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7-27-2015

Postpartum Contraception and Rapid

Repeat Pregnancies in Rural, Low-Income

Black Women with Baseline Risk Factor

Comparisons

KAREN LI GEORGIA STATE UNIVERSITY

ABSTRACT

POSTPARTUM CONTRACEPTION AND RAPID REPEAT PREGNANCIES IN RURAL, LOW-INCOME BLACK WOMEN WITH BASELINE RISK FACTOR COMPARISONS

By

KAREN LI

July 27, 2015

INTRODUCTION: The residents in the Low Country region of South Carolina consist of a predominantly low-income, African American population with a history of trauma and experiences of racism. Chronic conditions, unintended pregnancies, and adverse birth outcomes are prevalent. Many women experience rapid repeat pregnancies (RRP) due to lack of access to choices in contraceptive methods or lack of education on the dangers of RRP and prevention through contraception. Low Country Healthy Start (LCHS) aims to ensure that perinatal women and adolescents in the service area who enrolled received adequate prenatal and postpartum care, educational and counseling services, and contraceptive methods, including a Depo Provera injection at discharge (D1) after their index birth in LCHS. Previous research agree that black women, adolescents are less likely to retain a form of contraception that requires maintenance and proper usage.

AIM: To (1) examine the effect of D1 and other variables on time to RRP; and to (2) examine the effect of receiving various forms of contraception and their use over time, including the Depo injection (D2) on time to RRP.

METHODS: Clients included in the analysis either delivered a baby while enrolled in LCHS or had complete data on all necessary variables (n=761). The Cox regression model was fitted to model the effect of receiving different contraceptive methods as well as relevant and statistically significant (α =0.05) risk factors on time to RRP.

RESULTS: For Aim 1, D1 resulted in a hazard rate about 46% lower than that of a non-D1 (unadjusted HR = 0.54, 95% CI: 0.36- 0.83; adjusted HR = 0.52, 95% CI: 0.34-0.8). However, after adjusting for other variables (age, unplanned index pregnancy, physical abuse during pregnancy, and postpartum depression score) and the time-varying effect of D1, D1 resulted in a HR of 29.63 (β = 3.39, 95% CI: 6.049- 145.141), that decreased at a natural log function of time (HR = 0.22, β = -1.53, 95% CI: 0.12-0.40).

For Aim 2, D2 resulted in a lower hazard rate than non-D2 (unadjusted HR = 0.17, 95% CI: 0.09-0.32; adjusted HR = 0.16, 95% CI: 0.08-0.31). Adjusting all variables in Aim 2, including D2, D1 resulted in a statistically insignificant lower HR of 0.88 (p = 0.544, 95% CI: 0.57-1.34). There was no significant interaction between D1 and D2 or between D1 and any other contraceptive type. LARC showed a highly protective but not statistically significant effect against RRP (adjusted HR = 0.05, p = 0.093, 95% CI: 0.002-2.26), but that protective effect decreased multiplicatively by about .25 with each passing month (HR = 1.25, p = 0.029, 95% CI: 1.02-1.53).

DISCUSSION: These findings indicate that the Depo injection, although important to receive at discharge, must be continued consistently to have a significant protective effect in preventing a RRP. LARC methods in general are strong protective factors. Being issued a contraceptive method that required adherence predicted a shorter inter-pregnancy interval (IPI), but this reflects the client's adherence to the contraceptive method, and not its biological effectiveness. Future research should examine the effect of receiving the Depo injection at discharge on the continuation of different contraceptive methods, as well as the effect of counseling and educational services on contraceptive use and time to RRP.

POSTPARTUM CONTRACEPTION AND RAPID REPEAT PREGNANCIES IN RURAL, LOW-INCOME BLACK WOMEN WITH BASELINE RISK FACTOR COMPARISONS

by

Karen J. LI

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APPROVAL PAGE

POSTPARTUM CONTRACEPTION AND RAPID REPEAT PREGNANCIES IN RURAL, LOW-INCOME BLACK WOMEN WITH BASELINE RISK FACTOR COMPARISONS

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Author's Statement Page

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Karen Li

Signature of Author

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Introduction

1.1 Background

Rapid repeat pregnancies (RRP), defined by medical and social science journals as subsequent pregnancies in which the time period from birth of the index child to next conception, or the inter-pregnancy interval (IPI), are either less than 24 months (Barnet et al., 2009; Crittenden et al., 2009; Damle et al., 2015; L Patchen et al., 2009; L Patchen et al., 2009; Raneri & Wiemann, 2007), 18 months (Gemmill & Lindberg, 2013; Gillmore et al., 1997; Waggoner et al., 2012), 12 months (Bennett et al., 2006; Templeman et al., 2000; Tocce et al., 2012), or sometimes 6 months (Patchen & Lanzi, 2013). They are a major public health issue, especially for populations that have a high rate of poverty, low education, chronic conditions, and adolescent pregnancy. Adolescent pregnancy presents an enormous responsibility that the girl and her family cannot afford, disrupts her educational path, and pulls her even deeper into a life in poverty. Lack of knowledge or access to effective prevention methods and other personal obstacles or influences perpetuate perceptions and behaviors, putting girls and women at higher risk of a shorter IPI (Bennett et al., 2006; Crittenden et al., 2009; Gemmill & Lindberg, 2013; Gillmore et al., 1997; R. Gold et al., 2004; James-Hawkins & Sennott, 2015; L Patchen et al., 2009; Patchen & Lanzi, 2013; Raneri & Wiemann, 2007). After delivery, for example, a woman who resumes intercourse, while neither breastfeeding nor using an effective method of contraception, is at risk of pregnancy within three weeks regardless of next menses (Sober & Schreiber, 2014; Tepper et al., 2011).

The Low Country region of South Carolina consists of a predominantly black, lowincome, rural population. The inhabitants face a lifetime of economic hardships, psychological stressors, chronic conditions, and infant morbidity and mortality. One birthing hospital serves all four counties in Low Country: Allendale, Bamberg, Hampton, and Orangeburg. Financial barriers to health care hinder the ability for women to obtain effective contraception and knowledge of, leading to negative outcomes of great magnitude, both direct and indirect, for both infant and maternal health. Other issues that are prevalent in the population, such as adolescent pregnancy, easily exacerbate the conditions.

1.2 Purpose

In 2007, the Low Country Healthy Start program (LCHS) was implemented as an effort to improve all aspects of perinatal and family health, including family planning and pregnancy spacing, for women (clients) who enroll in the program. Several benchmarks are set at the federal level with target figures. For example, Healthy Start aims to promote quality by reducing the proportion of Healthy Start pregnancies conceived within 18 months of a previous birth to 30%. Services include counseling about effective contraceptive choices in the prenatal and postpartum period. LCHS collaborates with doctors and midwives to offer the Depo Provera injection to each client upon discharge from the hospital after giving birth. Client navigators (CNs) coach clients individually to ask for the Depo injection if not offered. In 2012, 59.4% of enrolled women left the hospital after delivery with an effective contraceptive method, up from 43.9% in 2003. Even with the extensive measures that the program takes, at least 40% were not offered, declined, or did not ask for the Depo injection. Such cases require comprehensive casework to assess these clients for influential factors such as intent of pregnancy, intent to breastfeed, perceptions of contraceptive methods and of carrying a baby, and behavioral and social influences. Overcoming current challenges requires thorough coordination and communication between case managers, LCHS personnel, and health providers.

Barriers still exist that prevent adequate knowledge about the inter-pregnancy period from being disseminated effectively in regions such as Low Country. For a population that is prone to RRP in the midst of perpetual economic hardship, LCHS must ascertain the factors that lead to RRP in order to help women with family planning, including effective contraceptive use, to achieve longer IPIs. This study has two primary aims: (1) to evaluate the effect of receiving the Depo injection at discharge on time to subsequent pregnancy, accounting for other risk factors and potential confounders, and (2) to investigate the effect of receiving Depo injections over time on time to RRP, relative to using other contraceptive methods over time. We believe that receiving the Depo injection at discharge will be a protective factor against shorter IPIs. Secondly, we believe that receiving Depo injections over time or receiving a long-acting reversible contraceptive (LARC) during the postpartum period will also protect against shorter IPIs. Separate analyses will be done to accomplish Aim 1 and Aim 2.

Literature Review

The literature that was selected in relevance to this study presents past research on predictors of short IPIs among at-risk and marginalized women. First, we discuss both demographic factors and pregnancy-related factors that have been shown to lead RRPs, including African American race and adolescence. Pregnancy-related factors include characteristics such as mental health, intention of pregnancy, and behavioral tendencies. Next, we present evidence of factors that influence the choice of a postpartum contraceptive method. Whether or not a woman should use postpartum contraception and which one heavily depends on both health risks and the woman's behavior and lifestyle postpartum (i.e. breastfeeding, resuming sexual intercourse). Furthermore, whether or not a woman actually takes the contraceptive method and continues it may depend on several psychological and behavioral factors. Finally, the literature discusses how different methods of contraceptives actually affect IPIs in the presence of characteristics of women similar to the Low Country population.

2.1 Characteristics That Lead to Short Inter-pregnancy Intervals (IPI)

Gemmill and Lindberg (2013) conducted a cross-sectional study on a nationally representative sample (n = 2,253) of self-reported subsequent pregnancies in the US. They found that 35% of the pregnancies were conceived within 18 months of a previous birth. Black women, 15-19 year old adolescents, and women reporting an unintended pregnancy were significantly more likely to experience a RRP. Use of contraceptive method was not included in the study, but women who had a Medicaid delivery were more likely to report the pregnancy as unintended.

The CDC Morbidity and Mortality Weekly Report (MMWR) stated that, out of over 367,000 adolescent (15-19 years old) births from 16 Pregnancy Risk Assessment Monitoring System (PRAMS) sites across the US (15 states and New York City) from 2007-2010, almost 20% were repeat births (Gavin et al., 2013). This report similarly found that black adolescents are more likely than white adolescents and Hispanic adolescents to experience a rapid repeat pregnancy (Gavin et al., 2013; Gemmill & Lindberg, 2013).

Crittenden et al. (2009) looked at self-reported mental health factors, behavioral factors, and past experiences that led to RRP (< 24 months) in a sample of mostly black adolescents (n = 354). Baseline reports of later age at menarche and a greater likelihood of physical aggression were associated with RRP. James-Hawkins and Sennot (2015) performed a qualitative study that consisted of narratives describing 30-60 minute interview sessions with 40 low-income women, 20 black and 20 white, and their child-bearing experiences throughout their life course. The narratives exhibit trends of self-claimed young naiveté in instances of adolescent pregnancy, hyper-fertility (failure of contraceptive methods), and inclination toward mainstream social norms (i.e. having one's first baby at an appropriate age) even if they themselves violated them ("young and dumb"). They reveal common perceptions among low-income women in that they would prefer to wait to have children, and that they often felt that their pregnancies were beyond their control or due to youthful lack of education on the matter. Although the more recent studies of factors of RRP lack a large sample size and high quality methodology or analysis, the findings support associations of the above important characteristics that need to be examined further, more rigorously, and in the context of contraceptive practice.

Patchen et al. (2009) conducted a preliminary study (n = 58, 59% black) with prevalence estimates of mental health and trauma indicators in adolescent mothers who had a subsequent pregnancy (SP) within 24 months and adolescent mothers who did not (NSP, comparison group: random sample of the NSPs, matched for age and ethnicity). In this small sample, significantly more SP adolescent mothers than NSP adolescent mothers had recorded mental health issues (from discouragement to attempting suicide) and trauma (rape, physical or emotional abuse, sexual abuse, or death of a loved one) in their prenatal and postpartum assessments. They conducted another study (n = 279) on maternal depression and RRP (< 6 months) in first-time mothers (ages 15-36 years) and found that women diagnosed with moderate to severe depression had significantly higher odds (7.24) of RRP than women diagnosed with minimal to mild depression (Patchen et al., 2013). However, the comparison was based on a small outcome of 12 RRPs. Although the study began with a small sample size and experienced a high attrition rate, the follow-up period lasted 36 months with a RRP cutoff at 6 months. They reported no significant difference between races, although their only indicators were white and non-white.

Studies using older data from the early 1990s to determine social and socioeconomic factors, while disregarding use of contraceptives, either found no difference in time to RRP

(Gillmore et al., 1997; Gold et al., 2004, 2005) or occurrence of RRP (Raneri & Wiemann, 2007) between different races, or their samples consisted mostly of white women (Gillmore et al., 1997). This could be an indication of the influence of welfare reform, since the results of the studies are more consistent within time periods (Raneri & Wiemann, 2007). All studies found on the matter agree that adolescent mothers are at high risk of RRP (Crittenden et al., 2009; Damle et al., 2015; Gavin et al., 2013; Gemmill & Lindberg, 2013; Patchen & Lanzi, 2013; Raneri & Wiemann, 2007; Sober & Schreiber, 2014; Templeman et al., 2000; Tocce et al., 2012; Waggoner et al., 2012).

2.2 Postpartum Contraceptive Methods

There are many important considerations in choice of contraceptive method that, in turn, require a variety of choices in order to ensure mother and infant health and adequate pregnancy spacing (Sober & Schreiber, 2014). In terms of safety, the CDC's US *Medical Eligibility Criteria for Contraceptive Use* (2011) revised recommendations for postpartum contraceptive methods include specific timelines of safe usage for breastfeeding versus non-breastfeeding women, as well as for women at risk of venous thrombosis (VT). Sober and Schreiber (2014) reviewed the different methods, considerations and processes that postpartum mothers should adhere to for health, safety and prevention. A postpartum woman's plan to breastfeed is a critical decision that affects both her choices in postpartum contraceptive methods as well as her chances of experiencing a short IPI. If she chooses to breastfeed, she must use either a non-hormonal form of contraception or a progestin-only form in order to avoid affecting the breast milk or the infant. While breastfeeding and depending on the frequency and duration, a postpartum woman will experience lactation amenorrhea (LAM), in which her resumed ovulation will be delayed.

However, for LAM to be achieved, the postpartum mother must be breastfeeding exclusively and less than 6 months postpartum.

Other factors that influence a woman's choice of contraceptive method, and the continued use, are insurance coverage, perinatal counseling and health services, and types of contraception that are made available and accessible (Gavin et al., 2013; Miller et al., 2000; O'Neil-Callahan et al., 2013; Tang et al., 2013). Influences within the woman's life, including perceived barriers or effectiveness of contraceptive methods (James-Hawkins & Sennott, 2015; Miller et al., 2000) and psychological, social, and behavioral factors also show potential to predict both postpartum contraception use and RRP (Bennett et al., 2006; Tang et al., 2013; Templeman et al., 2000; Waggoner et al., 2012). Miller et al. (2000) examined postpartum contraceptive choices among a sample of mostly single, black women who were eligible for Medicaid (n = 299). The main risk factor was the baseline prenatal perception of each method as "Most Effective," "Safest," or "Best for [Her]." Due to resource restrictions, the study was only able to include the OCP, DMPA, condoms, and tubal ligation. The study found a low rate of consistent use postpartum among women who chose OCP (54.7%) and among women who chose condoms (31.3%). The nature and results of this study reflect both the lack of choices and the indecision (due to lack of knowledge, lack of counseling, etc.) experienced among Medicaideligible women.

The MMWR (2013) reported that black adolescents were significantly less likely to use highly effective contraceptive methods postpartum (14.3%) than non-Hispanic white teens (24.6%) and Hispanic teens (27.9%). As discussed in Section 2.3, these statistics are likely to be closely related to the demographic population's higher likelihood of RRP. Each study highlights the need for increased access as well as contraceptive education and counseling from the prenatal period through the postpartum period, although with varying degrees of bias and contextual access to services.

2.3 Postpartum Contraception Use and Rapid Repeat Pregnancies

Adherence to non-LARCs, which require either daily or weekly maintenance, is prone to failure, so such methods are deemed by several publications to be less effective. A mixed race (61.2% black), multi-site study (*n* = 227) examined participant characteristics, 6-month contraception use, and RRP (< 18 months) among postpartum women aged 14-36 (Waggoner et al., 2012). Contraceptive choices were long-acting (sterilization, Norplant, implant, IUD, DMPA, or injectables) and others (OCP, condoms, diaphragm, patch, sponge, abstinence, withdrawal, etc.). The majority of the sample was black, but there were no significant differences between race and RRP. The study also found teens to be at significantly higher risk for RRP than adult women, controlling for education and ethnicity. Interestingly, a greater proportion of participants who had a goal-oriented intention for their next pregnancy (e.g. completing education) chose a long-acting contraceptive than participants who wanted never to have another pregnancy. 21.6% of the 'never again' patients were pregnant again within 18 months. Participants ages 14 to 16 were over twice as likely to experience a RRP as adult women, and using a LARC at 6 months decreased risk of a RRP by 70% compared to using no method.

Bennett et al. (2006) conducted a study (n = 643, 68.9% black, age ≥ 19) that considered low education as the main predictor of unintended rapid repeat pregnancies, while testing for mediating effects of depression and contraceptive method. They considered highly effective methods to be oral and transdermal hormonal contraception (always in use during intercourse), DMPA, and combination hormone contraception (used monthly). They found that education status had a strong effect on unintended RRP. Less effective methods were also associated with unintended RRP, but neither contraceptive method nor depression mediated the effect of education. This study also found that 22.3% of the women breastfed at 3 months after delivery, with similar rates between education levels. By 11 months postpartum, however, 9.1% (7.1%) of high (low) education participants were still breastfeeding. Both studies that factored in postpartum contraception found that depression had no effect on rapid repeat pregnancy, which conflicts with studies mentioned earlier that did not consider contraceptive method.

Damle et al. (2015) looked at contraceptive choices as factors of RRP (< 2 years) using data on adolescent mothers in a mostly black, Medicaid insured sample (*n* = 340). The available LARCs were LNG IUD, copper IUD, and subdermal implant, measured at initiation within 8 weeks postpartum. DMPA injections were the only inpatient contraceptive method available. Other contraception indicators were 'nothing documented,' declined, condoms, OCP, patch and ring. Getting the DMPA injection before discharge resulted in significantly fewer RRPs than declining the injection. Use of LARCs and postpartum visits within 8 weeks also significantly reduced RRPs, but patients who reported intent to use LARC but had not yet initiated it by their postpartum visit had the same pregnancy rate as those who did not plan to use LARC. Notably, prenatal care, social worker involvement, and participation in a specialized teen pregnancy program were all insignificant in predicting RRP. Limitations included inadequate follow-up documentation and possible under-reporting of subsequent pregnancies.

An older study (*n* = 206) compared RRP (< 12 months) in postpartum adolescents who delivered in 1997 and chose either the DMPA or OCP upon discharge (Templeman et al., 2000). Follow-up for updates on contraceptive use and pregnancy status lasted at least 12 months. DMPA users had almost twice the retention rate of OCP users, and OCP users were 9.09 times as likely to experience RRP. All three studies show significant reductions in RRP for LARC users compared to non-LARC users. However, they used either logistic regression with longitudinal data or Kaplan Meier estimates to track contraceptive changes, so precise trends could not be captured.

2.4 Interventions against RRP

Barnet et al. (2009) conducted a randomized controlled trial and used a Cox proportional hazards model to examine the association between specialized counseling sessions and time to repeat pregnancy in a sample of mostly black, Medicaid insured adolescent mothers (n = 235). The computer-assisted motivational intervention (CAMI) was designed to prevent RRP in adolescents through quarterly sessions until 2 years postpartum and a single home visit. It used a trans-theoretical model that assessed sexual relationships, contraception-use intentions and behaviors, and readiness to engage in pregnancy prevention. CAMI+ also included a multicomponent home-based intervention and monthly visits, while the control group received standard usual care. The CAMI+ group resulted in a significantly lower rate of RRP than the control group, but the CAMI-only group did not. Completing at least 2 CAMI sessions in either CAMI group significantly reduced the rate of RRP. The study may have had issues with implementation fidelity: the CAMI+ group consisted of more interactive components, which likely ensured greater compliance. Participants who became pregnant during the trial were required to cease the intervention, because it used an algorithm that could not accommodate pregnancies. Still, the study highlights the benefit of frequent counseling. Depressive symptoms, drug use, and, notably, wanting another child within 2 years were all insignificantly associated with RRP.

Finally, Patchen et al. (2013) sought to determine the effect of an integrated services program aimed at promoting contraceptive use and preventing subsequent pregnancies (< 24

months) among participants (n = 187, 61.3% black). The intervention was stratified by site: hospital-based health center (HHC, 89.8% black) or community-based health center (CHC, 78.1% Hispanic). 43.9% of the HHC participants' family received public assistance, and 50% of the HHC participants' mother was a teen parent. HHC participants had a higher rate of graduation or GED, and both parents also had a higher rate of graduating from high school. The study only reported prevalence of contraceptive use and subsequent pregnancy among each site and their total. In such an integrated services setting with free contraceptive counseling and issuance, rate of use decreases at a slow rate over time. Rates of both subsequent pregnancy and subsequent birth were higher in the CHC participants than the HHC participants. Major limitations to the study were a high attrition rate and lack of a comparison group. The comparisons between sites, however, provided a proximate indicator of race. Compared to CHC participants, HHC participants had a higher rate of RRP (21.1% vs. 16.4%).

2.5 Summary

According to the literature, the women of LCHS are in a demographic group that is more susceptible to a short IPI. The psychological stressors and trauma that they are more likely to experience, as found by Patchen et al. (2009), make them prone to depression. This study controls for physical abuse during the index pregnancy and postpartum depression. The literature presents evidence that black women with low socioeconomic status are at a higher risk of not using an effective form of contraception, and that postpartum adolescents who choose a Depo injection over OCP are more likely to continue use and prevent a RRP. Choosing a postpartum contraceptive method is a critical point in the stages of family planning that has been researched at length. Evidence indicate LARCs to be the most effective form of contraception when available, and that LARC and DMPA injections are the safest choice for women with risk of VT and for women who plan to breastfeed. The OCP is highly effective (Bennett et al., 2006), but only when used correctly; research shows that it has a lower retention rate and a lower rate of proper maintenance and usage. This study will model time to RRP according to indicators related to the above risk factors.

Methods

3.1 Study Population

Clients who enroll in LCHS are residents of the four counties that make up Low Country, South Carolina. The region consists of a predominantly black, low-income population with a history of chronic conditions and other hardships that perpetuate a prevalence of adverse birth outcomes for mothers and infants. Both pregnant women and mothers are accepted into LCHS, but the target population for this study is women and adolescents who either (1) entered LCHS with a pregnancy or (2) entered LCHS recently postpartum. At the time of the study, the number of clients enrolled in LCHS was 2,460. 2,259 clients were eligible for this study, with correctly entered data and sufficient records of index delivery (first delivery while enrolled in LCHS) and contraceptive method issuance.

3.2 Low Country Healthy Start Program Strategy and Data Collection

The program is an ongoing case management intervention, with a client navigator (CN) who works with each clients during home visits to screen for referrals and services based on their identified needs from the initial risk assessment that is to be completed upon entry into the program. The initial risk assessment is a comprehensive risk screening tool that was developed and modified for over 12 years by LCHS. It is administered by the CN to the client and is used to assess the participant's health and well-being, based elements such as income, family size,

demographic characteristics, previous pregnancy outcomes, stress, social and behavioral factors (e.g. smoking, alcohol or drug use), personal and family medical history, physiological data, and medical and psychosocial risk factors and conditions (e.g. diabetes, hypertension, depression, family conflict, domestic violence). Through the risk screening, the CN refers the client to the appropriate appointments and educational services, and they work closely with each client to track these services, both prenatal and postpartum.

LCHS activities related to interconceptional care (ICC) and family planning (FP) include

- home visits that incorporate a strong educational curriculum for ICC and FP;
- collaborations with other local health systems to facilitate collective impact on women's access to a consistent and seamless service delivery and support system;
- case management services for each client to effectively navigate the system;
- follow-up support to help clients establish a medical home as a permanent connection to the health care system;
- follow-up support to ensure a that a client leaves the hospital post-delivery with a contraceptive method in hand; and
- follow-up support to ensure that women are effectively using a contraceptive method at periodic intervals over the 24-month postpartum enrollment.

LCHS personnel and the obstetricians and nurse midwives at the hospital form a collective effort to increase the number of clients who leave the hospital with a Depo Provera injection after delivery. CNs coach prenatal women to ask for the injection. Some methods to ensure that women receive follow-up of some form is by scheduling immunization or Well-Child appointments, to which clients are obliged to bring their children for required visits and are able

to receive a check-up themselves. The program protocol compensates the client with cash for each appointment, since client retention becomes more difficult during postpartum. LCHS tracks all appointments and assessments in a web-based database system that is managed by the South Carolina Budget and Control Board, Division of Research and Statistics-Health Demographics.

3.3 Measures

3.3.1 Outcome measure. The outcome measure of interest for both Aim 1 and Aim 2 was time, in months, to RRP, given the clients who experienced the outcome as well as the clients who, in her length of recorded enrollment in LCHS, did not experience a short IPI (≤ 24 months). LCHS enters information for each time that a client delivers an infant while enrolled in the program. If a client enters the program during her postpartum period, the study used her index delivery date based on her self-report. When a client confirms a subsequent pregnancy, this new pregnancy start date is estimated from her latest reported menstrual cycle. The IPI was measured, in months, from the delivery date of the index child to the estimated start date of the subsequent pregnancy.

3.3.2 Explanatory variables.

Postpartum contraceptive decisions. It is important to emphasize that the contraceptive methods adjusted for in these two analyses represent the client's choice, adherence and consistency to the contraceptive methods. Biologically, the contraceptive methods, if used correctly, do protect against pregnancy, with the exception of condom breakage. For Aim 1, the Depo injection is measured at discharge from the hospital after the client's index delivery, so that a client either received a Depo injection at discharge (1) or did not receive a Depo injection at discharge (0). For Aim 2, the Depo injection is measured at each issuance of the injection, as are the other contraceptive methods that LCHS offers to its clients. The CN that works with the

client tracks each date that each method of contraception is given to the client and records the expiration date of the contraceptive method and, thus, the next required follow-up visit date. Based on past literature and the purposes of the research question, the other contraceptive methods were categorized into maintenance (OCP, patch, ring), barrier (vaginal spermicide, condom, film), and LARC (Implanon, Norplant, Mirena, IUD). For the Aim 2 analysis, each category of contraceptive method was coded as a time-varying dichotomous value, in which the method is considered to be in use (1) starting from its issue date and ending on its expiration date. The method is considered in nonuse (0) starting from the expiration date and ending on the next date that the client receives the same method.

Demographic risk factors. LCHS records each client's date of birth as well as her date of entry into the program. The study used the client's age at entry (number of years between entry date and client's date of birth) into LCHS as a proximate measure of her age at the conception of her index baby, treated as a continuous variable. Of the available socioeconomic characteristics that LCHS records for each client during the initial risk assessment, educational status was reported the most by clients, and was thus chosen for a potential explanatory variable. The study treated limited education as a dichotomous variable, indicating whether the client did not finish high school before she became pregnant (1) or she did finish high school (0).

Psychosocial risk factors. The study considered prenatal and postpartum depression for potential inclusion into the models. Upon entry into LCHS, each client completes the Edinburg Depression Screening (EPDS) questions to detect any risk for prenatal depression, if they entered the program while pregnant, or for postpartum depression, if they entered the program after giving birth. Clients who were screened for prenatal depression were screened again four weeks postpartum for risk of postpartum depression. The EPDS consists of ten short statements and a

four-level Likert scale in response to each statement. For LCHS purposes, an EPDS score of 12 or greater indicates a high risk of depression. The study treated both prenatal and postpartum depression scores as continuous variables.

The study took into account whether or not a client's index birth resulted in a live birth or a fetal death (birth outcome). If the client enters the program after her index delivery, she is asked during the initial risk assessment to list her past pregnancies and the birth outcome of each. If she enters the program while pregnant, the CN reports the details of the delivery, including birth outcome, into the database. In the initial risk assessment, for deliveries that occurred prior to entry into LCHS, LCHS categorizes birth outcomes as a live birth, a fetal death, or an infant death before his or her first birthday. For deliveries that occurred while the client was enrolled in LCHS, LCHS categorizes birth outcomes as a live birth, a spontaneous abortion (miscarriage or loss of fetus <28 weeks), an elected abortion, or a fetal death (fetus >28 weeks of gestation). For this study, birth outcome was treated as a dichotomous variable for either a live birth (1) or a fetal death (0), in which any outcome that was not reported as a live birth was categorized as a fetal death. For each pregnancy that the client reports happening prior to entry into LCHS, as well as for each pregnancy that she experiences while in LCHS, the CN records whether or not the pregnancy was unplanned. The study treated the intention of the index pregnancy as a dichotomous variable, either unplanned (1) or planned (0).

Other factors that were tested for potential inclusion into the models, specifically important aspects of the client's relationship health, were whether or not (1) the father of the index baby is involved, (2) a male is emotionally involved, (3) the client's partner drinks, (4) the client experienced emotional abuse, and (5) the client experienced physical abuse during her index pregnancy. These characteristics are self-reported by the client in her initial risk assessment. The study treated each of these variables as dichotomous on a yes (1) or no (0) basis.

Behavioral risk factors. LCHS reports pregnancy-related behaviors, including a client's plan to breastfeed, the trimester that she started prenatal care, and the trimester that she entered LCHS, for each delivery that she experiences while enrolled. The study took into account a client's decision to breastfeed (1) or not (0) after her index delivery. For the trimester that the client began prenatal care and for the trimester that she entered LCHS, the CN records either first trimester, second trimester, third trimester, or not applicable/postpartum for each. For the study, the two variables were treated as dichotomous, so that the client either received prenatal care during her first, second, or third trimester (1) or did not receive prenatal care (0), and that she either enrolled in LCHS while in her first, second, or third trimester (1) or postpartum (0).

The remaining available behavioral risk factors that the study considered are measured during the initial risk assessment by the client's self-report as yes (1) or no (0). The study included whether a client was physically active (1) or not (0) as a potential explanatory variable. Although the literature lacks much information on the relationship between physical activity and IPI, there may exist some linkage between the behavioral and biological aspects of physical activity and whether or not a woman experiences a RRP. The study also took into account clients who reported having sex without a condom (1) versus clients who reported that they did not have sex without a condom (0). Finally, the study also considered whether the client reported having multiple sex partners (1) or did not have multiple sex partners (0).

3.4 Analysis

3.4.1 Overview. The study used descriptive statistics to describe the study population, excluded clients, and final sample. We used t-tests and chi-square tests of association, where appropriate, to compare the final sample with the excluded clients. We used Kaplan Meier survival curves to observe time to RRP for each covariate in the final sample as well as between the study sample and the final sample used for analysis. Age at entry and prenatal depression score were stratified on their means for the Kaplan-Meier survival curves. We performed two analyses, one using a model to fit significant covariates for Aim 1 (Model 1) and one using a separate model with the same baseline covariates for Aim 2 (Model 2). Unadjusted and adjusted hazard ratios were calculated for both models. Data merging and preparation, hazard ratios, confidence intervals for the hazard ratios, and p-values were all obtained using Statistical Analysis System (SAS) version 9.4.

3.4.2 Model building and diagnostics. First, for Aim 1 model building, all potential explanatory variables were tested separately for association with IPI using Kaplan-Meier survival curves and the log-rank test, with a more conservative α of 0.1 in order to avoid excluding predictors that may have been significant after adjusting for other covariates. Covariates that were statistically significant were included in the initial choices for Model 1. The exceptions were age and Depo injection at discharge, which were included in the model regardless of statistical significance. Variables in Model 1 that were no longer significant after adjusting for other covariates were removed using a backward elimination, unless the partial log likelihood test for the model with and without a particular covariate resulted in a significant difference, in which case the variable remained in the model. Variables whose log-rank test statistics were not significant were inserted separately into the adjusted Cox model to test for

statistical significance ($\alpha = 0.05$), adjusting for other variables. Martingale residuals with a lowess smoothed plot were used to test for a linear relationship between the continuous variables (age and prenatal depression score) against the outcome (time to RRP). Once the appropriate main effects and transformations were obtained for the model, each explanatory variable was tested for interaction with each other explanatory variable ($\alpha = 0.05$). Deviance residuals were used to detect the percentage and extent of poorly predicted outcomes. Schoenfeld residuals fit to a lowess smoothed plot and rank-transformed time were used to test the proportional hazards assumption for each explanatory variable. Any explanatory variable that did not meet the proportional hazards assumption was tested for interaction with time. The difference in sample log cumulative hazard functions for the covariate over time was used to choose the function of time interaction. Finally, score residuals were used to detect influential cases. The same main effects that were fitted to the adjusted model in Aim 1 for statistical significance were also fitted to the adjusted model for Aim 2, which took into account the time-varying use of contraceptive methods, specifically Depo injections over time, maintenance methods, barrier methods, and LARC methods. The same procedures for testing for interactions, linearity, and proportional hazards were used for the Aim 2 model building.

3.4.3 Censored data. The analysis took into account right censoring of the data, in which a client did not have a record within LCHS of experiencing a subsequent pregnancy. For the purpose of this study, IPIs were observed only if the client experienced one within 24 months of her index birth into LCHS. Thus, the analysis includes both clients who were censored prior to the 24-month cutoff point as well as clients who were censored at 24 months. 37 (1.75%) of the 2,115 clients who were not observed to have a RRP were censored at 24 months, while the other 2,078 were censored prior to 24 months.

3.4.4 Missing data and exclusion criteria. For the analysis, SAS was not able to include any records with missing covariates in the Cox model. Thus, all clients with any missing explanatory variable were excluded from the final sample. Clients with only a single record in the data set were excluded, as well. T-tests and chi-square tests of association were used to compare continuous and dichotomous covariates, respectively, between the excluded clients and the final sample. Because of missing data for the explanatory variables, the final sample size could only be known after the appropriate explanatory variables were determined for the adjusted model.

Results

5.1 Descriptive Statistics

Out of the 2,260 clients eligible to be included in the study, 761 were included in the analysis with the above exclusion criteria. Table 1 includes descriptive statistics for relevant demographic variables for the overall study population, those excluded from the analysis, and those included in the analysis of the Cox model. The final sample reflects the demographic characteristics of the Low Country region, specifically a predominantly African American

(96.98%), non-Hispanic (99.64%) population. The tests of differences between the included and excluded samples showed which variables are not missing completely at random for the study population. Overall, the included sample consisted of a much greater proportion of IPIs shorter than 24 months, $c^2(1, N = 2,260) = 102.6$, p < 0.001, although it had a mean IPI about two months longer than the excluded sample, t(927.53) = 10.36, p < 0.001. The majority of clients were younger than 23, and the final sample was younger by a statistically significant yet small difference in magnitude, t(1648.6) = 4.23, p < 0.001.

Table 2 contains similar statistics and comparisons for the pregnancy-related variables. A much greater proportion of those included in the study received the Depo injection at discharge, $c^2(1, N = 2,260) = 85.86$, p < 0.001, and a much greater proportion of those included in the study ever received a Depo injection over time, $c^2(1, N = 2260) = 141.9$, p < 0.001. For all contraceptive method categories, a significantly greater proportion of clients who were included in the analysis had ever received a contraceptive method of that type. Also, the average length of time that a client was prescribed a contraceptive method was significantly greater for those included in the analysis than those who were excluded, except for the barrier method, in which the difference in proportion was not significant. In the included sample, 3.89% more clients planned to breastfeed than the excluded sample, $c^2(1, n = 1,840) = 5.27$, p = 0.022. A significantly smaller proportion of clients included in the final sample reported having sex without a condom, $c^2(1, N = 1808) = 7.55$, p = 0.006, as was the case for being emotionally involved with a male, $c^2(1, N = 1957) = 11.48$, p < 0.001.

Characteristics (% missing)	Study population (n=2,260)		Excluded (<i>n</i> =1499)		Final sample (<i>n</i> =761)		Р
Experienced a short IPI	140	6.19	38	2.54	102	13.40	< 0.00
Time to RRP*, M (SD)	10.11	(5.89)	8.60	(5.30)	10.68	8 (6.02)	< 0.00
Age at entry into LCHS (0.53), M (SD)	21.90	(5.07)	22.23 (5.19)		21.27 (4.78)		< 0.00
12-17	422	18.8	254	17.08	168	22.08	_
18-23	1136	50.5	734	49.36	402	52.83	_
24-29	476	21.2	342	23.00	134	17.61	_
30-35	177	7.9	130	8.74	47	6.18	—
36-42	37	1.7	27	1.82	10	1.31	-
Race (0.27)							0.034
Black or African American	2145	95.16	1407	94.24	738	96.98	_
Caucasian	94	4.17	71	4.76	23	3.02	_
Asian	6	0.27	6	0.13	_	_	_
American Indian or Alaska Native	2	0.09	2	0.13	_	_	_
Native Hawaiian or other Pacific	2	0.09	2	0.13	_	—	_
Unknown/Other	5	0.22	5	0.33	—	-	-
Ethnicity (20.97)							0.00
Not Hispanic or Latino	1746	97.76	1200	96.93	546	99.64	_
Hispanic or Latino	19	1.06	17	1.37	2	0.36	_
Unknown	21	1.18	21	1.70	_	_	_
Limited education, less than high school (29.73)	819	51.57	497	53.56	322	48.79	0.06

Table 1: Descriptive Statistics for Demographic Variables

Note. n % unless otherwise noted.

* Kaplan-Meier test of time to RRP (results of log-rank test)

Table 2: Descriptive Statistics for Pregnancy-Related Variables

Characteristic (% missing)	Study Population (n=2,260)		Excluded (<i>n</i> =1,499)		Final sample (<i>n</i> =761)		Р
Received Depo injection at discharge (0)	655	28.98	340	22.68	315	41.39	< 0.001
Ever received a Depo injection	936	41.42	489	32.62	447	58.74	< 0.00
Total length of Depo use, $M(SD)$		(4.85)		(4.24)	4.35	5 (5.57)	< 0.00
Ever received a maintenance method of contraception (0)	486	21.50	248	16.54	238	31.27	< 0.00
Total length of maintenance use, <i>M</i> (<i>SD</i>)	1.11 (3.15)	0.77 (2.57)		1.80 (3.97)		< 0.00
Ever received a barrier method of contraception (0)	187	8.27	96	6.40	91	11.96	< 0.00
Total length of barrier use, $M(SD)$	0.26 (1.29)	0.23 (1.25)		0.31 (1.35)		0.159
Ever received a LARC (0)	343	15.18	182	12.14	161	21.16	< 0.00
Total length of LARC use, M (SD)	0.34 (1.95)	0.27	(1.77)	0.46	5 (2.25)	0.04
Trimester began prenatal care (20.04)							0.53
First trimester	1,438	79.58	812	77.41	626	82.59	—
Second trimester	282	15.61	184	17.54	98	12.93	-
Third trimester	62	3.43	40	3.81	22	2.90	-
No prenatal care	24	1.33	13	1.24	12	1.58	-
Trimester began LCHS (18.54)							0.95
First trimester	758	41.17	407	37.69	351	46.12	_
Second trimester	674	36.61	401	37.13	273	35.87	_
Third trimester	382	20.75	256	23.70	126	16.56	-
Postpartum	27	1.47	16	1.48	11	1.45	-
Plan to breastfeed (18.58)	279	15.16	181	16.77	98	12.88	0.02
Index birth outcome (18.81)							0.01
Live birth	1,773	96.62	1,028	95.72	745	97.90	_
Spontaneous abortion	44	2.40	36	3.35	8	1.05	_
Fetal death	13	0.71	6	0.56	7	0.92	_
Still birth	4	0.22	3	0.28	1	0.13	_
Elected abortion	1	0.05	1	0.09	_	_	-
Postpartum depression risk, $EDS \ge 12$ (59.03)	33	3.56	3	1.82	30	3.94	_
M (SD)	1.62	(3.63)	.903	3 (2.80)	0) 1.77 (3.77)		0.00
Father is involved (7.57)	1,697	81.24	1,099	82.14	598	79.63	0.15
Emotionally involved with a male (13.41)	1,631	83.34	1,062	85.51	569	79.58	0.00
Emotionally abused (4.91)	165	7.68	107	7.70	58	7.63	0.95

Characteristic (% missing)	StudyExcludedPopulation(n=1,499)(n=2,260)		Fi sai (<i>n</i> =	Р			
Physically abused during pregnancy (4.73)	57	2.65	38	2.73	19	2.50	0.747
Partner drinks (4.82)	752	34.96	494	35.54	258	33.90	0.447
Unplanned index pregnancy (29.60)	1,342	84.35	694	83.61	648	85.15	0.399
Multiple sex partners (39.51)	180	13.17	111	14.68	69	11.29	0.065
Has sex without a condom (20.00)	1,195	66.10	756	68.54	439	62.27	0.006
Physically active (40.93)	39	2.92	20	2.73	19	3.15	0.651

Note. n % unless otherwise noted.

5.2 Model Building and Diagnostics

Table 3 shows the results of the Kaplan-Meier survival estimate log-rank tests for each potential explanatory variable. The variables that were significantly associated ($\alpha = 0.1$) with time to RRP by the nonparametric test of the survival function were first entered into the adjusted Cox model. Figure 1 illustrates the Kaplan-Meier survival curves for those who received the Depo injection at discharge and for those who did not receive the Depo injection at discharge, in the final sample. Epanechnikov kernel-smoothed hazard functions corresponding to the Depo injection at discharge are given in Figure 2, and they indicate that the hazard rates do not change proportionally over time. The diagnostics for this occurrence will be discussed further below. After entering the covariates into the Cox model, variables were deleted for statistically insignificant association, either by the Wald chi-square test or by the partial log-likelihood test, in the following order: prenatal care, prenatal entry into LCHS, prenatal depression score, father involvement, birth outcome, plan to breastfeed, sex without a condom, and physical activity. Plan to breastfeed initially contributed to a significant change in partial log-likelihood when included in the model, but it was no longer a significant variable after removing sex without a condom and physical activity.

0.124 0.661 <0.001 <0.001 0.095
<0.001 <0.001
< 0.001
0.095
0.075
0.019
0.058
0.394
0.301
0.004
0.008
0.034
0.048
0.226
0.014
< 0.001

Table 3: Difference in K-M Estimated Survival Rates for the Study Population

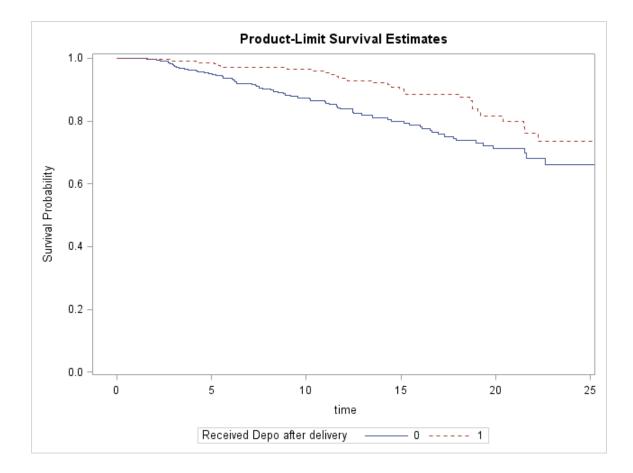


Figure 1: Kaplan-Meier Survival Curves for Depo Injection at Discharge, Final Sample

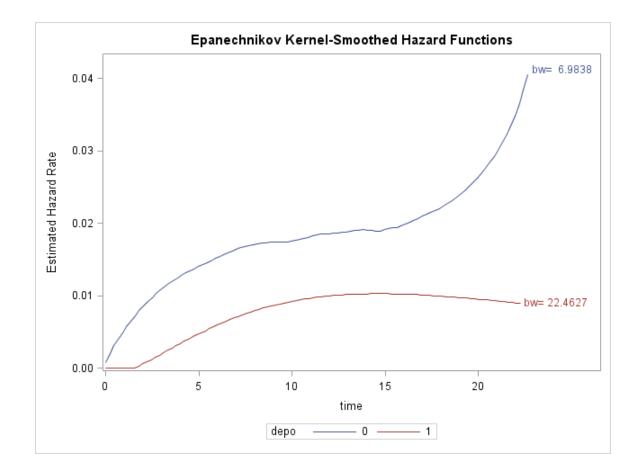


Figure 2: Hazard Function for Depo at Discharge, Unadjusted, Final Sample

Figure 3 shows the lowess smoothed line fit to the martingale residuals for postpartum depression score and age. In the right-hand panel, age shows a relatively linear trend over time, indicating that a linear prediction of age is appropriate for the model. In contrast, the left panel shows a lowess smoothed line with a nonlinear trend over time for postpartum depression score, indicating that a transformation is needed for that variable. A square root transformation for postpartum depression score gave it a linear trend over time in relation to time to RRP, therefore satisfying the linearity assumption for the Cox model.

No covariate interaction was found for during the model building for Aim 1. Depo injection at discharge did not meet the proportional hazards assumption, according to the Schoenfeld residuals (Figure 4, left panel), and the variable showed a significant interaction ($r = 0.22, c^2 = 4.99, p = 0.026$) with time with a lowess smoothed line that showed systematic deviation from the line at $\beta(t) = 0$ with a slope of 0 over the ranked time. In contrast, unplanned index pregnancy (Figure 4, right panel), resulted in a lowess smoothed line that had a relatively linear slope approximately equal to 0, indicating that it did not demonstrate evidence of non-proportionality, $r = -0.07, c^2 = 0.51, p = 0.477$. The difference between the sample log cumulative hazard functions between those who did not receive the Depo injection at discharge and those who did declined steeply over time, indicating that a log function of time was appropriate in modeling the time-varying effect of Depo injection at discharge (Figure 5). The final model included Depo injection at discharge as well as its interaction with the log function of time, unplanned index pregnancy, physical abuse during pregnancy, postpartum depression score, and age. Figure 6 shows the cumulative hazard plot for Depo injection at discharge, not adjusting for its time-varying effects.

Table 4 displays the regression model parameter estimate, standard error, hazard ratio, and 95% confidence interval for each variable term. The column labeled "Unadjusted" contains such information for each variable as a separate model. The middle column, labeled "Adjusted" contains HRs that are comparable to those of the unadjusted models for each variable. The righthand column, labeled "Adjusted with Interaction," contains the model that adjusts for the timevarying effects of Depo injection at discharge, as necessary due to the variable's nonproportional hazard function.

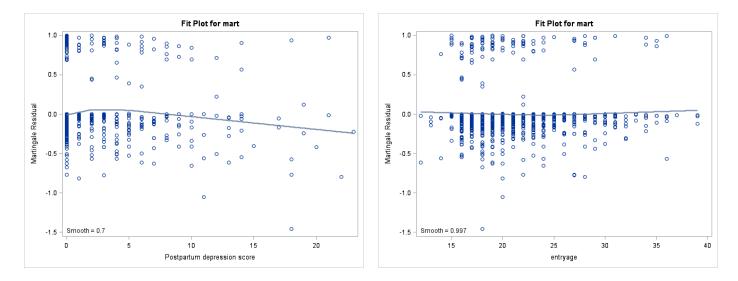


Figure 3: Martingale Residuals for Postpartum Depression Score (left) and Age (right)

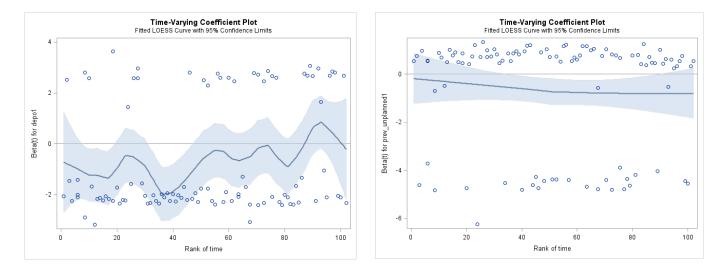


Figure 4: Schoenfeld Residuals for Depo Injection at Discharge (left) and Unplanned Index Pregnancy (right)

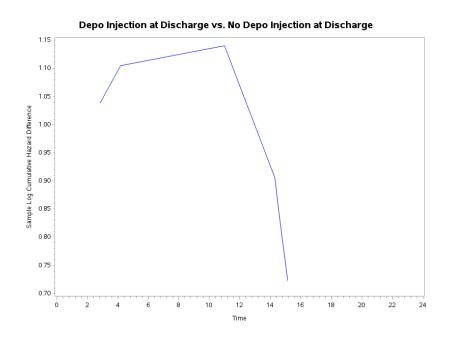


Figure 5: Difference in Sample Log Cumulative Hazard Functions, Final Sample

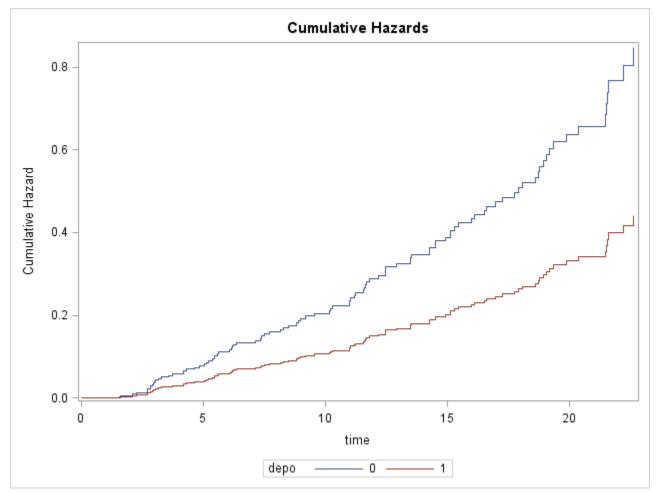


Figure 6: Cumulative Hazard Plot for Depo injection at discharge in Aim 1

Unplanned index pregnancy, physical abuse during pregnancy, postpartum depression score, and age were similarly included, along with the time-varying contraceptive method variables, in the model building for Aim 2. In the adjusted model, receiving Depo injections over time satisfied the proportional hazards assumption, r = -0.03, $c^2 = 0.12$, p = 0.74. As seen in Figure 7, receiving Depo injections over time provided a strong protective factor against RRP, as expected. A significant interaction existed between physical abuse during pregnancy and postpartum depression score in the adjusted model for Aim 2. LARC did not meet the proportional hazards assumption, r = 0.24, $c^2 = 6.37$, p = 0.012, and the variable showed a significant interaction with time. Finally, a significant interaction existed between physical abuse during pregnancy and postpartum depression score. Table 5 displays the results of the model building for Aim 2 in the same manner as Table 4 does for the model building for Aim 1.

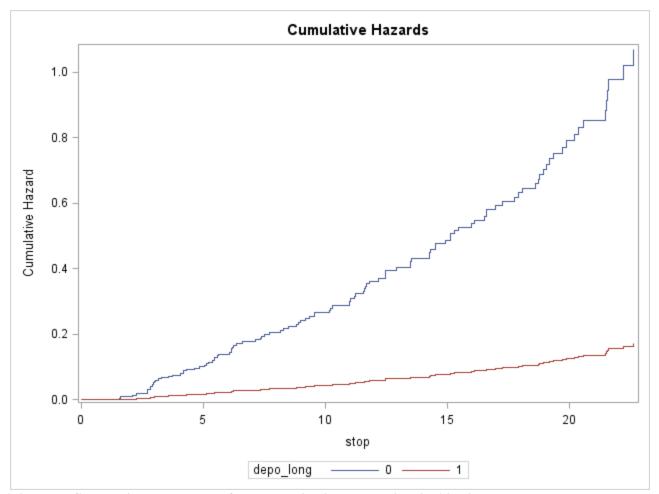


Figure 7: Cumulative Hazard Plot for Depo Injections over Time in Aim 2

 Table 4: Cox Proportional Hazards Model Fitting for Aim 1

Variable	<u>Unadjusted*</u>					Adjusted							Adjusted with interaction			
	β	SE	Р	HR	95% CI	β	SE	Р	HR	95% CI	β	SE	Р	HR	95% CI	
Received Depo injection at discharge	-0.61	0.22	0.004	0.54	0.36-0.83	-0.66	0.22	0.003	0.52	0.34-0.80	3.39	0.81	<.001	29.63	6.05-145.14	
Index pregnancy was unplanned	-0.66	0.23	0.004	0.52	0.33-0.81	-0.64	0.23	0.005	0.53	0.34-0.83	-0.61	0.23	0.007	0.54	0.35-0.85	
Physical abuse during pregnancy	0.82	0.46	0.073	2.28	0.93-5.60	0.93	0.47	0.047	2.54	1.01-6.36	0.84	0.47	0.071	2.32	0.93-5.77	
Postpartum depression score	0.30	0.07	<.001	1.34	1.18-1.53	0.27	0.07	<.001	1.31	1.14-1.50	0.29	0.07	<.001	1.33	1.16-1.53	
Age at entry	-0.03	0.02	0.134	0.97	0.93-1.01	-0.04	0.02	0.078	0.96	0.92-1.00	-0.03	0.02	0.135	0.97	0.93-1.01	
Received Depo injection at discharge × log(Time)	_	_	_	_	_	_	_	_	_	_	-1.53	0.31	<.001	0.22	0.12-0.40	

* Unadjusted results are for separate Cox proportional hazard models including each covariate as a single predictor.

Table 5: Cox Proportional Hazards Model Fitting for Aim 2

Variable	<u>Unadjusted*</u>						Adjus		A	Adjusted with interaction					
	β	SE	Р	HR	95% CI	β	SE	Р	HR	95% CI	β	SE	Р	HR	95% CI
Received Depo injections over time	-1.80	0.33	<.001	0.17	0.09-0.32	-1.83	0.34	<.001	0.16	0.08-0.31	-1.82	0.34	<.001	0.16	0.08-0.32
Maintenance (OCP, ring, patch)	0.01	0.24	0.970	1.01	0.63-1.63	-0.48	0.25	0.058	0.62	0.38-1.02	-0.47	0.25	0.066	0.63	0.38-1.03
Barrier (vaginal spermicide, condom, film)	1.21	0.30	<.001	3.37	1.88-6.03	0.58	0.31	0.061	1.80	0.97-3.31	0.60	0.31	0.056	1.82	0.99-3.36
LARC (Implanon, Norplant, Mirena, IUD)	0.05	0.46	0.906	1.06	0.43-2.59	0.12	0.47	0.795	1.13	0.45-2.85	-3.05	1.82	0.093	0.05	0.001-1.66
Index pregnancy was unplanned	-0.73	0.21	0.001	0.48	0.32-0.73	-0.63	0.22	0.004	0.53	0.35-0.82	-0.62	0.22	0.005	0.54	0.35-0.82
Physical abuse during pregnancy	0.74	0.46	0.105	2.10	0.86-5.15	1.62	0.56	0.004	-	_	1.62	0.56	0.004	-	-
Postpartum depression score	0.33	0.06	<.001	1.39	1.23-1.57	0.28	0.07	<.001	-	_	0.28	0.07	<.001	-	_
Physical abuse during pregnancy × Postpartum depression score	_	_	_	_	_	-0.84	0.39	0.032	_	_	-0.83	0.39	0.035	_	_
Age at entry	-0.04	0.02	0.097	0.97	0.93-1.01	-0.05	0.02	0.020	0.95	0.91-0.99	-0.05	0.02	0.024	0.95	0.91-0.99
LARC × Time	_	_	-	_	_	—	_	_	_	_	0.23	0.10	0.029	1.25	1.02-1.53

* Unadjusted results are for separate Cox proportional hazard models including each covariate as a single predictor.

5.3 Model Interpretation

For Aim 1 (Table 4), a client who received the Depo injection at discharge had a RRP rate about 46% slower than that of a client who did not receive the Depo injection at discharge (unadjusted HR = 0.54, 95% *CI*: 0.36- 0.83; adjusted HR = 0.52, 95% *CI*: 0.34-0.8). However, after adjusting for the time-varying effect of Depo injection at discharge, receiving the Depo injection at discharge resulted in a much later RRP than not receiving the Depo injection at discharge (HR = 29.63, $\beta = 3.39$, 95% *CI*: 6.049-145.141). Over time, the HR for receiving the Depo injection at discharge decreased gradually (HR = 0.22, $\beta = -1.53$, 95% *CI*: 0.12-0.40), so that, by about 9.15 months¹ postpartum, receiving the Depo injection at discharge.

In order to estimate survival rates, it was necessary to disregard the time-varying effects of receiving the Depo injection at discharge. The survival estimates for each explanatory variable in Aim 1, not accounting for any time-varying effect, is given in Table 6. The survival rates for Depo injection at discharge were overestimated at 6 and 12 months, since earlier postpartum was associated with a higher hazard ratio for those who received the Depo injection at discharge. Comparing the survival estimates for each explanatory variable, adjusted for other covariates at their reference category (0) or mean values, to the reference set of covariates ("Reference baseline," Table 6), revealed approximate differences that those covariates produced on time to RRP. Physical abuse during pregnancy had a deleterious effect on rapid repeat pregnancy, although the confidence interval reaches 100% survival rate over each period of time. The survival rates for the postpartum depression score were calculated at the mean (EDS = 0) and at the 90% quantile (EDS = 6). The higher the postpartum depression score, the lower the survival

 $^{^{1}3.39 - 1.53 \}times \ln(9.15) \approx 0$, indicating the point in time that the parameter for the variable becomes negative.

rate over time. The older the client's age at pregnancy with her index child, the greater the survival rate over time.

Table 5 shows that, for Aim 2, receiving Depo injections over time resulted in a much lower hazard rate than not receiving Depo injections over time (unadjusted HR = 0.17, 95% CI: 0.09-0.32; adjusted HR = 0.16, 95% CI: 0.08-0.31). Due to the differing results between the time-varying effects of Depo injection at discharge and whether or not a client received the injection over time, we tested the addition of receiving Depo injection at discharge to the adjusted model for Aim 2 for association and interaction with other contraceptive methods. Adjusting for all other variables in the second model, including receiving Depo injections over time, receiving the Depo injection at discharge resulted in a lower hazard rate than not receiving the Depo injection at discharge, although the association was not significant (adjusted HR = 0.88, p = 0.544, 95% CI: 0.57-1.34). There was no significant interaction between receiving the Depo injection at discharge and receiving Depo injections over time. Similarly, there was no significant interaction between receiving the Depo injection at discharge and any other contraceptive method variable. Clients who received the other methods of contraception did not show statistically significant effects on time to RRP at $\alpha = 0.05$. LARC showed a highly protective but not statistically significant effect against RRP (adjusted HR = 0.05, p = 0.093, 95% CI: 0.002-2.26), but that protective effect decreased multiplicatively by about .25 with each passing month (*HR* = 1.25, *p* = 0.029, 95% *CI*: 1.02-1.53).

Table 6: Survival Rates over	r Time for Aim 1 Adjusted Model
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Variable	<u>6</u>	<u>Months</u>	12	Months	18 Months		
		%	95% CI	%	95% CI	%	95% CI
Reference baselin	89.1	84.0-94.4	74.4	65.4-84.7	59.4	47.7-73.9	
Depo injection at		94.2	91.0-97.5	85.8	79.3-92.9	76.3	66.7-87.4
discharge							
Unplanned index	94.1	91.8-96.4	85.0	81.5-89.9	76.0	70.2-82.4	
pregnancy							
Physical abuse du	74.5	54.6-100	47.3	21.9-100	26.6	6.96-100	
pregnancy							
Postpartum	0	92.2	88.2-96.3	81.3	73.6-89.8	69.4	58.6-82.2
depression score	6 ^b	85.5	78.8-92.8	67.2	56.0-80.6	49.5	36.3-67.6
Age at entry ^c 14		85.6	78.2-93.8	67.4	54.5-83.3	49.8	34.5-71.9
C V	18	87.6	81.8-93.8	71.4	61.2-83.3	55.2	42.5-71.8
	25	90.5	85.8-95.5	77.5	68.8-87.4	63.8	52.1-78.2
	30	92.1	87.4-97.1	81.2	71.8-91.9	69.2	56.1-85.5

^a All dichotomous variables set to 0, all continuous variables set to their mean (postpartum depression score = 1.77, age = 21.9).

^b 90% quantile of the final sample

^c Values chosen arbitrarily

When adjusting for all explanatory variables including the LARC interaction with time, the HR for physical abuse during pregnancy decreased as the postpartum depression score increased (At EDS = 0: HR = 5.05, 95% *CI*: 1.69-15.2; at EDS = 6: HR = 1.68, 95% *CI*: 0.62-4.55; at EDS = 6: HR = 0.67, 95% *CI*: 0.14-3.16). The 95% confidence intervals indicate that, at lower EDS scores for postpartum depression, physical abuse during pregnancy had a significant effect on time to RRP, but, at higher EDS scores, the effect of physical abuse during pregnancy was no longer statistically significant. Figure 8 displays the interaction effect between physical abuse during pregnancy and postpartum depression score on the cumulative hazard rates of time to RRP. The top left panel shows that, with no risk of postpartum depression, physical abuse during pregnancy results in a much higher hazard rate over time than no physical abuse during pregnancy. This difference decreases at the mean postpartum depression score for this sample (1.77), although the mean postpartum depression score indicates little risk of postpartum depression. The bottom panel shows the cumulative hazard plot for clients in the 90% quantile of postpartum depression scores (EDS = 6). For the clients experiencing that level of postpartum depression, those who were physically abused actually had a lower hazard rate for time to RRP than those who were not physically abused. For the purpose of estimating survival rates, the adjusted model was fitted without a time-varying effect of LARC, so that receiving LARC had a statistically insignificant adjusted HR of 1.13 ($\beta = 0.12$, p = 0.795, 95% *CI*: 0.45-2.85). Survival rates for the adjusted model for Aim 2, without the time-varying effect of LARC, are given in Table 7. For physical abuse during pregnancy, the survival rates displayed are at each level of postpartum depression that the client scored (0 and 6).

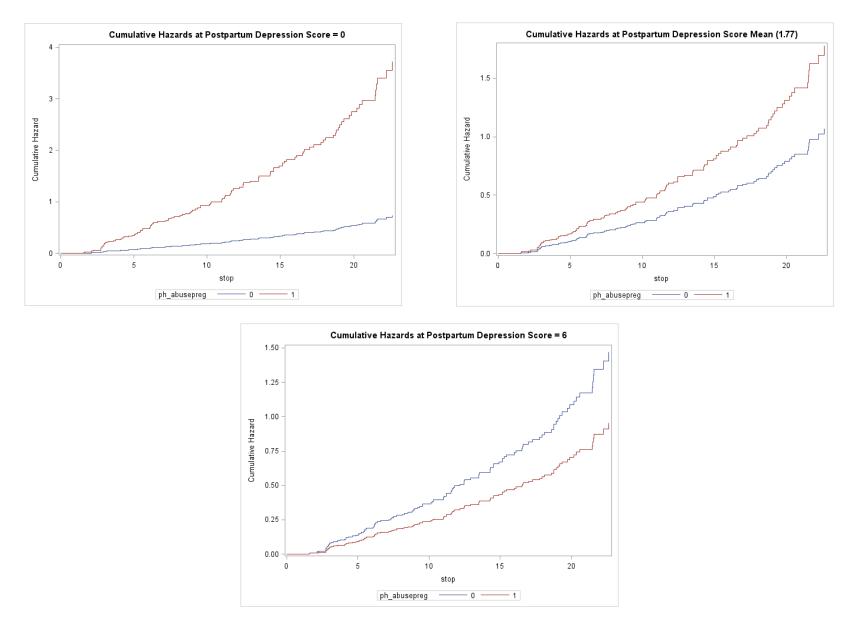


Figure 8: Cumulative Hazard Plots for Physical Abuse during Pregnancy at Various Postpartum Depression Scores

Variable		6	<u>Months</u>	12	Months	18 Months		
		%	95% CI	%	95% CI	%	95% CI	
Reference baseline ^a		86.5	80.5-93.0	69.1	59.0-81.0	52.4	40.2-68.4	
Depo injections over		97.7	96.0-99.4	94.3	90.4-98.3	90.2	83.8-97.0	
time								
Maintenance met	hod	91.4	86.5-96.7	79.6	70.0-90.4	67.1	54.0-83.4	
Barrier method		77.1	64.7-92.1	51.5	34.0-78.0	31.4	15.5-63.7	
LARC method		84.9	71.8-100	65.8	43.5-99.7	48.2	23.5-98.9	
Unplanned index	Unplanned index		89.7-95.5	82.1	77.1-87.4	70.8	70.2-82.4	
pregnancy	pregnancy							
Physical abuse du	iring							
pregnancy ^b								
Postpartum	0	60.5	33.6-100	27.7	6.3-100	10.6	0.8-100	
depression score	6 ^c	82.0	74.1-90.6	60.1	48.1-75.3	41.2	28.2-60.1	
Age at entry ^d	14	80.8	71.4-91.4	58.0	43.7-77.1	38.6	23.7-62.9	
	18	84.2	77.1-91.9	64.4	53.0-78.3	46.4	33.3-64.5	
	25	88.8	83.4-94.6	73.9	64.0-85.2	58.9	46.4-74.8	
	30	91.3	86.1-96.9	79.3	69.0-91.1	66.7	52.6-84.4	

Table 7: Survival Rates over Time for Aim 2 Adjusted Model

^a All dichotomous variables set to 0, all continuous variables set to their mean (postpartum depression score = 1.77, age = 21.9).

^b Measured at the given levels of postpartum depression score

^c 90% quantile in the final sample

^d Values chosen arbitrarily

Discussion and Conclusion

6.1 Depo Injection at Discharge and Depo Injections over Time

When receiving Depo injections over time, 90.2% (98% CI: 83.8-97.0) of clients had not conceived again at 18 months. For Aim 2, the most protective factor was continuing the Depo injections over time. Disregarding the time-varying effects of receiving a Depo injection at discharge, about 76.3% (95% CI: 66.7-87.4) of clients who received the Depo injection at discharge had not conceived again by 18 months. For Aim 1, adjusting for the time-varying effect of Depo injection at discharge indicated that the Depo injection at discharge had an increasingly protective effect across time. This does not reflect a time-varying effect of Depo at

discharge itself, which is biologically effective for three months. Instead, it may suggest a relationship between receiving the Depo injection at discharge and the continued use of the Depo injection or other highly effective contraceptive methods over time, which is the focus of the Aim 2 analysis. The drastically large HR at time zero occurs from the logarithmic transformation of time for the interaction. The large HR in the earlier months, therefore, may reflect the client's behavior with contraception soon after she received the Depo injection at discharge. The timevarying effect suggests that, for the first nine months, a client who received the Depo injection at discharge may not have kept immediate and consistent use of a contraceptive method after her Depo injection expired, hence experiencing a RRP. On the other hand, clients who retained a contraceptive method beyond nine months after receiving the Depo injection at discharge likely experienced a longer IPI or no RRP at all. Aim 2 showed that sustained use of the Depo injection is protective against RRP. Fitting Depo injection at discharge into Model 2 showed that it may not affect overall Depo use, but that it may matter indirectly, signifying that continued use of contraception method is an important outcome for future research. The hypothesis that receiving the Depo injection at discharge provides a protective factor against short IPIs holds true, but the results suggest underlying behavioral factors in clients who experience an IPI of less than nine months for which the hypothesis is rejected. The second hypothesis that receiving the Depo injection over time holds true, as would be expected for a client who consistently adheres to the proper usage.

6.2 Long-Acting Reversible Contraceptives

In the Aim 2 analysis, LARC had the largest effect, although it was not statistically significant. The time-varying effect of LARC becomes less and less negative, likely reflecting that as long as the client is on a LARC, they are protected. Biologically, being on a LARC

renders the chance of conception to be essentially zero, unless the LARC is removed and discontinued. Thus, the increasing hazard ratio over time must reflect the client's use of the LARC. The standard error for the effect of LARC is large, which is likely due to the low rate of use in the sample and the resulting sampling error.

6.3 Maintenance and Barrier Contraceptive Methods

Maintenance methods of contraception, such as the OCP, the ring, and the patch, have a small and marginally significant protective factor against RRP. This relationship is much more likely to reflect the client's adherence to the contraceptive method, rather than the effectiveness of the contraceptive methods, themselves. Templemen et al. (2000), likewise, found that the OCP had a significantly lower retention rate and had a significantly greater effect on the chances on RRP than did the Depo injection. Barrier methods of contraception, such as condoms, spermicide, and female condoms, have a small and marginally significant hazardous effect on RRP. This may reflect inconsistency in using condoms during sex or condom breakage.

6.4 Psychosocial Factors of RRP

For Aim 1, the most protective factor from a shorter IPI was found to be a client's unplanned index pregnancy. In both analyses, unplanned index pregnancies predicted a lower hazard rate than pregnancies that were planned. This is in contrast to another study that did not consider postpartum contraceptives, but found that previously unintended pregnancies were highly predictive of a RRP (Gemmill & Lindberg, 2013). It suggests that the clients in this sample who did not plan to get pregnant were more careful to prevent another pregnancy that they likely could not afford.

Physical abuse during and postpartum depression both have a hazardous effect on RRP in the Aim 1 analysis. Interestingly, but not surprisingly, the two variables interacted with each other in the Aim 2 analysis. These findings agree with Patchen et al. (2009) that women with trauma and mental health issues are at higher risk of RRP. The perinatal woman's relationship with the father or a male strongly affects her psychosocial health. Both financial and emotional support are crucial for the mother and the child; lack thereof creates a multitude of challenges for the mother; and, on the other end of the spectrum, abuse is obviously detrimental to the mother's health.

6.5 Age as a Predictor of Rapid Repeat Pregnancy

In contrast with other research findings, the age of the client at her index pregnancy did not have a statistically significant effect on time to RRP in the Aim 1 analysis. The effect itself, although increasingly protective with older clients, was miniscule. Only when adjusting for the time-varying contraceptive method use as well as the interaction of LARC with time did the protective effect of age become statistically significant, but it was still very small in magnitude. This may be due to the age distribution of the final sample, which consists mostly of younger clients (< 23 years old). The restriction of the age range likely prevented the model from detecting the effect that exists in other research.

6.6 Conclusion

As described in the LCHS program strategy, the federal Healthy Start program sets a benchmark goal that, out of the clients who have a repeat pregnancy while enrolled, 70% have an IPI longer than 18 months. Five clients were censored at 24 months, meaning that they experienced a repeat pregnancy, but it was not a RRP as defined for the study. Out of the 107 total repeat pregnancies in the final sample, 21 (19.63%) did not conceive again within 18 months. Out of the total study population that experienced a repeat pregnancy (n = 145), including clients who were excluded due to missing covariates, 24 (16.55%) did not conceive again within 18 months. Clearly, far too many women are experiencing repeat pregnancies too soon in their postpartum period, even with increased effort to distribute more postpartum contraception.

The current study has important limitations. It excluded all observations with missing covariates. Several of the t-tests and chi-square tests of association between the excluded sample and the included sample were significant, indicating that the missing observations were not missing completely at random. The final sample included a greater proportion of clients who received postpartum contraceptive methods and used them over a longer period of time. These clients had a more complete assessment, at least with the chosen covariates, and may have had more comprehensive case management and access to contraception. The rate of RRP in the final sample, however, was significantly higher than the rate of RRP in the excluded clients. Nonetheless, the mean IPI of the excluded clients was about two months shorter than that of the final sample. Since the vast majority of clients were censored prior to 24 months postpartum, this may suggest that more clients who had missing covariates dropped services with LCHS before the program could record a RRP for the client. These differences between the final sample and the excluded sample elucidate a strong likelihood of bias in the effect of postpartum contraception that may not be generalizable to the study population. Finally, in calculating the survival rates over time for each covariate, we were not able to capture any interactions with time, as the Cox model cannot estimate survival in the future. Thus, the effects of receiving the Depo injection at discharge in Aim 1 and the effect of receiving a LARC in Aim 2 were not

accurately captured for all lengths of time (6, 12 and 18 months), but rather each variable was assumed (incorrectly) to have proportional hazards in their respective adjusted models.

Critical questions emerged during the analysis that requires future research. Next steps include testing Depo at discharge and other baseline risk factors on predicting continued use or ever-use of the different contraceptive methods to determine that aspect of postpartum contraceptive use, since the issue is in the client's adherence instead of the biological mechanism of the contraceptives. As noted in the literature review, adolescents who received a comprehensive counseling service were less likely to experience an RRP (Barnet et al., 2009; Patchen et al., 2013). LCHS also tracks each counseling and educational service that a client attends. Future research should also take into account the effectiveness of attending the services that are related to family planning and contraceptive use on time to RRP.

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