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Improving Women's Health Services by Adding Long-Acting Reversible Contraceptive Methods into Primary Care-Focused Student Health

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Introduction

Unintended pregnancy among young women continues to be an issue in the United States (Finer & Zolna, 2011). Although several safe and highly effective contraceptives are available, nearly half of all pregnancies in the United States are unintended, with the majority occurring among women between the ages of 18-24, who are frequently college students, unmarried, low income, or not planning to conceive (Finer & Henshaw, 2006; CDC, 2013). Unintended pregnancies often result from inappropriate or inconsistent contraceptive use (Secura, Allsworth, Madden, Mullersman, & Peiper, 2010), and one in five unintended pregnancies ends in abortion (Pazol, Creanga, Burley, Hayes, & Jamieson, 2013). Long-acting reversible contraceptive methods (LARCs) are safe and highly effective contraceptive methods that can be used to prevent unintended pregnancy, but are currently only being utilized by a small portion of women - 5% of contraceptive users - in the United States (Secura et al.; Mosher & Jones, 2010).

Based on the 2011 enrollment report, the patient population of Student Health and Counseling Services (SHCS) of California State University, East Bay (CSUEB) consists of approximately 13,160 enrolled students, of which 60% (7,959) are female and 40% (5,201) are male, with an average age of 26 (Baker, Malhotra, & Weitzman, 2013; Office of Planning & Institutional Research, CSUEB, 2012). An American College Health Association (ACHA) survey conducted in spring 2010 found that the unintended pregnancy rate was reported as 4.9% among CSUEB respondents compared to national rates of 5%. Among all 23 CSU campuses, currently enrolled students are able to go to any nearby CSU, Student Health Services (SHS) for care if needed, but none of the CSU SHS listed the provision of LARCs service on the SHS home page by online search.

Assisting students in maintaining their optimal health to allow them to pursue academic and career goals is the main mission of Student Health and Counseling Services (SHCS, 2014). According to the 2012 ACHA, approximately 65% of college students reported having sexual partners within the last 12 months, and 49% of them reported not using any contraceptive method (ACHA-NHCA II, 2012). Furthermore, in 2013, the American College Health Association surveyed college students nationwide about contraceptive use, with a 34% response rate that consisted of 96,611 respondents (ACHA-NCHA II, 2013). Of the respondents, 46.5% reported not using any contraceptive methods during their last sexual intercourse within the past 30 days. The usage rate for intrauterine contraception (IUC) was reported at 5.5%, implant contraception was reported at 2.4%, and birth control shot was reported at 4.3%. Therefore, helping students prevent unintended pregnancy, especially freshmen and newly transferred students, is one of the measures to help maintain their optimum health.

Previous studies have shown that misperceptions about LARCs, lack of access, lack of education, and lack of training on IUC use among health professionals are common issues, and may be the major reason for their underuse (Secura et al., 2010; Khan & Shaikh, 2013; Kavanaugh, Jerman, Ether, & Moskosy, 2012). Family nurse practitioners can help these young women make an informed choice about contraception by providing evidence-based information and dispelling the misconceptions regarding LARCs. The purpose of this project is to provide evidence-based information regarding LARCs use and discuss the integration of LARCs services into a primary care-focused student health clinic.

Long-Acting Reversible Contraceptives (LARC)

Long-acting reversible contraceptives (LARCs) include three types of intrauterine devices and one type of implant that provide highly effective contraception, rapid fertility reversal after removal, and are non-user dependent after placement.

Intrauterine contraceptives

The World Health Organization (WHO) supports intrauterine contraceptive (IUC) use in adolescents starting from menarche with a level 2 recommendation, "benefits outweigh the risks" (WHO, 2004). Additionally, IUC is considered to be a first-line choice contraceptive method for both nulliparous and parous adolescents as recommended by the American College of Obstetricians and Gynecologists (ACOG) Committee Opinion in 2007 (Deans & Grimes, 2009; ACOG, 2007). IUC is one of the most effective contraceptive methods for unintended pregnancies because it is long-acting, reversible, safe, and requires low user maintenance. After adequate counseling, an IUC may be placed by a trained health care provider in an outpatient clinic. Currently, the three IUC devices available in U.S. include the Copper T 380A (ParaGard) and two levonorgestrel intrauterine systems (LNG-IUS), Mirena and Skyla (Deans & Grimes, 2009; Hatcher et al., 2011).

The Copper T 380A IUD was introduced in the United States in 1988. It is a non-hormonal, polyethylene T-shaped copper containing device with barium sulfate for x-ray visibility, placed inside the uterus for contraceptive use for up to 10 years. The device is 36 mm tall and 32 mm wide, and the total copper surface area is 380 ± 23 mm^2. The copper ions in the device prevent fertilization and implantation (Hatcher et al., 2011). The Copper T can be used as emergency contraception within five days of unprotected sexual intercourse (Hatcher et al., 2011) and has greater than 99% efficacy at pregnancy prevention. High efficacy and long duration of

use have made copper IUDs the most common contraceptive method in developing countries, especially in China (Arrowsmith, Aicken, Saxena, & Majeed, 2012).

There are currently two levonorgestrel intrauterine system (LNG-IUS) options available in the United States: Mirena and Skyla (Hatcher et al., 2011; Phelps, Murphy, & Godfrey, 2011; Medscape Reference, 2014). The first LNG-IUS, Mirena, was approved for use in the United States in 2000 and is a small T-shaped IUC device that contains 52 mg levonorgestrel, and initially releases about 20 mcg daily into the uterine cavity, with the amount gradually decreasing to 10 mcg daily by the fifth year (Hatcher et al., 2011; Phelps et al., 2011; Medscape Reference, 2014). The device is made of a Nova-T polyethylene frame with barium sulfate for x-ray visibility and a cylinder of a polydimethylsiloxane-levonorgestrel mixture molded around the vertical arm. The device is 32 mm tall & 32 mm wide (Hatcher et al., 2011; Medscape Reference, 2014). It is one of the most effective contraceptive methods and also has a number of non-contraceptive health benefits which include: decreasing menstrual blood loss, alleviating painful menstrual cycles, and protecting the endometrial layer during estrogen replacement therapy (Medscape Reference, 2014; Mansour, 2012). The efficacy of the LNG-IUS in preventing pregnancy is greater than 99%, and it is approved for contraceptive use for up to 5 years.

The second LNG-IUS, Skyla, contains 13.5 mg levonorgestrel and is the newest IUC, added to the US market in 2013. The device is 30 mm tall and 28 mm wide and releases about 14 mcg per day of levonorgestrel into the uterine cavity initially (Medscape reference, 2014). The amount of levonorgestrel gradually decreases to 5 mcg daily after three years of use (Medscape Reference, 2014). Levonorgestrel acts by thickening the cervical mucus to prevent sperm from entering into the uterus and changing the endometrium structure to prevent

implantation. This IUS prevents pregnancy for up to 3 years at greater than 99% efficacy. It also can provide non-contraceptive benefits to some female users with a history of painful or heavy menstrual cycles by decreasing the lining of the endometrial layer, decreasing menstrual blood loss, and preventing painful menstrual cycles (Hatcher et al., 2011; Medscape Reference, 2014; Mansour, 2012).

Etonogestrel contraceptive implant

The ENG-Implant is a single thin implant rod 4 cm long and 2 mm in diameter that is made of ethylene vinyl acetate and contains 68 mg of etonogestrel (3-keto-desogestrel), which is placed under the skin in the medial upper arm. The ENG-Implant provides unsurpassed contraceptive efficacy by inhibiting ovulation and thickening cervical mucus. It also provides effective contraception with a very low level of progestin and follicular phase estrogen that has been well tolerated, reportedly has decreased weight changes among users, and rare medical contraindications. It also decreases menstrual blood loss and painful menstrual cycles for at least 3 years. The effectiveness of the ENG implant to prevent pregnancy is greater than 99% (6 pregnancies in 20,648 cycles). Return of fertility is rapid among users with etonogestrel levels undetectable within 1 week (Davies, Feng, Newton, Van Beek, & Coelingh-Bennink, 1993); 44 of 47 women who were studied with ultrasound and serum progesterone levels ovulated within 1 month post removal (Croxatto & Makarainen, 1998).

Besides preventing unintended pregnancies, non-contraceptive benefits of LARCs can be used to help individuals with chronic medical conditions, such as anemia, heavy menstrual bleeding, and painful menstrual periods (Hatcher et al., 2011). LARCs will be suitable for patients with chronic conditions who take medications which can cause adverse effects. LARCs

are especially appropriate for patients who are treating their medical conditions with teratogenic medications (US MEC, 2012).

Local problem

The Need for LARC services

There are a few triggers leading this project's initiation. First, highly effective long-acting reversible contraceptive methods are not available at SHCS, even though most other contraceptive methods are provided. Second, students who are interested in LARC methods are referred to off-campus Planned Parenthood (PP) clinics or nearby community health centers for LARC placement services, but the nearby PP clinics have been closed due to financial difficulties (Mieszkowski, 2010). Also, according to an on-line search, none of the 23 California State Universities (CSU), student health clinics currently lists the service of LARCs on their student health clinic's home pages.

Unintended pregnancy is a substantial social and economic problem in the United States. Even though there are many contraceptive choices available, 49% of the 6.4 million pregnancies every year in the United States are unintended (Trussell, 2007). Among women 15-44, the rate of unintended pregnancies was 51 per 1,000 women, with the majority occurring among women aged 18-24, who are often unmarried, low-income, low-education level, and minority ethnicity (Finer, 2006). In the U.S., unintended teenage pregnancy has a significant fiscal impact, costing taxpayers at least $10,900,000,000 annually (H.R.2678, 2011). In 2009, there were nearly 750,000 teenage pregnancies, and a total of 409,840 infants were born to 15-19 year-olds with a live birth rate of 39.1 per 1,000 women (CDC, 2011). Women with an unintended pregnancy will usually delay prenatal care, which can affect the health of both the fetus and the woman.

Pregnant teenagers also face more medical and socioeconomic concerns such as increased risk of pre-term delivery, low birth weight, neonatal mortality, delays to antenatal care, lower educational levels, higher rates of poverty, and other poorer "life outcomes" compared with women in their twenties and thirties (CDC, 2011; Chen et al., 2007).

According to the 2013 American College Health Association survey of contraception use among U.S. college students (ACHA-NCHA II with n=96,611), the IUC usage rate was 5.5%. Of the respondents, 46.5% reported not using any contraceptive methods during sexual intercourse within the past 30 days. About 18.8% of the female respondents reported using emergency contraceptive pills ("the morning after pill") in the last 12 months and 1.9% of the respondents reported experiencing an unintended pregnancy in the past 12 months.

Inappropriate or inconsistent contraceptive use is the most common cause of unintended pregnancy, (Secura et al., 2010) and approximately one in five unintended pregnancies ends in abortion (Pazol et al., 2013). Due to the misuse or infrequent use of contraceptives, unintended teen pregnancy in the Unites States continues to be a persistent problem (Martinez, Copen, & Abma, 2011). Prevention of unintended teen pregnancy is of particular importance to the health and quality of life for young people throughout the United States. Additionally, improving maternal health is one of the United Nations Millennium Development Goals for 2015 (UNDP, 2012). Recommended strategies will effectively improve maternal health, such as increased contraceptive use and improved health care access.

Student Health Services are outpatient clinics on college campuses that offer primary medical care and women's health care to students. Generally, they are staffed by physicians, nurse practitioners, registered nurses, medical assistants, and counselors. The mission of the

Student Health Services is to assist students in achieving their academic and career goals by providing resources to help them maintain optimal health and to provide high quality, low cost health care to all enrolled students. Highly effective long-acting reversible contraceptive methods, such as the implant contraceptive and IUC, are not listed as available services at the majority of on-campus Student Health Services (SHS) in California.

Healthy Campus 2020, initiated by American College Health Association's (ACHA) Healthy Campus Coalition and derived from Healthy People 2020, targets reducing unintended pregnancy, increasing contraception use, and facilitating emergency contraception access at SHS to meet the student family planning objectives by 2020. Long-acting reversible contraception (LARC) methods are very safe and effective contraceptive methods that can be used to prevent unintended pregnancy, but are currently only being utilized by a small portion of women in the United States (Secura et al., 2010; Mosher & Jones, 2010). Increased highly effective contraceptive method use and increased access to such health care options are recommended as strategies to improve family planning and maternal health by United Nations (UNDP, 2012). Integrating LARC services into College Student Health Services is needed to help the healthcare system effectively meet these goals.

Intended Improvement

The goal to add the highly effective, non-user dependent LARC methods to the services of SHCS for students will enhance SHCS's mission to provide the best quality, low-cost health care to help students maintain their optimal health in order to pursue their academic and career goals.

The first objective of this project is to study the clinical contraceptives services currently provided and continuing usage by individual students. The second objective is to promote contraceptive use and add the service of highly effective LARC methods for sexually active students to lower students' stress by reducing the number of off-campus referrals, to prevent unintended pregnancy, and to help students maintain optimal health conditions to pursue their university degrees and careers. The third objective is to collaborate with the health promotion department to educate students and to promote the use of highly effective contraceptives.

The purpose of this proposal is to add highly effective long-acting reversible contraceptives (LARCs) service at SHCS for university students to help maintain their optimal health, to treat medical conditions, and to prevent unintended pregnancies.

Review of the Evidence

Also, many misperceptions regarding the use of IUC among patients and health providers need to be addressed (Khan & Shaikh, 2013; Mansour, 2012) prior to integration of IUC services into a primary care focused student health clinic. Providing the most up-to-date and accurate information about LARC methods will assist in dispelling rumors and myths. Myths can be defined as a belief, often false or unproven, that have accrued around a person, phenomenon, or institution. Rumors can be defined as unverified information of uncertain origin received from another (American Heritage Dictionary, 2000). Misconceptions and rumors have negatively impacted the uptake of LARC methods. The facts presented below will help address common misconceptions about the LARC methods.

IUC & the Facts

Although IUCs are safe, highly effective, and economical contraceptive methods, they are currently underutilized, especially among adolescents. Clinical providers are still reluctant to provide the service due to misperceptions stemming from the 1970s. Memories remain of the Dalkon Shield product, an IUC released in 1971 and withdrawn from the market in 1974, whose unique shape and its multifilament string tail caused removal difficulties, pelvic infections, septic abortions, and other infections (Cheng, 2000). Approximately 200,000 claimants worldwide filed lawsuits against the manufacturer even after the product was withdrawn from the market in 1974.

Myths about IUC use and function abound, nevertheless the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010 (U.S. MEC), and the U.S. Selected Practice Recommendations for Contraceptive Use, 2013 (U.S. SPR) for health care providers are excellent resources for education, implementation, continuing care, and management of IUC.

A common misperception is the mechanism of action of an IUC. An IUC is not an abortifacient (Phelps et al., 2011). IUC alters the uterine environment by promoting a foreign-body reaction inside the uterine cavity that prevents fertilization and/or implantation (Hatcher et al., 2011; Mansour, 2012). With the copper IUD, copper repels sperm and generates an inflammatory foreign body reaction to prevent fertilization (Hatcher et al., 2011; Phelps et al., 2011). The LNG-IUS works by releasing high concentrations of LNG within the uterine cavity, which results in endometrial atrophy and thickens the cervical mucus to create a barrier to sperm penetration, thereby preventing sperm-egg binding (Hatcher et al., 2011; Phelps et al., 2011).

Historical problems with the Dalkon Shield have falsely created the belief that the IUC is not appropriate for nulliparous women. The WHO and the ACOG, support the use of IUC in

both nulliparous and parous adolescents (WHO SPR, 2004; ACOG, 2007; Mestad et al., 2011; Godfrey et al., 2010). IUC for nulliparous use is a level 2 recommendation from the U.S. Medical Eligibility Criteria; the benefits of IUC generally outweigh the risks for women who have not had children (US MEC, 2010) (see appendix L).

Similarly, misperceptions about infertility persist. An IUD does not cause infertility and does not limit one's chances of getting pregnant in the future. Most cycles in women using LNG-IUS are ovulatory because there is no reduction in estradiol levels (Mansour, 2012). For women wanting to conceive, the 12-month pregnancy rate (92%) following removal of LNG-IUS is similar to women using natural family planning (Mansour, 2012). Historically, there was concern that IUC increased the spread of sexually transmitted infections (STIs). If STIs are not treated, they can scar the fallopian tubes and prevent women from getting pregnant. Research shows that today's IUC does not increase the risk of STIs and does not lead to infertility. For women who are at a low risk of sexually transmitted infections, such as those who are in monogamous relationships, the risk of developing pelvic inflammatory disease (PID) with IUC use is less than 1 in 100 and is even less in women who use LNG-IUS (Mansour, 2012). Women who use IUC and develop an STI or PID rarely need to have the device removed. Mansour (2012) found that discontinuation rates due to PID were 0.5 and 2.0 per 100 women at 3 years ($p=.013$) for the LNG-IUS and copper IUD, respectively, and 0.8 and 2.2 per 100 women ($p<.05$), respectively, at 5 years. When a woman develops an STI or PID, she should be treated with antibiotics right away. The IUC can remain in place if symptoms improve within 72 hours. If symptoms persist, the IUC should be removed (Hatcher et al., 2011).

IUC does not increase the risk of ectopic pregnancy, regardless of whether a woman has had a prior ectopic pregnancy. Ectopic pregnancy occurs 10 times more frequently in women

who do not use contraceptives than in IUC users. Mansour (2012) found that ectopic pregnancy rates were 0.045 and 0.22 per 100 LNG-IUS users at 1 and 5 years, respectively. For women who did not use any contraception, an estimated rate was 1.4 per 100 pregnancies. The U.S. MEC found no restriction to use for patients with history of ectopic pregnancy (US MEC, 2010).

Mansour (2012) also found no significant abnormal cytopathological effects on the LNG-IUS users in a 7-year long-term study of cervical smear samples. Progestin-releasing intrauterine contraception has been shown to reduce the incidence of endometrial cancer because it is more effective in reducing endometrial hyperplasia than oral progestin, and the LNG-IUS also prevents endometrial polyps in women taking tamoxifen for up to 4.5 years (Hatcher et al., 2011; Mansour, 2012). The copper IUC's mechanism of action is unclear, but the endometrium alterations may be related to the presence of copper; (Hatcher et al., 2011) therefore, both types of IUCs may reduce the risk of endometrial cancer (Hatcher et al., 2011; Mansour, 2012).

Literature Review

The currently used intrauterine devices are very safe and more effective than other types of contraceptives (Secura et al., 2010). IUC efficacy is similar to sterilization at 99%, but fertility can be reversed rapidly after the device's removal. An IUC can be used by both parous or nulliparous adolescent women (ACOG, 2007). However, it is currently underused among adolescents who are in the high risk group for unintended pregnancies, and this is largely due to a lack of knowledge regarding IUC. Furthermore, clinical providers are often reluctant to provide IUC services due to historical problems with outmoded devices, ongoing misconceptions, and lack of training.

A literature review was conducted to evaluate the effectiveness, acceptability, and continued use of these highly effective contraceptive methods by the young female population. Due to scarce data on long-acting reversible contraceptive (LARC) use among the adolescent group, it is important to determine whether LARCs are acceptable among this age group. Mestad et al. (2011) conducted a longitudinal, observational study in St. Louis, MO -- the Contraceptive CHOICE Project -- to promote LARC with no financial barriers and to evaluate use, satisfaction and comparison of continuation between LARC and non-LARC methods. The LNG-IUS, Copper IUD, and subdermal implant are included among LARC methods. Combined and progestin-only oral contraceptives, depot medroxyprogesterone acetate, the vaginal contraceptive ring, the transdermal contraceptive patch, and barrier methods are included in the non-LARC methods. There were 5086 female residents of St. Louis participants, aged 14-45 years, who were evaluated for their contraceptive method preferences by age. All methods of reversible contraception were offered without cost to women for 3 years. This study objective was to estimate the association of age and preference for LARC or other methods, and preference for specific LARC method among adolescents aged 14-20 years. LARC methods were chosen by 70% (n=3557) of study participants, but among the adolescents age 14-20 years, 62% (658/1054) chose a LARC method. Among 14-17-year-olds, 69% (148/214) chose a LARC method, whereas 61% (510/840) of 18-20-year-olds chose a LARC. Of the LARC methods, a subcutaneous implant was preferred among the 14-17 year olds (63% or 93/148); however, selection of a subcutaneous implant device was only 29% (146/510) among 18-20-year-olds. This study concluded that LARCs are acceptable among adolescents enrolled in this project and the implant was the most popular method among the younger group.

Fanarjian, Drostin, Garrett, & Montalvo (2012) conducted a retrospective cohort study to evaluate the effectiveness of free intrauterine contraceptives in reducing pregnancy rates among low-income women. The study, conducted in two North Carolina clinics between January 1, 2003 and June 30, 2009, included eligible uninsured women ages 15-44 years who desired contraception. Pregnancy rates were studied between groups with the exposure (IUC users) and the unexposed group (non-IUC users). Non-IUC users included women who chose to use other forms of contraception or no contraception at all. The original sample size was 321 women; however, over the course of the 6.5 year study all but 90 were lost to follow up by either phone or mail. A Levonorgestrel IUC was used in 65 participants; 25 non-users comprised the control group. Seven pregnancies (11%) occurred in the user group; the IUC had been removed prior to pregnancy in all 7 subjects. Of the 7 pregnancies in the user group, 3 were planned. Eight pregnancies (8/25 or 32%) occurred in the non-IUC users. Even though a small study sample due to the low response rate (32%) was the main restriction of the study, the final result showed no pregnancy per 100 women years in the IUC user group compared to 16.2 pregnancies per 100 women for the unexposed group.

Godfrey and colleagues (2010) investigated the effectiveness of LARCs in a multicenter, randomized, controlled pilot study (n=23) of 14-18-year-old females divided into groups who were randomized to receive a copper T 380A IUD or LNG-IUS. At 6 months of follow up, the continuation rate for the levonorgestrel group was 75% compared with 45% for the copper T 380A group ($p = .15$). Among those participants at 6 months, 100% in the LNG-IUS group and 83% in Copper T380A group planned to continue their IUC use after the study ($p=.36$). Both methods were rated favorably by study participants, but there was a non-statistically significant

lower continuation rate at 6-month follow up among the copper T 380A users. The pilot study results warrant a larger scale study of IUD use among adolescents in the future.

Short, Dallay, Omokanye, Hanisch, & Inki (2012) published an interim analysis report at the end of the first year of an observational study regarding the acceptability of levonorgestrel IUS (LNG-IUS) and etonogestrel implant (ENG implant) use among young European women, ages 20–35 years. The study included 454 women from 4 countries (France, Ireland, Slovakia, and the United Kingdom) who opted to switch from oral contraception to either the LNG-IUS or the ENG implant. At the planned interim analysis in September 2010, follow-up data had been obtained from 311 women out of the original 454. Among 311 study subjects, there were 211 in the LNG-IUS group and 100 in the ENG implant group. The continuation rates at 12-months were 93% for LNG-IUS and 86% for ENG implant. At 1-year follow up, there were no pregnancies, pelvic inflammatory disease, perforations, or other complications recorded. Participants' satisfaction was evaluated with a 5-degree Likert-like scale at the 12-month follow-up visit or at discontinuation. About 62% of LNG-IUS users were satisfied with their contraceptive method compared to 36% of the ENG implant users. The difference in level of overall satisfaction between the two groups was statistically significant ($p<0.001$). Most users were satisfied with their method of contraception after 1-year of follow-up. The conclusion of the study showed that both the LNG-IUS and ENG implant are highly acceptable contraceptives among women, but the LNG-IUS users showed the highest continuation and satisfaction rates.

A systematic review of the literature regarding IUD use among adolescents was conducted by Deans and Grimes (2009). Six cohort studies and seven case-series were included, but none of the IUDs included in the study are currently in use in the United States. Generally, the IUD has similar or better continuation rates when compared with combined oral

contraceptives. The cumulative pregnancy rate among IUD users was low, ranging from 2% at 6 months to 11% at 48 months. Even though the published studies show improved rates of IUC use in adolescents, the literature on IUC use among adolescents is sparse. Further randomized control trials and cohort studies are needed.

Mansour (2012) also provided updated information of the risk and benefits associated with use of levonorgestrel IUS through a literature review. Rapid fertility return after discontinued use is well established. Even though transient menstrual disturbances during the first few months of use is typical, the condition will generally resolve itself with continuing use and the total amount of menstrual blood loss will also decrease. Available data from the literature does not show adverse effects on bone health, cardiovascular events, breast, or uterine cancers, and it can be used by a wide range of populations.

Overall, research demonstrates that IUCs are acceptable, safe, highly effective, and non-user dependent. The evidence strongly supports the integration of IUC services into primary-care services, and student health clinics are ideal locations for the provision of IUC services.

Evidence-Based Practice

Evidence-based practice involves the usage of quality studies as evidence to prevent errors in information, which will contribute to better clinical practice and quality patient care. In order to identify the strengths and weaknesses of a research article and validate its findings, the critical appraisal process of a research study must be used to find the most relevant, high-quality studies (Young & Solomon, 2009). In this project, the project leader independently completed the literature review process, which may lead to possible bias such as information selection bias. The STROBE (Strengthening the Reporting Observational Studies in

Epidemiology) criteria was used to evaluate observational studies, including cohort, case-control and cross-sectional studies (Young & Solomon, 2009) in hopes of assessing study quality and lessening study selection bias (Sanderson et al., 2007; von Elm et al., 2007) (see table 1 & 2 on page 85-89).

Conceptual/Theoretical Framework

Since the 1960s when the nurse practitioner (NP) role was developed, NPs have become increasingly important to serving as primary care providers who provide comprehensive services including health promotion, disease prevention, and counseling. The 2010 Institute of Medicine (IOM) report *The Future of Nursing: Leading Change, Advancing Health* recommended that nurses should be providing health care services as fully as they were trained in their educational programs (IOM, 2011). Following the implementation of the Affordable Care Act in 2010, more than 16 million individuals are projected to gain health insurance coverage by 2016. Combined with the rapidly aging population, NPs are increasing in demand as primary care providers. An up-to-date literature review of NP practices by the National Governors Association (NGA) found that the quality of care provided by an NP and resultant patient health outcomes, is comparable to care provided by a physician (Schiff, 2012).

NPs can serve successfully as primary care providers and can be differentiated from physician's services as human caring is being blended into NPs scientific-based training and clinical practices (Hagedorn & Quinn, 2004). Human Caring is depicted by the Chinese characters "關心", and this topic was discussed in an article by Jean Watson during in 1970s. Human caring is essential in nursing practice, and this concept empowers nurses to ensure patient safety and better patient health outcomes. The core concepts of Watson's theory of

human caring/caring science is derived from carative to caritas that was assembled and published by the Watson Caring Institute (2010). Her carative factors are the basis for current nursing practices. Watson's human caring theory, such as caritas processes, also called caring practices, have been applied into daily clinical practice. For example, human caring for others and for self is the first core concept that is based on the moral, ethical, and philosophical foundation of love and values. Respect for the person, including clinical staff and patients, and commitment to protecting human dignity are all aspects of care provided to meet their needs, routines, and rituals. Increasing awareness of presence to the humanism of self and others and caring for self, others, and environment are also core concepts of Watson's human caring theory.

As primary care providers, NPs meet the complex challenges of translating rapidly expanding knowledge into practice and function in a changing health care environment. The NP Core Competencies emphasize independent and inter-professional practice, analytic skills for evaluating and providing evidence-based, patient centered care across settings, and advanced knowledge of the health care delivery system (NONPF, 2012). The human caring theory is also essential for practice NPs to provide quality patient care, ensure patient safety, and empower patients to make informed decisions about their care. This will improve patient's self-care and health outcomes, and care for the environment.

Methods

Ethical issues

As a health care provider with ethical obligations, one of the trademarks of professionalism is the responsibility to respect the clients' interests above all else. After reviewing the Belmont Reports, established in 1979 by the National Commission for the

Protection of Human Subjects of Biomedical and Behavioral Research, the three general ethical principles, identified to the ethical conduct of research with humans, are also essential in daily clinical practice. The first ethical principle is "Respect for persons," the concept that a client's autonomy must be acknowledged and each individual should participate in informed decision-making of their own care. The second principle is "Beneficence," or "Do no harm," meaning that providers should make decisions in order to maximize benefits while minimizing possible risks. The third, "Justice," requires that the patient is treated fairly, equally, and appropriately (Beauchamp & Childress, 2009). These three general principles establish the foundation for the conduct of research; similarly, clinical practice principles are guided by informed consent, risk/benefits assessment, and care provided fairly.

This quality improvement (QI) project for adding LARC services into primary care-focused student health is based on the observational study of the current clinical services of women's health care and contraceptive use by current students. Prior to initiation of this project, the project proposal was approved by the DNP Department and Institutional Review Board approval (Appendix A-1 & A-2) was completed to ensure patients' safety & privacy. Contraceptive use was evaluated by retrospective chart review from all women's health related clinical visits without involving any demographic data of individual student identities to ensure patients' privacy. LARC protocol and informed consent have been completed and approved by the administrative committee as well as all providers to ensure patient's safety in receiving LARC services.

Also, addressing the misperceptions regarding the use of IUC among patients and health providers can facilitate smooth integration of IUC services into a primary care focused student health clinic. The U.S. MEC is an essential tool that is useful to health care providers in the

clinic to counsel female patients and couples on safe choices for contraceptive methods and to assist women with medical conditions understand their choices for contraception (U.S. MEC, 2010). Informed decisions made by patients in clinical practice will lead to better patient self-care and health outcomes. A consultation appointment to explain the mechanisms of the LARCs along with obtaining informed consent (see Appendix B) is essential to help patients & partners dispel their fears & misconceptions about the methods that they decide on.

Setting

Student Health and Counseling Services (SHCS) of California State University, East Bay (CSUEB) is an on-campus outpatient clinic accredited by the Accreditation Association of Ambulatory Health Care, Inc. (AAAHC), which offers mainly primary medical care to students and is staffed by three full-time and two part-time physicians, one full-time and one part-time nurse practitioner, two full-time registered nurses, one full-time licensed vocational nurse, and five full-time medical assistants. There are also health promotion and counseling departments within SHCS that are staffed with many health educators and counselors. There is a staffed pharmacy and laboratory on site. According to the 2011 Enrollment Headcount Report, there were 13,160 enrolled students composed of about 60% (7,959) female and 40% (5,201) male students with an average age of 26 (Baker et al., 2013).

The mission of SHCS is to assist students in achieving their academic and career goals by providing resources to help them maintain optimal health, to provide high quality, low cost health care to all CSUEB students, and to be pioneers in the university health and wellness services.

Planning the intervention

Market Analysis

To understand the current state of the need to provide LARC service, a SWOT analysis has been completed (see Appendix C). Based on the SWOT analysis of the strengths of the project, one skilled staff nurse practitioner is able to consult, insert and follow up with students who have chosen a LARC method and will help train staff physicians and assist with their first few procedures. Care is provided on campus at the SHS which is a convenient location for students. There is no restriction per student on the number of clinical appointments, and students with concerns who wish to meet with a provider will be able to book the earliest appointment available by calling in or by self-booking online. LARC methods are fully reimbursed by the Family Pact Program. The SWOT analysis also point out weaknesses of the project. Concerns center on the need to train three staff physicians on LARC use and follow up, and the expense of acquiring LARC devices before providing the service. The third SWOT analysis, opportunities, indicates that there will be many opportunities to provide LARC services, as none of the other CSU campuses provide the services, the Planned Parenthood clinics and community health clinics where students used to be referred are all located off campus, and not all students have cars to visit clinics off campus. To visit clinics off-campus is very time consuming to students. Also, staff physicians will gain new skills to serve patients. Finally, to analyze threats to the project, the cost of each LARC unit is currently approximately $700 dollars. Competition for services include Planned Parenthood Mar Monte which provides clinic services at their Central Hayward location, although with restricted hours, and the Community Health Care Network clinics, Women's Clinic of Alameda County Medical Center, and private health clinics. Currently, SHCS does not accept any medical insurance; therefore, students who are interested in

LARCs and not eligible for coverage by Family Pact program will need to seek care from their own primary care providers or pay out-of-pocket.

Gantt chart

The Gantt chart depicted in appendix D provides information about LARCs service project planning and monitors progress for tasks such as training providers, staff, meeting with the administrative team, and service launch. The Gantt chart is posted on a Google drive file to share with all staff in the clinic.

Critical Activities

To ensure a safer patient care environment by preventing errors and mitigating the risk of causing harm to patients and staff, a clinical protocol and policy regarding the LARC procedure and medical errors also must be established. Prior to starting the LARCs service, the potential risks of patient adverse outcomes needs to be carefully evaluated and precautions put in place to ensure the safest patient care at SHCS. The Failure Modes and Effects Analysis (FMEA) or Failure Modes, Effects, and Criticality Analysis (FMECA) is a systematic, proactive method to investigate potential risks that focuses on identifying vulnerability and preventing future failures. FMECA focuses on system design and process rather than on a single incident such as in root-cause analysis (IHI, 2004; Nagamine & Williams, 2005). When doing a FMEA, we should include a review of the following steps in the process: failure modes (what could go wrong?), failure causes (why would the failure happen?), and failure effects (what would be the consequences of each failure?) (IHI, 2004; Larson & Gray, 2011). An example for this project is shown in Appendix E. Every specific step in the process that can possibly go wrong is listed in the flowchart with the consensus of the group. All possible causes are identified for each failure

mode listed. Next, the group is assigned a numeric value (known as the Risk Priority Number, or RPN) from 1 -10 for likelihood of occurrence, likelihood of detection, and severity. Then, multiplying the three scores, we obtained the RPN for each failure mode. Therefore, in order to focus improvement efforts on the most important area of the process, it is helpful to find out the failure modes with high RPNs.

The activities have been evaluated for potential risks, which were included in a "things to look for" section during the presentation to the administrative team, and also reviewed while comprehensively training providers, keeping an updated list of supplies, tools, LARC units, and establishing an account with pharmaceutical companies for purchasing of LARC units. An informed consent for patients and LARC protocols (appendix B-2 and B-3) are established and approved for the staff to use. Advertising on campus is via text message, email, through the SHCS home page, and advertisements sent to other CSU campuses.

Plan for Variance Control and Evaluation Criteria

We use data collection forms (Appendix F) to collect information from scheduled women's health related appointments by all providers. To prevent errors and to make it easier to trace errors for correction, individual providers tally their data on the data collection form each week. For providers who have missing data, the project leader follows up at the end of each data collection period. Using data from the summer & fall quarter allow us to gain a perspective from a mixed student population. For example, there are more junior & senior students in summer quarter and more freshmen students in the fall quarter.

Evaluation Criteria

The forms used for data collection were made by the primary investigator based on the study inclusion criteria derived from the Female Medical History Form that is part of the recommended documentation by the Family Pact Program: age, history of pregnancy, sexual partners, method of contraceptive use, and length of usage (Family Pact, 2014).

Before providing new medical services in the primary care clinic according to affordable care act (ACA) expectations, the primary care providers and internists must attend new training workshops. County or local specialists contact information has been updated for consultation or referral as needed. Annual refresher courses will be planned as needed depending on the amount of services provided.

Risks Prevention

A risk breakdown structure (RBS) (appendix G) is used to help identify risks from the macrosystem to microsystem that affect adding the new service in order to mitigate risks and prevent adverse events in advance (Larson, 2011). The risks can be identified in four categories: technical, external, organizational, and project management. The subcategories under technical risk include skills for the procedure, reliability and quality of the service. The external risks include regulatory, policy and procedure, market, and customer. Resources, funding and prioritization are considered under the category of organization. For project management, estimating, planning, control, and communication are considered.

Institutional Review Board (IRB) training and completion (see appendix H) is required by the Project leader to ensure human subject protection and to minimize risks from the study. No patients' identities are included in the data processing or reports.

An Ishikawa diagram (Appendix I) is used to help plan the project and identify potential risks that will affect the project (Nelson, Batalden, & Godfrey, 2007). The diagram also is used for continuing evaluation of the project as it progresses, and updates will be provided and discussed during the weekly provider/staff meeting and monthly QI meeting.

Implementation of the project

A retrospective review of electronic records from approximately 1000 clinical notes of all women's health related visits during summer & fall quarter from June 24 to December 24, 2013 has been completed. The chart review and data collection was performed from December 2013 through the end of January 2014. A form with the necessary information and key criteria for study in Appendix F was developed during summer 2013 and was continuously revised throughout the fall quarter. Data were analyzed by project leader in April 2014.

An advertisement and marketing program is important and needed for this new service, including but not limited to text messages sent to students and emails broadcasting to other CSU campuses. The nursing department is responsible for organizing the required supplies and instruments on the list provided by the Nurse Practitioner who also will continue to update the list as needed. A meeting with the Clinic Director, the Administrative Analyst for purchasing LARC units was completed at the beginning of summer quarter 2014. Students who are interested in LARCs will be required to have a consultation appointment prior to scheduling a LARC placement appointment, and these consultation appointments may be scheduled anytime per the student's request. The service was planned to be provided to students starting summer quarter 2014, but has been delayed to fall quarter because the procurement process is still pending and the summer quarter students' health clinic coverage was changed by the university.

A list has been established during the spring quarter and summer quarter for students who are interested in LARC and wished to be contacted when the service is available. On October 20th, the nurse practitioner received a call from the pharmacist that one of LARC units, the contraceptive implant, has been approved to start. A secure message was sent to individual students on the list regarding the approval of the service.

Planning the study of the intervention

Action Plan of LARC Services

On college campuses, Student Health Clinics have the unique role of helping students maintain their optimal health which allows them to succeed in academic study, future career, and in life. The majority of enrolled students are females between the ages of 18 and 24, and do not plan to conceive while they are pursuing their college education (ACHA-NCHA II, 2013). Preventive health services, including family planning and the provision of highly effective long-acting reversible contraception, are essential and should be integrated into primary-care focused student health clinics. To prepare for the integration of LARC services into primary-care focused Student Health Clinics, the action plan includes staff education, patient counseling, risk prevention, administrative issues, and establishment of equipment protocols (clinical minutes, ARHP, 2013). The goals are to increase access to LARC services, empowering patients, improving efficiency, and improving staff knowledge.

Staff education: Staff education is essential to integrating LARC services into the college student health clinics. This means new skills and scientific-based evidence for the primary care providers and internists who do not specialize in the area of women's health care. LARC placement and removal training is the first step. Annual refresher courses to update skills and

knowledge will be planned as needed depending on the amount of service provided (see Table 4 provider training plan on page 87). The U.S. MEC is an important resource for health care providers to counsel their patients and to help them make safe choices for contraceptive methods (US MEC, 2010). Furthermore, nurse practitioners and health care providers also use the U.S. SPR as guidance for clinical contraceptive management to help reduce the unintended pregnancies rate among college students (US SPR, 2013).

Patient education: Clinicians are providing individualized counseling for contraception choices, the efficacy, benefits, and side effects of method chosen (US MEC, 2010; US SPR; Hathaway, 2013), and utilizing the "Teach-Back" method to assess, teach, and confirm student's understanding of the information (AHRQ, 2010; Moritsugu, 2006; Brach et al., 2012; White, Garbez, Carroll, Brinker, & Howie-Esquivel, 2013). Clinicians must provide time for students to review and sign the Informed Consent Forms for the LARC procedure.

Risk prevention: Policy and LARC clinical practice protocols have been established to help plan the services, to identify and mitigate potential risks, and to prevent negative outcomes. Patient selection criteria and contraindications according to the U.S. MEC for LARC method are included in LARC clinical protocols. Any patient, whose desired LARC with U.S. MEC 3 and 4 conditions will be excluded, so clinical protocols for consultation or referral to local specialists have been established. Risks that have been addressed include ensuring that providers have the necessary skills, that standard of care is maintained, and that appropriate policies and communication channels are in place if any adverse incidents are to occur.

Administrative issues: The administrative team has addressed the purchase of LARCs prior to beginning services. In addition, an appointment policy has been developed. On average,

three appointments (consultation, insertion, and follow up) are needed for each patient. A consultation appointment will be required from students who are interested in LARC prior to an LARC placement. Billing and coding training have been completed for reimbursement of LARC services that included management of costs of all necessary health care services and supplies. Advertisement and marketing are also important when offering a new service. To spread the word about services text messages and emails are employed.

Equipment protocol: New instruments exclusively for LARC placement or removal have been requested and completed. The Nursing Department is responsible for coordinating equipment inventory, organizing the required supplies, and ordering and restocking LARC devices. The supplies include: miscellaneous supplies (clean gloves, sterilized gloves, betadine swab sticks package, sterilized gauze, long big cotton swabs, silver nitrate sticks, Maxi pads, and patient instruction), instruments (sterilized speculum, ring forceps, tenaculum, uterine sound, and long scissors), and LARC devices.

LARC service evaluation: The program will be evaluated quarterly. The following outcomes can be used to measure program progress & success - number of LARC consultations, number of LARC placements, continued contraception use, training progress, quarterly billing and reimbursement, and satisfaction of the services from patients and staff. Students will be followed every 6 months by secure message system within their electronic record or by phone with electronic documentation until they graduate.

A retrospective evaluation of LARC services to assess the success and long-term sustainability of the program is necessary. Off campus referral rates, adverse procedure incidents, infection rates, and staff and provider satisfaction regarding the process must be studied.

Improvement measures for continuation of the service should be discussed monthly to assure that the best quality of care is delivered and patient safety is maximized at Student Health Services.

Analysis

According to the ACHA-NCHA II Spring 2013 nationwide survey results, 64.4% of sexually active college students used hormonal contraceptives including oral contraceptive pills, patches, and rings; 3.4% received DMPA injection; 1.8% used contraceptive implant; and 6.9% used IUC. The current usage of LARC among our students, who use a contraceptive method and have visited SHCS, is 1% for contraceptive implant and 3% for IUC (See Appendix J). LARC usage by our students is much lower than the national benchmarks (see Table 1), which may be partially associated with the fact that the LARC services are not available in our SHCS.

Results

Description of Data:

Records from all female university students who visited SHCS during summer and fall quarter 2013 for women's health related care were reviewed. All female students in any age, race, and ethnicity were included. Electronic medical records of all visits and demographic information were reviewed and analyzed by the primary investigator from February to March 2014. A faculty member in the statistics department was a consultant for the on-campus study in the summer 2013. A few of the female patients who were seeking care for women's Health related issues were under age 18 at the time of study and their parental consents and clinic care consents for care were on file; otherwise, their records were excluded in this study.

Evidence of Data Collection: the Primary Investigator conducted a chart review of clinical visits through the electronic health record (health history, medical record, lab report) at the beginning of 2014 at SHCS. A data collection form (See Appendix F) that was developed during the summer quarter was used. For the study, we tracked client data by electronic chart review based on the clinical visit notes during June 24 to December 20, 2013. A retrospective review of 1031 subjective notes of all women's health related visits during summer and fall quarter from June 24-December 20, 2013 was performed. The chart review and data collection took place in January-February 2014. A form with the necessary information for study was developed during summer 2013 has been used to tally the data. Data were analyzed by the project leader. The analysis was complete in April 2014. (See Appendix J)

Study Results: After reviewing a total of 1031 visits electronically from June-December 2013, the project leader found that most of our clients (71%) were 24 years-old or younger. The contraceptives used by our clients were: 52% hormonal contraceptives, including oral contraceptive pills, patches, and rings; 7% DMPA injection; 1% contraceptive implant; and 3% IUC. (See Appendix J)

Program evaluation/Outcomes

The program will be evaluated at the end of every academic quarter. The following key performances will be used to measure program progress and success including number of LARC consultations, number of LARC placements, pregnancy rate, training progress, monthly financial reports, and satisfaction surveys from patients, providers, and staff. Providers will follow up with patients every 6 months by secure message system or phone until they graduate. A weekly

update of project progress will uploaded to a google drive file to share with all providers and the QI committee, and a monthly report will be given at the all-staff meeting.

By June 30, 2015, a retrospective study for this LARCs service will be held. Besides the key service performances, the off campus referral rates, adverse procedure incidents, infection rates, and unintended pregnancy rates will be studied. The final report will be delivered in QI committee meeting and the first all-staff meeting in the fall quarter. Based on the study results, the improvement measures for the future service will be started during the weekly provider meetings during the fall quarter 2015 to assure the best quality of care is delivered and patient safety is maximized at SHCS.

Discussion

Summary

Compared to the ACHA-NCHA II Spring 2013 nationwide survey results, LARCs usage by our students is much lower than the national benchmarks, which may be partially accounted for by the fact that the LARC services are not available in our SHCS.

Potential benefits: The study results will help to guide implementation and improvement of women's Health services at SHCS. Because this is based on a retroactive chart review, no compensation or other incentives will be provided to any of the students.

Potential risks: Privacy and emotional discomfort (unrelated to the direct effects of the study) may be potential risks that will be felt by some students who visited SHCS during the time of the study.

Risk reduction: Any patient's identifying information will not be used during the data collection and this helps to minimize the potential risks to any student included in the study.

Risk/Benefit: The potential risks to the subjects, such as privacy and emotional discomfort felt by some of the students who visited SHCS during the study period were not related to the direct effects of the study.

Study limitation: The study was conducted for the purpose of quality improvement at the on campus student health clinic of CSUEB, so the study demographic was limited only to students registered with CSUEB during the study period. The results will help clinic services and quality improvement, but further study will be needed to determine the applicability to other colleges and student health clinics.

Study unexpected benefit: Improvements in clinical documentation for better service & care to the clinic patient is very important. From the data collected, it was determined that about 14% (143/1031) patients' past obstetrics, gynecology, and sexual history information were missing (See study results, p32.). This information is very pertinent history for women who are seeking contraceptive care. The importance of this data will be emphasized throughout project implementation and improvements tracked.

Barriers to implementation/Limitations: Adding new patient services means that clinic providers must learn new skills or be able to perform a skill that they may not comfortable or familiar with. All of the providers in our clinic graduated from their medical schools or nurse practitioner programs over 15 – 20 years ago. For seasoned clinical providers, learning new clinical skills can be a challenge, and the many misconceptions about LARC use and the notorious history of the Dalkon Shield IUD about 30 years ago are keeping both patients and

providers at a distance. Despite the safety and efficacy of modern LARC devices, dispelling misconceptions and rumors, training providers and staff, patient counseling and informed decision making with evidence-based information are all barriers that must be addressed prior to the effective integration of LARC services into primary care-focused student health clinics.

Conclusions

Unintended pregnancy is still a significant social issue that affects the quality of life for parents and their children. Since the highest rates of unintended pregnancy occur in college age women, and about 80% of college women are sexually active without planning to become pregnant (Kavanaugh et al., 2012), it is very important to provide these women with effective contraceptive methods. To help prevent unintended pregnancies, integrating LARC services into primary care-focused health clinics and student health services is necessary. Provider training and patient counseling to dispel misconceptions regarding LARC use has been shown to improve usage and continuation rates of LARC contraception (Arrowsmith et al., 2012; Garber et al., 2013). To help young college aged women make an informed decision about contraception use, Nurse Practitioners and Medical Providers need to eliminate the misconceptions and provide evidence-based information to educate adolescents and young women about LARC methods and access. All of these steps will help reduce unintended pregnancy, help to increase contraceptive use and adherence, promote healthy behaviors, decrease sexually transmitted infections, and increase access to the health care system.

Other information: Provider Training and Funding

Provider training

This project was received very enthusiastically by the Student Health Center. All full time and part time providers have attended the Nexplanon training session by Pharmaceutical company and have received Nexplanon certification. All full time providers have also received training for Mirena insertion and removal. 1 Family Practice physician and 1 internist have completed training of Paraguard IUD, and they will continue onto the next steps of training – observation, supervised insertion, and supervised removal of all LARC devices. Future training sessions for the remaining providers will be scheduled based on their availability (see Table 4 Provider LARC training plan on page 87).

Budget presentation

Direct costs for this project include providers, equipment, and supplies. Providers include one nurse practitioner (1FTE), three physicians (3 FTEs), two part-time physicians (total of 0.4 FTE), 7 FTEs of supporting staff including two registered nurses, and five medical assistants. The supply costs will cover miscellaneous supplies (clean gloves, sterilized gloves, Betadine 3-swab package, 2x2 sterilized gauze, 3 ml syringe, injection needles, 1% Xylocaine injection solution, long cotton swabs, Maxipads, instruction handouts), tools (5 of each—sterilized speculum, ring forceps, long kelly clamp, tenaculums, metal or plastic sounds, long scissors), and starter LARC units (5 of each ENG-Implant, Copper T 380A IUD, and LNG-IUS). Indirect costs include 1 FTE center director, 2 FTEs administrative assistants, 4 FTEs front desk staff, 1 FTE IT staff, 1 FTE housekeeping, 1 FTE health promotion staff, educational and advertising material, computer, office, etc.

A pre-paid package includes a total of fifteen LARCs units, or five of each type, which will costs about $11,000 plus $2,000 of supplies, for a total of $13,000. On average, three

appointments will be needed for each patient including one 30-min LARCs consultation, one 30-min LARC placement, and a 15-min appointment for 2-month follow up after LARC placement. The medical assistant needs about15 minutes to set up the exam room and intake the patient. A male provider will require a chaperone while performing the pelvic examination or procedure.

The cost of providing the LARC services to students at SHCS will be reimbursed by the Family Pact Program. After consulting with the providers and staff at SHCS, all parties believe that providing this service is feasible and will be beneficial for both students and SHCS. The funding for a few LARC units and the initial set-up are required in order to start the service. Budget projection for the pre-paid LARC units and reimbursement are estimated and outlined in Appendix K-1. Since the Implant Contraceptive has been approved to purchase in October 2014, a budget projection for Implant Contraceptive service is estimated in Appendix K-2.

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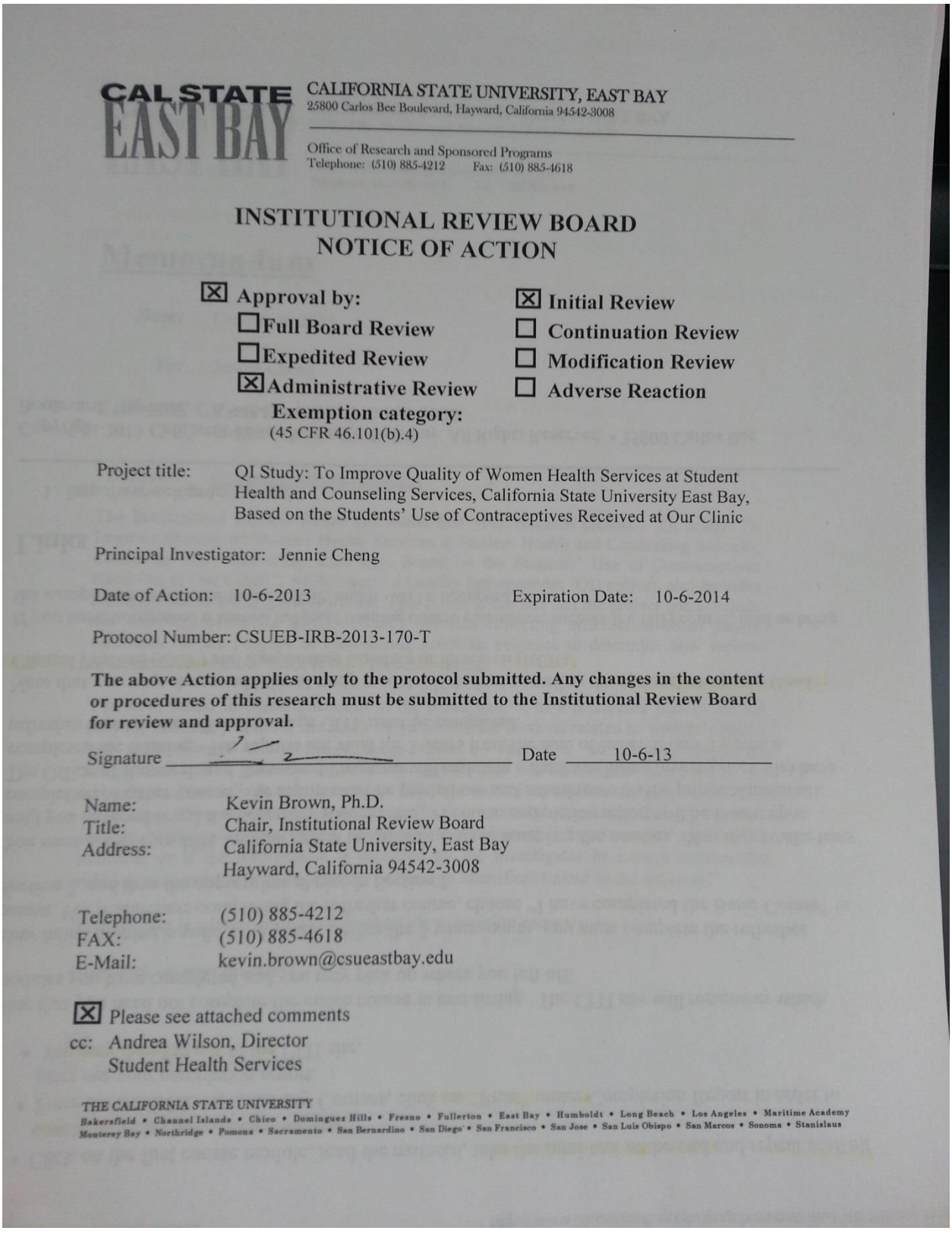
Appendix A-1 IRB approval 2013 and 2014



CAL STATE EAST BAY

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25800 Carlos Bee Boulevard, Hayward, California 94542-3008

Office of Research and Sponsored Programs
Telephone: (510) 885-4212 Fax: (510) 885-4618

INSTITUTIONAL REVIEW BOARD
NOTICE OF ACTION

☒ Approval by:
- ☐ Full Board Review
- ☐ Expedited Review
- ☒ Administrative Review

Exemption category:
(45 CFR 46.101(b).4)

☒ Initial Review
- ☐ Continuation Review
- ☐ Modification Review
- ☐ Adverse Reaction

Project title: QI Study: To Improve Quality of Women Health Services at Student Health and Counseling Services, California State University East Bay, Based on the Students' Use of Contraceptives Received at Our Clinic

Principal Investigator: Jennie Cheng

Date of Action: 10-6-2013 Expiration Date: 10-6-2014

Protocol Number: CSUEB-IRB-2013-170-T

The above Action applies only to the protocol submitted. Any changes in the content or procedures of this research must be submitted to the Institutional Review Board for review and approval.

Signature _____ Date 10-6-13

Name: Kevin Brown, Ph.D.
Title: Chair, Institutional Review Board
Address: California State University, East Bay
Hayward, California 94542-3008

Telephone: (510) 885-4212
FAX: (510) 885-4618
E-Mail: kevin.brown@csueastbay.edu

☒ Please see attached comments

cc: Andrea Wilson, Director
Student Health Services

CAL STATE EAST BAY
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25800 Carlos Bee Boulevard, Hayward, California 94542-3008

Office of Research and Sponsored Programs
Telephone: (510) 885-4212 Fax: (510) 885-4618

Memorandum

Date: October 6, 2013

To: Jennie Cheng

From: Kevin Brown, Chair
Institutional Review Board

Subject: Comments on your protocol

The Institutional Review Board has found that your research protocol "QI Study: To Improve Quality of Women Health Services at Student Health and Counseling Services, California State University East Bay, Based on the Students' Use of Contraceptives Received at Our Clinic", while clearly a Quality Improvement (QI) project, also includes elements of human subjects research. This is due to the fact that the project goals include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how various contraceptive methods achieve their intended results.

You have stated in communications to the board that "I, as a researcher plan to extract only the necessary data for the study by reviewing the sections related to women's health and their current contraceptive usage status. Therefore, no patient identifying information will be recorded for the study, and the data will be analyzed as a whole." As a result, the board finds that the project falls into federal exemption category 4, which is as follows, "The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

Your project is administratively approved via exemption category 4.

Good luck on your research!

KB
cc: Andrea Wilson, Director

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INSTITUTIONAL REVIEW BOARD
NOTICE OF ACTION

☒ **Approval by:**
- ☐ **Full Board Review**
- ☐ **Expedited Review**
- ☒ **Administrative Review**

Exemption category:
(45 CFR 46.101(b).4)

☐ **Initial Review**
☒ **Continuation Review**
☒ **Modification Review**
☐ **Adverse Reaction**

Project title: Follow up QI Study: To Improve Quality of Women Health Services at Student Health and Counseling Services, California State University East Bay, Based on the Students' Use of Contraceptives Received at Our Clinic

Principal Investigator: Jennie Cheng

Date of Action: 8-15-2014 Expiration Date: 8-15-2015

Protocol Number: CSUEB-IRB-2014-234-T

The above Action applies only to the protocol submitted. Any changes in the content or procedures of this research must be submitted to the Institutional Review Board for review and approval.

Signature _____ Date 8-15-14

Name: Kevin Brown, Ph.D.
Title: Chair, Institutional Review Board
Address: California State University, East Bay
Hayward, California 94542-3008

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E-Mail: kevin.brown@csueastbay.edu

cc: Andrea Wilson, Director
Student Health Services

Appendix B-1. LARC Informed Consent

STUDENT HEALTH & COUNSELING SERVICES
California State University, East Bay
Hayward, California 94542-3060

Informed Consent For NEXPLANON Placement or Removal

A. Consent For Procedure(s)

I authorize _____,MD/NP to perform the following procedure(s):

NEXPLANON (etonogestrel implant) Radiopaque Subdermal Use Only

I have read and understand the Patient Information for NEXPLANON. I have discussed NEXPLANON with my healthcare provider who answered all my questions. I understand that there are benefits as well as risks with using NEXPLANON. I understand that there are other birth control methods and that each has its own benefits and risks.

I also understand that this Patient Consent Form is important. I understand that I need to sign this form to show that I am making an informed and careful decision to use NEXPLANON, and that I have read and understand the following points.

- NEXPLANON helps to keep me from getting pregnant.
- No contraceptive method is 100% effective, including NEXPLANON.
- NEXPLANON has an implant that contains a hormone.
- It is important to have the NEXPLANON implant **placed in my arm** at the right time of my menstrual cycle.
- **After the implant is placed in my arm, I should check that it is in place by gently pressing my fingertips over the skin where the implant was placed. I should be able to feel the implant.**
- The implant must be removed at the end of three years. The implant can be **removed** sooner if I want.
- If I have trouble finding a healthcare provider to **remove** the implant, I can call **1-877-467-5266** for help.
- The implant is placed under the skin of my arm during a procedure done in my healthcare provider's office. There is a slight risk of getting a scar or an infection from this procedure.
- Removal is usually a minor procedure. Sometimes, removal may be more difficult. Special procedures, including surgery in the hospital, may be needed. Difficult removals may cause pain and scarring and may result in injury to nerves and blood vessels. If the implant is not removed, its effects may continue.
- **Most women have changes in their menstrual bleeding patterns while using NEXPLANON. I also will likely have changes in my menstrual bleeding pattern while**

using NEXPLANON. My bleeding may be irregular, lighter or heavier, or my bleeding may completely stop. If I think I am pregnant, I should contact my healthcare provider as soon as possible.

- I understand the warning signs for problems with NEXPLANON. I should seek medical attention if any warning signs appear.
- I should tell all my healthcare providers that I am using NEXPLANON.
- I need to have a medical checkup regularly and at any time I am having problems.
- NEXPLANON does not protect me from HIV infection (AIDS) or any other sexually transmitted diseases. After learning about NEXPLANON, I choose to use NEXPLANON.

B. Consent For Anesthesia

When local anesthesia is used for NEXPLANON placement or removal by the MD/NP on page one, Section A:

I consent to the administration of such local anesthesia, 1% **LIDOCAINE without Epinephrine** as may be considered necessary by the MD/NP in charge of my care. I understand that the risks of local anesthesia include: local discomfort, swelling, bruising, allergic reaction to medications, and seizures.

C. Patient Signature:

After learning about NEXPLANON, I choose to **use** or **remove** a NEXPLANON on my **right/left** upper arm. By signing below I state that I have read or had explained to me the contents of this form and I agree to receive the care, treatment or service listed on this consent. I have had a chance to ask questions and all of my questions have been answered.

_____ _____

(Name of patient) (Student ID)

_____ _____

(Patient Signature) (Date)

D. Physician or Nurse Practitioner Statement/Signature & Witness Signature:

I have explained the procedure(s) stated on this form, including the possible risks, complications, alternative treatments (including non-treatment) and anticipated results to the patient and/or her representative. The patient and/or their representative has communicated to me that they understand the contents of this form. The patient above has signed this consent in my presence after I counseled her and answered her questions.

_____ _____

(Signature of MD or NP) (Date & Time)

_____ _____

(Signature of Witness) (Date & Time)

Appendix B-2 Protocols

STUDENT HEALTH & COUNSELING SERVICES
California State University, East Bay
Hayward, California 94542-3060

Protocol For Contraceptive Implant (Nexplanon)

Definition:

The ENG-Implant is a thin rod 4 cm long and 2 mm in diameter and contains 68 mg etonogestrel that is placed in the subdermal tissue of the inner upper non-dominant arm. The ENG-Implant provides effective contraception, decreases menstrual blood loss, and painful menstrual cycles for at least 3 years. The effectiveness of ENG implant to prevent pregnancy is greater than 99%.[9,10] The mechanisms for contraception are changing endometrium tissue and changing cervical mucus to prevent fertilization.

Many women prefer the convenience and efficacy of implantable progestin-only method. A woman who experiences unacceptable estrogen-related side effects or who has contraindications to estrogen-containing contraceptive methods may be to use progestin-only birth control methods successfully. Progestin-only methods may be preferred to combination hormonal methods for women with chloasma, hypertension, VTE, severe headaches, chronic asymptomatic hepatic disease, breastfeeding, tobacco use and age $\geq$ 35 with a BMI greater than 30. The typical use first year failure rates for progestin-only implants are at least as low as sterilization and with correct and consistent use may be as low as 0.1% and are not affected by obesity. Progestin-only implants are often more popular among adolescent women. It is likely that all progestin-only methods reduce the risk of endometrial cancer, especially in anovulatory women. Several studies have reported that structured counseling, especially about longer acting methods may be very useful in helping women choose more effective methods and maximize continuation rates.

Personnel:

Subjective:

Must include:

1. LNMP and PMP.
2. Medical, sexual and contraceptive history (initial or update).
3. Evaluation for allergies to any component of the method or to antiseptic or local anesthesia, if considering implant.
4. History of any recent unprotected intercourse.

Must exclude:

- Any US MEC Category 4 and 3 conditions for her desired method.

Note: Breastfeeding women can initiate any systemic progestin-only method immediately postpartum, despite labeling recommendations, as long as the women can tolerate a slight increase in lochial blood loss. There is no increase in postpartum depression due to progestin-only methods.

Objective:

Must include:

1. BP.
2. Weight, BMI (obesity is not a contraindication to any progestin-only method. The efficacy of implants and injections is not affected by patient weight.)

Note: Progestin-only methods may be initiated or restarted without pelvic examination in asymptomatic women who have not had recent exams. Routine STI testing may be performed using urine or self vaginal swab specimens, if indicated.

Laboratory:

Must include:

Negative sensitive urine pregnancy test (UCG) only if patient has unexplained irregular or delayed menses or symptoms of pregnancy. Routine pregnancy testing is unwarranted. There may be more need to document that pregnancy has been ruled out for implant candidate seeking placement at unconventional times.

Assessment:

Candidate for systemic progestin-only hormonal method.

Plan:

1. Refer patient if any US MEC category 3 and 4 conditions for desired method.
2. If implant selected, place only if confident patient is not pregnant:
    a. No backup method is needed if implant placed at any of the following times:
        1) During first 5 days of menses.
        2) At any time if switching from combined hormonal contraception, include hormone free intervals of COCs, patch, or vaginal ring.
        3) At any time if switching immediately from progestin-only method, including progestin-only pills, DMPA injection, LNG-IUD or implant.
        4) If exclusively breastfeeding, and amenorrheic in the first 6 months following delivery, may place immediately if no recent unprotected intercourse.
        5) Within 5 days of first trimester pregnancy loss.
        6) Within 28 days after second or third trimester pregnancy loss or delivery.
    b. If placing at any other time, confirm pregnancy test negative, provide EC, if needed, and advise abstinence or provide barrier method for 7 days after implant placement.
    c. If placing this visit:
        1) Explain risks and benefits of implants. Counsel about bleeding changes that may be expected.
        2) Obtain informed consent using SHCS consent form for implant contraceptive (Nexplanon) that includes all the information found in FDA-approved form.
        3) Place implant according to manufacturer's instructions.
        4) Verify placement of implant.
        5) Provide post-placement instructions and precautions. Advise abstinence or back-up contraception for 7 days, if needed.

6) Document a placement procedure note.

d. Have patient return for annual examination and PRN problems.

Patient Education:

1. Remind the patient that this method of contraception is safer for her health than pregnancy would be.
2. Advise women that progestin-only methods do not protect against STIs, including HIV. Recommend safer sex practices if patient is at risk for STIs.
3. For Implant:
   a. Inform patient that she should:
      1) Keep the pressure dressing on for 24 hours.
      2) The steri-strips can be taken off in 3-5 days, although it is better to wait until they fall off by themselves. Steri-strips should not be removed by patient until scab over the placement site had fallen off.
      3) If her arm is sore, she may also take Tylenol or Ibuprofen for the discomfort or place ice packs (20 minutes an hour) as needed.
   b. Advise patient to expect slight bruising and soreness around implant site for a few days after placement, and that the implant may be slightly visible after healing.
   c. Advise patient to watch for these rare warning signs and seek medical care promptly if any of the following appears:
      1) Bleeding from the placement site.
      2) Increasing tenderness, redness, warmth or pus around the implant.
      3) Fever, chills.
      4) Any sign that the implant is being expelled.
   d. Advise patient that protection from pregnancy begins immediately if placement is timed according to manufacturer's recommendation. Otherwise she should not rely on the implant for 7 days after placement.
   e. Advise patient that bleeding may be less predictable with implant use. Over time, she will usually have less bleeding.
      1) Counsel her that if her bleeding is acceptable in the first 3 months, she can expect that following cycles will be acceptable.
      2) If her first 3 cycles are abnormal, tell her that she has a 50% chance that her bleeding will improve in subsequent months. The time between periods may vary and she may have spotting in between periods.
      3) Suggest she keep a menstrual calendar and carry a light day panty liner with her.
   f. Remind her to use back up methods if she starts using any St. John's Wort or prescription drugs that can reduce the effectiveness of her implant.
   g. Counsel patient that there is no harm to her health if she misses her periods, but instruct her to return for pregnancy testing if she has any symptoms of pregnancy or is concerned about the possibility of pregnancy.
   h. Advise patient of possible weight changes and other potential side effects including headache, mood swings, hair changes, prolonged ovarian cysts and other effects listed on package insert.

1) Remind her that most of those "side effects" are not due to the implant. For example, in a trial comparing the implant with non-hormonal IUD, both groups of women gained the same amount of weight.

i. Advise her to always mention her implant whenever she is seen by medical personnel/clinician.
j. Remind her that the implant is effective for 3 years. Tell her she will be given a user card that will remind her of this date. Remind her that she is to keep the card in a secure place. Advise patient that a new implant may be placed in 3 years if desired.
k. Counsel her that fertility returns promptly after removal of her implant.
l. Advise patient that she may request to have her implant removed at any time for any reason.
m. Encourage patient to return for routine well woman exams.

Referral:

1. Any patient with US MEC category 3 and 4 conditions for this method she desires to use.
2. Patient who declines pelvic examination but has symptoms or signs indicating need for evaluation.
3. Patient with a difficult implant removal.
4. Patient with anaphylactic shock with the procedure.

Reference:

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2. American College of Obstetricians and Gynecologists Committee on Gynecologic Practice. ACOG Committee Opinion No. 415: Depot medroxyprogesterone acetate and bone effects. *Obstet Gynecol*. 2008;112(3):727-30.
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16. Kapp N, Curtis K, Nanda K. Progestogen-only contraceptive use among breastfeeding women: a systematic review. *Contraception*. 2010;82(1):17-37.
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Attachment:
Summary of recommendation for Implant method initiation and management

Initiating Implant Use	Number of Days Back-up Method or abstinence Needed	EC Need If Any Unprotected Coitus in Last 5 days*
Starting cycle day 1 – 5	0	No
During hormone free interval of OCs, patch or vaginal ring		
At any time with progestin-only pills	0	No
At time next DMPA injection is due (up to 15 weeks from last injection)	0	No
At time of implant or IUD removal	0	No
Within 5 days of first trimester pregnancy loss	0	No
Within 28 days after 2nd trimester pregnancy loss	7	Yes
Within 28 days after 3rd trimester delivery	7	Yes
Exclusively breastfeeding in the first six months and amenorrheic with no unprotected intercourse	0	No
Placement at any other time	7	Yes

- If unprotected intercourse in last 5 days, consider repeat pregnancy test in 3 weeks if no menses.

Supplies for the implant procedure

Appendix B-3: Protocol

STUDENT HEALTH & COUNSELING SERVICES
California State University, East Bay
Hayward, California 94542-3060

Protocol For Intrauterine Device (IUD)

Definition:

Intrauterine contraceptive (IUC) is a small device placed in the uterus to prevent pregnancy. Currently there are three FDA approved intrauterine devices (IUDs) available in the US. The Copper T-380A IUD (ParaGard®) is effective for at least 10 years. In typical use, the copper IUD has a first year failure rate of 0.8%; its 10 years cumulative failure rate is 2.7%. The Levonogestrel intrauterine systems (LNG-IUS)–20 mcg/24 hr (Mirena®) is effective for 5 years and has a first year and 5 year failure rate in typical use of less than 1%. Mirena offers many non-contraceptive health benefits related to menstrual suppression. The LNG-IUS-13.5 mg (Skyla®) is approved for up to 3 years of use. First year failure rate is 0.41%. IUDs may be used by nulliparous women.

Personnel:

Physician and Nurse Practitioner/Certified Nurse Midwife with demonstrated skill under supervision of experienced clinician and/or experience with IUD insertion and removal can place or remove IUDs.

Identification of Candidate:

The U.S. Medical Eligibility Criteria (US MEC) are used as a basis for recommendations for this protocol.

Subjective:

Must include:

1. LNMP and PMP.
2. Document any unprotected coitus in last 5 days.

Must exclude:

- Any US MEC Category 4 and 3 conditions for her desired IUD.

Objective:

Must include:

1. Normal pelvic exam (Bimanual and speculum exams).
2. Complete uterine involution (after 6 weeks postpartum) is needed following pregnancy.
3. Patient's uterine size on bimanual exam must be consistent with a uterine depth of:
   a. ParaGard: 6.0-9.0 cm.

b. Mirena: 6.0-10 cm.
c. Skyla: large enough to accommodate IUD, generally 6-10cm best.

Must exclude:

- Any US MEC Category 4 and 3 conditions for her desired IUD.

Laboratory:

Must include:

1. Hgb/Hct if recent history of excessive menstrual blood loss or anemia.
2. Patient does not need any testing done to qualify for IUD if she has no signs or symptoms of infection. If indicated by age, screening guidelines, sexual history or symptoms, perform needed tests to rule out GC or Chlamydia cervicitis or Trichomonas vaginitis. It is not necessary to delay IUD placement until results are available. Prompt (within 7 days) treatment will prevent PID if the woman does have a cervical infection at the time of IUD placement.
3. Negative pregnancy test if patient has had any unprotected intercourse at any time in her cycle that could result in pregnancy, or if she has had any irregular menses recently or any symptoms of pregnancy.

Must exclude:

- Any US MEC Category 4 and 3 conditions for her desired IUD.

Assessment: Candidate for IUC/IUD use.

Plan:

3. Select IUD. If patient has copper allergy, Wilson's disease, anemia (Hgb less than 10 g/dL), excessive menstrual bleeding or severe dysmenorrhea, she is a better candidate for a LNG-IUS rather than for the copper IUD. If she prefers monthly bleeding or does not want to use hormones, ParaGard® would be a better choice.
4. Instruct patient to read and answer all questions on patient product information brochure. Answer all of patient's questions. Have her sign the manufacturer's consent form and any clinic consent form required. See manufacturer's website to get additional copies of the patient brochure and the consent forms in her language. Tell the woman who wants to use one of the LNG-IUSs that she will have to sign another copy of the consent form for her particular IUS after the procedure is done.
5. Consider advising patient to take a nonsteroidal anti-inflammatory agent 1 to 4 hours prior to IUD/IUS placement if not medically contraindicated. It will not reduce pain during IUD placement, but may reduce cramping and pain afterwards.
6. If possible, place the IUD at this visit (See *IUD Placement* protocol). If IUD not placed during this visit, insure she has an interim birth control method and tell patient when to return for placement according to the type of IUD she desires.
7. Schedule Copper IUD (ParaGard®) placement any time in the cycle when the woman is not pregnant.

a. Placement after completion of menses may reduce early expulsion risk. If possible, avoid placing IUD during heavy menstrual flow days.
b. Copper IUD is effective as post-coital emergency contraceptive for up to 7 days after exposure.
c. May place a new IUD (copper or hormonal one) immediately after removing an existing IUD, if she is a candidate for her desired new IUD.
d. Postpartum women will wait for an IUD placement until uterine involution is complete (usually 6-8 weeks).

8. Schedule a levonorgestrel IUS (Mirena or Skyla®) placement according to the following instructions for on-label placement:
   a. Within first 7 days of cycle. To reduce early expulsion rates, try to avoid placement on heavy flow days.
   b. Women who are not cycling (e.g. due to breast-feeding or DMPA-induced amenorrhea) may have placement at any time they are not pregnant and have not had recent unprotected intercourse. Advise 7 days use of abstinence or back-up method after IUS placement.
   c. Women switching from OCs, advise completion of pill pack, especially if IUS is placed during the last week of active pills.
   d. May place new IUS immediately after removal of existing IUS if she is still a candidate. Removal is recommended on menses but if removed at other time in cycle, advise 7 days of abstinence or use of a backup method following replacement. Consider EC if she has had recent intercourse. Neither LNG-IUS is a post coital contraceptive.
   e. Placement of an IUS for postpartum women should probably be after uterine involution is complete (usually 6-8 weeks).
   f. If placement is desired at any other time in cycle or under different conditions, make sure the patient is not pregnant and have her use abstinence or a back-up method for 7 days following IUS placement.

Patient Education:

1. Reinforce IUD education as described in manufacturer's brochure. Provide information about mechanisms of IUD/IUS action, stress the importance of safer sex practices, describe possible placement complications, and schedule follow-up as needed if problems arise after placement. Reassure patient that as an ongoing method, all IUDs work as contraceptives by preventing fertilization.
2. Discuss risks of IUD/IUS if pregnancy occurs: ectopic pregnancy; preterm labor; need for IUD removal if possible; intrauterine levonorgestrel exposure (Mirena and Skyla®).
3. Inform patient that Mirena is the most effective medical treatment for heavy menstrual bleeding, can reduce symptoms of endometriosis and problems with anemia. By providing progestin, Mirena® also helps reduce the risk of endometrial cancer and precancer, especially in women with anovulatory cycles.

4. Discuss the expected short term side effects following placement, including unscheduled bleeding and cramping. Advise that many of these symptoms may subside over time.
5. Discuss the intermediate and longer term effects of each IUD.
    a. ParaGard: Monthly bleeding will increase by an average of 30-50%, but that increase can usually be reversed by the use of NSAIDs during menses.
    b. Mirena:
        1) Unscheduled bleeding and spotting may be frequent in the first 4 months of use, but will diminish over time.
        2) Total blood loss will be significantly reduced with longer use of Mirena.
        3) 20% of women will have no spotting or bleeding at all by 12 months of use. By that time, most other women will have only 1-3 days of spotting a month.
        4) Some women experience headaches or breast tenderness, especially with early use, but usually the symptoms are only temporary or are due to other causes.
        5) Mirena is the most effective medical therapy for heavy or prolonged menstrual bleeding. It may also help reduce dysmenorrhea.
    c. Skyla:
        1) Unscheduled bleeding and spotting may be frequent in the first 4 months of use, but will diminish over time.
        2) Total blood loss will be significantly reduced with longer use.
        3) 12% of women will have no spotting or bleeding at all by 3 years of use.
        4) Some women experience headaches or breast tenderness, especially with early use, but usually the symptoms are only temporary or are due to other causes.
6. Remind women that the pregnancy protection, non-contraceptive benefits and the side effects disappear almost immediately following IUD removal.

Referral:

1. Any patient with US MEC category 3 and 4 conditions to IUD she desires to use.
2. Any patient who will need antibiotic prophylaxis for IUD placement.
3. Refer women desiring IUD with labile or uncontrolled hypertension.

Reference:

1. ACOG Practice Bulletin No. 114: Management of endometriosis. *Obstet Gynecol*. 2010;116(1):223-36.
2. ACOG Practice Bulletin No. 121: Long-acting reversible contraception: Implants and intrauterine devices. *Obstet Gynecol.* 2011;118(1):184-96.
3. Centers for Disease Control and Prevention (CDC). U.S. Medical Eligibility Criteria for Contraceptive Use 2012 Available at http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm
4. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines. Available at http://www.cdc.gov/STD/treatment/

5. Centers for Disease Control and Prevention. US Selected Practice Recommendations for Contraceptive Use, 2013 *MMWR Recomm Rep* 1013; 62:1-60.
6. Flamant A, et al. Rates of continuation and satisfaction of immediate intrauterine device insertion following first- or second- trimester surgical abortion: a French prospective cohort study. *Eur J Obstet Gynecol Reprod Biol.* 2013;169(2):268-74.
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8. Hatcher RA, et al (editors). *Contraceptive Technology*, 20th Ed. New York: Ardent Media. 2011 147-192.
9. Hubacher C, et al. Side effects from the copper IUD: Do they decrease over time? Contraception 2009;70:356-62.
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12. Mirena website: http://www.mirena-us.com.
13. Nelson A. Intrauterine contraceptives. Glob Libr Women's Med. (ISSN: 1756-2228) 2008 May. Available at: http://www.glowm.com/?p=glowm.cml/section_view&articleid=393.
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15. ParaGard website: http://www.paragard.com/hcp/resources-for-your-patients.
16. Sivin J. Utility and drawbacks of continuous use of a copper IUD for 20 years Contraception 2007;75(6supp):S70-75.
17. Wiebe ER, et al. Motivation and experience of nulliparous women using intrauterine contraceptive devices. J Obstet Gynaecol Can. 2010;32:335-8.
18. Whiteman MK, Tyler CP, Folger SG, et al. When can a woman have an intrauterine device inserted? A systematic review. Contraception. 2013;87(5):666-73.

Intrauterine Device (IUD) Placement:

Definition:

This protocol outlines the steps needed to reconfirm that the patient is a candidate for the intrauterine device (IUD) she desires and the steps to be followed in placing that IUD. Whenever possible, IUD placement should be done at the initial visit to reduce barriers to access and unintended pregnancy. Practice with plastic models helps reduce complications (especially uterine perforation).

Subjective:

Must include:

1. LNMP and PMP.

2. Patient previously assessed to be eligible for IUD use according to *Identification of Intrauterine Contraceptive Candidate* protocol and desires IUD placement after reading product consent form.
3. Medical and sexual history update with special attention to reconfirm IUD candidacy.
4. No symptoms of pregnancy.
5. Reconfirm that this is an appropriate time for IUD placement.

Must exclude:

- Any US MEC Category 4 or 3 conditions for her desired IUD.

Objective:

Must include:

1. Blood pressure $\geq$ 140/90, provide alternate method and refer to off campus clinic for the IUD service.
2. If placing IUD in absence of recent pregnancy, must have normal pelvic examination on day of placement demonstrating each of the following:
   a. Complete uterine involution.
   b. No sign of current vaginal or cervical infection.
   c. No signs of pregnancy.

Must exclude:

- Any US MEC Category 4 condition or 3 conditions for her desired IUD.

Laboratory:

- No Routine laboratory tests needed for IUD placement, except pregnancy test if patient at risk.

Must exclude:

- Any laboratory results indicating a US MEC Category 4 or 3 conditions for her desired IUD, such as current cervicitis, etc.

Assessment:

Candidate for placement of intrauterine contraceptive.

Plan:

1. Review patient product information brochure with patient, answer all her questions, obtain her informed consent and have her sign all appropriate forms. Place forms into patient's record.
2. Premedication has not been found to decrease discomfort of IUD placement, but may be indicated in the following situations:
   - NSAIDs (Ibuprofen 400-600mg orally every 6 hours) to reduce cramping after placement.
3. If patient found to have BV, treat with systemic not topical antibiotics. No need to delay IUD placement, but reinforce the importance of taking her antibiotics.
4. If no recent pregnancy, place IUD according to manufacturer's instructions with close attention to aseptic technique. Important elements include:
   a. Gently place tenaculum on the portion of the cervical lip that is further away from introitus (e.g. posterior lip with anteverted

uterus) to straighten axis of uterus and to stabilize uterus. Apply traction on tenaculum to reduce risk of perforation.

b. Careful uterine sounding to confirm that patient is candidate for her desired IUD.
    1) ParaGard 6.0-9.0 cm.
    2) Mirena 6.0-10.0 cm.
    3) Skyla – no dimensions set, but generally 6-10cm best.
c. Open IUD package, load IUD and place IUD following manufacturer's instructions.
d. Trim tailstrings to fit around cervix.

5. Write procedure note which records uterine position and size, depth of uterine sounding, depth to which IUD placed, and length to which the tailstrings trimmed, how well the patient tolerated the procedure, as well as any complications that may have been encountered during the procedure. Document IUD type, lot number and expiration date.
6. Instruct patient to return to clinic for routine well woman care and earlier PRN problems with her IUD. No routine post-placement visit needed.
7. Provide backup method for 7 days is LNG IUS placed at any time other than specified (e.g., within 7 days of LMP, delivery or at time of hormonal method change).
8. Unless patient has contraindications to use of NSAIDs, advise use PRN problem with cramping or bleeding. Typical recommendation: Ibuprofen 400-600 mg orally every 6 hours when needed for cramping or heavy bleeding. Other NSAIDs at equivalent doses may be used.
9. If patient has BP ≥140/90 verified at least one additional time in clinic with no smoking or caffeine for 30 minutes, refer for evaluation of possible hypertension.

Patient Education:

1. Reinforce IUD education, including checking strings monthly, signs and symptoms of possible IUD complications (e.g. infection, expulsion, perforation, pregnancy)**.**
2. Instruct patient to seek care urgently if any symptoms of PID, pregnancy or expulsion or if she experiences heavy vaginal bleeding or severe cramping.
3. Instruct patient to return for re-evaluation of appropriateness of method if she becomes at risk for PID.
4. Instruct patient with ParaGard that IUD removal is recommended on label by 10 years, but that the actual length of use may be longer. On label the Mirena should be changed every 5 years, but new information may change that recommendation in the future. Skyla is approved for up to 3 years of use.
5. Encourage routine health care.

Referral:

1. Any patient who has difficult placement.
2. Any patient with elevated blood pressure or US MEC category 3 or 4 conditions

3. Patient who presents for LNG IUS insertion at times in her cycle not specified on product labeling.
4. Any patient who has history of any complication of IUD placement.

Reference:

1. ACOG Practice Bulletin No. 121: Long-acting reversible contraception: Implants and intrauterine devices. *Obstet Gynecol*. 2011;118(1):184-96.
2. Allen RH, Bartz D, Grimes DA, et al. Interventions for pain with intrauterine device insertion. *Cochrane Database of Systematic Reviews* 2009;(3):CD007373.
3. Bergin A, Tristan S, Terplan M, et al. A missed opportunity for care: two-visit IUD insertion protocols inhibit placement. *Contraception.* 2012;86(6):694-7.
4. Çelen Ş, Sucak A, Yıldız Y, et al. Immediate postplacental insertion of an intrauterine contraceptive device during cesarean section. *Contraception*. 2011;84(3):240-3.
5. Centers for Disease Control and Prevention (CDC). U.S. Medical Eligibility Criteria for Contraceptive Use, 2012. *MMWR Recomm Rep*. 2012;59(RR-4):1-86. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf.
6. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines. Available at http://www.cdc.gov/STD/treatment/ .
7. Centers for Disease Control and Prevention (CDC). US Selected Practice Recommendations for Contraceptive Use, 2013 *MMWR Recomm Rep* 1013;62:1-60.
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10. Grimes DA, et al. Immediate post-partum insertion of intrauterine devices. *Cochrane Database Sys Rev.* 2010;(5):CD003036.
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14. Khadivzadeh T, Erfanian F. The effects of simulated patients and simulated gynecologic models on student anxiety in providing IUD services. *Simul Healthc*. 2012;7(5):282-7.
15. Kapp N, Curtis KM. Intrauterine device insertion during the postpartum period: a systematic review. *Contraception.* 2009;80(4):327-36.
16. Nelson A. Intrauterine contraceptives. *Glob Libr Women's Med.* (ISSN: 1756-2228) 2008 May. Available at: http://www.glowm.com/?p=glowm.cml/section_view&articleid=393.

17. Nelson AL, Chen S, Eden R. Intraoperative placement of the Copper T-380 intrauterine devices in women undergoing elective cesarean delivery: a pilot study. Contraception. 2009;80(1):81-3.
18. ParaGard website: http://www.paragard.com/hcp/resources-for-your-patient.
19. Scavuzzi A, Souza AS, Costa AA, et al. Misoprostol prior to inserting an intrauterine device in nulligravidas: a randomized clinical trial. Hum Reprod. 2013;28(8):2118-25.
20. Shimoni N, Davis A, Ramos ME, et al. Timing of copper intrauterine device insertion after medical abortion: a randomized controlled trial. Obstet Gynecol. 2011;118(3):623-8.
21. Steenland MW, Tepper NK, Curtis KM, et al. Intrauterine contraceptive insertion postabortion: a systematic review. Contraception. 2011;84(5):447-64.
22. Sufrin CB, Postlethwaite D, Armstrong MA, et al. Neisseria gonorrhea and Chlamydia trachomatis screening at intrauterine device insertion and pelvic inflammatory disease. Obstet Gynecol. 2012;120(6):1314-21.
23. Whiteman MK, Tyler CP, Folger SG, et al. When can a woman have an intrauterine device inserted? A systematic review. Contraception. 2013;87(5):666-73.
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IUD Removal:

Definition: Steps to follow in removing a patient's Intrauterine Device (IUD).

Subjective:

Must include:

1. NMP and PMP.
2. Medical and sexual history update.
3. History of any recent intercourse, if patient not currently menstruating (may want to delay removal if recent exposure).
4. Documentation of reason for IUD removal request.
5. If patient wants to continue IUD use, but is requesting removal because her IUD has been in place for the number of years for which it is recommended, refer patient to off campus clinics such as Planned Parenthood Clinic or Community Health Center for the service.

Objective:

Must exclude: BP ≥ 140/90

Must include:

1. BP<140/90
2. Pelvic examination—Check for any signs of infection or incorrect IUD placement.

Laboratory:

Must include:

1. Hgb/Hct (if history of excessive bleeding).
2. Negative sensitive pregnancy test.

Assessment:

Candidate for IUD removal.

Plan:

1. If IUD strings visible:
   a. Obtain patient's informed consent for IUD removal acknowledging the risks of bleeding, pain, infection and failure to remove.
   b. If there are any signs or symptoms of cervical infection or PID, provide appropriate systemic antibiotics and administer first dose prior to removal.
   c. If the patient required antibiotic prophylaxis against endocarditis by AHA guidelines when she had her IUD placed, refer this patient to off campus clinic for IUD service.
   d. Remove IUD following manufacturer's instructions.
   e. For postmenopausal women with stenotic os, refer this patient to off campus clinic for IUD service.
2. If IUD string(s) are missing or break during removal attempt, refer patient to off campus clinic for IUD service.
3. If IUD has been in place for more than 5 years or if patient has been experiencing any signs or symptoms of upper tract infection (e.g., vaginal discharge or lower abdominal pain), refer patient to off campus clinic for care & IUD service.
4. If patient seeking pregnancy, provide preconceptional counseling.
5. If patient desires contraception:
   a. If patient has re-qualified for an IUD, do not remove IUD and refer patient to an off campus clinic for IUD service.
   b. If patient desires another method, provide it.
6. If patient has had intercourse in the last five days and is at risk for pregnancy if IUD removed, offer emergency contraception or delay removal of IUD.
7. If patient with no prior history of hypertension has BP ≥ 140/90 verified at least one additional time this visit with no smoking or caffeine for 30 minutes, refer for evaluation of possible hypertension.

Patient Education:

1. Counsel regarding risk of pregnancy or ectopic pregnancy if IUD removed in absence of menses with recent intercourse; tell patient IUD no longer protects her from pregnancy. Encourage EC use.
2. Encourage women desire IUD removal in order to become pregnant to take folic acid supplement for at least 1 – 3 months prior to removal or at least to conception.
3. Advise women who have IUD removed but are not seeking pregnancy to immediately initiate another effective method. Remind them that the IUD provides no residual contraceptive protection once it is removed.

Referral:

1. Patient who requires antibiotic prophylaxis for prevention of endocarditis.
2. A patient with elevated BP or difficult IUD removal.

Reference:

1. ACOG Practice Bulletin No. 121: Long-acting reversible contraception: Implants and intrauterine devices. *Obstet Gynecol*. 2011 Jul;118(1):184-96.
2. Centers for Disease Control and Prevention. U.S. medical eligibility criteria for contraceptive use, 2010. *MMWR. Morb Mortal Wkly Rep*. 2010;59:1-6. Available at http//www.cdc.gov/mmwr/preview/mmwrhtm/rr59e0528al/htm.
3. Centers for Disease Control and Prevention (CDC). US Selected Practice Recommendations for Contraceptive Use, 2013 *MMWR Recomm Rep* 1013;62:1-60.
4. Hatcher RA, et al (editors).Contraceptive Technology 20th edition Ardent Media. New York, NY 2011:147-92.
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6. Nelson AL. Intrauterine contraceptives. *Glob.libr.women's med*., Available at: http://www.glowm.com/
7. Sivin I. Utility and drawbacks of continuous use of a copper T IUD for 20 years. *Contraception*. 2007;75(6 Suppl):S70-5.

List of supplies for IUC procedure:

All lab results – Pap/GC/ CT
Consent form for Paraguard or Mirena
Ibuprofen (600 – 800 mg)
Speculum
Cotton swab (a bunch in a basin or a small basket)
Betadine swabs (3)
Tenaculum
Sound (plastic or metal)
IUC – Paraguard or Mirena
Sterile gloves
Scissors
Silver Nitrate or Monsel solution
Maxi Pads
IUC information card
Slip for f/u appt (after first menstrual period)
Smelling salt

Appedix B-4: NEXPLANON –SOAP template

S: LNMP:_____ PMP:_____ Current Contraceptive:_____

Last Pap:_____ Last CT/GC test:_____ G___ P___ Tab___ Sab___

I. Absolute Contraindications: None /Other:
   1. Known or suspect pregnancy
   2. Current or past history of DVT/PE
   3. Liver tumors/active liver disease
   4. Hypersensitivity to any component of NEXPLANON
   5. Undiagnosed vaginal bleeding
   6. Current or past history of breast cancer
   7. Lupus
   8. < 4 weeks postpartum

II. Relative Contraindications: None /Other:
   1. HIV+ / immunosuppressed
   2. Ischemic heart disease or stroke history
   3. Desired pregnancy before 1 year
   4. WT > 30% BMI

III. Risk Factors for STD's': None /Other:
   1. Multiple partners
   2. High risk partner (multiple partners, injection drugs, HIV risk)
   3. Increased risk HIV

O: No Exam

1. See previous pap / other lab results
2. Pregnancy test result: Negative / Positive (Date:)
3. Pelvic Exam:

A: V25.43 Implanon Surveillance; NEXPALNON information & consent visit

P: Reviewed the following with patient:

1. Other available contraceptives
2. NEXPLANON benefits
3. NEXPLANON insertion procedure / NEXPLANON removal procedure
4. NEXPLANON ROD check procedure
5. NEXPLANON problems, risks, side-effects
6. NEXPLANON cost
7. NEXPLANON Consent Form Reviewed and signed
8. Patient to make insertion visit / follow up visit as desired

Adopted the form (last revised 03/14) from University Health Services, Tang Center, University of California, Berkeley.

Appendix C

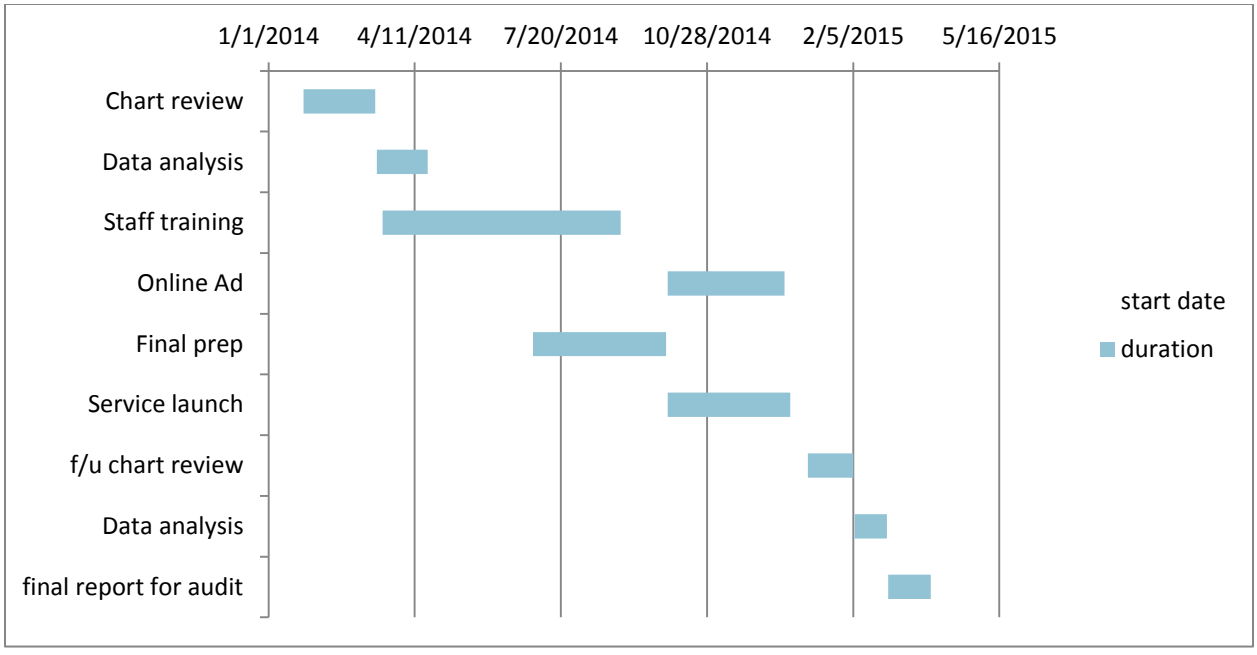

SWOT ANALYSIS
S
Strengths
•Quality health care at convenient location
•Unlimited clinic visits as an appointment available
•One skilled staff nurse practitioner with LARC procedures who will support newly trained providers
•The procedures can be fully reimbursed
W
Weaknesses
•With referrals, students needs to travel off campus clinics for services
•Three Newly trained physicians
•Need to purchase a few units of LARC before starting service
O
Opportunities
•Service is demanding and will benefit both students and SHCS
•Almost all of the CSU SHS not offer the services
•Incovenient to travel to off campus clinics
•Staff physicians will gain new clinical skills
T
Threats
•Expensive: ~ $700+ per unit
•PP Mar Monte clinics are starting service in central Hayward
• Community Health Care Network clinics in Alameda are providing services
•Private women's clinics around the area

Appendix D Project Gantt Chart

Table 1. Project Gantt Chart

	Task	start date	duration	complete date
Task1	Chart review	1/25/2014	49	3/15/2014
Task2	Data analysis	3/16/2014	35	4/20/2014
Task3	Staff training	3/20/2014	163	8/30/2014
Task4	Online Ad	10/1/2014	80	12/20/2014
Task4	Final prep	7/1/2014	91	9/30/2014
Task5	Service launch	10/1/2014	84	12/24/2014
Task6	f/u chart review	1/5/2015	31	2/5/2015
Task7	Data analysis	2/6/2015	22	2/28/2015
Task6	final report for audit	3/1/2015	29	3/30/2015

Chart 1. Project Gantt Chart



Appendix E Failure Mode, Effect, and Criticality Analysis for LARC service

Process	Copper T IUD procedure as emergency contraception→	Care provided by new/inexperienced provider→	Administration of Copper T IUD→	Patient
Potential/Failure Mode	No emergency response team; no back up experienced gynecologist	Inexperienced provider	Adverse events such uterine perforation	
Potential/Effect on Patient	5	5	10	
Frequency of Failure Mode	2	5	2	
Likelihood of Reaching Patient	2	5	2	
Criticality of Failure Mode	20	125	40	
Root Causes	No standard clinical guidelines to require a back-up gynecologist	No supervision for inexperienced providers	Not familiar with possible adverse effects of the procedure	
Strategies for Improvement	Develop a system guideline for emergency response; policy for patient referral process; training and checking competency by a contract gynecologist	Observing 3-5 procedures before hand-on; periodical competency review; continue education to update skills;	Risk prevention & elimination plan prior to project; patient care by emergency response team; guidelines for patient care and care transfer;	

Appendix F Contraceptive Method Data Collection Form (2013 & 2014)

Appendix E-1. Contraceptive Method Data Collection Form (06/24-12/20/2013)

Date		Age group				continue use of a method					
		≤ 20	21 - 24	25-29	≥ 30	< 6 m	> 6 m	> 12m	total		
Pregnancy	Never										
	History of										
	Unknown										
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx											
Partner	Yes										
	No					xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx					
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx											
Birth Control Methods	Pills										
	Patch										
	Ring										
	Injection										
	*Condom										
	Implant										
	Mirena										
	Paragard										
	Skyla										
	**Other										

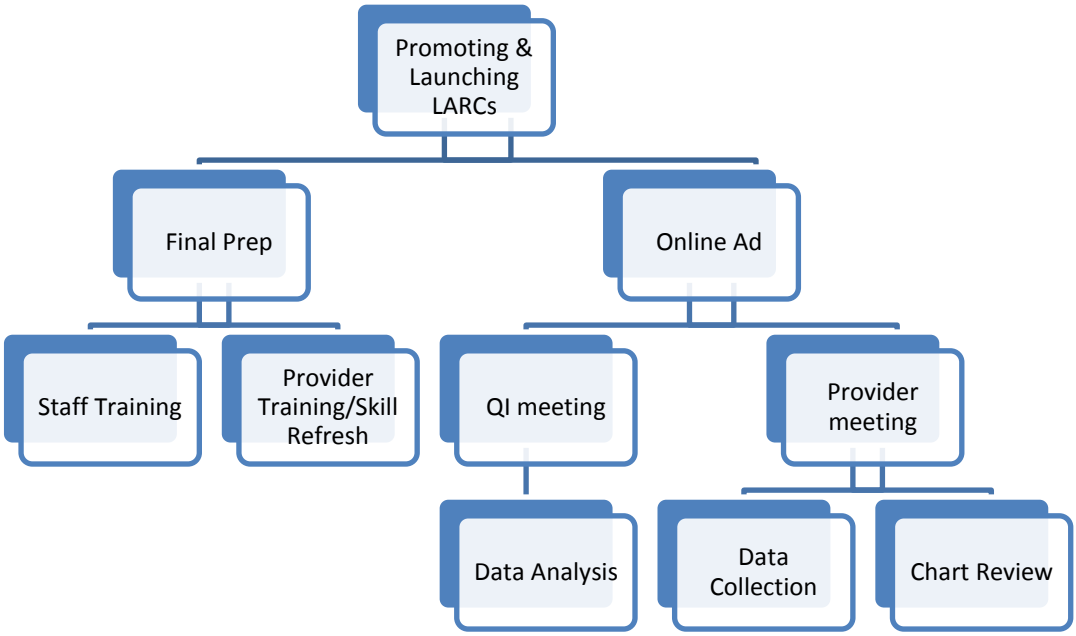
ther includes not use any method, coitus interuptus, film,
* "Condom" may include other types of barrier methods.

Appendix E-2. Contraceptive Method Data Collection Form (06/24-12/20/2014)

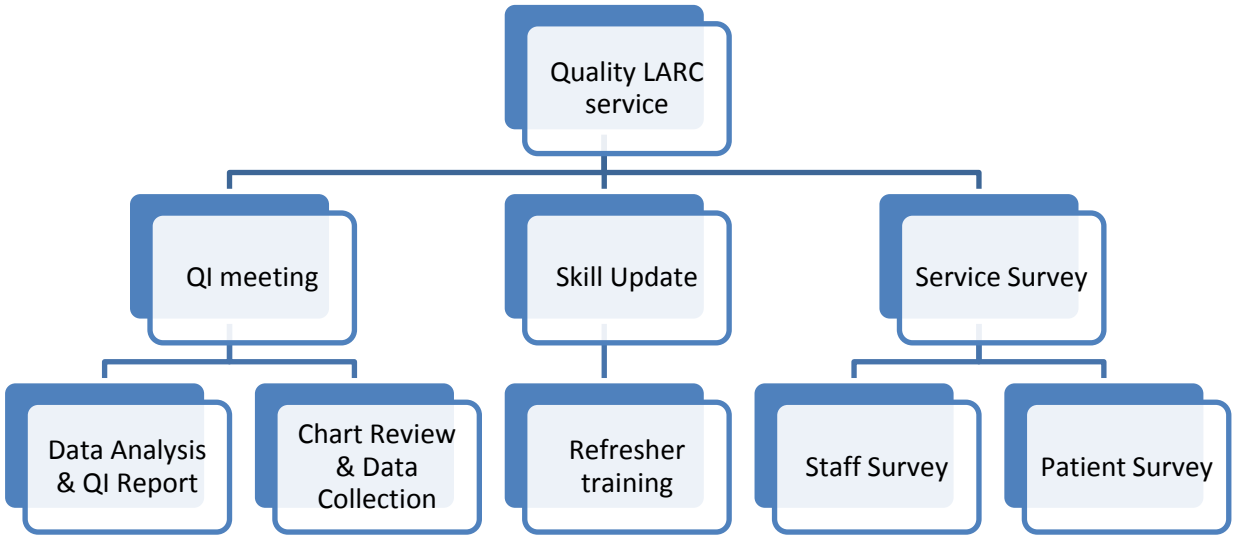
new form	up to age 20	age 21 - 24	age 25 - 29	age 30 & >	use < 6m	use > 6 m	use > 12m	C/Initiate	Total	
G0								....		
> G1								....		
G???								....		
....								....	....	
partner-y								....	....	
partner-N					XXXXXXXXXXXXXXXXXXXXXXXX			....	....	
partner???					XXXXXXXXXXXXXXXXXXXXXXXX			....	....	
....								....	....	
OCP								....		
patch								....		
ring								....		
Depo-inj.								....		
condom								....		
implant										
mirena										
paragard										
skyla										
other								....		

*other includes no BCM, coitus interuptus, film, etc.
* "Condom" may include other types of barrier methods.
* C/I: Counseling, to initiate, or to refer/Initiating

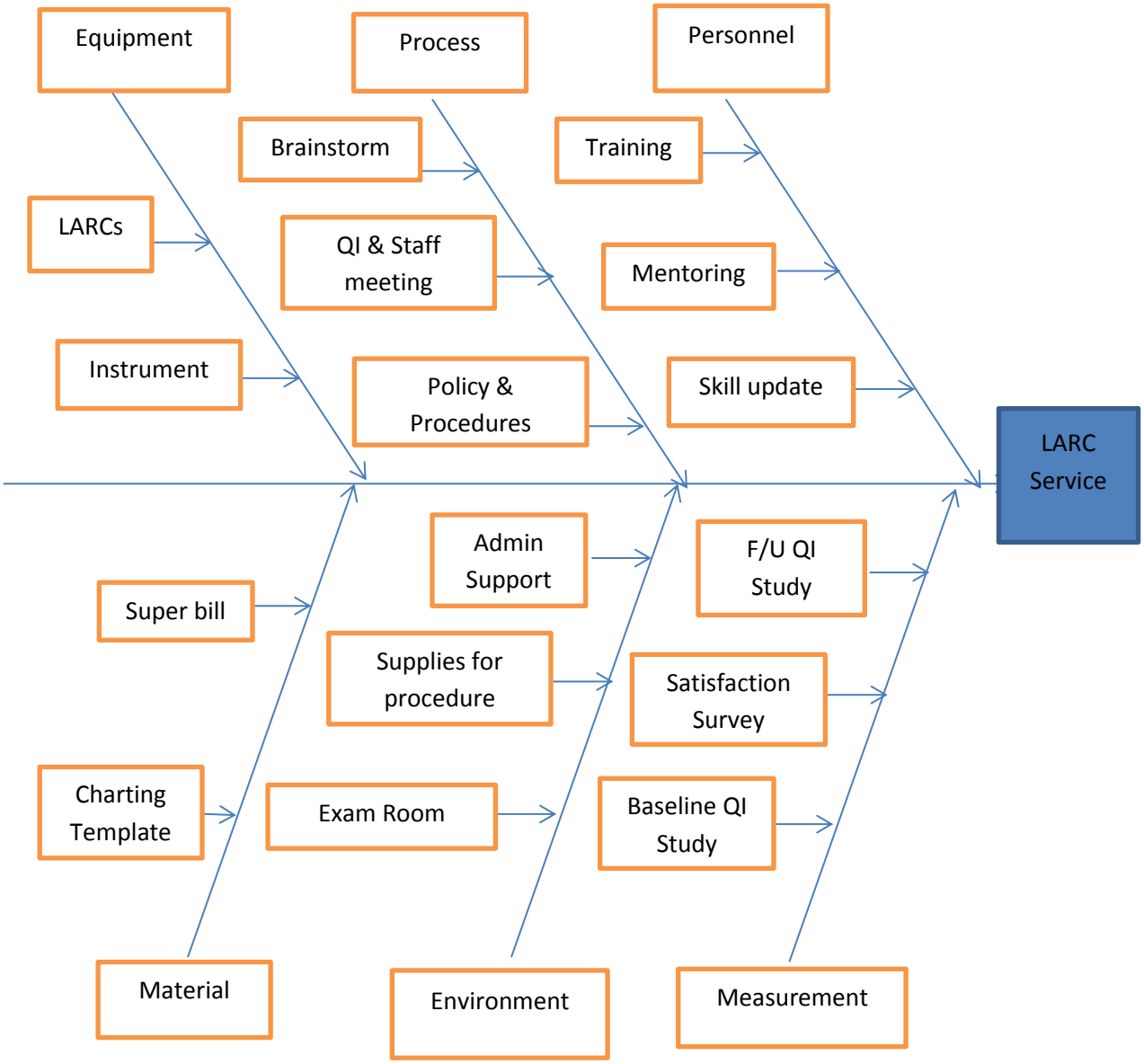
Appendix G-1 Initial WBS



G-2 WBS for Follow-up QI study



Appendix I Ishikawa Diagram

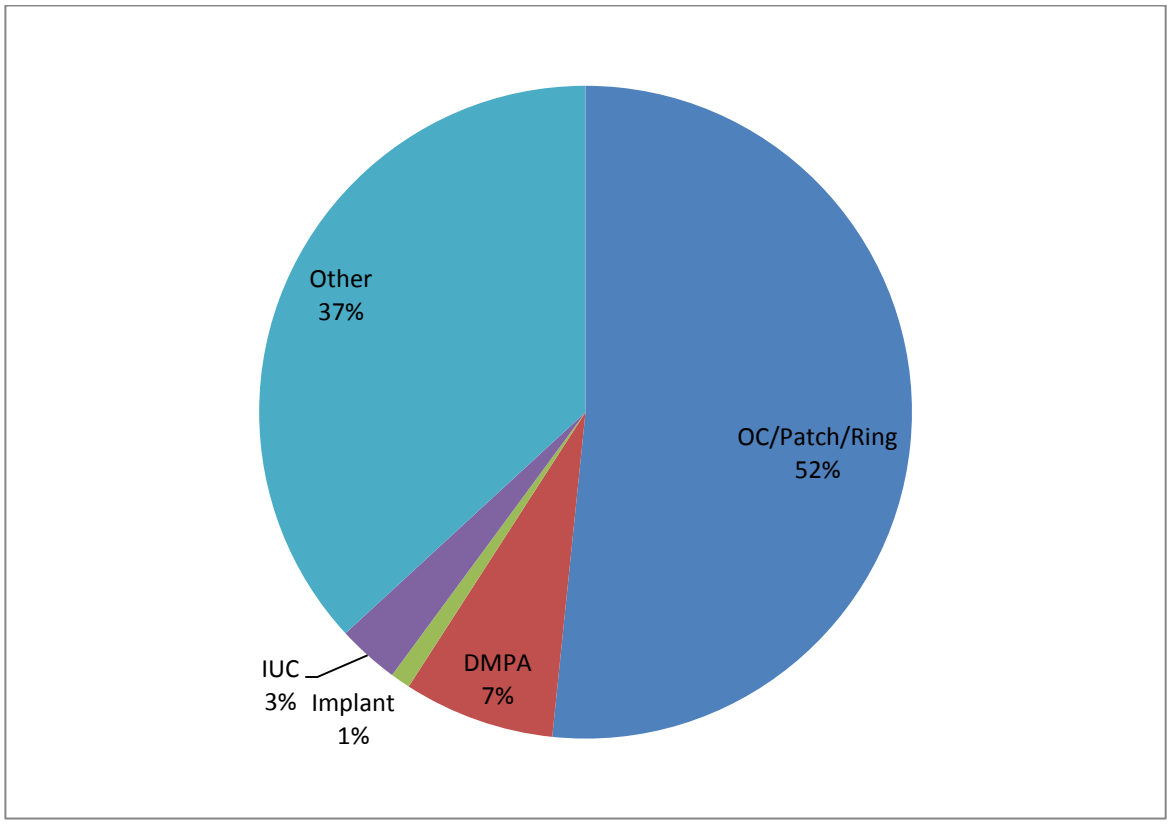


Appendix J

Table 1. Observation of Contraceptive Use from Women's Health Visits in June-December 2013

visits 2013	q4w Total	≤ 24 yo	OC/Patch/Ring	Injection	Implant	IUC	Other
6/24/2013	85	66(78%)	31/1/1	6	0	M4/P0	38
7/22/2013	62	48(77%)	33/2/1	1	0	M1/P2	23
8/19/2013	67	48(72%)	30/3/1	1	0	M4/P1	29
9/16/2013	223	116(52%)	109/6/10	20	2	M2/P2	75
10/14/2013	300	240(80%)	135/4/8	27	4	M6/P1	97
11/11/2013	294	222(76%)	126/11/11	21	4	M4/P5	112
Total visits	1031	733(71%)	464/28/32(50%)	76% (75)	10(1%)	M21/P11(3%)	347(37%)
	IUC-Intrauterine Contarceptives; M-Mirena; P-Paragard						

Chart 1 Current Contraceptive Used (June-December 2013)



Appendix K-1

Budget Projection for LARCs Purchase and Reimburse

LARC service

	Month1	Month2	Month3	Month4	Month5	Month6	total
LARC/units need per month	3	6	3	8	8	4	32
Reimbursed for procedures provided each month	$2,571	$4,285	$2,571	$6,856	$6,856	$3,428	$27,424
pre-paid (total of 15 units)	($2,130)	($4,260)	($2,130)	($2,130)			($10,650)

A smaller number of LARC services will be expected for the first 6 months and during the quarter breaks.

Appendix K-2

Budget Projection for Implant Contraceptive (approved in late October, 2014)

	Month1	Month2	Month3	Month4	Month5	Month6	total
LARC/units need per month	3	6	3	8	8	4	32
Reimbursed for procedures provided each month	$2,690	$5,380	$2,690	$7,170	$7,170	$3,580	$28,690
pre-paid (total of 5 units)	($1,980)	($1,320)					($3,300)

Appendix L

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use (Updated in June 2012)

Medical Eligibility Criteria Categories

1 = A condition for which there is no restriction for the use of the contraceptive method.

2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

http://www.arhp.org/uploadDocs/choosingqrg.pdf

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG--IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Age		Menarche to <40=1		Menarche to <18=1		Menarche to <18=2		Menarche to <18=1		Menarche to <20=2		Menarche to <20=2	
		≥40=2		18-45=1		18-45=1		18-45=1		≥20=1		≥20=1	
				>45=1		>45=2		>45=1					
Anatomic abnormalities	a) Distorted uterine cavity									4		4	
	b) Other abnormalities									2		2	
Anemias	a) Thalassemia	1		1		1		1		1		2	
	b) Sickle cell disease‡	2		1		1		1		1		2	
	c) Iron-deficiency anemia	1		1		1		1		1		2	
Benign ovarian tumors	(including cysts)	1		1		1		1		1		1	
Breast disease	a) Undiagnosed mass	2*		2*		2*		2*		2		1	
	b) Benign breast disease	1		1		1		1		1		1	
	c) Family history of cancer	1		1		1		1		1		1	
	d) Breast cancer‡												
	i) current	4		4		4		4		4		1	
	ii) past and no evidence of current disease for 5 years	3		3		3		3		3		1	
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*		2*		2*		2*					
	b) 1 month or more postpartum	2*		1*		1*		1*					
Cervical cancer	Awaiting treatment	2		1		2		2		4	2	4	2
Cervical ectropion		1		1		1		1		1		1	
Cervical intraepithelial neoplasia		2		1		2		2		2		1	
Cirrhosis	a) Mild (compensated)	1		1		1		1		1		1	
	b) Severe‡ (decompensated)	4		3		3		3		3		1	
Deep venous thrombosis (DVT) /Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy												
	i) higher risk for recurrent DVT/PE	4		2		2		2		2		1	
	ii) lower risk for recurrent DVT/PE	3		2		2		2		2		1	
	b) Acute DVT/PE	4		2		2		2		2		2	
	c) DVT/PE and established on anticoagulant therapy for at least 3 months												
	i) higher risk for recurrent DVT/PE	4*		2		2		2		2		2	
	ii) lower risk for recurrent DVT/PE	3*		2		2		2		2		2	
	d) Family history (first-degree relatives)	2		1		1		1		1		1	
	e) Major surgery												
	(i) with prolonged immobilization	4		2		2		2		2		1	
	(ii) without prolonged immobilization	2		1		1		1		1		1	
	f) Minor surgery without immobilization	1		1		1		1		1		1	
Depressive disorders		1*		1*		1*		1*		1*		1*	
Diabetes mellitus (DM)	a) History of gestational DM only	1		1		1		1		1		1	
	b) Non-vascular disease												
Diabetes mellitus (cont.)	(i) non-insulin dependent	2		2		2		2		2		1	
	(ii) insulin dependent‡	2		2		2		2		2		1	
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*		2		3		2		2		1	
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*		2		3		2		2		1	
Endometrial cancer‡		1		1		1		1		4	2	4	2
Endometrial hyperplasia		1		1		1		1		1		1	
Endometriosis		1		1		1		1		1		2	
Epilepsy‡	(see also Drug Interactions)	1*		1*		1*		1*		1		1	
Gallbladder disease	a) Symptomatic												
	(i) treated by cholecystectomy	2		2		2		2		2		1	
	(ii) medically treated	3		2		2		2		2		1	
	(iii) current	3		2		2		2		2		1	
	b) Asymptomatic	2		2		2		2		2		1	
Gestational trophoblastic	a) Decreasing or undetectable ß-hCG levels	1		1		1		1		3		3	

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG--IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
disease	b) Persistently elevated ß-hCG levels or malignant disease‡	1		1		1		1		4		4	
Headaches	a) Non-migrainous	1*	2*	1*	1*	1*	1*	1*	1*	1*	1*	1*	
	b) Migraine												
	i) without aura, age <35	2*	3*	1*	2*	2*	2*	2*	2*	2*	2*	1*	
	ii) without aura, age ≥35	3*	4*	1*	2*	2*	2*	2*	2*	2*	2*	1*	
	iii) with aura, any age	4*	4*	2*	3*	2*	3*	2*	3*	2*	3*	1*	
History of bariatric surgery‡	a) Restrictive procedures	1		1		1		1		1		1	
	b) Malabsorptive procedures	COCs: 3 P/R: 1		3		1		1		1		1	
History of cholestasis	a) Pregnancy-related	2		1		1		1		1		1	
	b) Past COC-related	3		2		2		2		2		1	
History of high blood pressure during pregnancy		2		1		1		1		1		1	
History of pelvic surgery		1		1		1		1		1		1	
HIV	High risk	1		1		1*		1		2	2	2	2
	HIV infected (see also Drug Interactions)‡	1*		1*		1*		1*		2	2	2	2
	AIDS (see also Drug Interactions) ‡	1*		1*		1*		1*		3	2*	3	2*
	Clinically well on therapy	If on treatment, see Drug Interactions								2	2	2	2
Hyperlipidemias		2/3*		2*		2*		2*		2*		1*	
Hypertension	a) Adequately controlled hypertension	3*		1*		2*		1*		1		1	
	b) Elevated blood pressure levels (properly taken measurements)												
	(i) systolic 140-159 or diastolic 90-99	3		1		2		1		1		1	
	(ii) systolic ≥160 or diastolic ≥100‡	4		2		3		2		2		1	
	c) Vascular disease	4		2		3		2		2		1	
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	2/3*		2		2		1		1		1	
Ischemic heart disease‡	Current and history of	4		2	3	3		2	3	2	3	1	
Liver tumors	a) Benign												
	i) Focal nodular hyperplasia	2		2		2		2		2		1	
	ii) Hepatocellular adenoma‡	4		3		3		3		3		1	
	b) Malignant‡	4		3		3		3		3		1	
Malaria		1		1		1		1		1		1	
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)	3/4*		2*		3*		2*		2		1	
Obesity	a) ≥30 kg/m^2 body mass index (BMI)	2		1		1		1		1		1	
	b) Menarche to < 18 years and ≥ 30 kg/m^2 BMI	2		1		2		1		1		1	
Ovarian cancer‡		1		1		1		1		1		1	
Parity	a) Nulliparous	1		1		1		1		2		2	
	b) Parous	1		1		1		1		1		1	
Past ectopic pregnancy		1		2		1		1		1		1	
Pelvic inflammatory disease	a) Past, (assuming no current risk factors of STIs)												
	(i) with subsequent pregnancy	1		1		1		1		1	1	1	1
	(ii) without subsequent pregnancy	1		1		1		1		2	2	2	2
	b) Current	1		1		1		1		4	2*	4	2*
Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function												
	(i) < 6 months	4		1		1		1		2		2	
	(ii) ≥ 6 months	3		1		1		1		2		2	
	b) Moderately or severely impaired cardiac function	4		2		2		2		2		2	
Postabortion	a) First trimester	1*		1*		1*		1*		1*		1*	
	b) Second trimester	1*		1*		1*		1*		2		2	
	c) Immediately post-septic abortion	1*		1*		1*		1*		4		4	
Postpartum (see also Breastfeeding)	a) < 21 days	4		1		1		1					
	b) 21 days to 42 days												
	(i) with other risk factors for VTE	3*		1		1		1					

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG–IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
	(ii) without other risk factors for VTE	2		1		1		1					
	c) > 42 days	1		1		1		1					
Postpartum (in breastfeeding or non-breastfeeding women, including post-cesarean section)	a) < 10 minutes after delivery of the placenta									2		1	
	b) 10 minutes after delivery of the placenta to < 4 weeks									2		2	
	c) ≥ 4 weeks									1		1	
	d) Puerperal sepsis									4		4	
Pregnancy		NA*		NA*		NA*		NA*		4*		4*	
Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		2/3*		1		2	1	2	1
	b) Not on immunosuppressive therapy	2		1		2		1		1		1	
Schistosomiasis	a) Uncomplicated	1		1		1		1		1		1	
	b) Fibrosis of the liver‡	1		1		1		1		1		1	
Severe dysmenorrhea		1		1		1		1		1		2	
Sexually transmitted infections (STIs)	a) Current purulent cervicitis or chlamydial infection or gonorrhea	1		1		1		1		4	2*	4	2*
	b) Other STIs (excluding HIV and hepatitis)	1		1		1		1		2	2	2	2
Sexually transmitted infections (cont.)	c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1		1		1		1		2	2	2	2
	d) Increased risk of STIs	1		1		1		1		2/3*	2	2/3*	2
Smoking	a) Age < 35	2		1		1		1		1		1	
	b) Age ≥ 35, < 15 cigarettes/day	3		1		1		1		1		1	
	c) Age ≥ 35, ≥15 cigarettes/day	4		1		1		1		1		1	
Solid organ transplantation‡	a) Complicated	4		2		2		2		3	2	3	2
	b) Uncomplicated	2*		2		2		2		2		2	
Stroke‡	History of cerebrovascular accident	4		2	3	3		2	3	2		1	
Superficial venous thrombosis	a) Varicose veins	1		1		1		1		1		1	
	b) Superficial thrombophlebitis	2		1		1		1		1		1	
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4		3		3	3	3		3		1	1
	b) Severe thrombocytopenia	2		2		3	2	2		2*		3*	2*
	c) Immunosuppressive treatment	2		2		2	2	2		2		2	1
	d) None of the above	2		2		2	2	2		2		1	1
Thrombogenic mutations‡		4*		2*		2*		2*		2*		1*	
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid	1		1		1		1		1		1	
Tuberculosis‡ (see also Drug Interactions)	a) Non-pelvic	1*		1*		1*		1*		1		1	
	b) Pelvic	1*		1*		1*		1*		4	3	4	3
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	2*		2*		3*		3*		4*	2*	4*	2*
Uterine fibroids		1		1		1		1		2		2	
Valvular heart disease	a) Uncomplicated	2		1		1		1		1		1	
	b) Complicated‡	4		1		1		1		1		1	
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		2		2		2		1	1	1	
	b) Heavy or prolonged bleeding	1*		2*		2*		2*		1*	2*	2*	
Viral hepatitis	a) Acute or flare	3/4*	2	1		1		1		1		1	
	b) Carrier/Chronic	1	1	1		1		1		1		1	
Drug Interactions													
Antiretroviral therapy	a) Nucleoside reverse transcriptase inhibitors	1*		1		1		1		2/3*	2*	2/3*	2*
	b) Non-nucleoside reverse transcriptase inhibitors	2*		2*		1		2*		2/3*	2*	2/3*	2*
	c) Ritonavir-boosted protease inhibitors	3*		3*		1		2*		2/3*	2*	2/3*	2*
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		1		2*		1		1	
	b) Lamotrigine	3*		1		1		1		1		1	
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		1		1		1	
	b) Antifungals	1		1		1		1		1		1	
	c) Antiparasitics	1		1		1		1		1		1	
	d) Rifampicin or rifabutin therapy	3*		3*		1		2*		1		1	

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable
* Please see the complete guidance for a clarification to this classification: www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm
‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

Table 1. Description of Studies Included

Study	Year Published	Study Design	Goal(s) of Study	Study Outcomes
Mestad, Secura, Allsworth, Madden, Zhao, & Peipert	2011	A longitudinal observational study	Contraceptive method preferences by age	LARCs were chose by 70% of study participants. Subcutaneous Implants were preferred among age 14-17 and IUDs were preferred among age 18-20.
Fanarjian, Drostin, Garret, & Montalvo	2012	Retrospective cohort study	The effectiveness of free IUC in reducing pregnancy rates among low-income women.	No pregnancy per 100 women years were found in the IUD user group and 16.2 pregnancies per 100 women years in the non-IUD user group
Godfrey & colleagues	2010	A Multicenter randomized controlled pilot study	The effectiveness and continuation rates of LARCs	At 6-month f/u, the continuation rate was 75% in the LNG-IUS group vs 45% in the Copper T IUD group. 100% of LNG-IUS group and 83% in Copper T group planned to continue the use of IUC after the study.
Short, Dallay, Omokanye, Hanisch, & Inki	2012	One-year results of an observational study	The acceptability of LNG-IUS and ENG-implant use among age 20-35 years European women	The 12-month continuation rates were 93% in LNG-IUS group and 86% for the ENG-implant group. About 62% of LNG-IUS users were satisfied with their method compared to 36% of the ENG-implant user.
Deans & Grimes	2009	A systematic review of 6 cohort study and 7 case-series studies	IUD use among adolescents for continuation and pregnancy rates	The IUD has similar or better continuation rates compared to combined oral contraceptives. The cumulative pregnancy rate among IUD users was 2 % at 6 months to 11% at 48 months.

Table 2. Evaluation of Studies Using the STROBE Checklist

STROBE	Mestad	Fanarjian	Godfrey	Short	Deans*
1a	Y	Y	Y	Y	Y
1b	Y	Y	Y	Y	Y
2	Y	Y	Y	Y	Y
3	Y	Y	Y	Y	Y
4	Y	Y	Y	Y	Y
5	Y	Y	Y	Y	Y
6	Y	Y	Y	Y	Y
7	Y	Y	Y	Y	Y
8	Y	Y	Y	Y	N
9	Y	Y	Y	Y	Y
10	Y	Y	Y	Y	Y
11	Y	Y	Y	Y	N
12	Y	Y	Y	Y	N
13	Y	Y	Y	Y	Y
14	Y	Y	Y	Y	Y
15	Y	Y	Y	Y	N
16	Y	Y	Y	Y	N
17	Y	Y	Y	Y	Y
18	Y	Y	Y	Y	Y
19	Y	Y	Y	Y	Y
20	Y	Y	Y	Y	Y
21	Y	Y	Y	Y	Y
22	Y	Y	Y	Y	N

Continued on next page

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed

	Case-control study—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
	(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Table 4. Provider LARC Training Plan

	Implant Contraceptive	**IUD**
Lecture	**All completed & certified**	**3 providers completed**
Simulation Lab/practice model	**All completed/own individual practice model**	**3 providers completed/a refresher lab needed**
Observation (optional)	**In progress**	**Not approved/ prn**
Supervised insertion	**3 cases**	**5 cases**
Supervised removal	**3 cases**	**0**