to keep moving forward.

I would also like to thank the other two members of my committee. Dr. Pamela Reis who challenged me to think ahead and beyond the obvious. Dr. Tana Hall who was an advocate for me within my department and offered not only expertise in obstetrics but in grammar and writing.

I thank my DNP faculty for your guidance and Kerry Sewell the health sciences librarian who assisted me with my literature search. Thank you to Dr. Charles Hodson for his help in establishing a secure storage location for my data and to the rest of the ECU OB/GYN department for allowing me to conduct my project in our practice setting. Dr. Jimmy Efird deserves more thanks than is possible to give. Many after-work hours were spent coding and analyzing data.

Finally thank you to my friends who did not abandon me even when I became all but a prisoner in my home and to my computer. Most of all, thank you to my family for your long distance love and support. I will make up those missed visits to see you somehow.

Table of Contents

Improving Contraception Use in the Postpartum Period

Chapter 1: Introduction

In the U.S. there are 6.4 million pregnancies per year (Curtin, Abma, Ventura, & Henshaw, 2013), over half of which (51%) are unintended (Finer & Zolna, 2014). In 2010, North Carolina's unintended pregnancy rate of 49 per 1,000 women was slightly higher than the national state median. Nationally state median rates fall between 32 per 1,000 women and 62 per 1,000 women aged 15-44 (Guttmacher Institute, 2015). At the time of hospital discharge many women do not have a postpartum contraception plan which puts them at risk for an unintended pregnancy. The consequences of unintended pregnancy for women, children, society and the healthcare system (Dehlendorf, Rodriguez, Levy, Borrero, & Steinauer, 2010; Sonfield, Kost, Gold, & Finer, 2011) can be devastating. HealthyPeople 2020 (2015) recognized pregnancy and postpartum health behaviors as national objectives but did not include contraception. In 2015, the World Health Organization (WHO) reported an especially high need for contraception in postpartum women.

ECU OB/GYN is the obstetrical and gynecological practice for East Carolina University's Brody School of Medicine. Along with its affiliate Vidant Medical Center (VMC), ECU OB/GYN serves 29 counties in eastern North Carolina. ECU OB/GYN delivered 1271 infants between July 2014 and June 2015. This translates into 648 unplanned deliveries, which according to known trends in unintended pregnancy does not include the unplanned pregnancies that were miscarried or terminated.

This author has noted many women do not have a postpartum contraception plan at the time of hospital discharge or when they return for their postpartum visit. This is troubling

because of the impact unintended pregnancies and births can have on the women, children and communities of eastern North Carolina.

A key factor in improving pregnancy outcomes is the ability to plan for a pregnancy (Perritt, Burke, Jamshidli, Wang, & Fox, 2013). Unintended pregnancies are associated with unhealthy behaviors, including drug and alcohol abuse; poor birth outcomes (Kost, Landry, & Darroch, 1998); and shorter pregnancy intervals (Center for Disease Control and Prevention [CDC], 2011a). Shorter pregnancy intervals (six months or less) are associated with increased risk of maternal morbidity such as bleeding, postpartum endometritis, and death; while intervals of 18 months or less are associated with increased risks of perinatal, neonatal, and infant morbidity such as low birth weight, small for gestational age (SGA) and pre-term delivery (WHO, 2005; Zhu, Rolfs, Nangle, & Horan, 1999).

Children resulting from unintended pregnancies are more likely to experience developmental delay and poor relationships with their mothers (Baydar, 1995). Young mothers with unintended pregnancies may be destined to a life of poverty, poor educational achievement, and behavioral problems (Boden, Ferguson, & Harwood, 2008). Additionally these adolescent mothers often lose out on educational and employment opportunities (Boden et al., 2008; Klepinger, Lundberg, & Plotnick, 1995; Moore et al., 1993). And finally, the cost burden placed on the federal and state governments extends into the billions of dollars. In 2010, 1.5 million (68%) unintended pregnancies were publicly funded (Sonfield & Kost, 2015).

The Pitt County Community Assessment (North Carolina Department of Health and Human Services [NCDHHS], 2011) identified two known associations with unintended pregnancy, (1) short interval pregnancies and (2) low birth weight. Short interval pregnancies accounted for 13.5% of the births at VMC in 2005-2009 as compared to 12.9% for North

Carolina. The prevalence of low birth weight infants in Pitt County was 11.2% as compared to 9.1% in North Carolina (NCDHHS, 2011). Based on these two factors alone, unintended pregnancies are a significant problem within the ECU OB/GYN and VMC patient population and present an unmet need for postpartum contraception.

The unmet need for contraception in the postpartum period is well documented in the literature. There is a consensus that both the antenatal and postpartum period prior to hospital discharge presents a unique opportunity to provide postpartum contraceptive counseling. Unfortunately much of the information provided to women is either poor or inadequate (Di Giacomo, Sbarlati, Bagnasco, & Sasso, 2013; Glazer, Wolf, & Gorby, 2011). The most effective timing and approach to educational counseling are less clear. Several studies focused on counseling in the postpartum period prior to hospital discharge (Depineres, Blumenthal, & Diener-West, 2005; Glazer et al., 2011; Lopez, Grey, Chen, & Hiller, 2014; Proctor, Jenkins, Loeb, Elliot, & Ryan, 2006) while others examined a combination of antenatal and postpartum counseling (Adanikin, Onwudiegwu, & Loto, 2013; Adegbola & Okunowo, 2009; Glazer et al., 2011; Hernandez, Sappenfield, Goodman, & Pooler, 2012; Perritt et al., 2013; Wilson, Fowler, & Koo, 2013; Yee & Simon, 2011) . Several studies focused on the mode of counseling delivery; face-to-face, in-depth, multiple encounters, one-time sessions, written leaflet, and multiple modalities (Adanikin et al., 2013; Perritt et al., 2013; Saeed, Fakhar, Rahim, & Tabassum, 2008; Yee & Simon, 2011). The results of searches and screening of potentially relevant studies in the literature are outlined in Figure 1.

Problem Statement

No set standard for postpartum contraceptive counseling has been established. The need for postpartum contraception with an effective timing and method of educational counseling is

essential to improve the outcomes of women, children, and the use of publicly funded resources at VMC and ECU OB/GYN. The purpose of this project was to implement a prenatal/postpartum contraception education plan for both providers and patients with the intent that postpartum patients would have a clear contraceptive method plan at the time of hospital discharge.

Methodology

Prior to implementation of the project, organizational and institutional review board approval was obtained (Appendix A). Both retrospective and prospective chart reviews of patient records occurred with the following inclusion criteria: prenatal and postpartum care at ECU OB/GYN, at least 36 weeks estimated gestational age (EGA), participated in at least three prenatal visits, were English speaking and 18 years old or greater. The global billing code (CPT Codes: 59610 [vaginal delivery], 59510 [cesarean delivery]) database was used to capture patient records that met inclusion criteria.

A retrospective chart review (n=118) ECU OB/GYN was used to assess if postpartum contraception education was introduced prenatally and at hospital discharge. Social and demographic information (age, race, body mass index [BMI], ethnicity, marital status, employment status, and method of payment) and obstetrical/contraception information (gravidity, parity, pregnancy interval, number of prenatal visits, gestational age when contraception education was provided, and type of contraception method chosen at time of discharge) was collected and stored in an Excel formatted data collection tool (Appendix B). Postpartum counseling documentation by any provider (Certified Nurse-Midwife [CNM], resident physician, or attending physician) any time during the pregnancy was identified by the chart review. Using the data collected from the chart review and the literature review an educational intervention for providers with the Diffusion of Innovation (Rogers, 1995) as a

framework was created and implemented. Once the educational intervention was developed, introduction to the project and educational intervention was disseminated to residents, attending physicians, and CNMs at one of the weekly resident educational sessions. Providers within the department who were not present at the weekly resident educational session were sent an email introducing them to the project and followed up at the next monthly faculty meeting. OB residents introduced off service residents to the project during their one-month rotation through the obstetrical service. To promote utilization of the educational intervention, the nurses and medical office assistants (MOAs) were introduced to the project at a clinical staff meeting to enlist their assistance in encouraging provider participation in the educational intervention. Implementation of the educational intervention extended for an eight-week period.

Barriers to the use of the educational counseling were identified at the provider educational session. Easily legible and attractive reminders were posted throughout the clinical area at workstations (Appendices C1 and C2). Weekly chart reviews were made to identify the utilization of the educational counseling.

Upon completion of the eight-week implementation period a prospective review of patient records (n=110) was performed and compared to the retrospective chart review data. Prior to implementation of the project, organizational and institutional review board approval was obtained. This project was scheduled to take place over the course of a 12-month period beginning June 2015 through July 2016 (see Appendix D for timeline).

Conceptual and Theoretical Framework

Conceptual framework. The Plan-Do-Study-Act (PDSA, Figure 2.) is a continuous four-step performance improvement process model (Deming, 2015) endorsed by the Institute for Healthcare Improvement (2015) as a powerful yet simple tool to frame and guide performance

improvement. The model focuses on three questions: (1) "What are we trying to accomplish?" (2) "How will we know that a change is an improvement?" and (3) "What change can we make that will result in improvement?" (Associates in Process Improvement, [API], 2015; NHS Institute for Innovation and Improvement, 2013). The process begins with the Plan step. A goal, theory, or purpose is identified with a set of metrics that are put into place to gather data. Next, the Do step involves implementing a plan, intervention, or product. The Study step measures the progress or success of the plan. It also identifies barriers, problems, and areas in need of improvement. The last step– Act – completes and integrates the process, adjusts the goals, and re-formulates the process if indicated. The process then repeats again and again for as long as needed (API, 2015; IHI, 2015).

Theoretical framework. In 1962 E. M. Rogers developed one of the oldest social science theories, the Diffusion of Innovation theory ([DOI], 1995). Diffusion is defined by four main elements "process in which an innovation is communicated through certain channels over time among the members of a social system" (1995, p. 5). The DOI was chosen to examine ECU OB/GYN providers' adoption process of the educational counseling intervention. Adoption of a new idea or educational counseling intervention in this case does not happen simultaneously by all participants (Rogers, 1995). The ECU OB/GYN providers as social beings will affect the innovation system. According to Rogers (1995) the social system is a boundary in which the innovation will diffuse. The system norms, social structure, opinion leaders and change agents within the structure will affect the innovation decisions and consequences of the innovation.

The DOI will identify the providers' behaviors that are likely to help or serve as a barrier to the implementation of the educational counseling intervention. The providers will fall into one of five adopter categories: (a) innovators, (b) early adopters, (c) early majority, (d) late majority,

and (e) laggards, with the majority falling into one of the two middle (early and late majority) categories (Figure 3). Innovators described as "venturesome" are risk takers and are the ones who bring new ideas into the social system's boundaries. The *innovators* of the ECU OB/GYN social system will be the first to try the educational counseling intervention. They will be interested from the beginning and little will need to be done to obtain their interest in the educational counseling intervention. The *early adopters* are the established leaders who have already identified a need for change and "will trigger the critical mass when they adopt an innovation" (Rogers, 1995, p. 283). *Early majority* adopters rarely take on leadership roles but are willing to try new ideas. They will need documentation that the educational counseling intervention has merit as part of the intervention. *Late majority* adopters are skeptical of change. These participants will eventually join the effort once all other majority has accepted the educational counseling intervention. And finally, *laggards* will be the most difficult to convince to try the educational counseling intervention. The laggards will stick to tradition and will only try the educational counseling intervention once they feel they have no choice by being shown hard facts and feeling peer pressure from the group (Rogers, 1995).

One or more of the five DOI adoption categories will influence acceptance and sustainability of the educational counseling intervention:

- Relative Advantage - The degree to which an innovation is seen as better than the idea, program, or product it replaces.
- Compatibility - How consistent the innovation is with the values, experiences, and needs of the potential adopters.
- Complexity - How difficult the innovation is to understand and/or use.

- Triability - The extent to which the innovation can be tested or experimented with before a commitment to adopt is made.
- Observability - The extent to which the innovation provides tangible results. (Rogers, 1995, para. 3).

Project Questions

- Is there a difference in whether or not a plan for contraception is documented in the medical record before and after the implementation of the educational intervention?
- Will patients be more likely to select a contraceptive method by the time of delivery if counseled prenatally, postpartum, or both?
- Which group of providers is more likely to document the contraceptive plan of care in the patient's medical record during the antepartum period? Postpartum period?

Summary

When postpartum women do not receive proper contraceptive counseling prior to hospital discharge they are put at increased risk for an unintended pregnancy, which leads to potentially devastating consequences for women, children, society (Dehlendorf et al., 2010) and the health care system (Sonfield et al., 2011). The ability to plan a pregnancy is key to improving pregnancy outcomes (Perritt et al., 2013). The goal of this educational counseling intervention was to formulate a plan to ensure all postpartum patients received standard education regarding postpartum contraception and were discharged with a clear plan for contraception using the PDSA Cycle (Deming, 2015).

Chapter 2: Literature Review

The literature review includes a review of what is known about prenatal/postpartum contraceptive counseling, methods of providing postpartum contraception, and the women who

use postpartum contraception; a description of the conceptual framework and how it will guide the entire project; the theoretical framework and how it will guide the implementation of the project; and a discussion of any gaps in the literature.

Definitions

The CDC (2011a) defines short pregnancy interval (SPI) as less than 18 months between a live birth and the next pregnancy. The postpartum period is defined as the first six weeks following the delivery of the placenta and membranes in which the maternal anatomical and physiological changes of pregnancy return to a normal and non-pregnant state (Cunningham et al., 2014; Fahey, 2013). For the purpose of this project postpartum contraception is defined as contraception used in the first 18 months following delivery. Contraception methods are defined as combined hormonal contraception (combined oral contraception [COC], progestin only pills [POP], patch, vaginal ring), the intrauterine device (IUD), female sterilization, female condom, male condom, implants, vasectomy, and diaphragm. Traditional method of contraception is defined as withdrawal, lactational amenorrhea (LAM), and the calendar method (Adanikin et al., 2013; Akman, Tuzun, Uzuner, Basgul, & Kavak, 2010; WHO, 2016).

Review of the Literature

PubMed and CINAHL databases were searched for all articles in the English language published in peer-reviewed journals between June 06, 2005, and June 17, 2015, describing the postpartum period and contraception. Search terms included ("Postpartum Period"[Mesh] OR ("postpartum period"[MeSH Terms] OR ("postpartum"[All Fields] AND "period"[All Fields]) OR "postpartum period"[All Fields] OR "postpartum"[All Fields])) AND ("Contraception"[Mesh] OR ("contraception"[MeSH Terms] OR "contraception"[All Fields])) AND ("2005/06/20"[PDAT] : "2015/06/17"[PDAT]) AND ("2005/06/20"[PDat] :

"2015/06/17"[PDat]). Reference lists for articles retrieved using this strategy were manually searched to identify additional articles. Potentially relevant titles were reviewed: duplicates, summaries, non-scholarly articles, contraception following abortion. HIV topics, and editorials were excluded. Abstracts followed by the remaining full articles were reviewed with continuing medical education (CME) articles; postpartum contraception following abortion was excluded. No experts in the field were contacted as part of this review. Out of 235 potentially relevant articles, 17 research articles were selected for review in greater detail (Figure 1).

Three general areas of discussion emerged in this literature review; (a) the effect certain demographics (educational level, age, ethnicity, and parity) have on women's selection of a postpartum contraception method; (b) various modes of how postpartum contraception counseling was achieved (face-to-face, in-depth, multiple encounters, one-times sessions, written leaflet, and a combination of two or more) and (c) timing of providing postpartum contraception counseling were reported without a consensus for the best approach. The research available on postpartum contraception counseling consisted of low to moderate quality evidence (Lopez, Hiller, Grimes, & Chen, 2012; Lopez et al., 2014). The findings in these studies varied from intent to use postpartum contraception and the actual use of postpartum conception,

Education, Age, Marital Status, and Parity.

Intent to use postpartum contraception use was found to be associated with women who had a minimum of a high school diploma (Bastianelli, Farris, Benagiano, & D'Andrea, 2013; Depineres et al., 2005; Di Giacomo et al., 2013). Postpartum contraception counseling performed specifically during the prenatal period did show some increased effect on use in women with less than a high school education (Hernandez et al., 2012). A greater use of postpartum contraception use associated with women age 35 or less (Depineres et al., 2005). Contrary to Depineres et al.

(2005), the intention to use contraception increased with age in postpartum women. Additionally, the choice to use postpartum contraception seemed related to women with a higher education level (Di Giacomo et al., 2013). Married women (Depineres et al., 2005) and increased parity (Bastianelli et al., 2013) were associated with intent to use a contraceptive method in the postpartum period. In a descriptive study of predictors of contraception knowledge among postpartum adolescents in El Salvador Newmann, Goldberg, Aviles, Perez, and Foster-Rosales (2005) determined that although education level and literacy were predictors of contraception knowledge in this population they were not predictors of contraception use or intention to use. Newmann et al. (2005) concluded for adolescents to apply their contraceptive knowledge their risk of pregnancy perception must be realistic along with a sense of empowerment within their social network.

Postpartum contraception counseling timing and modes of delivery.

Timing of counseling delivery. The antenatal and immediate postpartum periods are a unique time to provide postpartum contraceptive counseling (Di Giacomo et al., 2013). In spite of the opportunity and the unmet need for contraception in the postpartum period postpartum counseling is often neglected (Bastianelli et al., 2013). Opinions are conflicted in the most effective timing and approach to postpartum contraception counseling. Depineres et al. (2005) focused on the postpartum period prior to hospital discharge for counseling in their mixed prospective /descriptive study of 4096 postpartum women (giving birth 60-183 days prior to the survey) and on factors associated with postpartum contraception use. The population studied was 51% (1970) Hispanic compared to 13% (502) Native American and 35% (1352) non-Hispanic white. Depineres et al. (2005) found a positive association in their study with postpartum contraception use and the postpartum visit. They concluded postpartum contraception counseling

is effective and especially important in the postpartum period to avoid unintended pregnancy (Depineres et al., 2005). Other studies examined prenatal counseling alone or a combination of antenatal and postpartum counseling (Adanikin et al., 2013; Adegbola & Okunowo, 2009; Glazer et al., 2011; Hernandez et al., 2012; Perritt et al., 2013; Wilson et al., 2013; Yee & Simon, 2011). Two studies found an increased use in postpartum contraception when counseling was offered on multiple occasions during the prenatal period (Adanikin, Onwudiegwu, & Loto, 2013; Yee & Simon, 2011). An additional two studies found a positive association with postpartum contraceptive use when prenatal contraception counseling was documented (Perritt et al., 2013; Wilson et al., 2013). Both Barber (2007) and Hernandez et al. (2012) noted a significant difference in postpartum contraception use in women who received contraception counseling prenatally compared to those who did not.

Modes of delivery. Several studies focused on the mode of counseling delivery; face-to-face, in-depth, multiple encounters, one-times sessions, written leaflet, and combinations of modes (Akman et al., 2010; Perritt et al., 2013; Proctor et al., 2006; Yee & Simon, 2011). The two randomized studies in this review compared patient satisfaction (Proctor et al., 2006) using different contraception counseling modalities to determine the impact of counseling with educational leaflets on contraception practices of couples (Saeed et al., 2008). Proctor et al. (2006) saw a significant trend in patient satisfaction when counseling was provider to patient compared to video presentation or educational literature. Alternatively Saeed (2008) observed an increase in the number of patients who used contraception after receiving counseling with an educational pamphlet. There was also a shift in method use from less reliable to more reliable contraception methods in the intervention group (Saeed et al. 2008).

Theoretical and Conceptual Framework

Conceptual framework. The continuous four-step performance improvement process model PDSA (Deming, 2015) is used in many improvement projects by health care organizations and in many countries to improve health care processes and outcomes (IHI, 2015; U.S. Department of Health and Human Services Health Resources and Services Administration, [HHS], 2011).

Plan. The PDSA Plan (Figure 4.) step begins with a goal, theory, or purpose identified with a set of metrics put into place to gather data. ECU OB/GYN sees a myriad of obstetrical patients ranging in age from the very young to age 40 years and greater. Patients range from healthy and at low risk for pregnancy complications to those with multiple and often severe co-morbidities. There is diversity in education, socio-economic status, and ethnicity. Anecdotal observations suggests that many ECU OB/GYN obstetrical patients do not have a postpartum contraception plan at the time of hospital discharge or when they return for their postpartum visit. Absence of postpartum contraception at hospital discharge puts women at risk for unintended pregnancy and the risks associated with unintended pregnancy: (1) drug/alcohol abuse, (2) poor birth outcomes (Kost et al., 1998) and (3) shorter pregnancy intervals (CDC, 2011b) leading to potential increased risk of maternal mortality perinatal, neonatal, infant mortality and pre-term delivery (WHO, 2005; Zhu et al., 1999).

Observation of patients returning for their postpartum visits led to the anecdotal conclusion there is an unmet need for postpartum contraception for ECU OB/GYN patients. To answer the PDSA focus question, “What are we trying to accomplish?” (API, 2015; NHS Institute for Innovation and Improvement, [NHSIII], 2013); a project that examines the

frequency of postpartum counseling provided to patients was the selected focus medium chosen to address this unmet need.

Do. To implement the project there were several questions that would need to be answered; what is known about postpartum contraception counseling in the literature? How do ECU OB/GYN providers currently counsel patients regarding postpartum contraception? And a second PDSA model focus question, "What change can we make that will result in improvement?" (API, 2015; NHSIII, 2013). Implementation of the patient postpartum educational counseling by providers using a specially prepared supplemental brochure will help answer these two questions for this project.

Study. This step measured the progress of this project and answered the final focus question of the PDSA model; how will we know if the change is an improvement?" (API, 2015). Identification of barriers, problems that were not initially anticipated was addressed and modifications made where needed. The data collected (before and after the postpartum contraception counseling intervention) was analyzed and examined against the evidence discovered in the literature review.

Act. Upon completion of the project the Act of PDSA is the process where adjustments are made to the improvement project. This was an opportunity for provider feedback and reflection on the whole process (API, 2015; NHSIII, 2013). It was the "what can we do different or better?" stage. For any evidence of success and benefit of the project the next step would be to implement a department wide standardized postpartum contraception counseling for ECU OB/GYN patients.

Theoretical framework. The DOI was chosen to examine ECU OB/GYN providers' adoption process of the educational counseling intervention. The adoption of an educational

counseling intervention is not expected to happen simultaneously by all of the participants according to the DOI theory (Rogers, 1995). The DOI would help understand provider behaviors that were likely to help or serve as a barrier in the implementation of the educational counseling intervention. The participants (providers) of this project were expected to fall into one of five DOI categories: (a) innovators, (b) early adopters, (c) early majority, (d) late majority, and (e) laggards, with the majority falling into one of the two middle (early and late majority) categories (Rogers, 1995). Figure 3 demonstrates a visual of the DOI model.

There are five main factors (relative advantage, compatibility, complexity, trialability, and observability) in the DOI that influence adaptation (Rogers, 1995) of the postpartum contraception counseling. The DOI serves as a roadmap to ensure success in the implementation of the counseling. The project was introduced to the providers (residents, attending physicians, and CNMs) at one of the weekly resident educational sessions (see Appendix E for an outline of the presentation) and an email for any resident, or faculty (attending physicians and CNMs) member who may not have been in attendance for the initial presentation. A review of the current literature with the relative advantage and compatibility of this postpartum contraception-counseling project was presented to the providers.

Triability was evident as the project progresses. Each adopter contemplated the idea of participating in the project and considered the relative advantage, compatibility, and complexity of the project to them personally before making a commitment to participate. For this reason it was essential to consider perceived barriers in advance and address those in the methodology and implementation of the project so as many providers as possible would accept and participate. Their participation was a key element in the success of the project. Observability, the ability to

observe and identify any tangible results is perhaps the most simplistic of DOI factors of influence to obtain and will be determined in the synthesis of the results.

Research Gaps

Contraception counseling in the postpartum period has been shown to be especially important. Adverse health and social consequences for both mother and newborn have been associated with short interval pregnancy (Jacoby, Gorenflo, Black, Wunderlich, & Eyler, 1999; Johnson & Johnson, 1980; King, 2003; Population Reference Bureau PRB. International Programs, 1992) and leads to fewer unplanned pregnancies (Akman et al., 2010). Yet there is no standard on how to best approach postpartum contraception counseling. Approaches to counseling are in conflict and while there are several studies on postpartum contraception counseling in the postpartum period (Wilson et al., 2013), few studies looked at the impact the prenatal period has on postpartum contraception counseling (Akman et al., 2010). Studies in which there was a significant increase in use or intent to use postpartum contraception were low to moderate quality because of design or their generalizability. Two Cochrane systematic reviews reported consistent findings. Lopez et al. (2012) reported the limited research available was very low and showed no effect on many of the comparisons. Likewise, the Lopez et al (2014) study reported limited research, low to moderate quality evidence, limited design, analysis, reporting and inability to generalize to postpartum women. Quality of methodology, heterogeneity differences, and risk of bias were addressed in each review. The limitations of both reviews were similar; 10 studies met inclusion criteria to determine the effectiveness of educational interventions on postpartum contraception use (Lopez et al., 2012) and only six non-randomized studies examining the association between interventions to improve postpartum

contraction use met inclusion criteria. Half the studies were conducted prior to published guidelines for observational studies (Lopez et al., 2014)

The few quality and low evidentiary studies leave a tremendous gap in the available evidence. To improve the quality and level of evidence future research is needed and should be published using the most recent published guidelines for the study design. Future research should focus on assessing postpartum contraception intervention success (Wilson et al., 2013; Yee & Simon, 2011) optimal education practices (Glazer et al., 2011).

Summary

With over half of 6.4 million U.S. pregnancies unintended (Curtin et al., 2013; Finer & Zolna, 2014) and the prevalence of contraception use and the unmet need for family planning world wide as a key indicator for measuring access to reproductive health (WHO, 2015) it is clear the need for postpartum contraception is not being met (Ross & Winfrey, 2001). The postpartum period is an exceptional time to assess for contraception needs. Along with prenatal visits it is an obvious and unique time to provide postpartum contraception counseling because it provides daily contact with the woman's health care provider while in the hospital recovering from the birth (Glazer et al., 2011). Many factors and influences must be considered to effectively address this unmet need. Basic demographics- age, marital status, education level, and parity (Bastianelli et al., 2013; Depineres et al., 2005; Di Giacomo et al., 2013; Hernandez et al., 2012) can impact the knowledge of patients and the likelihood of using postpartum contraception. Timing of postpartum contraception education (prenatal versus postpartum or both) and how many times it was provided during the postpartum period impacts the use or intent to use postpartum contraception (Perritt et al., 2013; Proctor et al., 2006; Yee & Simon, 2011). The delivery mode (provider to patient one-to-one discussion, education by video or by

educational handout) can also impact use and intent to use postpartum contraception (Saeed, Fakhar, Rahim, & Tabassum, 2008) with provider to patient counseling noted as an effective measure in a couple of studies (Bastianelli et al., 2013; Proctor et al., 2006).

Chapter 3: Methodology

Design

The proposed quality improvement project involved a retrospective/prospective chart review approach in the collection of data. The retrospective data collected helped identify the current practice of postpartum contraception counseling by OB/GYN providers. The prospective data were collected after providers implemented a postpartum contraception counseling intervention designed for the purposes of this project.

Retrospective designs are often used in conducting quality control studies and in identifying the current status of an organization (Schmidt & Brown, 2015). To improve postpartum contraception use the current counseling practices by the OB/GYN providers participating in this project first had to be identified. Through the retrospective chart review data were collected from the existing prenatal and postpartum counseling methods. Prospective study designs are non-experimental designs often used in epidemiological studies and help identify presumed cause by following subjects into the future (Schmidt & Brown, 2015). Following the completion of the eight-week counseling implementation phase a prospective chart review and data collection was performed to analyze for documentation of postpartum contraception counseling during prenatal and postpartum care.

Setting

Approval to conduct the project within the ECU Department of OB/GYN at the Brody School of Medicine was granted by the department Chair (Appendix F). Data was collected from

the electronic health record (EHR) of ECU OB/GYN obstetrical patients. ECU OBGYN has a large tertiary care practice located in Greenville, North Carolina. The practice serves Pitt and 28 other counties in eastern North Carolina. ECU OB/GYN billed for 1271 deliveries the months of July 2014- June 2015. Pitt County alone consists of 59% white residents, 34% African-American, 5.5% Hispanic and the remaining population is represented by Asian, American Indian, Alaska Native, and Native Hawaiian. Twenty-seven percent are female and childbearing age between the ages of 15 and 44 (North Carolina Department of Health and Human Services, 2011).

Providers at ECU OB/GYN are categorized by attending physicians, resident physicians (intern 1st year, junior, 2nd year, senior 3rd year, chief 4th year and off-service [family medicine and emergency medicine] residents who rotate through obstetrics for one month periods) and CNMs. CNMs and attending physicians each provide obstetrical care independently. Obstetrical care by residents is provided under the supervision of the attending physicians.

Sample

The Clinical Department Administrator and Medical Billing Manager were consulted for the most effective means to capture patient records that received their prenatal/postpartum care at ECU OB/GYN. After discussing several search methods and a review of prenatal patient and delivery numbers over a six-month period, the global billing code (CPT Codes: 59610 [vaginal delivery], 59510 [cesarean delivery]) database was selected as the most effective means to collect records that would meet proposed inclusion criteria. The total number of records was a convenience sample of 225 ECU OB/GYN obstetrical patients, English speaking, 18 years or older who were at least 36 weeks at delivery, received a minimum of three prenatal visits at ECU

OB/GYN, and were delivered by ECU OB/GYN providers for both the retrospective and prospective data collection.

Methods

The retrospective data were collected for the months of January through April 2015. The records with CPT Codes: 59610 (vaginal delivery), 59510 (cesarean delivery) were downloaded into an excel spreadsheet. Data collected and entered into a separate excel spreadsheet were age, race, ethnicity, marital status, education level, employment status, gravidity and parity, method of payment, number of prenatal visits, pregnancy interval if applicable, if contraception counseling was performed prenatally (number of times) and at hospital discharge, gestational age at the time of the counseling, type of contraception chosen, and provider type (resident physician, attending physician or CNM). Education level was excluded from the data collection process after discovering the designated location for this data within the EHR was not routinely used.

A didactic introduction to the project and intervention was given to the providers at a weekly Ground Rounds/resident educational conference (Appendices C1 and C2). In addition to introducing the project the didactic content included a review on current contraceptive methods, how to document the educational encounters, and how to use the educational visual aids. An email was sent out to all department CNMs, attendings, and residents to capture any providers who were not present at the conference. Off-service residents who rotated through the OB service were introduced to the project after their orientation.

English speaking patients who were at least 28 weeks gestation received postpartum contraception counseling face-to-face by a provider along with a brochure (Appendices G1 and G2) prepared for this project to be used at the initial education encounter. The brochure was

developed and funded by the author at an eight grade reading level using the Automated Readability Index (Test Statistics, 2016). It provided a brief overview of postpartum ovulation, risks of unintended pregnancy, safety of contraception, and most effective and suitable methods of postpartum contraception. A brief face-to-face follow-up education encounter was performed at the 35 to 37 week prenatal visit. This encounter was used as an opportunity for patients to ask questions that had developed since the first counseling encounter, for the provider to clarify and document a choice of contraception if one had been made, and to counsel any patient whom had not previously received counseling. Documentation of the education encounter was placed in a predetermined location within the EHR (Appendix H1).

The final educational component was a brief face-to-face patient encounter in the immediate postpartum period prior to hospital discharge. The educational summary leaflet used at the initial counseling encounter was used as a supplement to the follow-up and postpartum counseling encounters. Like the 35-37 week prenatal visit, this encounter was used as an opportunity for patients to ask questions, and for the provider to clarify and document a choice of contraception if one had been made, and to counsel any patient whom had not previously received counseling. Documentation of the final education encounter was placed in the inpatient EHR first postpartum day note using an EHR "smartphrase" (Appendix H2).

The prospective data using the same inclusion criteria and data collection tool as the retrospective chart review were collected after the providers implemented the educational strategy for the months of January through April 2016.

To promote utilization of the educational intervention, the nurses and medical office assistants (MOAs) were introduced to the project at a clinical staff meeting to enlist their assistance in reminding provider participation in the educational intervention. Legible and

attractive reminders were posted throughout the clinical area at workstations. Weekly chart reviews were made to identify the utilization of the educational counseling.

Protection of Human Subjects

An expedited Internal Review Board (IRB) approval (Appendix A) and Health Insurance Portability and Accountability Act (HIPPA) waiver authorization were granted (Appendix I) on the basis there was minimal risk and the probability of harm or discomfort anticipated was no more that would ordinarily be encountered in daily life during the performance of this project (Health and Human Services [HHS], 2009). Data collected was stored on an ECU Information Technology and Computing Services (ICTS) HIPPA acceptable storage device (OB/GYN department research folder piratedrive).

Data Analysis

The retrospective (no contraception plan) and the prospective (contraception plan) groups were compared to demographic and clinical characteristics using Fisher's exact tests to compare categorical variables and enhanced education (prenatal and postpartum education vs. one or the other). Logistic regression was used to assess for relative risks between the two groups and demographic and clinical characteristics. Provider types between the retrospective and prospective groups were compared using Fisher's exact tests. *P* values less than .05 were considered significant. Statistical analysis was generated using SAS software. Copyright © (2013) SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

Limitations and Summary

There are several limitations of this project: small sample size, the use of convenience sampling, lack of randomization or a control group, retrospective design, and the potential for

confounding variables and differences in the groups in ways other than in the variables of interest. The potential for bias is less prevalent in retrospective as compared to prospective study designs. The limited timeframe in which the prospective arm of the project was conducted may limit conclusions about the intervention. While the second part of the project was a prospective chart review it was not an experimental design and was therefore limited to only comparisons between the retrospective data and the prospective data. Since the project was implemented in one tertiary OB practice in North Carolina and not over multiple sites the conclusions were not generalizable to other tertiary care practices or smaller private practices.

Chapter 4: Results

This chapter presents the results of the data analysis. Demographics are described and key findings highlighted. A total of 355 EHR were selected using the CPT Codes: 59610 (vaginal delivery), 59510 (cesarean delivery) and were downloaded into an excel spreadsheet. Following exclusion of duplicate records, ages less than 18 years, and non-English speaking patients were identified, 234 EHR met inclusion criteria for data collection and analysis. Following preliminary analysis Asians (n=3) and Native Americans (n=7) were excluded from further analysis due to the small numbers for a total of 225 records. Most patients were less than 35 years of age in both the no contraception (86%) and the contraception (87%) groups, black (57% and 51%, respectively), and single (62% and 63%, respectively). There was no significant difference between the two groups in demographics, clinical characteristics, or the enhanced education intervention (prenatal, postpartum or both). However, while still not significant blacks, Hispanics, obese patients, the unemployed and those receiving Medicaid were less likely to choose a contraception plan demonstrated by a decrease in relative risk. While not statistically significant there was an increased association in multiparous women and those with a pregnancy

interval of less than 18 months in choosing a contraception plan prior to hospital discharge (Table 1.).

Forty-one providers were categorized into provider type (attending, CNM, OB resident, and off-service resident) and by in-hospital and outpatient prenatal provider. The provider categories were not mutually exclusive. There was no significant difference between the two groups (contraception and no contraception) and provider types.

Discussion

This DNP scholarly project began as a quality improvement in response to an anecdotal observation. In the practice setting of the author it appeared many postpartum women at the time of their hospital discharge were undecided or had not considered postpartum contraception. According to DiGiacomo (2013) a unique time to provide postpartum contraceptive counseling is in the antenatal and immediate postpartum period. With over half of all pregnancies in the U.S. unintended (Finer & Zolna, 2014) and postpartum women discharged from the hospital without contraception at risk for unintended pregnancy (Kost et al., 1998) the purpose of this project became to implement a contraception counseling plan ECU OB/GYN providers could share with antenatal and postpartum patients.

Contraception counseling is routinely provided in the prenatal period as recommended by ACOG (2005) but a standard does not exist on how it should be approached. A few low to moderate quality studies exist reporting the timing and delivery mode of postpartum contraception counseling. The contraception-counseling plan for this project was modeled using a combination of modalities (multiple discussions prenatal/postpartum, provider/patient face to-face counseling, and supplemental material (contraception brochure) found in the current literature. Several studies found an increased intent to use contraception with counseling

performed face-to-face between provider and patient (Adanikin et al., 2013; Adegbola & Okunowo, 2009; Proctor, Jenkins, Loeb, Elliot, & Ryan, 2006). Two studies suggest multiple short discussions take place over the antenatal period. Adanikin et al. (2013) found multiple counseling discussions had a significant impact on patients who had previously been undecided on a contraceptive method while Yea and Simon (2011) suggest more desirable long-term outcomes may be a result of this counseling approach. Likewise, this project recommended counseling women in the antenatal as well as postpartum period.

In addition to the combination of modalities the final modality of this contraception-counseling plan is the signature piece of the plan and what the author believes set it apart from other plans. The brochure was designed to briefly address the quick return to ovulation in the postpartum period, risks of unintended pregnancy and present the most effective and available methods of postpartum while recommending each patient choose the method most suited to her individual needs. This approach was adopted based on conclusions drawn that women who received more information regarding postpartum physiology, contraception, contraception methods and promoting reproductive health were more willing to use contraception (Di Giacomo et al., 2013).

Conceptual and Theoretical Framework

Conceptual Framework. The project followed the Plan-Do-Study-Act, a continuous cycling conceptual model used by the IHI (2015) to advance improvement in population health, improve care, and reduce costs per capita. The project moved forward smoothly as projected. During the presentation of the project to the providers just prior to the implementation phase it was suggested to change the documentation strategy in the postpartum period by placing documentation of the postpartum contraception counseling in the first postpartum day note

instead of the originally planned discharge summary note. The reasoning for the change was that the provider making the first day postpartum rounds would have more time to provide the more in-depth counseling than would the provider at time of discharge. The discharge provider could then reinforce the plan and method of contraception choice.

The change later proved to make postpartum period counseling data collection difficult. Although the changes were suggested and made on behalf of providers who would be documenting the postpartum counseling; no provider used the "smart phrase" developed to be used in the first postpartum day note nor was it used in the discharge summary in spite of documentation reminders posted at each work station (Appendices C1 and C2). Thus each postpartum note and discharge summary of every record in the database was read to determine if the postpartum contraception counseling had been implemented. This created two problems (1) data collection became more time consuming than previously anticipated and (2) some bias may have been introduced because the postpartum notes and discharge summary had to be interpreted by the author. However, since the author was the sole data collector interpretation was not subject to more than one individual. The question arises if this change was implemented based on the suggestion of those who would be providing the counseling and documenting "why was the documentation not used since the change was implemented based on the provider's suggestions?" Firstly, in addition to OB residents, off-service (family medicine and emergency medicine) residents who rotate a month at a time on the OB service see the postpartum patients. The off-service residents did not attend the Wednesday afternoon OB conference time and therefore did not receive the initial instruction and description of the postpartum contraception-counseling project. The off-service residents were not introduced to the project in the some manner or introduced at all to the project by their fellow OB residents. Secondly, "complexity"

one of the five factors in the DOI (Rogers, 1995) framework that influences adaption of change may have been a component.

Theoretical Framework. Rogers' (1995) five adopter categories (Innovators, Early Adopters, Early Majority, Late Majority, and Laggards) are distributed over a normal distribution curve (Figure 3). Although, the adoption process was not measured it was noted by feedback from providers individually and collectively based on the interest and excitement expressed in the project. According to the availably of the project brochure to use as a supplement in counseling patients this group of providers fell into the early adopters and early majority categories. Out of the five factors that influence adaptation (Rogers, 1995) "complexity" was the factor that most likely influenced this project. "Complexity is the degree to which an innovation is perceived as relatively difficult to understand and use" (Rogers, 1995, p. 257). For the off-service residents who may have little knowledge or understanding of the project the reminders positioned at each workstation were likely not enough explanation for them to document according to the desired protocol. If they received any instruction from the OB residents it may have only been brief and without explanation sufficient for buy-in. The "smartphrases" developed to insert documentation into the EHR could have also presented a confusing picture because they were similar in nomenclature. The antenatal smartphrase was ".postpartumcontraception" and the postpartum smartphrase was ".contraceptionpostparptum". A different terminology for one of the smartphrases may have improved documentation.

Implication of Findings

This project originated as a quality improvement to assure all obstetrical patients within the authors practice received a standard and effective postpartum contraception counseling by the providers. Because of the small sample size (n=225) and the design of the project encompassed

intent to treat group (those receiving the enhanced postpartum contraception counseling) it also represented the components of a pilot research study.

The results in detail are presented in Table 1. Demographics of the study sample differed from Pitt County demographics. There were more blacks (57% [no contraception] and 51% [contraception]) compared to Pitt County's 34% black population and fewer Hispanics (5%) in the sample compared to Pitt County (8.4%). Greater than half of the sample was unemployed compared to the unemployment rate in Pitt County (NCDHHS, 2011).

Consistent with the findings of Hernandez et al. (2012), there was no significant difference in race, ethnicity, and parity in women who chose a postpartum contraception method. Additionally, in this study there was no statistical difference in any demographic or clinical characteristics. In fact when examined, there was either no difference or a decreased (while not significant) incidence of a documented use of a postpartum contraception following the enhanced counseling. There was some difference (although not significant) found by pregnancy interval less than 18 months being associated with unintended pregnancy and multiparity. It is conjectured the results may have reached a level of significance with a larger sample size and an increase in power.. Finally, there was no indication any provider type was more likely to document the contraception plan of care in the prenatal or postpartum medical record. These findings suggest other factors influence patient's decisions to choose a postpartum contraceptive method or plan.

Limitations

There are several limitations of this project: small sample size, the use of convenience sampling, lack of randomization or a control group, retrospective design, and the potential for

confounding variables and differences in the groups in ways other than in the variables of interest.

The primary limitation of this project was time and limited data due to time. The time from conception to completion was a year. Prenatal care is covered over the span of weeks (late prenatal care) to an ideal time period of approximately nine months. In order to allow time for data collection and analysis the implementation period was limited to a period of eight weeks. Sample size would have been increased with an extended implementation phase and increased power and effect size.

The DOI (Rogers, 1995) theoretical framework describes five factors that influence adaptation. The complexity factor is a limitation of the overall project. Because off-service providers were not introduced to the project in the same manner as other providers they may not have had the same understanding of relative advantage to the project as the other providers. Secondly, if this project were to be repeated, the manner in which postpartum contraception counseling is documented needs to be revised. Confusion in how and where to document was a limiting factor and added to the complexity of the project. Time for data collection was time consuming because postpartum notes and discharge summaries had to be critically reviewed as opposed to a quick search for the key “smartphrase” in the documentation.

Finally, because of the demographic difference in the sample population to the demographics of surrounding Pitt County and the study setting is a tertiary care practice serving 29 counties of eastern North Carolina, the results are not generalizable to more rural or private practices.

Implications for practice

Providing postpartum contraception counseling in this setting on multiple occasions prenatally and in the immediate postpartum period using an educational brochure made no difference. The take away is not that education does not make a difference, but that *this* education did not show a statistical significance. More educational practices need to be explored, and further research needs to be done. An idea that resonates from the literature review but was not used in this project was the influence of husband and partner attitudes toward contraceptives (Adegbola & Okunowo, 2009). Questions to consider are "what social factors, other than the obvious demographics, influence the use of postpartum contraception?" and "What role does self-efficacy play in a woman's choice to use postpartum contraception?"

Conclusion

It is important to note while there was no statistical difference found a clinical significance does exist. The residents expressed a raised awareness to implement postpartum contraception counseling in their practice. Providers stated they liked having "something to give patients" to enhance their postpartum contraception discussion and often used the brochure in counseling their gynecological patients on contraception as well. If an outcome for one mother or child was improved through the prevention of one unintended pregnancy then this project was a success.

References

Adanikin, A. I., Onwudiegwu, U., & Loto, O. M. (2013). Influence of multiple antenatal counselling sessions on modern contraceptive uptake in Nigeria. *The European Journal of Contraception & Reproductive Health Care: The Official Journal of the European Society of Contraception, 18*(5), 381-387. doi:10.3109/13625187.2013.816672 [doi]

Adegbola, O., & Okunowo, A. (2009). Intended postpartum contraceptive use among pregnant and puerperal women at a university teaching hospital. *Archives of Gynecology and Obstetrics, 280*(6), 987-992. doi:10.1007/s00404-009-1056-6 [doi]

Akman, M., Tuzun, S., Uzuner, A., Basgul, A., & Kavak, Z. (2010). The influence of prenatal counselling on postpartum contraceptive choice. *The Journal of International Medical Research, 38*(4), 1243-1249.

American College of Obstetricians and Gynecologists. (2005). *The importance of preconception care in the continuum of women's health care*. (Committee Opinion No. 313). Washington, D.C.: The American College of Obstetricians and Gynecologists.

Associates in Process Improvement, [API]. (2015). Model for improvement. Retrieved from http://www.apiweb.org/

Barber, S. L. (2007). Family planning advice and postpartum contraceptive use among low-income women in Mexico. *International Family Planning Perspectives, 33*(1), 6-12. doi:3300607 [pii]

Bastianelli, C., Farris, M., Benagiano, G., & D'Andrea, G. (2013). Unmet needs and knowledge of postpartum contraception in Italian women. *Clinical and Experimental Obstetrics & Gynecology, 40*(4), 514-518.

Baydar, N. (1995). Consequences for children of their birth planning status. *Family Planning Perspectives, 27*(6), 228. Retrieved from http://search.proquest.com.jproxy.lib.ecu.edu/docview/1306079512?accountid=10639

Boden, J. M., Ferguson, D. M., & Harwood, J. L. (2008). Early motherhood and subsequent life outcomes. *Journal of Child Psychology and Psychiatry, 49*(2), 151-160. doi:10.1111/j.1469-7610.2007.01830.x

Centers for Disease Control and Prevention. (2011a). Pediatric and pregnancy nutrition surveillance system. Retrieved from http://www.cdc.gov/pednss/what_is/pnss_health_indicators.htm#Maternal Health Indicators

Centers for Disease Control and Prevention. (2011b). Update to CDC's U.S. medical eligibility criteria for contraceptive use, 2010: Revised recommendations for the use of contraceptive methods during the postpartum period. *MMWR: Morbidity & Mortality Weekly Report, 60*(26), 878-883. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=2011205471&site=ehost-live

Cunningham, F. G., Leveno, K., Bloom, S., Dashe, J., Hoffman, B., Casey, B., & Sheffield, J. (2014). The puerperium. *Williams obstetrics* (24th ed.). New York, NY: McGraw-Hill Education.

Curtin, S. C., Abma, J. C., Ventura, S. J., & Henshaw, S. K. (2013). *Pregnancy rates for U.S. women continue to drop*. (No. 136). Hyattsville, MD: National Center for Health Statistics: NCHS.

Dehlendorf, C., Rodriguez, M. I., Levy, K., Borrero, S., & Steinauer, J. (2010). Disparities in family planning. *American Journal of Obstetrics and Gynecology, 202*(3), 214-220. doi:http://dx.doi.org.jproxy.lib.ecu.edu/10.1016/j.ajog.2009.08.022

Deming, W. E. (2015). The plan, do, study, act (PDSA) cycle. Retrieved from https://www.deming.org/theman/theories/pdsacycle

Depineres, T., Blumenthal, P. D., & Diener-West, M. (2005). Postpartum contraception: The New Mexico pregnancy risk assessment monitoring system. *Contraception, 72*(6), 422-425. doi:S0010-7824(05)00249-0 [pii]

Di Giacomo, P., Sbarlati, A., Bagnasco, A., & Sasso, L. (2013). Woman's contraceptive needs and preferences in the postpartum period: An Italian study. *Journal of Clinical Nursing, 22*(23), 3406-3417. doi:10.1111/jocn.12432

Fahey, J. (2013). Anatomy and physiology of postpartum. In T. L. King, M. C. Brucker & J. M. Kriebs (Eds.), *Varney's midwifery* (5th ed., pp. 1101--1110). Sudbury, MA: Jones and Bartlett Learning.

Finer, L. B., & Zolna, M. R. (2014). Shifts in intended and unintended pregnancies in the United States, 2001-2008. *The American Journal of Public Health, 104*(2), 43.

Glazer, A. B., Wolf, A., & Gorby, N. (2011). Postpartum contraception: Needs vs. reality. *Contraception, 83*(3), 238-241. doi:10.1016/j.contraception.2010.07.002 [doi]

Guttmacher Institute. (2015). State facts about unintended pregnancy: North Carolina. Retrieved from https://www.guttmacher.org/statecenter/unintended-pregnancy/NC.html

Health and Human Services [HHS]. (2009). Code of federal regulations: Protection of human subjects. Retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Healthy People 2020. (2015). Maternal, infant, and child health. Retrieved from http://www.healthypeople.gov/2020/leading-health-indicators/2020-lhi-topics/Maternal-Infant-and-Child-Health

Hernandez, L. E., Sappenfield, W. M., Goodman, D., & Pooler, J. (2012). Is effective contraceptive use conceived prenatally in Florida? The association between prenatal contraceptive counseling and

postpartum contraceptive use. *Maternal and Child Health Journal, 16*(2), 423-429. doi:10.1007/s10995-010-0738-9 [doi]

Institute for Healthcare Improvement. (2015). How to improve. Retrieved from http://www.ihi.org/resources/Pages/HowtoImprove/default.aspx

Jacoby, M., Gorenflo, D., Black, E., Wunderlich, C., & Eyler, A. E. (1999). Rapid repeat pregnancy and experiences of interpersonal violence among low-income adolescents. *American Journal of Preventive Medicine, 16*(4), 318-321. doi:S0749-3797(99)00029-X [pii]

Johnson, F. C., & Johnson, M. R. (1980). Family planning: Implications for marital stability. *Journal of Divorce, 3*(3), 273-281. doi:10.1300/J279v03n03_07 [doi]

King, J. C. (2003). The risk of maternal nutritional depletion and poor outcomes increases in early or closely spaced pregnancies. *The Journal of Nutrition, 133*(5 Suppl 2), 1732S-1736S.

Klepinger, D. H., Lundberg, S., & Plotnick, R. D. (1995). Adolescent fertility and the educational attainment of young women. *Family Planning Perspectives, 27*(1), 23-28. Retrieved from http://www.jstor.org/stable/2135973

Kost, K., Landry, D. J., & Darroch, J. E. (1998). Predicting maternal behaviors during pregnancy: Does intention status matter? *Family Planning Perspectives, 30*(2), 79-88. Retrieved from http://www.jstor.org/stable/2991664

Lopez, L. M., Grey, T. W., Chen, M., & Hiller, J. E. (2014). Strategies for improving postpartum contraceptive use: Evidence from non-randomized studies. *The Cochrane Database of Systematic Reviews, 11*, CD011298. doi:10.1002/14651858.CD011298.pub2 [doi]

Lopez, L. M., Hiller, J. E., Grimes, D. A., & Chen, M. (2012). Education for contraceptive use by women after childbirth. *The Cochrane Database of Systematic Reviews, 8*, CD001863. doi:10.1002/14651858.CD001863.pub3 [doi]

Moore, K. A., Myers, D. E., Morrison, D. R., Nord, C. W., Brown, B., & Edmonston, B. (1993). Age at first childbirth and later poverty. *Journal of Research on Adolescence (Lawrence Erlbaum), 3*(4), 393-422. doi:10.1111/1532-7795.ep11301350

Newmann, S. J., Goldberg, A. B., Aviles, R., de Perez, O., & Foster-Rosales, A. (2005). Predictors of contraception knowledge and use among postpartum adolescents in El Salvador. *American Journal of Obstetrics & Gynecology, 192*(5), 1391-1394. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=2005105809&site=ehost-live

NHS Institute for Innovation and Improvement. (2013). Plan, do, study, act (PDSA). Retrieved from http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/plan_do_study_act.html

North Carolina Department of Health and Human Services. (2011). Pitt county community health assessment. Retrieved from http://publichealth.nc.gov/lhd/cha/reports.asp

Perritt, J. B., Burke, A., Jamshidli, R., Wang, J., & Fox, M. (2013). Contraception counseling, pregnancy intention and contraception use in women with medical problems: An analysis of data from the Maryland pregnancy risk assessment monitoring system (PRAMS). *Contraception, 88*(2), 263-268. doi:10.1016/j.contraception.2012.11.009 [doi]

Population Reference Bureau PRB. International Programs. (1992). Family planning saves lives. *Integration (Tokyo, Japan), (34)*(34), 18-25.

Proctor, A., Jenkins, T. R., Loeb, T., Elliot, M., & Ryan, A. (2006). Patient satisfaction with 3 methods of postpartum contraceptive counseling: A randomized, prospective trial. *The Journal of Reproductive Medicine, 51*(5), 377-382.

Rogers, E. M. (1995). *Diffusion of innovations*. New York: Free Press.

Ross, J. A., & Winfrey, W. L. (2001). Contraceptive use, intention to use and unmet need during the extended postpartum period. *International Family Planning Perspectives, 27*(1), 20. Retrieved from http://search.proquest.com.jproxy.lib.ecu.edu/docview/235834333?accountid=10639

Saeed, G. A., Fakhar, S., Rahim, F., & Tabassum, S. (2008). Change in trend of contraceptive uptake — effect of educational leaflets and counseling. *Contraception, 77*(5), 377-381. doi:10.1016/j.contraception.2008.01.011

Schmidt, N., & Brown, J. (Eds.). (2015). *Evidence-based practice for nurses* (3rd ed.). Burlington, MA: Jones & Bartlett Learning.

Sonfield, A., & Kost, K. (2015). *Public costs from unintended pregnancies and the role of public insurance programs in paying for pregnancy-related care: National and state estimates for 2010*. (). New York: Guumacher Institute.

Sonfield, A., Kost, K., Gold, R. B., & Finer, L. B. (2011). The public costs of births resulting from unintended pregnancies: National and state-level estimates. *Perspectives on Sexual and Reproductive Health, 43*(2), 94-102. doi:10.1363/4309411

Test Statistics. (2016). Readabilitly-score.com. Retrieved from https://readability-score.com

U.S. Department of Health and Human Services Health Resources and Services Administration, [HRSA]. (2011). Testing for improvement. Retrieved from http://www.hrsa.gov/quality/toolbox/methodology/testingforimprovement/part2.html

Wilson, E. K., Fowler, C. I., & Koo, H. P. (2013). Postpartum contraceptive use among adolescent mothers in seven states. *The Journal of Adolescent Health: Official Publication of the Society for Adolescent Medicine, 52*(3), 278-283. doi:10.1016/j.jadohealth.2012.05.004 [doi]

World Health Organization. (2005). *Report of a WHO technical consultation on birth spacing*. (). Geneva, Switzerland: World Health Organization.

World Health Organization. (2015). Unmet need for family planning. Retrieved from http://www.who.int/reproductivehealth/topics/family_planning/unmet_need_fp/en/

World Health Organization Health Organization. (2016). Family planning. Retrieved from http://www.who.int/mediacentre/factsheets/fs351/en/

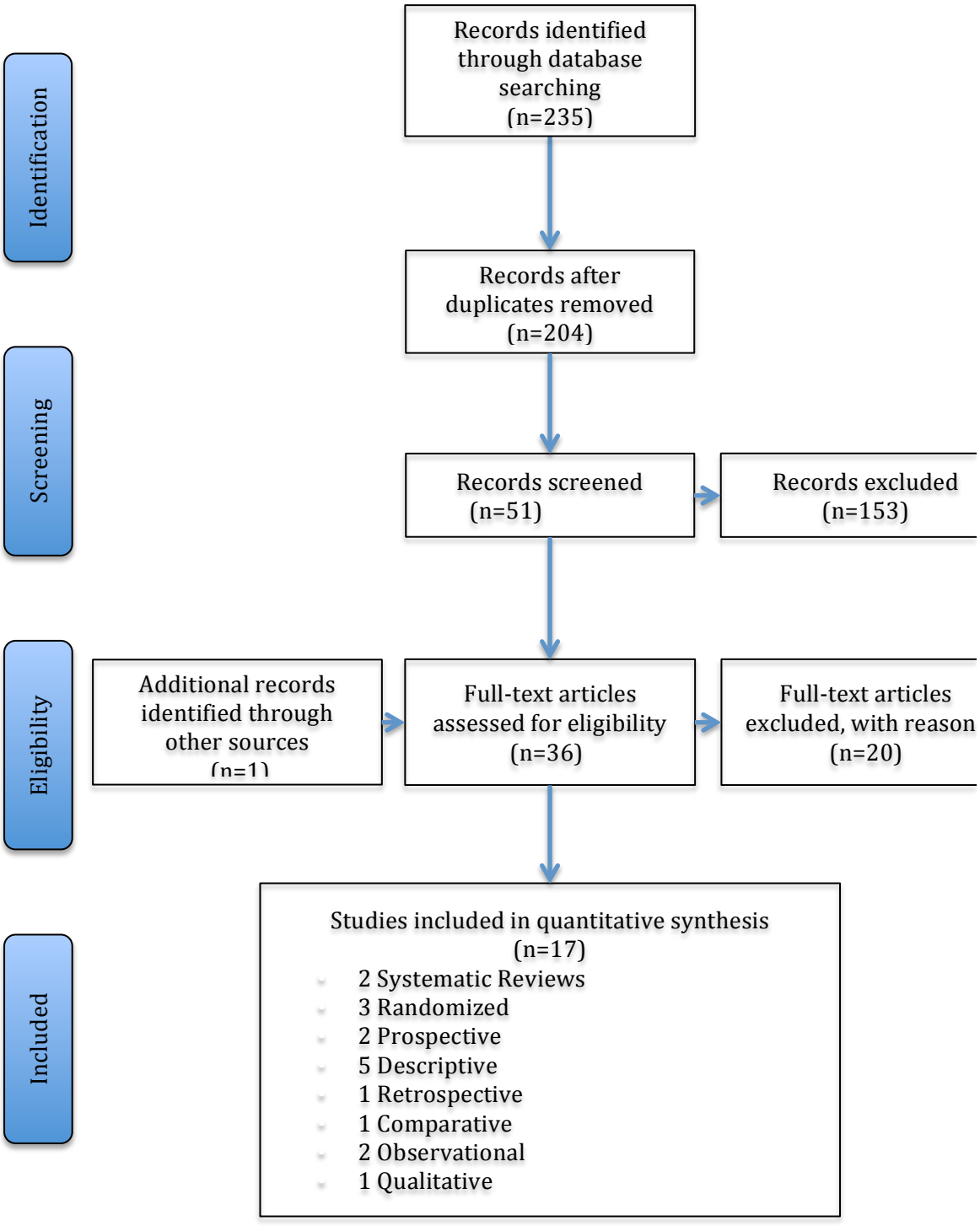
Yee, L., & Simon, M. (2011). Urban minority women's perceptions of and preferences for postpartum contraceptive counseling. *Journal of Midwifery & Women's Health, 56*(1), 54-60. doi:10.1111/j.1542-2011.2010.00012.x

Zhu, B., Rolfs, R. T., Nangle, B. E., & Horan, J. M. (1999). Effect of the interval between pregnancies on perinatal outcomes. *The New England Journal of Medicine, 340*(8), 589-594. Retrieved from http://search.proquest.com.jproxy.lib.ecu.edu/docview/223951963?accountid=10639

Table 1. Patient Characteristics

Characteristic	Contraception Plan n (%)	No Contraception Plan n (%)	p value[a]	Univariable RR (95%CI)	Multivariable	
					Model 1[§] RR (95%CI)	Model 2[¶] RR (95%CI)
Demographic						
Age >35 (y)	29 (13)	3 (14)	1.0	1.0 (.89-1.1)	1.0 (.89-1.1)	1.0 (.92-1.2)
Black	105 (51)	12 (57)	.65	.98 (.90-1.06)	.97 (.89-1.05)	.97 (.89-1.06)
Hispanic	11 (5)	1 (5)	1.0	.99 (.83-1.2)	.95 (.88-1.03)	1.0 (.9998-1.0002)
BMI >30	120 (59)	11 (52)	.64	.98 (.89-1.1)	.99 (.90-1.09)	1.0 (.999-1.0001)
Married	76 (37)	8 (38)	1.0	1.0 (.92-1.1)	1.0 (.95-1.05)	1.0 (.97-1.1)
Employed	99 (49)	10 (48)	1.0	1.0 (.92-1.1)	.95 (.88-1.03)	1.0 (.9998-1.002)
Medicaid	141 (69)	13 (62)	.62	.97 (.88-1.1)	.92 (.83-1.03)	
Clinical						
Pregnancy Interval <18 (m)	78 (38)	12 (57)	.11	.93 (.85-1.02)		1.1 (.95-1.3)
Prenatal Care visits >10	87 (43)	8 (38)	.82	.98 (.90-1.1)		1.0 (.9998-1.002
Multigravida	153 (75)	13 (62)	.20	.94 (.84-1.04)		1.0 (.85-1.2)
Multiparous	130 (64)	9 (43)	.097	.92 (.84-1.01)		
Prenatal Counseling[#]	156 (76)	14 (67)	.30	.95 (.85-1.06)		.96 (.85-1.09)
In Hospital Provider						
Attending Physician[β]	1 (<1)	0 (0)	1.0	•		
First Year OB Resident[β]	83 (41)	11 (52)	.36	•		
Second Year OB Resident[β]	33 (16)	5 (24)	.36	.96 (.87-1.04)		
Third Year OB Resident[β]	10 (5)	1 (5)	1.0	.95 (.83-1.08)		
Fourth Year OB Resident[β]	2 (1)	0 ()	1.0	1.0 (.83-1.2)		
Off Service Resident[β]	75 (37)	4 (19)	.15	1.1 (.99-1.2)		
No Provider[β]	0 (0)	0 (0)	1.0	•		
Outpatient Prenatal Provider						
Attending Physician[β]	4 (2)	0 (0)	1.0	•		
CNM[β]	78 (38)	9 (43)	.81	.98 (.90-1.07)		
First Year OB Resident[β]	46 (23)	5 (24)	1.0	.99 (.90-1.1)		
Second Year OB Resident[β]	17 (8)	2 (10)	.69	.99 (.84-1.2)		
Third Year OB Resident[β]	18 (9)	0 (0)	.39	•		
Fourth Year OB Resident[β]	21 (10)	0 (0)	.23	•		
No Provider[β]	201 (99)	21 (100)	1.0	•		
Intervention						
Enhanced Education	98 (48)	12 (57)	.57	.97 (.89-1.05)	.94 (.88-1.02)	.97 (.88-1.07)

Figure 1. Study flow diagram of potentially relevant studies

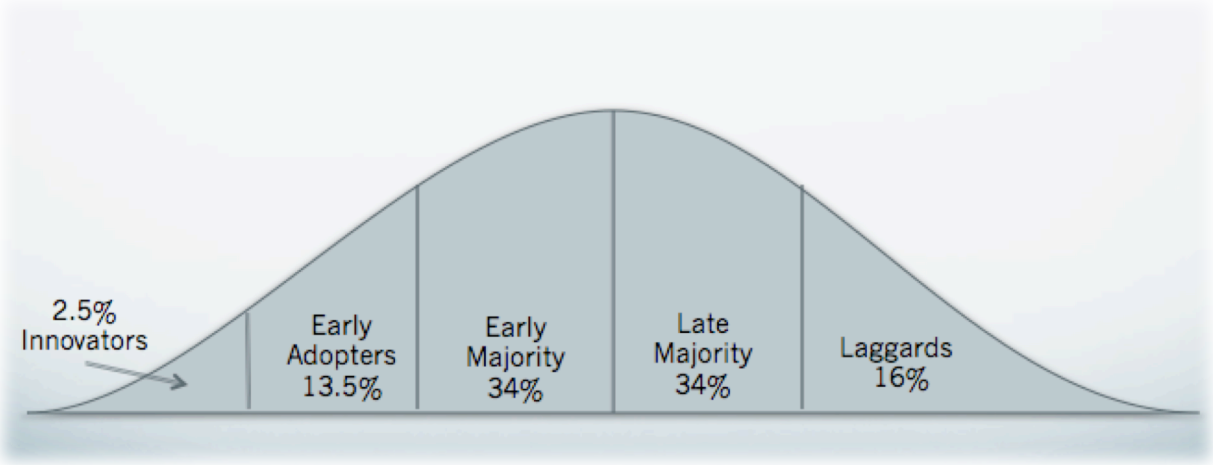


·*Adapted from:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group(2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(6): e100(doi:10.1371/journal.pmed1000097

Figure 2. Plan-Do-Study-Act (PDSA) Cycle

Source:(Deming, 2015)

Figure 3. Diffusion of Innovation Theory



.

· Source: Diffusion of Innovation Theory. by E. M. Rogers (1995)

Figure 4. Illustration of project application to PDSA model

Adapted from Source: (Deming, 2015)

Appendix A

IRB Approval Letter

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board Office
4N-70 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914** · Fax **252-744-2284** · **www.ecu.edu/irb**

Notification of Initial Approval: Expedited

From: Biomedical IRB
To: Monica Horne
CC: Rebecca Bagley
Date: 12/9/2015
Re: UMCIRB 15-001645
Improving Contraception Use in the Postpartum Period

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) is for the period of 12/9/2015 to 12/8/2016. The research study is eligible for review under expedited category # 5. The Chairperson (or designee) deemed this study no more than minimal risk.

Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The Investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Name	Description
Data Collection Sheet	Data Collection Sheet
HIPAA Waiver of Authorization Application	HIPAA Authorization
Improving Contraception Use in the Postpartum Period	Study Protocol or Grant Application

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

Appendix B

Data Collection Tool

ID	Patient age	Patient Ethnicity	Patient Race	Patient Marital Status	Patient Education	Patient Employment Status	Gravida	Para	Method of Payment	Pregnancy Interval	Number of Prenatal Visits	Was Contraceptive counseling Documented prenatally?	Was Contraceptive Counseling documented prior to hospital discharge?	Gest. Age at the time the Counseling was documented prentally	Type of Contraception chosen at discharge	Provider Type
1																
2																
3																
4																
5																
6																
7																
8																
9																
10																
11																
12																
13																
14																
15																
16																
17																
18																
19																
20																
21																
22																
23																
24																
25																
26																
27																
28																
29																
30																
31																
32																
33																
34																
35																
36																
37																
38																
39																
40																
41																
42																
43																
44																
45																
46																
47																
48																
49																
50																

Appendix C1

Workstation Reminder Chart (side 1)

Improving Contraception Use in the Postpartum Period

Guide to prenatal and postpartum counseling

Initiate counseling at 28 weeks EGA and follow up at 36 weeks

Face-to-face counseling

- Why use birth control?
- Is birth control safe?
- What method is right for me?
- Types of birth control suited for postpartum use

Supplement with the counseling brochure

Postpartum contraception		Please document date and choice
28 week counseling		
Late 3rd trim. counseling		
Method selected		

Document

Document your counseling using the smartphrase *.postpartumcontraception*

Appendix C2

Workstation Reminder Chart (side 2)

Include postpartum contraception counseling in discharge teaching

Counsel

- Follow up counseling prior to discharge
- Supplement counseling with the contraception counseling brochure

Postpartum contraception was discussed. *The "I'm Still Pregnant. Do I Really Need to Think About Birth Control Now?"* educational leaflet was given and will be using *** for contraception.

Document

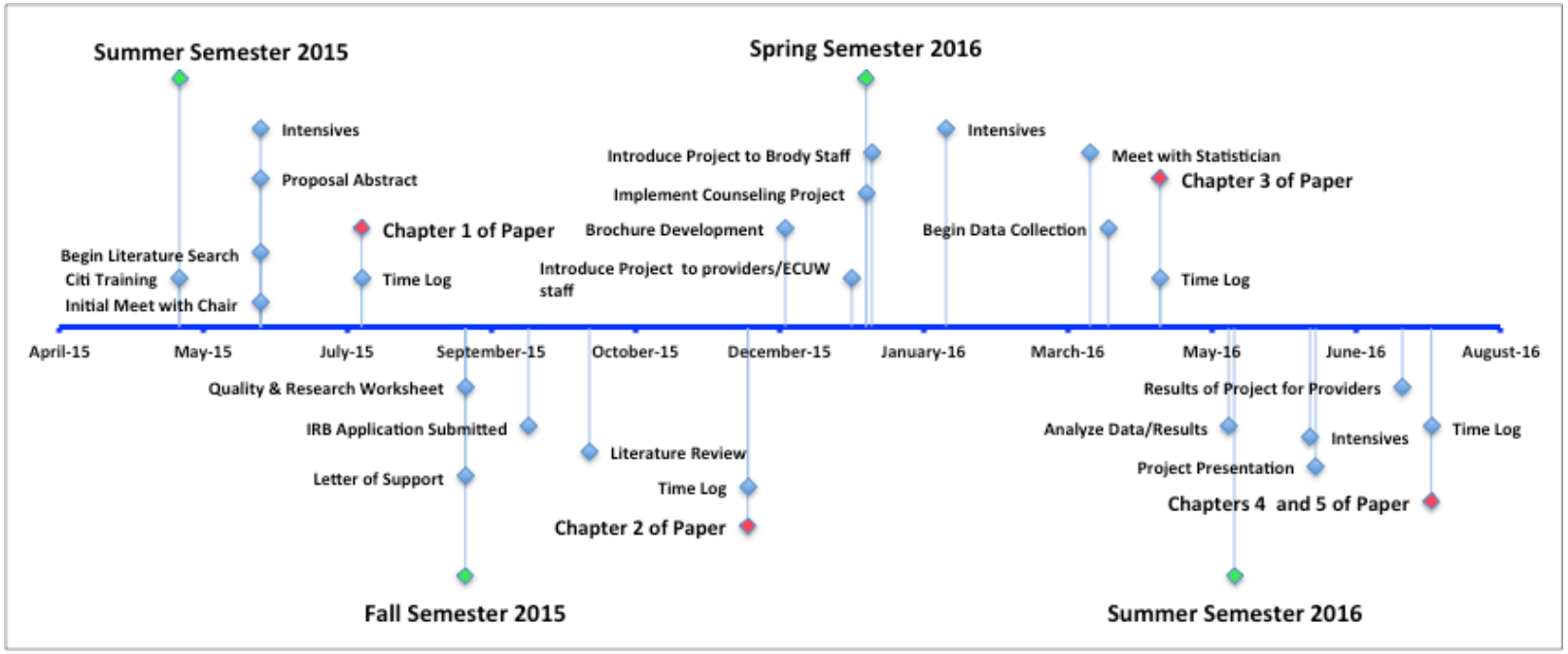
- Document your counseling using the smartphrase *.contraceptionpostpartum* in the first postpartum day note

For more information on contraception counseling?

- http://www.cdc.gov/reproductivehealth/unintendedpregnancy/contraception_guidance.htm
- http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/PDF/Contraceptive_methods_508.pdf
- Hatcher, R., Trussell, J., Nelson, A., Cates, W., Kowal, D., & Policer, M. (Eds.). (2011). *Contraceptive technology* (20th ed.). New York, NY: Ardent Media, Inc.

Appendix D

Project Timeline



Appendix E

Outline of Project Presentation for Providers

What is Quality Improvement (QI)?	
Principles of Quality Improvement QI Work as Systems and Process • Focus on Patients • Focus on Being Part of the Team • Focus on Use of the Data	5 min
QI is Essential to a Health Care Organization • Improve patient health and health outcomes • Improve efficiency of managerial and clinical processes	
Model for Improvement- Plan-Do-Study-Act (PDSA)	
QI Project- Improving Contraception Use in the Postpartum Period • Background • Purpose • Project Questions • Review of the Literature • Applying the PDSA model • Methodology • Inclusion criteria • Chart Review • "I'm Still Pregnant. Do I Really Need to Think About Birth Control Now?" brochure & face-to-face counseling • Documentation process of counseling	25 min
Questions & Discussion	15 min

· Source- (Institute for Healthcare Improvement, 2015)

Appendix F

Letter of Support

East Carolina University

Obstetrics and Gynecology
Brody School of Medicine
East Carolina University
Greenville, NC 27834

252-744-4610 office

Clifford Hayslip, MD
Professor and Chair
Department of Obstetrics and Gynecology
Vidant Medical Center
Medical Annex 170
Greenville, NC 27834
252-744-5695

General Obstetrics and Gynecology
252-744-5903 or 252-744-1466
Tana Hall, MD, Division Chief
Cynthia D. Barker, MD
James deVente, MD, PhD
Jason Hildebrand, MD
Adam Kansagor, DO
Keith Nelson, MD
Sarah Smith, MD
Jill Sutton, MD
Debra Hanson, CNM, MSN
Monica Horne, CNM, MSN
Monica Newby, CNM, MSN
Jan Salstrom, CNM, MSN

Maternal-Fetal Medicine
252-744-4662
Christy Isler, MD, Interim Division Chief
Raymond Dombroski, MD
Edward R. Newton, MD
Charles Hodson, PhD
Diana Strickland, BSBA, RDMS

Reproductive Endocrinology and Infertility
252-744-3849
Clifford Hayslip, MD, Division Chief

OB/GYN Clerkship
252-744-4669

OB/GYN Residency
252-744-4669

Patient Appointments:
ECU Women's Physicians
252-744-3850 phone
252-744-3894 fax

Brody Outpatient Clinic
252-744-2350 phone
252-744-2967 fax

September 2, 2015

To Whom It May Concern

I have reviewed Monica Horne's DNP Scholarly Project title "Improving Contraception Use in the Postpartum Period". Ms. Horne has departmental support and approval to conduct her project within the Department of Obstetrics and Gynecology at the Brody School of Medicine. I understand that for Ms. Horne to achieve completion of the DNP program, a public presentation and manuscript submission related to the scholarly project will be required by the University.

Ms. Horne is working with her professor to determine if the project will need IRB approval or if it will be exempt.

Thank you,

Clifford C. Hayslip, MD
Professor/Chair
Department of Obstetrics and Gynecology

Appendix G1

Contraception Counseling Brochure (inside view)

Why Use Birth Control?

You can become pregnant *as early as three weeks* after having your baby if you are not breastfeeding. You ovulate before your period starts.

Using birth control to plan your pregnancies helps put you in control of your body and your future.

You can avoid an unintended pregnancy.

If you become pregnant *before you plan* to be, you are at higher risk for:

- Drug and alcohol abuse
- Living in poverty
- Being a victim of domestic abuse
- Depression
- Difficulty finding or keeping a job
- Failure to graduate from high school or college
- Closely spaced pregnancies
  This puts your infant at risk for low birth weight, preterm birth, developmental delay, and poor relationship with you. You are at risk for bleeding, infection and even death.
- Problems for your health or your baby's health
  If you have high blood pressure

Is Birth Control Safe?

For the most part birth control is much safer than pregnancy, abortion or delivery.

Risk of using birth control may be greater if you have a medical problem.

Talk with your provider to choose the method safest for you.

What Method is right for me?

First think about:

- Your health
- If you plan to have more children and when
- Side effects of each method
- Your comfort level using the method
- Remember for the birth control to be effective you must use it correctly

Types of Birth Control that are most suited for postpartum contraception

Implantable Devices- inserted by your provider

- *Copper IUD*- good for up to 10 years. No hormones. 8 out of

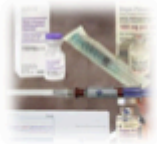
- *IUD with progestin*- good for up to 3-5 years. 2 out of 1000 women may still become pregnant

  Possible side effects are irregular bleeding, no periods, or cramping
- *Implantable rod*- good for up to 3 years. Flexible, the size of a matchstick, placed under the skin in the arm.

  Possible side effects are irregular bleeding, weight gain, headache, or mood changes

Hormonal Methods

- *Injection* "the shot"- Progestin shot every 3 months. 6 out of 100 women may still become pregnant



  Possible side effects are irregular bleeding, headaches, or weight gain.
- *Vaginal ring*- releases estrogen and progestin. You place the ring inside the vagina. It is worn for 3 weeks. 9 out of 100 women may still become pregnant

  Possible side effects are vaginal discharge, discomfort, or mild irritation.
- *Patch*- estrogen and

Appendix G2

Contraception Counseling Brochure (outside view)

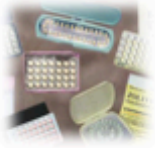
buttocks or back. Changed once a week. 8 out of 100 women may still become pregnant. May be less effective in obese women

A possible side effect is skin irritation. Risks- exposed to higher levels of estrogen compared to combined oral contraceptives. May be at increased risk for blood clots compared to women who use combined oral contraceptives.

- *Combined oral contraceptives* "the pill"-  estrogen and progestin hormones in a pill taken every day at the same time of day. 9 out of 100 women may still become pregnant.

  Possible side effects are changes in menstrual cycle, nausea, breast tenderness, or headache.

  Less common serious side effects- may develop high blood pressure, blood clots, heart attack, or stroke.

- Progestin-only pill "the mini pill"- only one hormone (progestin). Taken every day at the same time of day. 9 out of 100 women may still become pregnant. 

  Possible side effects are irregular bleeding, headache, breast tenderness, or nausea

Barrier Methods

- *Male condom*- thin sheath placed over the erect penis before sex. Must be removed before the penis softens. 18 out of 100 women may still become pregnant. 
- *Female condom*- thin lubricated pouch placed in the vagina. 21 out of 100 women may still become pregnant 

  Male and Female condoms are for single use only. No prescription needed. Protect against sexually transmitted infections. May cause irritation

Lactation Amenorrhea Method (LAM)- requires full breastfeeding with no menstrual period, for the first 6 months after delivery. If you decrease or stop breastfeeding, begin your menstrual period, or your baby is greater than 6 months old, you must use another from of birth control. 1 to 2 out of 100 women may still become pregnant.

Sterilization- highly effective permanent surgical procedure

- Female
  - Tubal ligation "tying tubes"
  - Trans cervical implant
- Male
  - Vasectomy

**This brochure gives you only brief information about the methods of postpartum birth control. It allows you to plan in advance for the method that will work best for you. When you decide what method you would like or for more detailed information ask your provider.

"I'm Still Pregnant. Do I Really Need to Think About Birth Control Now?"

Discussing Your Postpartum Contraception Options

Appendix H1

Prenatal Documentation Table

Postpartum contraception		Please document date and choice
28 week counseling		
Late 3rd trim. counseling		
Method selected		

Appendix H2

Inpatient EHR First Postpartum Day Note

Postpartum contraception was discussed. *The "I'm Still Pregnant. Do I Really Need to Think About Birth Control Now?"* educational leaflet was given and will be using *** for contraception.

Appendix I

HIPPA Waiver Authorization

UMCIRB # 15-001645 **PI: Monica Todd Horne**

University and Medical Center Institutional Review Board
Application for Waiver of Authorization

1. Select the types Protected Health Information (PHI) to be collected:
   - [☒] Billing records
   - [☐] Mental Health records
   - [☐] Physician/clinic records
   - [☐] other:
   - [☐] Hospital/medical records (in and out patient)
   - [☐] Lab, pathology and/or radiology results
   - [☐] PHI previously collected for research purposes

2. Select the responses below for all the identifiers to be captured in the research study:
   - [☐] Postal address
   - [☒] Account /medical record number
   - [☐] Certificate/license number
   - [☐] Name of relatives
   - [☐] E-mail address
   - [☐] Health plan numbers
   - [☐] Name
   - [☐] Name of employers
   - [☐] Photographic images
   - [☐] Finger or voice prints
   - [☐] Telephone number
   - [☐] Internet Protocol (IP) address number
   - [☐] Web universal resource locator (URL)
   - [☐] Fax number
   - [☐] Any device or vehicle identifiers and serial numbers, including license plate numbers
   - [☐] Date of birth, admission date, discharge date, date of death, all ages over 89
   - [☐] Any other unique identifying number, characteristic or code

Please note: Pursuant to North Carolina law, **social security numbers are not permitted to be collected in reliance on this waiver of authorization**. Unless social security numbers are required by law to be collected, the study subject must be given a written disclosure which (i) states that providing social security number is not required; and (ii) describes the purpose for which the social security number will be used.

3. Select the response below on how participant's Protected Health Information (PHI) is protected against improper use or disclosure:
   - [☐] Research team members will sign a Confidentiality Agreement.
   - [☒] The information will not be shared unless it is stripped of all 18 identifiers.
   - [☐] The information will be shared with a random code as outlined in the research protocol.

4. Explain the data management measures to protect the confidentiality of participant's data such as storage and access issues, including (i) safeguards for storage of any identifiers on computer workstations; and (ii) safeguards for storage of any identifiers on laptop computers, flash drives or any other portable electronic device, as applicable.

   All PHI (billing codes, medical records numbers) will be kept on the investigator's ECU pirate drive. The computer used to manage the data will be password protected.

5. Data will be stripped of all identifiers upon completion of:
   - [☐] subject participation
   - [☐] data analysis
   - [☐] FDA approval
   - [☐] specimen processing
   - [☒] other (please specify): chart review

   OR

   Identifiers will be retained indefinitely because:
   - [☐] the study is longitudinal
   - [☐] of federal requirements (specify):
   - [☐] other (specify):

6. Provide any additional explanations on why the use/disclosure of PHI involves no more than minimal risk to participant privacy

   The subjects will not be present at the time of data collection. Medical record numbers will be used to access charts for review. Once medical record is accessed, no PHI will be collected.

7. Explain why the participant's Authorization cannot be attained and, therefore, research cannot be practicably carried out without the Waiver of Authorization.

   The subject medical record numbers will not be known or identified by the investigator until after the billing and coding is completed by the billing department- as this is the means for identifying the subjects.

8. Select the response or explain why research cannot practicably be conducted without the participant's PHI.
   - [☒] PHI is needed to identify eligibility for the study
   - [☐] PHI is the focus of the study (e.g. – epidemiological studies)
   - [☐] Other (specify):

UMCIRB version 3/12/10
References: 45 CFR 160 and 164, Standards for Privacy of Individually Identifiable Health Information; Final Rule
NC Gen. Stat. Sect. 132-1.10 (Social Security Numbers and Personal Identifying Information)