Guideline Recommendations for the Management of Bleeding Irregularities in LARC Users

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Abstract

Purpose of Project: The purpose of this project was to analyze a change in women's health nurse practitioners' frequency in recommending interventions for the treatment of irregular menstrual bleeding associated with LARC use to their patients.

Methodology: Interrupted time series study was conducted comparing nurse practitioners' adherence to guideline recommendations prior to project intervention and after.

Results: The results of this project demonstrated an increase in nurse practitioners' adherence from 36% prior to intervention, to 86% post-intervention. The results illustrate a positive relationship between provider education and adherence to nationally recognized guideline recommendations for the management of bleeding irregularities in LARC users.

Implications for Practice: This increase in adherence positively impacts women using LARC; by consistently offering them evidence-based interventions to manage the undesirable side-effect of bleeding irregularities providers are able to increase satisfaction and continuation rate of their patients' chosen LARC methods.

Keywords: long-acting reversible contraceptive, bleeding, intrauterine device, implant, guidelines

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Introduction

Long-acting reversible contraceptives (LARC), which includes intrauterine devices and contraceptive implants, are the most effective reversible contraceptive methods available to patients. LARC have proven to be highly effective choices in preventing unintended pregnancy (The American College of Obstetricians and Gynecologists [ACOG], 2017). Unintended pregnancies result in negative maternal and fetal outcomes and cost the nation an average of $12,770 for every publicly funded birth (Centers for Disease Control and Prevention [CDC], 2018). Currently available in the United States (U.S.) are five intrauterine devices (IUD); one copper-containing IUD, four intrauterine devices containing levonorgestrel; and one etonogestrel-releasing contraceptive implant (ACOG, 2017). Unfortunately, bleeding irregularities, a manageable side effect, are the most common reported reason for discontinuation of these most effective contraceptive methods. This project has analyzed a change in women's health primary care providers' attitudes of recommended interventions for the treatment of irregular menstrual bleeding associated with LARC use.

Background and Significance

Although the long-acting reversible contraceptive methods of today have gained popularity for their ease of use, high efficacy in preventing pregnancy, and acceptability among various populations of women, the history of LARC has been trying (Strasser, Borkowski, Couillard, Allina, & Wood, 2016). In 1968, the first generation of IUDs became available in the U.S. and included material such as plastic and copper (Strasser et al., 2016). The IUD gained notoriety, and in 1971 the Dalkon Shield came on the market; its popularity skyrocketed and two million women used the product during the four years it was available (Strasser et al., 2016).

However, with increased IUD use, growing health concerns were raised about pregnancy rates, pelvic inflammatory disease- which when not treated, can lead to infertility and even death- as well as septic miscarriages (Strasser et al., 2016). In 1973, Congress began hearings about the threats the devices posed to women's health and the CDC began a survey of IUD-related complications observed by physicians. The CDC's survey identified over 3,500 cases of IUD-related hospitalizations from January to June of 1973 (Strasser et al., 2016). After reports of the CDC findings were published and public awareness grew, the manufacturer of Dalkon Shield suspended sales in the U.S. By 1985, hundreds of thousands of women had brought forth lawsuits and the manufacturer filed for bankruptcy (Strasser et al., 2016). The Dalkon Shield created enormous public awareness and identified a need for stronger U.S. regulation on medical devices. In 1976, the Medical Device Amendments were created requiring manufacturers to register devices and follow quality control measures. Additionally, the law allows the Food and Drug Administration (FDA) to review medical devices and authorizes their ability to ban devices which create substantial deception or unreasonable risk of injury or illness (Strasser et al., 2016).

The history of implantable contraceptives is much shorted as the first implant, Norplant, came on the market in 1991 (Strasser et al., 2016). The implant consisted of six plastic levonorgestrel-releasing capsules which was placed under the skin of the upper arm. The device was approved for pregnancy prevention for up to five years and was celebrated as a major advance in offering new ways to provide pregnancy prevention and eliminate user error (Strasser et al., 2016). Norplant was favored for its high efficacy in pregnancy prevention for five years with a quick return to fertility once removed. In its first year an estimated 100,000 women were using the implant and three years later, nearly one million women in the U.S. received the Norplant implant (Strasser et al., 2016). As quickly as Norplant rose to popularity, it just as

quickly declined as women reported unfavorable side effects such as breast tenderness, headaches, mood and weight changes; with menstrual bleeding irregularity was cited as the most bothersome (Strasser et al., 2016). Complaints and concerns also arose from difficulty of removal. Although providers received training regarding insertion, removal training was less common and the removal of six plastic capsules often proved difficult. In the late 1990s, tens of thousands of lawsuits were filed against the manufacturer of Norplant and in 2002, they suspended their sales (Strasser et al., 2016). The single-rod contraceptive implant, first introduced as Jadelle, now Nexplanon, became available in the U.S. in 2006.

Although LARC methods of the past may have had a difficult history, IUDs and contraceptive implants of today are the most effective reversible contraceptive method and are a vital component in preventing unintended pregnancy. The copper-containing IUD, Paragard, is a T-shaped device made of polyethylene and barium sulfate (Copper Surgical, 2018). A wire coil of 176mg of copper is positioned around the vertical stem and a 68.7mg copper collar on each side of the horizontal arm (Copper Surgical, 2018). Its contraceptive effects are achieved through its interference with sperm transport and fertilization of an egg. This IUD is effective for 10 consecutive years and reports a failure rate of less than one pregnancy per one hundred women each year (Copper Surgical, 2018). According to Cooper Surgical, menstrual irregularities were the most common reported reason for discontinuation of Paragard (Copper Surgical, 2018). The copper IUD is favorable among women who have comorbidities limiting their choice of highly effective contraception. Providers who have concerns regarding patient comorbidities should always reference the CDC evidence-based guide, the U.S. Medical Eligibility Criteria for Contraceptive Use.

Levonorgestrel-releasing intrauterine devices, Mirena, Liletta, Kyleena, and Skyla are all comprised of a T-shaped polyethylene frame with a steroid reservoir containing levonorgestrel consistently released over the course of its approved duration. Mirena and Liletta each contain 52mg of levonorgestrel and are effective for five years (ACOG, 2017). Kyleena contains 19.5mg of levonorgestrel and is also approved for five years of pregnancy prevention (Bayer HealthCare Pharmaceuticals [Bayer], 2017a). Skyla, a slightly smaller IUD compared to Mirena or Liletta, contains the least amount of levonorgestrel, 13.5mg and is effective for three years (Bayer HealthCare Pharmaceuticals [Bayer], 2016). The ACOG (2017) report most women using levonorgestrel-releasing IUD continue to ovulate, but experience less frequent, lighter menses with continued use despite bleeding irregularities.

Nexplanon, is currently the only implantable contraceptive available in the U.S. The single-rod implant is four centimeters in length, two millimeters in diameter, and implanted subdermally in the inner aspect of the non-dominant upper arm (ACOG, 2017). Nexplanon contains 68mg of etonogestrel in an ethylene vinyl copolymer core which allows for controlled release of the hormone over the approved three years of use (ACOG, 2017). The contraceptive implant is the most effective LARC method with a pregnancy rate of 0.05% (ACOG, 2017). In Nexplanon clinical trials involving 942 women, change in menstrual bleeding patterns was the most commonly reported adverse reaction (11.1%) leading to discontinuation of the implant (Merck Sharp & Dohme Corp [Merck], 2015).

ACOG (2017), along with the CDC and World Health Organization, identify long-acting reversible contraception as the most effective reversible contraceptive methods. The CHOICE project, a prospective cohort study of 9,256 women aged 14-45 aimed at increasing LARC use by removing the barriers of cost, patient knowledge, and access. One of the most impactful study

findings was how much more effective LARC methods are at preventing unintended pregnancy when compared to short-acting methods like pills, patch, and vaginal ring; "non-LARC users were more than twenty-two times as likely to experience an unintended pregnancy compared to their LARC counterparts" (McNicholas, Tessa, Secura, & Peipert, 2014, p. 639). In 2009, the Colorado Family Planning Initiative resulted similar findings to those of the CHOICE project. The initiative provided LARC methods at no cost through Title-X funded clinics to 37 of 64 counties making up 95% of the population. Between 2010 to 2013, LARC use increased and birth rates and abortion rates dropped by 29% and 34% respectively among teenagers (Ricketts, Klingler, & Schwalberg, 2014). Among young women, birth and abortion rates decreased as well, 14% and 18%, respectively (Ricketts et al., 2014).

Long-acting reversible contraceptives have proven to be highly effective choices in preventing unintended pregnancy. Unintended pregnancies result in negative maternal and fetal outcomes. Healthy People 2020, reports negative outcomes for women associated with unintended pregnancies may include increased risk of maternal depression, increased risk of physical violence during pregnancy, reduced likelihood of breastfeeding, and delays in initiating prenatal care (U.S. Department of Health and Human Services [USDHHS], 2013). The negative consequences for teen parents are even greater. Teen mothers account for 20% of all unintended pregnancies and are less likely to graduate from high school or earn a GED by age 30, earn an about $3,500 less per year than women who had children in their twenties, and receive nearly twice as much federal aid (USDHHS, 2013). Newborns and children are negatively affected as well; children with birth defects and low birth weights, are more likely to experience poor mental and physical health during childhood years, and have more behavioral issues in their teen years (USDHHS, 2013). As a result, Healthy People 2020 included two pregnancy-focused family

planning objectives: to “increase the proportion of pregnancies that are intended” and “to reduce the proportion of females experiencing pregnancy despite use of a reversible contraceptive method” (USDHHS, 2013).

The CDC (2018) also identified the prevention of unintended pregnancy as one of six initiatives included in the 6|18 Initiative aimed at improving health and controlling costs of six common and costly health conditions. About half of all pregnancies in the U.S. are unintended (CDC, 2018). In 2010, the public cost of births resulting from unintended pregnancies was estimated as $21 billion, half of the $40.8 billion spent for all publicly funded pregnancies in that same year (USDHHS, 2013). In 2010, a publicly funded birth including prenatal care, labor and delivery, post-partum care, and twelve months of infant care cost an average of $12,770 (CDC, 2018). The 6|18 Initiative identified the use of long-acting reversible contraception as a key intervention to improve health and control costs at individual, state, and federal levels. Although, LARC may be more expensive to initiate than short-acting reversible contraception, in time LARC may be far more cost-effective in terms of medication costs and unintended pregnancy (CDC, 2018). In fact, “for every public dollar spent on pregnancy prevention, $4.02 was shown to be saved on maternity and infant care among Medicaid-eligible women whose unintended pregnancies we prevented” (CDC, 2018, para. 25).

Long-acting reversible contraceptive has proven to be the most effective methods in preventing pregnancy and in controlling healthcare costs. Unfortunately, undesirable side effects, such as menstrual bleeding irregularities, lead to patient discontinuation of these highly effective methods. The pathogenesis of menstrual irregularities in women using hormonal is not well understood and is believed to be multi-focal, but it is hypothesized vascular changes related to a

thick endometrium transitioning to a thin endometrium as a result of the effects of progestin of hormonal contraception play a crucial role (Edelman & Kaneshiro, 2018).

According to Cooper Surgical (2018), menstrual irregularities were the most common reported reason for discontinuation of the copper intrauterine device, Paragard (Copper Surgical, 2018). The levonorgestrel-releasing IUDs, Mirena, Liletta, Kyleena, and Skyla, have a lower bleeding profile likely due to the mechanism of action, which alters the endometrium lining the uterus (Bayer HealthCare Pharmaceuticals [Bayer], 2017b). Of the 1,184 implant users in the CHOICE Project, 35% reported an increase in bleeding frequency at three months of use (Diedrich, Zhao, Madden, Secura, & Peipert, 2015).

Needs Assessment

In an effort to increase continued use of highly effective LARC methods, clinical recommendations for the management of unscheduled bleeding have been developed. As the first step toward user satisfaction, contraceptive counseling should focus on the needs of the woman including effectiveness, safety, access, and acceptability (Vollavicencio & Allen, 2016). Providers may then provide appropriate options based on the contraceptive expectations of the woman. Anticipatory guidance regarding side effects, especially bleeding patterns, should always be explicitly discussed during contraception counseling of all methods. Providers should discuss frequency, course, and significance of unscheduled bleeding (Edelman & Kaneshiro, 2018). Patient should be reassured bleeding irregularities are to be expected with LARC methods and are not associated with decreased contraceptive efficacy.

ACOG (2017) recommends women using LARC contraception be provided reassurance of anticipated bleeding irregularities; however, if bleeding persist or abruptly changes, clinical evaluation should be conducted to rule out serious medical concerns such as pregnancy, pelvic

inflammatory disease, infection, or malignancy (ACOG, 2017). After differential diagnoses have been ruled out, medication management may be prescribed as deemed appropriate.

Menstrual irregularities can be expected in about 70% of copper IUD users in the first three to six months and may be treated with nonsteroidal anti-inflammatory drugs (NSAID), such as ibuprofen, if bothersome to the woman (Vollavicencio & Allen, 2016). UpToDate authors suggests first offering 800mg ibuprofen every eight hours to reduce bleeding and cramping by inhibiting prostaglandin production (Pocius & Bartz, 2018); ibuprofen may be trialed for two to three cycles or months. Similarly, Naproxen 500mg twice daily may also be used for five days. If NSAIDs are not effective, a trial of oral contraceptive pills, combined or progestin-only, may be prescribed based on the woman's risk factors and preference (Pocius & Bartz, 2018). Theoretically, a low dose combined hormonal contraceptive pill would help thin the uterine lining.

Levonorgestrel-releasing IUD associated bleeding irregularities may be treated similarly to that of the copper-IUD; NSAID followed by low-dose combined hormonal contraceptive pill (Pocius & Bartz, 2018). However, ACOG only mentions NSAID in the treatment of bleeding irregularities associated with levonorgestrel-releasing IUD (ACOG, 2017). Bleeding patterns of Nexplanon, contraceptive implant, are unpredictable and cited as the most common reported reason for discontinuation of the method (ACOG, 2017). Recommendation for treatment of this unpredictable bleeding are similar to other LARC. ACOG recommends beginning with a short 5-7 day course of NSAID, if bleeding persist and the woman is medically eligible, a low-dose combined oral contraceptive pill may be effective. With any of the methods, if a woman is ultimately unhappy with her selected LARC, discontinuation and removal must always be provided as an available option. No studies currently exist that examine providers' perception or

attitudes of recommended interventions for the treatment of irregular menstrual bleeding associated with LARC use.

Problem Statement

The undesirable side effect of menstrual bleeding irregularities causes individuals to discontinue highly effective long-acting reversible contraception, often times selecting less effective contraceptive options as replacement. Unintended pregnancies result in negative maternal and fetal outcomes and cost the country billions of dollars each year. It is important that women are offered management of undesired bleeding side effects prior to the removal of LARC. While recommendations have been made to manage bleeding in women using LARC using nonsteroidal anti-inflammatories and estrogen, uptake of these recommendations has been slow. To address this, evidence-based education on recommended interventions for the treatment of irregular menstrual bleeding associated with LARC use was provided to women's health primary care providers. The purpose of this project was to analyze a change in women's health primary care providers' frequency in recommending interventions for the treatment of irregular menstrual bleeding associated with LARC use to patients.

Clinical Question

The clinical question guiding this project was "Does providing nurse practitioners education on recommended management of women with bleeding irregularities while using long-acting reversible contraception increase clinical practice of recommended management rather than removal of long-acting reversible contraception methods to patients?"

Aims and Objectives

To increase continuation rates of long-acting reversible contraception, this project aimed to investigate nurse practitioners' knowledge and clinical practice of recommended management

for women with bleeding irregularities while using a long-acting reversible contraception method. The objectives of this project were as follows:

1. Conduct a three-month retrospective chart audit to determine the exact number of long-acting reversible contraceptive methods that were discontinued prior to related to bleeding irregularities.
2. Develop provider education, based on evidence supported by nationally recognized leaders in the field, regarding the current recommended management of women with bleeding irregularities while using long-acting reversible contraception.
3. Provide nurse practitioners with findings of the retrospective chart audit and education about the current recommendations for the management of bleeding irregularities in LARC users
4. Assess nurse practitioners' implementation of current recommended management of women with bleeding irregularities while using long-acting reversible contraception by conducting a second three-month chart audit of LARC users with complaints of bleeding irregularities.
5. Analyze the findings of chart audits, before and after the education intervention, to evaluate the strength of the education intervention.

Review of Literature

A comprehensive literature search was conducted of all English-language studies regarding long-active reversible contraception, bleeding irregularities, and effective management in the primary care setting. An initial search of PubMed, CINAHL, and MEDLINE databases included key terms *contraceptive* and *bleeding* which produced 8,529 results. Additional key terms, *intrauterine*, *implant*, and *guidelines* were added and results were refined by limiting

publication dates from 2014 to the present to extract the most current research available. University research librarians assisted in this search.

Inclusion criteria consisted of original research, systematic reviews, and clinical practice guidelines in peer-reviewed journals that explored bleeding irregularities in females using long-acting reversible contraception including levonorgestrel-releasing intrauterine device, copper intrauterine device, and etonogestrel subdermal implant. Exclusion criteria omit contraceptive devices or medication not available in the U.S., such as levonorgestrel subdermal implant; research using long-acting reversible contraception for treatment of disease processes rather than pregnancy prevention; research conducted outside of primary care or in geographical locations that limit generalizability to medical practice in the U.S.. After applying exclusion criteria and a thorough analysis of the literature, eleven references were selected for inclusion in this review; one literature review, two clinical practice guidelines, and eight research publications.

Of the nine research publications selected, two were systematic reviews, three were randomized control trials, an additional three were non-experimental or qualitative, and one was quasi-experimental. The selected literature was appraised for evidence levels and quality using the Johns Hopkins Research Evidence Appraisal Tool. Of the nine research studies, four were of high quality, four were of good quality, and one was of low quality due to an unanticipated small number of participants resulting in an insufficient sample size for the study. The research studies were also appraised for evidence level; three were level I, randomized control trials; two were level II, and three were level III. The non-research, two clinical practice guidelines of high quality and an evidence level IV, and one literature review of good quality and an evidence level V (see Appendix A for Table of Evidence).

Bleeding side effects remain the most reported reason for long-acting reversible contraception user dissatisfaction and discontinuation (Weisberg, Bateson, McGeechan, & Mohapatra, 2014). Undesirable bleeding has been identified as unpredictable, increase in the amount of bleeding, or the number of bleeding days. Users often reported menstrual irregularities to be bothersome or negatively impacting their daily life. Bleeding patterns vary between individuals and contraceptive methods, and unfortunately, the pathophysiology of bleeding associated with long-acting reversible contraceptive use is not well understood. Weisburg, et al. (2014) studied the bleeding patterns, side effects, satisfaction, and the reason for discontinuation of etonogestrel subdermal implant compared to levonorgestrel intrauterine device over three years. The study concluded that by month 36, a total of 47% of implant users had discontinued their method due to frequent bleeding or spotting, compared to 27% of intrauterine device users; the most reported reason for discontinuation among both implant and IUD users was undesirable bleeding patterns (Weisberg et al., 2014). Carvalho et al. (2017) conducted a study of 231 women evaluating satisfaction with the use of the levonorgestrel intrauterine device was conducted; an association had been identified between satisfaction, duration of use, and amenorrhea. Most participants reported being highly satisfied due to amenorrhea, followed by satisfied with reduction in a quantity of bleeding, fewer days of bleeding per month, and fewer bleeding episodes per year (Carvalho et al., 2017). This may suggest if providers can reduce bleeding irregularities, women may experience greater satisfaction with the chosen contraceptive method and will likely increase continuation rates.

Managing expectations regarding changes in menstrual bleeding can be achieved through routine contraceptive counseling and reassurance (Modesto, Bahamondes, & Bahamondes, 2014). Modesto et al. (2014), conducted a randomized clinical trial to study the LARC

discontinuation rates of women who received routine contraceptive counseling and those who received intensive counseling. Routine and intensive contraceptive counseling included efficacy, safety, and side effects including menstrual irregularities; intensive counseling was further enhanced by providing patients with informational. The study concluded there was no significant effect on discontinuation rates between routine counseling and intensive counseling (Modesto et al., 2014). The findings of this research suggest that routine contraceptive counseling, including potential side effects and changes in bleeding patterns, may be sufficient; however, routine counseling is poorly defined by the literature thus making it difficult to standardize contraceptive counseling context for all providers.

Effective management of bothersome bleeding associated with the use of long-acting reversible contraception has been identified. The use of the copper intrauterine device has been associated with an increased amount of menstrual bleeding as well as more painful menses (ACOG, 2017). The literature supports the use of non-steroidal anti-inflammatory drugs (NSAIDs), which have been studied most often, for the reduction of bleeding irregularities in females using a copper intrauterine device. Ibuprofen, 400mg by mouth, three times a day for 10 days beginning on day one of menses has been recommended for prophylactic treatment of bleeding and pain associated with the copper IUD for new users; tranexamic acid, an antifibrinolytic, 500mg by mouth twice a day for five days has also been recommended (Friedlander & Kaneshiro, 2015). Friedlander and Kaneshiro (2015), also identified ibuprofen and other NSAIDs such as mefenamic acid, indomethacin, and diclofenac to be of benefit in reducing heavy menstrual bleeding in existing users. The use of NSAIDs and tranexamic acid for the treatment of spotting, heavy, or prolonged bleeding is consistent with the recommendations of the World Health Organization (WHO, 2016). ACOG (2017) only recommends NSAID use

and does not identify the effectiveness of one NSAID medication over another. Based on the literature and clinical practice guidelines, non-steroidal anti-inflammatory drugs, possibly ibuprofen due to accessibility, should be offered for the treatment of menstrual irregularities associated with the use of the copper intrauterine device.

The hormonal intrauterine device containing levonorgestrel has been approved for the treatment of heavy menstrual bleeding and has a fairly low discontinuation rate due to undesirable bleeding (Carvalho et al., 2017). However, if an individual does express concerns regarding spotting or irregular bleeding, reassurance should be provided. Medication supported by the literature for the treatment of bleeding in the levonorgestrel-releasing intrauterine device includes NSAIDs; Naproxen 500mg, by mouth, twice a day for five days beginning the day after device insertion and repeated monthly for three menstrual cycles (Friedlander & Kaneshiro, 2015). The use of NSAIDs like Naproxen is consistent with ACOG clinical practice guidelines (ACOG, 2017). The WHO (2016) recommends removal of the levonorgestrel IUD if bleeding is consistent, signs of anemia present, or the individual expresses dissatisfaction with the method. The summary of literature regarding the treatment of bleeding in levonorgestrel IUD users illustrates the various recommendations and a potential barrier for providers' willingness to recommend treatment.

The subdermal implant containing the hormone etonogestrel has the largest reported discontinuation and dissatisfaction as a result of bothersome bleeding (Weisberg et al., 2014). Several treatment options have been studied to evaluate the efficacy of reducing bleeding irregularities. ACOG (2017) supports the use of a five to seven-day course of non-steroidal anti-inflammatory; a low-dose combined oral contraception for those who are medically eligible is also an option for those with subdermal etonogestrel implant users. A randomized controlled trial

studied monophasic combined oral contraceptive pills for the reduction of bothersome bleeding; specifically, 150mg levonorgestrel/ 30mg ethinyl estradiol. Thirteen of 16 women reported improvement in bleeding when this course was continued for two to three months (Hou, McNicholas, & Creinin, 2016). These research findings, though limited by the small number of participants, align with ACOG recommendations regarding combined oral contraceptive pills. A second randomized controlled trial studying the same monophasic combined oral contraceptive pills produced similar results - those receiving combined oral contraceptive pills were more than eleven times more likely to have complete cessation of menstrual bleeding than the placebo group during the fourteen-day course (Guiahi, McBride, Sheeder, & Teal, 2015). Tamoxifen for the treatment of breakthrough bleeding was examined in a third randomized controlled trial (Simmons, Edelman, Fu, & Jensen, 2017). While results illustrate tamoxifen treatment effective in decreasing bothersome bleeding and an association with increased satisfaction (Simmons et al., 2017). Tamoxifen, an antineoplastic used in the treatment of various cancers, is not supported by ACOG or the WHO. The WHO did not make recommendations for bothersome bleeding in individuals using the etonogestrel implant.

The variations in available and recommended treatment options for the management of bleeding irregularities in women using long-acting reversible contraception found in the literature, highlights a potential barrier for providers to recommend bleeding management to their patients rather than the removal of long-acting reversible contraception. Furthermore, it identifies the need for management options to be delivered in a concise, streamlined, format providers can easily identify and recommend to their patients.

When various recommended treatment options exist, as is the case of the management of bleeding irregularities in women using LARC, the use of guidelines may be inconsistent and

unpredictable. Barriers may be related to providers, the guidelines themselves, or both. The systematic review conducted by Fischer, Lange, Klose, Greiner, & Kraemer (2016) identified specific barriers and provided specific implementation strategies to effectively facilitate the use of guidelines into provider practice. A lack of awareness or lack of familiarity has been identified as barriers to provider implementation of guidelines (Fischer et al., 2016). These are likely some of the barriers facing women's health providers when addressing the care of patients with bleeding irregularities associated with LARC use. Interventions include more frequent dissemination of guidelines. This can be achieved with standard dissemination of guidelines, through emails or written material, and active learning through professional education meetings (Fischer et al., 2016). Audit and feedback have been highlighted as an effective way to increase provider familiarity with guidelines as well as awareness of the implementation of guidelines (Fischer et al., 2016). Audit and feedback strategies were also proven to be particularly effective in provider adherence to guidelines (Chan et al., 2017).

A lack of agreement may also present a barrier to the implementation of guidelines. Variations in the management of menstrual irregularities between widely recognized and respected medical bodies such as between the WHO and ACOG, likely adds to the inconsistency of bleeding management offered to patients by providers. For this reason, it is prudent to involve providers in the development of decisional support systems (Fischer et al., 2016). Educational meetings can also facilitate the expression of provider opinions and concerns. Involving end-use providers early in the implementation process is an effective use of both time and resources.

Guidelines themselves may create barriers to implementation or adherence. Recognized guideline-related barriers include a lack of evidence, accessibility, and the lack of trial (Fischer et al., 2016). These barriers can be addressed by affording providers evidence-based education to

illustrate a strong level of evidence of high quality; creating decisional support systems such as algorithms or decision-making trees to make guidelines easier to follow; and creating pilot projects to trial implementation of guidelines (Fischer et al., 2016).

Theoretical Framework

Plan-Do-Study-Act (PDSA) is a tool used to implement change and knowledge translation. PDSA is part of the Model for Improvement (MFI) created by the Institute for Healthcare Improvement (IHI) (Langley et al., 2009). The IHI published *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance* in 1996 which details the MFI. The Model for Improvement has become the most commonly used approach for quality improvement. The MFI consists of two parts - three questions addressing the need for change and lays the foundation of the project, followed by PDSA to test change. The first of three questions *what are we trying to accomplish*, outlines the project aims and objectives. *How do we know a change is an improvement*, question two, establishes specific measures. Question three, *what changes can we make that will result in improvement*, assists in selecting effective change for implementation. The PDSA tool illustrates the cycle of plan, do, study, act and is used to test change. The PDSA is intended for action-oriented learning and rapid cycle processing. It is expected that a quality improvement project will cycle several times; beginning on a small scale, allowing for improvements and adjustments with each cycle, ultimately becoming its best version when it is implemented on a larger scale (Langley et al., 2009).

The Model for Improvement and the PDSA tool provides an excellent framework to guide this project through planning to implementation of provider education to assessment of bleeding management application (see Appendix B). PDSA has facilitated the progression of the project through each phase. The PDSA cycle begins with *plan*: developing a well-conceived

project idea by identifying an area for improvement, stating a clear research question, thoroughly reviewing the literature for current knowledge, developing a plan to test change, identifying the methodology, and creating education to present providers with guidelines for managing bleeding irregularities in patients using LARC. *Plan* is followed by *do*: implementation of provider education, document problems and concerns with implementation strategy, and collect data regarding provider implementation of recommended guidelines. *Study* is the third phase: analyze the data collected, consider possible connections, and summarize findings. The final phase of the cycle is *act*: plan for revisions and run another PDSA cycle or prepare for implementation of this intervention to a larger sample of providers in the women's health practice (Langley et al., 2009).

Methodology

As previously discussed, multiple recommendations for the management of bleeding irregularities may contribute to infrequent and inconsistent clinical application of these recommendations by providers. To address this, evidence-based education on recommended guideline interventions for the treatment of irregular menstrual bleeding associated with LARC was provided to nurse practitioners providing contraceptive care to women in the women's health practice. The purpose of this project was to analyze a change in nurse practitioners' frequency in recommending interventions for the treatment of irregular menstrual bleeding associated with LARC use to patients. This project used an interrupted time series design to evaluate change in the frequency of provider use of recommended guidelines for the management of bleeding irregularities in women using LARC methods, frequency of early removal of LARC methods, and patient reported reason for early removal of LARC methods.

Setting

Provider education regarding the management of bleeding irregularities in women using LARC methods was disseminated to nurse practitioners in the outpatient women's health practice of a Manhattan based teaching hospital. The women's health practice provides comprehensive gynecological and obstetrical care to women throughout the five boroughs of New York City. The practice cares for women of all ages with Medicaid and Medicare insurance. Each month, about 1,300 women are seen for care by residents or one of four nurse practitioners.

Study Population

This project examined the effects of provider education on clinical practice for the management of bleeding irregularities in women using LARC; therefore, licensed nurse practitioners must provide contraceptive care and must have prescribing privileges to have met inclusion criteria. Excluded from this project were residents, and nurse practitioners who did not provide contraceptive care. The project intervention was presented to nurse practitioners providing contraceptive care in the women's health practice, making this convenience sampling. To properly examine the impact of education on the clinical practice of nurse practitioners, the co-investigator (Co-I) needed to access and review pertinent patient charts. Patient charts included for review had one of the LARC methods in place, had complaints of bleeding irregularities related to their LARC method, or had requested removal of their LARC method.

A review of previous months revealed approximately 10 LARC are initiated each month by nurse practitioners; therefore, a three-month prospective chart review would include 30 charts. Based on this information, a sample size of 28 total charts were needed for a 95% confidence interval and a 5% margin of error.

Subject Recruitment

Subject recruitment began in September of 2019 with an email encouraging nurse practitioners to participate in an educational meeting regarding the management of bleeding irregularities in women using LARC methods. Three weekly repeating emails followed the initial email, to remind nurse practitioners of the educational meeting date and time. In-person recruitment was also conducted by the Co-I during the nurse practitioners' working hours. Flyers (see Appendix C) with the same information as the emails was placed on the bulletin boards in the nurse practitioner offices in the practice. The co-investigator's contact information was included in both emails and flyers to answer any questions or concerns.

Consent Procedure

Nurse practitioners willing to take part in this project were provided an informational sheet (see Appendix D) outlining the aims and objectives of this project, as well as their involvement. The informational sheet was distributed one week prior to the educational meeting to allow participants adequate time to review the informational sheet and voice possible questions or concerns. A waiver of consent was requested and approved for the review of patient charts. Review of patient charts were necessary to evaluate the effect of the educational meeting on the clinical practice of participants. All data collected from chart audits was void of patients' demographics or personal identification. The chart audits posed only minimal risk and no consent was needed for chart audits outside of the research context.

Risk/Harms/Ethics

This project had many potential benefits to both participants and their patients. Participants received education regarding the current ACOG and WHO recommendations for the treatment of bleeding irregularities in women using LARC. This education provided the

participants with clarity of various treatment options for bleeding irregularities and each received a pocket-sized decision-making tree for further ease of use in clinical practice. This provided participants with increased confidence in the management of bleeding irregularities for their patients using LARC. The project posed minimal risk to participants; however, participants may have felt uncomfortable with the recommended ACOG and WHO guidelines for the management of bleeding irregularities in women using LARC methods. No personal patient identification was collected during the chart audits; however, there was a small possibility that personal health information could be shared unintentionally. The benefits to participants of this project, greatly outweighed the potential risks.

Subject Cost and Compensation

Participants of this project received education at no cost and did not receive any compensation for their participation. This was made clear in both recruitment and consent.

Study Intervention

The intervention of this project was provider education regarding management of bleeding irregularities in women using LARC methods as recommended by ACOG and WHO. The information provided in this education included a brief history of IUDs and subdermal implants, the effects of unintended pregnancies, reasons for discontinuation of LARC, and background and treatment options for the various LARC methods (see Appendix E). Education based on the recommendations of ACOG and WHO was presented to nurse practitioners during an educational meeting in the conference room at the women's health practice. Education was conducted during a 60-minute lunch and learn meeting (40-minute of education followed by 20 minutes allowed for nurse practitioners to express questions and concerns). Education was provided through verbal and PowerPoint instruction. Nurse practitioners were provided with a

pocket-sized decision-making tree (see Appendix F) to facilitate the use of recommendations for the management of bleeding irregularities with each specific LARC method.

Retrospective chart audits, prior to intervention, were conducted to examine frequency of provider use of recommended guidelines for the management of bleeding irregularities in women using LARC methods, frequency of early removal of LARC methods, and patient reported reason for early removal of LARC methods. Retrospective chart audits prior to intervention, included charts of patients seen for contraceptive care for the three months prior to the intervention. At the conclusion of the intervention, a second chart audit took place examining frequency of provider use of recommended guidelines for the management of bleeding irregularities in women using LARC methods, frequency of early removal of LARC methods, and patient reported reason for early removal of LARC methods. This second chart audit included charts of patients seen for contraceptive care in the three months after the project intervention. This information was extracted from the electronic medical record of the women's health practice, Epic.

Outcome Measures

The effects of the study intervention was measured by comparing outcome measures of retrospective and prospective chart audits. A data collection tool (see Appendix G) was be used to collect pertinent data. Data collected to determine outcome measures include insertion date, the type of LARC method, the bleeding visit date, interventions that were offered, interventions that were ordered, was the LARC method was removed, the reason why LARC was removed, and if the nurse practitioner adhered to the guidelines. Each piece of data collected was imperative to answer the clinical question.

Collection of the insertion date of the LARC and the date of the visit allowed the Co-I to determine if the patient's complaint of bleeding irregularities occurred in the first six months after insertion when irregular bleeding is most common. The current guideline recommendations are specific to the type of LARC; therefore, it was important to identify the LARC method to determine if the correct guideline was implemented. To assess correct use of the guidelines, the Co-I extracted the interventions that were offered by the nurse practitioner and the interventions that were ordered by the provider and completed by the patient. It was believed that a patient who was satisfied with their chosen LARC method was more likely to continue its use; to assess continuation, it was important to know if the LARC was removed. Additionally, because the patient always has the right to refuse intervention and request removal of their LARC, the Co-I needed to determine if removal of LARC was at the request of the patient or was due to guideline recommendations. Lastly, the Co-I assessed adherence to the guideline recommendations.

Project Timeline

The project timeline, using a Gantt chart, can be found in Appendix H.

Resources Needed/Economic Considerations

The resources needed for this project included a reserved meeting space for educational material to be presented to nurse practitioners; this was arranged with the practice administrator. Resources for the printing of flyers and pocket-sized decision-making tree for providers was also needed. Additional considerations included the time invested by the Co-I and the potential to hire a statistician for assistance in analysis as the project progressed. Lunch provided at the educational meeting and all other costs related to the project was the responsibility of the Co-I.

Evaluation Plan

Data Analysis Plan

The statistical significance of chart audits prior to project intervention and after, was evaluated using a Pearson Chi-squared test. This allowed the Co-I to determine statistical differences in frequency of provider use of recommended guidelines for the management of bleeding irregularities in women using LARC methods, frequency of early removal of LARC methods prior to project intervention and after.

Data Maintenance and Security

Manual chart audits were conducted by the Co-I to collect frequency of provider use of recommended guidelines for the management of bleeding irregularities in women using LARC methods, frequency of early removal of LARC methods, and patient reported reason for early removal of LARC methods. The collection of this information did not include any patient demographics or personal identification; there was no link between the data collected and patient. A record of this data was transcribed onto a data collection sheet and was stored on a password protected laptop. Aggregate data will kept in a locked office of the principal investigator at Rutgers University (65 Bergen Street Newark, New Jersey) until completion of the project and closure of the IRB; at which time, all data was destroyed in accordance with Rutgers University guidelines.

Results

The project analyzed a change in nurse practitioner adherence to recommended guidelines for the management of bleeding irregularities in women using LARC. Retrospective and prospective charts of four nurse practitioners were audited to extract data to determine adherence. Charts considered for review included a patient complaint of irregular bleeding while

using LARC. A total of 60 charts were examined; 30 retrospective charts during the months of March, April and May of 2019, and 30 prospective charts during October and November of 2019. A Pearson's chi-square test was chosen to determine statistical significance between the retrospective and prospective adherence results. The Pearson's chi-square test examining nurse practitioner adherence to guideline recommendations for the management of bleeding in women using LARC between the retrospective and prospective groups determined a chi-square statistic of 15.864 with a p-value less than 0.001 (see Appendix I). The p-value was less than the chosen alpha value of 0.05; therefore, assume statistical significance. The results assume the educational intervention regarding recommended guidelines for irregular bleeding in women using LARC increased adherence to guidelines. A second Pearson's chi-squared test was conducted to determine relationship between adherence and removal of LARC which showed a chi-square statistic of 3.750 and a p-value of 0.053 (see Appendix J). The p-value of this test is greater than the chosen alpha value of 0.05 and therefore there is not a statistically significant relationship between the removal of LARC and adherence.

The data collection tool used for both retrospective and prospective chart audits included insertion date of LARC; type of LARC including Paragard, Mirena, Liletta, Skyla, and Nexplanon; visit date of bleeding complaint; interventions offered including reassurance, NSAID, hormones, other, or none; was LARC removed, yes/no; if LARC was removed, patient's request or guideline recommendation; and lastly, did the provider adhere to the guideline recommendation. "None" was the most offered intervention in the retrospective chart audit, accounting for 11 of 30 charts, followed by "reassurance"(n=10), "other"(n=8), "NSAID"(n=1), and "hormone" (n=0). In the prospective chart audit, "reassurance" was the most offered intervention; nurse practitioners offered reassurance to patients in 21 of 30 chart audits, followed

by “NSAID” offered 5 times and “none” 4 times; “other” and “hormone” interventions were not offered. The discussion of ACOG guideline recommendations during the provider education intervention, identified “reassurance” as the first intervention providers should offer patients who report bleeding irregularities while using LARC; therefore, an increase in “reassurance” intervention offered by nurse practitioners increased from 33% to 70% after the educational session. LARC removal decreased from 9 occurrences to 3; however, there was no statistically significant relationship between LARC removal and guideline adherence. All but one of the 12 LARC removals were due to patient request and not per guideline recommendations. Guideline recommendations were followed by nurse practitioners 36% of the time in the retrospective review and 86% of the time by nurse practitioners after the educational session.

Discussion

The results of the project answer the initial clinical question, does providing nurse practitioners education on recommended management of bleeding irregularities in women using long-acting reversible contraception increase clinical practice of recommended management rather than removal of long-acting reversible contraception methods to patients. The project demonstrated a clear increase in adherence after education intervention reviewing guideline recommendations for the management of bleeding irregularities in women using LARC. However, the results of the project did not indicate a statistical significance between adherence to guidelines and the removal of LARC.

This project aimed to investigate nurse practitioners’ knowledge and clinical practice use of recommended management for women with bleeding irregularities while using a long-acting reversible contraception method. This was demonstrated using SPSS to conduct comparison between retrospective and prospective chart audits and statistical analyses including Pearson’s

chi-square. The analysis showed statistical significance in adherence between charts audits prior to intervention and after. However, there was no statistically significant relationship between adherence and LARC removal. Based on the results of this project it can be reasonably assumed providing nurse practitioners education on recommended management of bleeding irregularities in women using long-acting reversible contraception increases clinical practice of recommended guidelines. The objectives of this project were achieved by closely following the Gantt timeline. All chart audits were conducted by manual appraisal of the electronic health record, Epic. Charts considered for audit must have been assigned to a nurse practitioner, must have been a gynecologic visit, and must have included a patient complaint of bleeding irregularity while using a LARC method. Retrospective charts were collected from the months of March, April, and May of 2019. Prospective charts were collected from the months of October and November, of 2019. Provider education was created based on ACOG guideline recommendations for the management of bleeding irregularities in women using LARC. PowerPoint was used to ensure all information was provided was available in both verbal and written format. A decision making tool was also created using ACOG recommendations and was made into a pocket-sized laminated card for providers to have on-hand with patients.

Time between date of LARC insertion and date of bleeding visit ranged from one month to three years. This result echoes that of Diedrich et al. (2015) who reported 35% of implant users reported bleeding by month three; and of Vollavicencio and Allen (2016) who reported menstrual irregularities can be expected in about 70% of copper IUD users in the first three to six months. While LARC removal was found to have no statistical relationship with the adherence of guideline recommendations by nurse practitioners, there was a decrease from 9 removals to 3 removals after the educational session. It is possible this was not a true reflection of the entire

practice, but rather was a result of sampling only the charts of nurse practitioners. Additionally, there was no correlation between the type of LARC method and the rate of adherence nor the rate of removals. This was surprising as the literature revealed by month 36 after initiation of LARC, 47% of implant users had discontinued their method due to frequent bleeding or spotting, compared to 27% of intrauterine device users (Weisberg et al., 2014).

Barriers and Facilitators

In accordance with the Plan Do Project Act (PDSA) cycle, after studying the outcomes, process evaluation is necessary for future PDSA cycles. Identifying barriers and facilitators will help to improve future PDSA cycles. One barrier identified in this project was that nurse practitioners' individual performance could not be measured. To protect the privacy of the nurse practitioners and remain non-punitive, the identification of the four nurse practitioner was not included in the data collection. This meant the retrospective and prospective data must be examined as a group and limited the analysis to see change in each nurse practitioner individually; this was an unintended consequence. Another barrier identified was the electronic health record. Although the electronic health record mase chart audits much more convenient, the system does not allow for the charts of specific chief complaints to be identified in its current state resulting in cumbersome manual chart audits to be collected by the user. While the electronic health record allowed for gynecology visits to be easily identified, the chief complaint had to be identified manually by reading the progress note of every gynecology visit seen by a nurse practitioner. This was not initially anticipated and was very arduous. For future cycles, including IT services in the data collection process may allow for a more efficient and manageable data collection process.

While evaluating nurse practitioners as a group may have led to some barriers in evaluating individual performance, evaluating nurse practitioners as a group, rather than individually, may have facilitated full participation by all four nurse practitioners. An additional facilitator identified was the fact that this project was initiated secondary to a noticeable trend specific to the women's health practice where the participants work. The problem of early LARC discontinuation was observed by the nurse practitioners in their own practice and therefore, they had vested interest in the aim and objectives of this project. Lastly, because the co-Investigator has worked at this practice for four years, trust and respect has been established between the medical director, nurse practitioners participating in this project and the co-Investigator. The nurse practitioners were very willing and eager to help facilitate this project and, ultimately, the improvement of an identified problem within the practice.

Implications

Implications for Clinical Practice

This project has demonstrated an increase in nurse practitioner adherence to guideline recommendations for the management of bleeding irregularities in women using LARC from 36% prior to intervention to 86% adherence after intervention. LARC removal also decreased from nine removals prior to intervention to just three removals after intervention. While the relationship between guideline adherence and LARC removal was not found to be statistically significant in this project, a second PDSA cycle to include resident physicians of the practice or with a larger number of chart audits may provide additional insight. Most importantly, the project demonstrated an increase in adherence to guideline recommendations from nationally recognized organizations. This increase in adherence to guideline recommendations by nurse

practitioners means patients are being offered evidence-based interventions to manage bleeding irregularities more often and more consistently.

Nurse practitioners reported the pocket-sized decision making tool as a major benefit to increase adherence. The literature review revealed a lack of awareness or lack of familiarity as barriers to provider implementation of guidelines (Fischer et al., 2016). These were likely some of the barriers nurse practitioners faced when addressing the care of patients with bleeding irregularities associated with LARC use. This was addressed by affording nurse practitioners evidence-based education to illustrate a strong level of evidence of high quality and creating decisional support systems such as the pocket-sized decision-making tree to make guidelines easier to follow, as suggested by the literature (Fischer et al., 2016). The decision-making tree could be reproduced and distributed to other members of the practice such as nurses, resident physicians, and attending physicians to increase adherence to guideline recommendations throughout the practice.

Implications for Healthcare Policy

The results from this project validate the provider education and decision making tool given to nurse practitioners. The project further exhibits a positive relationship between provider education and adherence to nationally recognized guideline recommendations for the management of bleeding irregularities in LARC users. Practice policy should reflect the need for all providers to receive the education intervention used in this project to increase adherence for all providers in the practice. Further policy development may include translating the decision making tool given to nurse practitioners into written policy for the management of bleeding irregularities in women using LARC. Offering evidence-based guideline recommended interventions for bleeding irregularities in patients using LARC consistently will improve the

care provided to patients of the practice. Written formal policy will also allow the providers a finite reference for review if questions arise in the contraceptive care of their patients.

Implications for Quality and Safety

It was anticipated that this project would improve the management of bleeding irregularities in women using LARC, adding to an increase in patient satisfaction with their chosen contraceptive methods, as well as, provider satisfaction in their ability to provide long-acting reversible, and highly effective contraception to patients for pregnancy prevention. As an anticipated result of increased patient satisfaction of chosen LARC methods, this project intervention was thought to also increase continuation rates of LARC use.

Offering evidence-based guideline recommendations from nationally recognized organizations to patients consistently in an effort to improve patient satisfaction with their chosen LARC methods was an initial goal of this project. Preventing undesired pregnancy may have a tremendous impact on the future health of women and children as well. Healthy People 2020 identified increased risk of maternal depression, increased risk of physical violence during pregnancy, reduced likelihood of breastfeeding, and delays in initiating prenatal care as some of the associated risks of unintended pregnancy (U.S. Department of Health and Human Services [USDHHS], 2013).

Providing the very best patient care should be the goal of all providers. A study of 231 women evaluating satisfaction with the use of the levonorgestrel intrauterine device was conducted; an association had been identified between satisfaction, duration of use, and amenorrhea. Most participants reported being highly satisfied due to amenorrhea, followed by satisfied with reduction in a quantity of bleeding, fewer days of bleeding per month, and fewer bleeding episodes per year (Carvalho et al., 2017). This may suggest if providers can reduce

bleeding irregularities, women may experience greater satisfaction with the chosen contraceptive method and will likely decrease discontinuation rates. While not statistically associated with guideline adherence, this project did illustrate a decrease in LARC removal from 9 removals to just 3 removals after project intervention. If LARC removal due to the dissatisfaction of bleeding irregularities can be reduced, women may be less likely to choose a less effective contraceptive method, be less likely to experience an unintended pregnancy, and be less likely to endure poor maternal and fetal outcomes.

Implications for Education

The education intervention provided to nurse practitioners in this project, can be offered to residents and attending physicians of the practice as well. The evidence-based education for the management of bleeding irregularities in women using LARC is consistent for all providers including nurse practitioners, physicians, and physician assistants. The literature highlighted more frequent dissemination of guidelines as a facilitator to increase adherence. This can be achieved with standard dissemination of guidelines, through emails or written material, and active learning through professional education meetings (Fischer et al., 2016). In an effort to disseminate learning in a convenient modality which allows for all providers to receive the education, the education can be developed for an e-learning module which can be made available through the organization's e-learning platform, SABA. Additionally, the education can be disseminated for use by the New York State Department of Health which has developed an initiative with hospitals in the five boroughs to improve access to long-acting reversible contraception.

Economic Implications

Preventing undesired pregnancy has a tremendous, positive impact on the future health of women and children as well. Healthy People 2020, identified increased risk of maternal depression, increased risk of physical violence during pregnancy, reduced likelihood of breastfeeding, and delays in initiating prenatal care as some of the associated risks of unintended pregnancy (U.S. Department of Health and Human Services [USDHHS], 2013).

Prevention of unintended pregnancy is also economically cost effective. The 6|18 Initiative identified the use of long-acting reversible contraception as a key intervention to improve health and control costs at individual, state, and federal levels (CDC, 2018). In fact, while the cost to initiate LARC may be relatively expensive compared to other contraceptive methods, the monetary savings associated with the prevention of unintended pregnancies and medication costs are exponential. Further highlighting the need to offer LARC users effective evidence-based interventions for the management of undesired side-effects such as irregular menstrual bleeding.

Sustainability

The education created for the nurse practitioners in this project can be developed for an e-learning module which can be made available to nurses, nurse practitioners, physicians, residents, and physician's assistants to improve clinical practice. During a second PDSA cycle, identification of individual performance by providers may prove beneficial. Identifying providers individually may allow for audit and feedback which has been demonstrated by the literature to be highly effective at increasing adherence to recommended guidelines. Including all providers of the practice will also allow for a larger sample size and may provide additional insight into the relationship between provider adherence to guideline recommendations for the management of bleeding irregularities and the removal of LARC. The education and decision-making tool can

also be offered to the New York State Department of Health for dissemination at on-going LARC initiatives to increase contraceptive access at hospitals in the surrounding five boroughs. Creating practice policy will also allow for this project to have a sustained positive impact on providers and patients of the practice and will allow for providers to have a concrete reference to address questions/concerns that may arise while caring for patients with bleeding irregularities associated with LARC use.

The decision-making tree can be shared with all providers of the women's health practice. The results of this project will translate into quality improvement for patients and providers; an improvement in patient care by offering management options for bleeding side effects of various LARC methods, and an improvement for providers in their knowledge and understanding of guideline recommendations for the management of bleeding irregularities in women using LARC. The improvements observed in this project may be used to create practice policy. Creating policy regarding the management of bleeding irregularities in women using LARC will ensure its sustainability within the women's health practice. Written formal policy will also allow the providers a finite reference for review if questions arise in the contraceptive care of their patients. The policy would be subject to the same periodic review as all department policy to ensure current evidence based practice.

Dissemination/Future Scholarship

The results of this project were disseminated to the medical director of the practice. The expectation is that this will become practice policy for the treatment of bleeding irregularities in women using LARC. Dissemination of this project will also take place at Rutgers University via paper, poster and presentation to members of the School of Nursing as part of the requirements

for the Doctor of Nursing Practice degree. Consideration will also be made for potential dissemination via manuscript publication or presentations at local, state, or national conferences.

Summary

The overall aim of this project was to analyze a change in practice by women's health nurse practitioners' frequency in recommending interventions for the treatment of irregular menstrual bleeding associated with LARC use to patients in an effort to increase the continuation of highly effective long-acting reversible contraception. This project demonstrated providing nurse practitioners with education regarding the recommended guidelines for the management of bleeding irregularities in women using LARC increased their adherence to follow these guideline recommendations. This increase in adherence positively impacts women using LARC by consistently offering them evidence-based interventions to manage the undesirable side-effect of bleeding irregularities; thereby increasing satisfaction and continuation rate of their chosen LARC methods.

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Appendix A

Table of Evidence

Clinical Question: Does providing nurse practitioners education on recommended management of women with bleeding irregularities while using long-acting reversible contraception increase clinical practice of recommended management rather than removal of long-acting reversible contraception methods to patients?

Article #	Author & Date	Evidence Type	Sample, Sample size, Setting	Study findings that help answer the EBP question	Limitations	Evidence level & quality
1	Carvalho et al., 2017	Qualitative research	Convenience sampling 251 women, age 18-45, using levonorgestrel IUD (LNG-IUD) Family planning clinic in Sao Paolo, Brazil	An association was found between satisfaction, duration of use, and amenorrhea. 93.1% were highly satisfied or satisfied with LNG-IUD Amenorrhea, bleeding less in the amount of blood, # of days per month, and # of days per year was associated with being highly satisfied or satisfied with LNG-IUD Dissatisfaction with prolonged bleeding and spotting reported at the	Data collected was subjective only. Data was collected via face-to-face interview which participants may have been uncomfortable with. Potential recall bias because data was collected retrospectively and women had LNG-IUD in place for 2-108 months. This was the second consecutive LNG-IUD	Level: III, Quality: A

				first and second interview	for some users. LNG-IUD was provided at no cost. Extensive counseling may have led to greater reported satisfaction.	
2	Chan et al., 2017	Systematic review	55 reviews	Audit and feedback interventions were effective in 23 reviews, particularly for guideline adherence. Reminder interventions were included in 27 reviews with inconsistent results.	Qualitative synthesis Did not use primary studies, which also risks studied and study results duplication. Many reports did not include items like demographics or comorbidities to inference context.	Level: IV, Quality: A
3	Fischer et al., 2016	Systematic review	69 articles: 42 studies, 27 review	Barriers identified were lack of awareness and lack of familiarity with the guideline, but discussed education as an effective implementation strategy.	PubMed was the only databased used for the search. Used narrow search algorithm.	Level: III, Quality: B

				Guideline itself may be a barrier due to complexity, access, design, applicability. This review suggests a user-friendly layout, concise information, and decisional support tools. Dissemination was identified as a crucial component of guideline implementation. Interventions such as educational meetings, audit and feedback, and educational materials were discussed.		
4	Friedlander & Kaneshiro, 2015	Non-research; Literature review	N/A	Copper: prophylaxis treatment with ibuprofen or tranexamic acid on day 1 of menses. Treatment is ibuprofen, indomethacin, mefenamic acid, diclofenac, also on day 1 of menses.	N/A	Level: V, Quality: B

				LNG: NSAID, Naproxen 500mg BID, 5 days, beginning the day after insertion and then monthly for 3 months was associated with a 10% reduction in bleeding and spotting. ENG Implant: Doxycycline 100mg BID for 5 days starting day 2 of menses, but no impact on future bleeding pattern. Ibuprofen had no effect. Mefenamic acid 500mg TID for 5 days and increased number of days without bleeding to more than 20.		
5	Guiahi, McBride, Sheeder, & Teal, 2015	Randomized control trial	32 women, age 18-44, using nexplanon who complained of bleeding and seen at 1 of 7 institution clinics	Monophasic oral contraceptive pill (OCP): 30mcg ethinyl estradiol/ 150mcg levonorgestrel The OCP group was 11.7 times more likely to induce	Small sample size. The average age of women participants was 21-22 years old. There was no assessment of bleeding after	Level: I, Quality: A

				temporary bleeding cessation. The placebo group reported continuous unpredictable bleeding. The average number of days for bleeding to subside was 5 in the intervention group and 9 in the placebo group- almost twice as long.	the 14-day treatment, therefore it is unknown if the treatment had an effect on future bleeding patterns.	
6	Hou, McNicholas, & Creinin, 2016	Randomized controlled trial	26 women, 17-34 years of age with complaints of bleeding irregularity while using Nexplanon	13 participants assigned to the intervention group were provided monophasic combined oral contraceptive pill (COC) 30mcg ethinyl estradiol/150mcg levonorgestrel 12 of 12 women in the intervention group (one lost to follow-up) reported improved bleeding. Only 8 of 12 women in the control group reported	Small sample size. Participants were women who were requesting management of bleeding with Nexplanon use; therefore, the experiences and results may not reflect all Nexplanon users with bleeding irregularities. There is no information on bleeding patterns after	Level: I Quality: C

				improved bleeding The average time for bleeding cessation to occur in the control group was 4.5 days; an average of 1 day was reported in the intervention group. 81% of participants reported improved bleeding pattern when COC was taken for 2 to 3 months.	participants discontinued treatment with COC.	
7	Modesto, Bahamondes, & Bahamondes, 2014	Quasi-experimental	297 women who elected one of three LARC menthods	This study compared the impact of routine contraceptive counseling to intensive contraceptive counseling. Routine counseling included efficacy, safety, and side effects including changes in bleeding patterns. The intensive counseling	The authors discussed the possibility of shared counseling information between participants in the two groups because they share the same waiting room. Premature discontinuation rates in this clinic were not significant	Level: II, Quality: B

				group received the same information as the routine counseling group with the addition of written materials. No significant change in continuation rates of LARC method between routine counseling and intensive counseling. The study suggests routine counseling is likely to be sufficient; however, it is difficult to generalize findings as there is no universal script to contraceptive counseling.	prior to the study; therefore, the counseling in this setting may have been sufficient prior to the study. Authors acknowledged that the information may not be generalizable.	
8	Simmons, Edelman, Fu, & Jensen, 2017	Randomized controlled trial	56 women, 15-45 years of age, using Nexplanon for at least 30 days	Tamoxifen group and control group both reach their first day without bleeding at about the same time; day 5 and	The authors acknowledge that bleeding recall bias may be possible as a result of retrospective data collection.	Level: I Quality: B

				day 6 respectively. However, those in the tamoxifen group experienced a longer duration of days without bleeding. Women using tamoxifen had fewer days of bleeding or spotting during the 30 days of treatment than participants in the placebo group.	High attrition rates throughout the study may obscure study end results at day 180. Bleeding patterns ins implant user improve with the continuation of use so some results could be compromised due to implant duration.	
9	The American College of Obstetricians and Gynecologist [ACOG], 2017	Non-research; Clinical practice guideline	N/A	ACOG recommends the use of non-steroidal anti-inflammatory drugs (NSAID) for the treatment of bleeding irregularities in copper IUD users. NSAIDs are recommended for bleeding reduction in levonorgestrel IUD users. ACOG specifically cites Naproxen in the reduction	N/A	Level: IV, Quality: A

				of bleeding in the first 3 months of levonorgestrel IUD use. For the treatment of bleeding associated with the use of a contraceptive implant, ACOG recommends NSAID use for 5 to 7 days. If bleeding does not improve and the implant user finds the bleeding undesirable, patients who are medically eligible may be prescribed a low-dose combined contraceptive pill. In all methods, ACOG recommends reassurance and education regarding bleeding pattern changes associated with LARC use as the first intervention.		

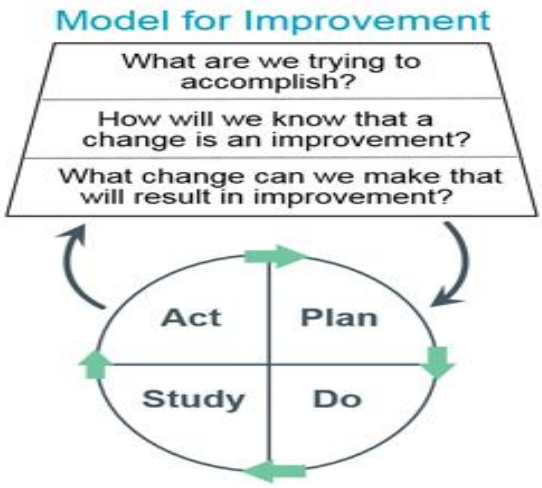
10	Weisberg, Bateson, McGeechan, & Mohapatra, 2014	Qualitative	349 women, 18 years of age or older, at a family planning clinic; 200 Mirena users, 149 Nexplanon users	Using a questionnaire, women were asked about bleeding patterns, side effects, satisfaction, and if they had discontinued their method, the reasoning. An assessment was completed at 6 weeks, 6 months, 12 months, 24 months, and 36 months. By the third year, 47% and Nexplanon and 27% of Mirena users had discontinued their chosen method. By the second year, amenorrhea was more common in Nexplanon users. Infrequent bleeding and spotting were more common in IUD users over the length of the study.	Participants of this study were not randomized therefore their chosen method may have been influenced by providers counseling. The interval questionnaires were self-administered and bleeding was self-reported by participants so the results are potentially unreliable.	Level:III Quality: B

				The single most common reason for Nexplanon removal, being unhappy with bleeding pattern, was reported in 54% of Nexplanon users compared to 23% of Mirena users		
11	World Health Organization [WHO], 2016	Non-research; Clinical practice guideline	N/A	The World Health Organization (WHO) recommends the use of non-steroidal anti-inflammatory drugs (NSAID) for the treatment of light bleeding or spotting in individuals using the copper IUD. NSAID use or tranexamic acid is recommended to manage heavy or longer menstrual bleeding. Individuals experiencing menstrual irregularities while using the levonorgestrel IUD, should be	N/A	Level: IV Quality: A

				offered the option of removing the device. The WHO makes no recommendations for treatment of the etonogestrel. The guidelines are for levonorgestrel implant not currently used in the United States.		

Appendix B

Theoretical Framework



(Langley et al., 2009)

Plan: developing a well-conceived project idea by identifying an area for improvement, stating a clear research question, thoroughly reviewing the literature for current knowledge, developing a plan to test change, identifying the methodology, and creating education to present providers with guidelines for managing bleeding irregularities in patients using LARC.

Do: implementation of provider education, document problems and concerns with implementation strategy, and conduct chart audits regarding provider implementation of recommended guidelines.

Study: analyze the data collected, consider possible connections, and summarize findings.

Act: plan for revisions and run another PDSA cycle or prepare for implementation of this intervention to a larger sample of providers in the women's health practice.

Appendix C

Recruitment Flyer

RUTGERS
School of Nursing

Guideline Recommendations for the Management of Bleeding Irregularities in LARC Users

ARE YOU FOLLOWING THE RECOMMENDED GUIDELINES?

Multiple recommendation for the treatment of bleeding irregularities in women using long-acting reversible contraception may contribute to infrequent and inconsistent clinical application of these recommendations. To address this, evidence-based education on recommended interventions for the treatment of these bleeding irregularities will be provided to nurse practitioners providing contraceptive care to women. The purpose of this research study is to analyze a change in nurse practitioners' frequency in recommending treatment interventions to their patients.

Are you a licensed nurse practitioner providing long-acting reversible contraceptive care to women?

Come to a no-cost 60-minute "lunch and learn" educational meeting about the recommendations for the management of bleeding irregularities in women using long-acting reversible contraception

WHERE: Women's health conference room [redacted]

WHEN: August 1, 2019 at 12 noon

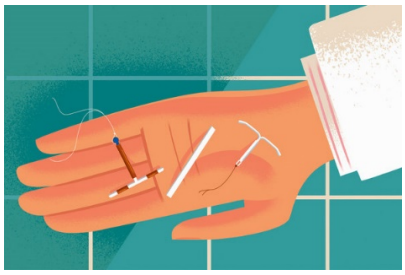
CONTACT: Alyssa Mitchell BSN, RNC-MNN (Co-Investigator)
65 Bergen Street Newark, NJ
Email: [redacted]

Version 1. 05/11/19

Appendix D

Participant Information Sheet

Guideline Recommendations for the Management of Bleeding Irregularities in LARC Users



Multiple recommendation for the treatment of bleeding irregularities in women using long-acting reversible contraception may contribute to infrequent and inconsistent clinical application of these recommendations. To address this, evidence-based education on recommended interventions for the treatment of these bleeding irregularities will be provided to nurse practitioners providing contraceptive care to women. The purpose of this study is to analyze a change in nurse practitioners' frequency in recommending treatment interventions to their patients.

A 60-minute "lunch and learn" educational meeting regarding the recommendations for the treatment of bleeding irregularities in women using LARC will be held on August 1, 2019. This meeting will consist of:

1) 40-minute discussion of recommendations
2) 20-minute question and answer session

Participants will not be asked to provide any information of any kind including surveys or questionnaires.

Following the educational meeting, 3 months of chart audits will be conducted to evaluate the implementation of the recommended interventions by nurse practitioners whose patients' express dissatisfaction with bleeding irregularities associated with LARC.

- No information collected in the chart audits will be used to identify a specific nurse practitioner.
- The findings of this study will be reported as a collective group of nurse practitioners.

Appendix E

Provider Education PowerPoint

Guideline Recommendations for the Management of Bleeding Irregularities in LARC Users

Alyssa Mitchell

Rutgers, The State University of New Jersey

School of Nursing

Brief history of IUDs

- In 1968, the first generation of IUDs became available in the U.S. and included material such as plastic and copper
- In 1971, the Dalkon Shield came on the market; two million women used the product during the four years it was available
- Health concerns were raised about pregnancy rates, pelvic inflammatory disease, as well as septic miscarriages
- CDC's survey identified over 3,500 cases of IUD-related hospitalizations from January to June of 1973
- In 1985, the manufacturer filed for bankruptcy after hundreds of thousands of women had brought forth lawsuits
- In 1976, the Medical Device Amendments were created- manufacturers must register devices and follow quality control measures
- This law also allows the Food and Drug Administration (FDA) to review medical devices and ban devices which create substantial deception or unreasonable risk of injury or illness

Brief history of subdermal implants

- The first implant, Norplant, came on the market in 1991
- It consisted of six plastic levonorgestrel-releasing capsules which were placed under the skin of the upper arm
- The device was approved for pregnancy prevention for up to five years
- Norplant quickly rose to popularity, then just as quickly declined when women reported unfavorable side effects (breast tenderness, headaches, mood and weight changes; menstrual bleeding irregularities reported as most bothersome)
- Complaints and concerns also arose from providers, as removing the six rods proved difficult
- Late 1990's, tens of thousands of lawsuits were filed and in 2002, they suspended sales
- In 2006, a single-rod implant was introduced under the name Jadelle

Effects of unintended pregnancies

- Health People 2020, reports negative outcomes for women associated with unintended pregnancies may include increased risk of maternal depression, increased risk of physical violence during pregnancy, reduced likelihood of breastfeeding, and delays in initiating prenatal care
- Teen mothers account for 20% of all unintended pregnancies and are less likely to graduate from high school or earn a GED by age 30; teen mothers also earn an about $3,500 less per year than women who had children in their twenties, and receive nearly twice as much federal aid
- Newborns and children are negatively affected as well; children with birth defects and low birth weights, are more likely to experience poor mental and physical health during childhood years, and have more behavioral issues in their teen years

Healthy People 2020 and 6 | 18 Initiative

- Healthy People 2020 included two pregnancy-focused family planning objectives: to "increase the proportion of pregnancies that are intended", and "to reduce the proportion of females experiencing pregnancy despite use of a reversible contraceptive method"
- The CDC also identified the prevention of unintended pregnancy as one of six initiatives included in the 6 | 18 Initiative, aimed at improving health and controlling costs of six common and costly health conditions
  - In 2010, the public cost of births resulting from unintended pregnancies was estimated as $21 billion, half of the $40.8 billion spent for all publically funded pregnancies in that same year
  - In 2010, a publicly funded birth including prenatal care, labor and delivery, post-partum care, and twelve months of infant care cost an average of $12,770
  - $4.02 is saved on maternity and infant care among Medicaid-eligible women for whom pregnancy is prevented for every dollar spent on pregnancy prevention

Reasons for discontinuation of LARC

- Menstrual irregularities were the most common reported reason for discontinuation of Paragard
- The levonorgestrel-releasing IUDs, Mirena, Liletta, Kyleena, and Skyla, have a lower bleeding profile likely due to the mechanism of action, which alters the endometrium lining the uterus
- Of the 1,184 implant users in the CHOICE Project, 35% reported an increase in bleeding frequency at three months of use

Paragard

- The copper-containing IUD, Paragard, is a T-shaped device
- Approved for 10 years of pregnancy protection
- Its contraceptive effects are achieved through its interference with sperm transport and fertilization of an egg
- Failure rate of less than 1:100 women each year
- Menstrual irregularities can be expected in about 70% of copper IUD users in the first three to six months

- **Treatment**:
  - 800mg ibuprofen every eight hours to reduce bleeding and cramping by inhibiting prostaglandin production for 2-3 menstrual cycles
  - Naproxen 500mg twice daily may also be used for five days

Levonorgestrel IUD

- T-shaped polyethylene frame with a steroid reservoir containing levonorgestrel consistently released over the course of its approved duration
- Approved for five years of use
- 0.7% unintended pregnancy rate

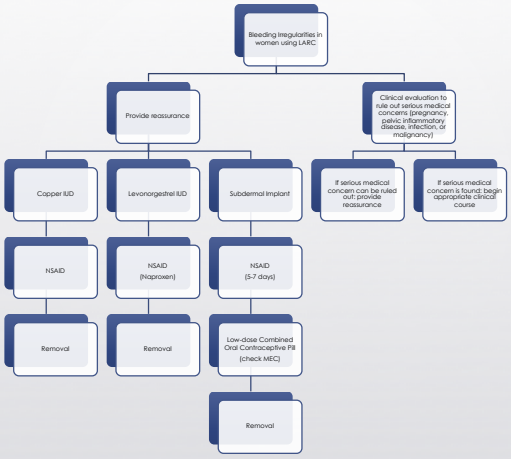
- **Treatment**:
  - Naproxen 500mg, twice a day for five days beginning the day after device insertion and repeated monthly for three menstrual cycles
  - Removal of the levonorgestrel IUD if bleeding is consistent, signs of anemia present, or the individual expresses dissatisfaction with the method

Subdermal Implant

- Single-rod implant measuring 4cm x 2mm
- Approved for 3 years of pregnancy protection
- The most effective LARC method with 0.5% pregnancy rate

- **Treatment**:
  - Five to seven-day course of non-steroidal anti-inflammatory
  - Low-dose combined oral contraception for those who are medically eligible

Treatment decision-making tree

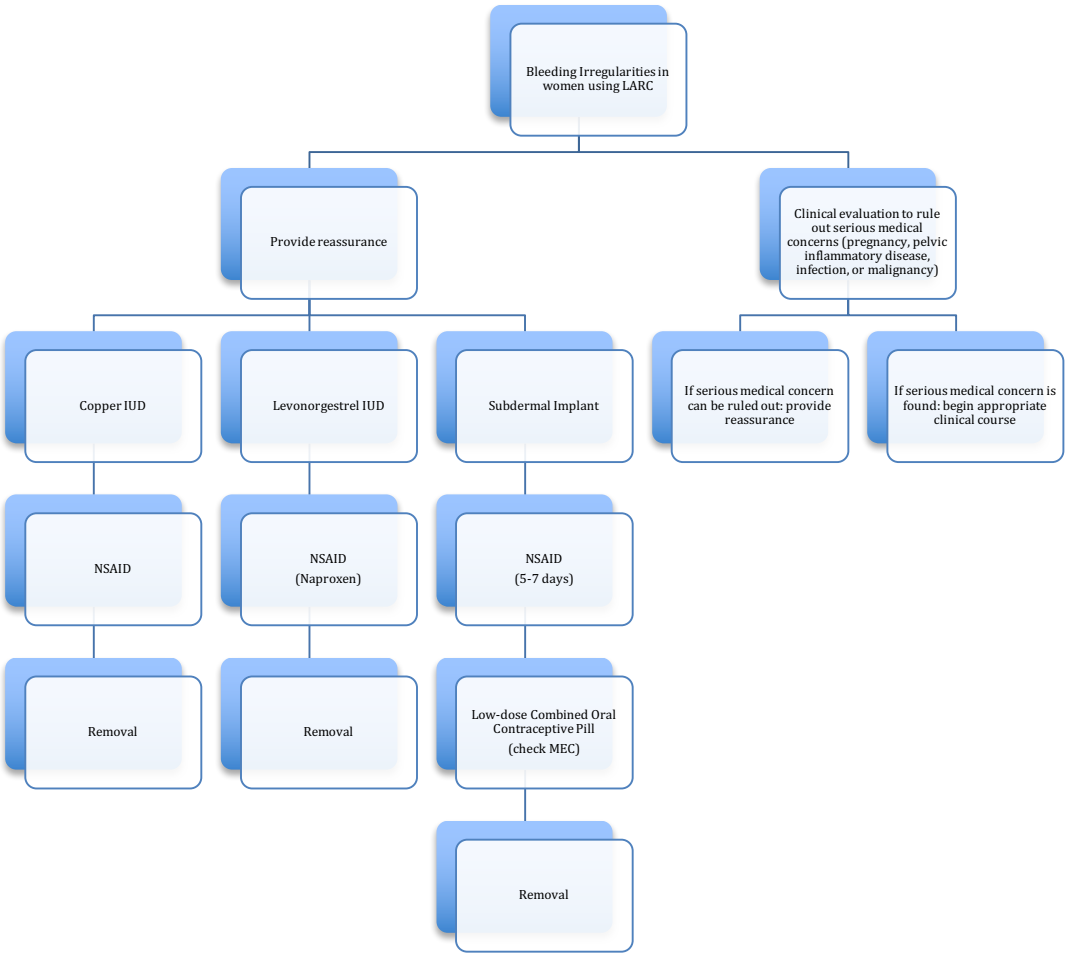


Based on ACOG, 2017


QUESTIONS?

Appendix F

Management for Bleeding Irregularities in Women using LARC



Based on: ACOG, 2017

Appendix G

Data Collection Tool

Insertion Date	Type of LARC	Bleeding Visit Date	Interventions Offered	Interventions Ordered/Completed	LARC Removed	If Removed: Patient request or Guideline Recommendation	Adherence to Guideline
<date>	<name>	<date>	<reassurance> <NSAID> <hormone> <none> <other>	<reassurance> <NSAID> <hormone> <none> <other>	<yes> <no>	<patient> <guideline>	<yes> <no>

Appendix H

Gantt Timeline

	JULY 2019	AUGUST 2019	SEPTEMBER 2019	OCTOBER 2019	NOVEMBER 2019	DECEMBER 2019
NYP IRB						
Rutgers IRB						
Flyer/Email Recruitment						
Data Collection (May, June, July)						
Intervention						
Data Collection (October, November, December)						
Final Presentation / Dissemination						

Appendix I

Pearson's Chi Square for Adherence

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Yes or No * Retrospective or Prospective	60	100.0%	0	0.0%	60	100.0%

Yes or No * Retrospective or Prospective Cross tabulation

		Retrospective or Prospective		Total
		Retrospective	Prospective	
Yes or No	No	19	4	23
	Yes	11	26	37
Total		30	30	60

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	15.864[a]	1	.000		
Continuity Correction[b]	13.819	1	.000		
Likelihood Ratio	16.891	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	15.599	1	.000		
N of Valid Cases	60				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 11.50.

b. Computed only for a 2x2 table

Appendix J

Pearson's Chi Square for LARC Removal

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Yes or No * Retrospective or Prospective	60	100.0%	0	0.0%	60	100.0%

Yes or No * Retrospective or Prospective Cross tabulation

		Retrospective or Prospective		Total
		Retrospective	Prospective	
Yes or No	No	21	27	48
	Yes	9	3	12
Total		30	30	60

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	3.750[a]	1	.053		
Continuity Correction[b]	2.604	1	.107		
Likelihood Ratio	3.891	1	.049		
Fisher's Exact Test				.104	.052
Linear-by-Linear Association	3.687	1	.055		
N of Valid Cases	60				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 6.00.

b. Computed only for a 2x2 table