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### LARC Method Appropriateness in Substance Use Treatment: A Quality Improvement Project for Integrated Care

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LARC Method Appropriateness in Substance Use Treatment:

A Quality Improvement Project for Integrated Care

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### Abstract

**Problem:** Individuals with substance use disorder (SUD) have disproportionately higher rates of unintended pregnancy when compared to the general population, estimated to be 85% (Heil et al., 2011). Not only are poor maternal and fetal outcomes associated with unplanned pregnancies, but pregnancies in women with SUD are further complicated by additional risks and adverse outcomes (Black & Day, 2016).

**Context:** Addiction treatment centers and programs are primed with opportunity to offer family planning services, when contact with medical providers is increased for substance use treatment. In response to the opioid crisis and unprecedented rates of unintended pregnancy, this project was designed to identify, develop, and implement an evidence-based approach to integrate birth control education and services, emphasizing long-acting reversible contraception (LARC) in substance use treatment.

**Interventions:** A two-part interdisciplinary training was designed to include best practice recommendations regarding LARC utilization and comprehensive contraceptive counseling, hands-on skills training with vaginal simulators, and subdermal implant training and certification. In addition, a site feasibility analysis was conducted, to include a client focus group, staff readiness for change survey, and site assessment, to develop and make recommendations for a future pilot program for offering birth control services in the on-site medical clinic.

**Measures:** A pre/post training assessment was utilized to assess change in provider confidence and readiness in offering contraceptive counseling and performing LARC procedures in preparation for service integration on site.

**Results:** Through data analysis, results indicated a 33.33% increase in provider comfort with providing contraceptive counseling, confidence in identifying LARC eligible candidates, and confidence in counseling clients about the LARC insertion procedure and follow-up. The greatest changes were seen in provider preparedness in providing counseling regarding LARC safety and efficacy, with a 44.44% increase and a 57.89% increase in provider comfortability with the Nexplanon insertion and removal procedure from the pre-training assessments.

**Conclusions:** Didactic and hands-on training are effective approaches to prepare providers for service expansion to include contraceptive services at addiction treatment centers. For future implementation, funding through grants or expanded billing for medical services need to occur.

**Keywords:** Unintended pregnancy, LARC, contraceptive counseling, substance use disorder, IUD, intrauterine device, birth control

## **Section II: Introduction**

### **Background and Problem Description**

Unintended pregnancy is a pervasive, preventable problem throughout the United States. Some of the highest rates of unplanned pregnancy have been identified in women with a substance use disorder (SUD). Both SUD and unplanned pregnancies are associated with their respective individual health challenges and sequelae that are further impacted when combined. This Doctor of Nursing Practice (DNP) project was designed to address and reduce barriers to family planning services among women of reproductive age with a SUD. Substance abuse and the geographical setting will be further discussed to provide a greater understanding of the target population and existing healthcare disparities.

Substance abuse is defined as “the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs” (World Health Organization, 2019, para. 1). Substance abuse has become a widespread problem, in part due to the opioid crisis. The over prescription of opioids led to astonishing rates of misuse (21% to 29%) and the development of opioid use disorder (8% to 12%) in the population (National Institute on Drug Abuse [NIDA], 2019). Despite the increasing demand for substance abuse treatment, less than 1% are able to receive treatment (NIDA, 2015). Peak drug usage occurs in the late teens to early twenties (NIDA, 2015). Illicit drug use is higher among males when compared with females, but the gap is decreasing (National Center for Health Statistics [NCHS], 2017). When identified by race, substance use rates are highest among White individuals, followed by those identified as two or more races and then by those who identified as American Indian or Alaskan Native (NCHS, 2017).



Demographic information regarding the geographical setting were explored to provide a greater understanding of substance abuse in the context of the greater community as a whole. Granite Wellness Centers is based in Grass Valley, one of three larger areas that comprise Nevada County. There are approximately 100,000 residents countywide (Nevada County Public Health Department, 2016). The median age of the population is 48.5 years, and the largest ethnic group is Hispanic at 9% (Nevada County Public Health Department, 2016). In 2014, approximately 20% of adults and 8% of children were uninsured (Robert Wood Johnson Foundation, 2015). Protective factors of the larger community include rates of normal BMI (48.4%), ranking 8th out of 57 counties in Health Factors and 11<sup>th</sup> in Health Outcomes (Robert Wood Johnson Foundation, 2015). However, important issues identified by community members involve financial stress, substance abuse, access to care, and mental health, with nearly 73% of the population noting substance abuse was an issue and 53% reporting it as a priority concern of the community. (Nevada County Public Health Department, 2016). When compared to California, Nevada County has higher rates of substance abuse, which is reflected in higher admission rates to substance abuse treatment (Shasta County Health and Human Services Agency, 2018).

### **The Problem: Unintended Pregnancy**

The United States has one of the highest rates of unintended pregnancies among industrialized nations of the world. Approximately 45% or 2.8 million pregnancies per year are unplanned among women ages 15 years to 44 years (Finer & Zolna, 2016). Rates of unintended pregnancy in women with SUD are estimated to be nearly double that of the general population at 85% (Heil et al., 2011). Overall contraceptive use is lower and fewer effective methods are preferred among women with opioid or other SUDs (Terplan, Hand, Hutchinson, Salisbury-Afshar, & Heil, 2015).

Costs related to unintended pregnancy are derived through the assumption of care through public funding. The majority (68%) of unplanned births are paid for through public insurance (Sonfield & Kost, 2015). Including prenatal care, labor and delivery, and postnatal care for the first year of life, costs are estimated at \$12,770 per pregnancy, or \$21 billion per year (Sonfield & Kost, 2015). Further medical costs may develop due to the increase in adverse maternal and fetal outcomes.

**Adverse maternal and fetal outcomes.** Unfortunately, poor maternal and fetal outcomes are associated with unplanned pregnancies. Mothers are more likely to experience a delay in receiving prenatal care, have an increased risk of depression, be exposed to physical violence while pregnant, and are less likely to breastfeed (Office of Disease Prevention and Health Promotion [ODPHP], 2014). Consequences to the neonate include low-birth weight and increased rates of birth defects (ODPHP, 2014).

Substance use during pregnancy is further associated with an increased risk for placental abruption, preterm birth, and stillbirth (Black & Day, 2016). Opioid use, in particular, is linked to a lack of prenatal care, fetal death, preterm labor, and intrauterine passage of meconium, and neonatal abstinence syndrome (Committee on Obstetric Practice & American Society of Addiction Medicine, 2017). Neonatal abstinence syndrome refers to a multisystem disturbance in neonates experienced as a result of chronic opioid exposure in utero and withdrawal at birth associated with irritability, poor feeding, and a high-pitch cry (Committee on Obstetric Practice & American Society of Addiction Medicine, 2017). Women with opioid use disorder are more likely to suffer from mental health conditions, experience poor nutrition, and to use other substances while pregnant (Committee on Obstetric Practice & American Society of Addiction Medicine, 2017).

**Disparities among women.** Unintended pregnancy is more common among certain groups of women. Age, relationship status, ethnicity, low income, and low education levels are noted to be factors and are addressed under the Healthy People 2020 goal to “improve pregnancy planning and spacing, and prevent unintended pregnancy” (ODPHP, 2014, para. 1). Barriers to access are more likely among the same groups of women, in addition to those who are uninsured (ODPHP, 2014).

**Contraceptive barriers.** Barriers to use of family planning services are multifactorial. Cost of service, limited access to publicly-funded services or insurance coverage, lack of awareness, transportation, clinic location, and hours are just a few noted difficulties in obtaining care (ODPHP, 2014). Access is one of the primary barriers noted to affect a woman’s ability to obtain contraceptive services. Insurance type and the number of visits required are important issues to consider in offering an intrauterine device (IUD). In a retrospective analysis, fewer women with Medicaid, when compared with women who had private insurance, received a long-acting reversible contraception (LARC) method in a clinic that required two visits for insertion (Higgins, Dougherty, Badger, & Heil, 2018). It was also noted that women with Medicaid were more likely to become pregnant in the year following the request for LARC (Higgins et al., 2018).

Women with SUD have unique barriers to contraceptive use that the general population may not experience, such as a past history of sexual abuse, fear of losing their existing custodial relationship as parents, and embarrassment regarding their substance use (Black & Day, 2016). Interestingly, one in four women in substance use treatment reported difficulty accessing healthcare providers, despite having consistent access to healthcare services, and reported they would utilize family planning services if offered at their treatment program (Terplan, Lawental,

Connah, & Martin, 2016). The perceived lack of access to healthcare services, more specifically family planning services, may be overcome through a formal policy change for service integration at addiction treatment centers.

Patient knowledge, or lack of knowledge, in LARC options is another potential barrier to women with an SUD. In a survey of women receiving medication-assisted treatment, 83% reported they were unlikely to use an IUD due to unspecified reasons and 69% due to concerns regarding side effects. These women most commonly reported very little knowledge about LARCs (Matusiewicz, Melbostad, & Heil, 2017). These findings suggest that the population may benefit from further contraception education, with the potential to influence high rates of disinterest.

### **Long-Acting Reversible Contraception**

Long-acting reversible contraception is a category of birth control methods inclusive of implantable and intrauterine devices. The subdermal implant and IUD are considered more effective than all other reversible forms of contraception, such as condoms, the pill, patch, rings, and the shot. Failure rates are less than 1% for the LARC methods (Office of Population Affairs, 2019). Higher rates of continuation and user satisfaction have been demonstrated with LARC devices (Luchowski et al., 2014).

**Safety and efficacy.** Historically, there was concern regarding the safety and appropriateness of IUD use in various groups of women. The safety of IUDs has been repeatedly demonstrated in most women, with broadening indications for appropriateness due to proven safety and efficacy. Age at the time of insertion, parity, and sexually transmitted infection (STI) risk have been thoroughly evaluated in recent literature.

Adolescent and younger women have traditionally failed to be recognized by providers as eligible candidates for an IUD. However, there have been no demonstrated differences among younger and older women in terms of adverse outcomes, including pregnancy, perforation, infection, and heavy bleeding (Jatlaoui, Riley, & Curtis, 2017). Women 25 years or younger have exhibited higher rates of expulsion, particularly with the copper (Cu) IUD (Jatlaoui et al., 2017). This is an important consideration for healthcare providers when offering counseling and education to younger women who request a Cu-IUD, but is not a contraindication to use.

Another safety concern regarding IUDs is the risk of genital tract infections, potentially limiting the appropriateness of LARC methods in younger women and those at high risk for STIs. Recent research has shown that in women with STI risk factors or with an asymptomatic chlamydial or gonorrheal infection at the time of IUD placement were found to have no increased risk of developing pelvic inflammatory disease when compared to other contraceptive methods (Jatlaoui, Simmons, & Curtis, 2016). Women with SUD often have several risk factors for STI, including multiple sexual partners, unprotected sex, intravenous drug use, age, or a history of previous genital tract infection. This should not preclude these women as appropriate candidates for an IUD. Chlamydia and gonorrheal testing at the time of insertion is appropriate in those with risk factors for STIs, so that prompt treatment may occur with the IUD in place.

Another subgroup of women who were not conventionally identified as candidates for IUDs were women who had not previously given birth. Yet, nulliparous women have not exhibited differences in rates of infection or expulsion when compared with parous women following IUD insertion (Foran, Butcher, Kovacs, Bateson, O'Connor, 2018). However, higher rates of insertion failure and moderate to severe pain have been noted among women who have not given birth (Foran et al., 2018). This is another important consideration for healthcare

providers to consider in contraceptive counseling and during insertion appointments. Higher levels of pain and potential insertion problems may be anticipated in women without children, but these are still rare complications.

### **Best Practice Recommendations**

The American College of Obstetrics and Gynecology (ACOG, 2017), in Practice Bulletin No. 186, stated that LARC methods should be routinely recommended as a first-line contraceptive method to women due to demonstrated efficacy and safety. Women who are nulliparous, adolescent, or considered to be of high risk for STIs are included in the LARC recommendation (ACOG, 2017). The ACOG also recommends that women at high risk for STIs should undergo STI testing, but that insertion should not be delayed for test results.

The National Institute of Health and Care Excellence (NICE, 2019) revised their clinical guidelines in 2019. They detail that even with use of a LARC method as short as 12 months, it is still more cost effective than oral contraceptives. The guideline aims to increase uptake of LARC methods through contraceptive counseling and education. In the recommendation, it is noted that increasing the utilization of LARC reduces the rate of unintended pregnancies (NICE, 2019).

The Centers for Disease Control and Prevention (CDC, 2014) report “Providing Quality Family Planning Services” provides evidence-based recommendations regarding contraceptive services. Recommendations include contraceptive counseling that provides information regarding a broad range of birth control options and incorporates efficacy rates. The report advises that substance use may be a factor in correct and consistent birth control use and should be considered by the provider (CDC, 2014). Recommended strategies for providing contraception include keeping different methods available on site, so they may be offered at the time of visit, and the provider is reasonably certain that the woman is not pregnant (CDC, 2014).

However, it is also noted that even if the provider cannot be reasonably certain, the benefits of initiating contraception likely outweigh the risks (CDC, 2014). Some examples of criteria for reasonable certainty include it has been less than or equal to seven days after the start of early menses, has not had sexual intercourse since the start of last menses, or has correctly and consistently been using contraception (CDC, 2014).

The American Academy of Pediatrics (AAP, 2014) issued recommendations for contraceptive use in the adolescent population. The AAP recommends contraceptive counseling based on efficacy rates, with LARC methods considered first-line in adolescents. AAP also highlights the importance of being aware of state and federal laws regarding the disclosure of confidential health information for minors. In the State of California, minors 12 years of age and older may consent to birth control, except sterilization, without parental consent under the California Family Code § 6925 (National Center for Youth Law, 2003).

### **Available Knowledge**

#### **Contraceptive Counseling**

Typically, contraceptive counseling and services occur within the setting of obstetrics and gynecology departments, family planning clinics, primary care, or sexual health clinics. There continues to be poor utilization of highly effective methods of birth control, known as LARC, among all women, and rates of unintended pregnancy remain high among women in the United States. This public healthcare issue has been recognized by the Office of Disease Prevention and Health Promotion and incorporated into the Healthy People 2020 initiatives. Increasing the utilization of long-acting contraceptive methods has been the focus of multiple evidence-based guidelines, including ACOG nationally and NICE internationally. However, according to the NCHS (2019), use of LARC methods among women ages 19 to 44 has only slightly increased,

from 8% to 11.3% since 2011, and continues to remain low. Effective contraceptive counseling has been proposed to improve LARC uptake among women of reproductive age. The effectiveness of contraceptive counseling on utilization and continuation of LARC is evaluated in the following literature review to improve utilization of LARC methods and to decrease the rate of unintended pregnancy among women who are at risk.

### **PICO Question**

The population, intervention, comparison, and outcome question guiding this project is: In women, how does implementation of comprehensive contraceptive counseling, compared with standard care, affect rates of utilization and continuation of LARC methods?

### **Literature Review**

**Search process.** A comprehensive search of the available literature was performed using the databases Cochrane, CINAHL, and PubMed. Search terms included contraception or contraceptive, counseling, women, long-acting reversible contraception or LARC, intrauterine device or IUD. Limits were placed to identify the most recent and relevant literature available. Only articles published between 2013 and 2018, including women of reproductive age, peer-reviewed, and published in the English language were reviewed. Articles including the male gender, with a sole focus on adolescents, immediately post-partum women, or post-menopausal women were excluded. Initial yield was 37 articles. After articles were reviewed for applicability and duplicates, 13 remained. The applicable articles were then evaluated with the Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool and prioritized by quality of evidence (Dang & Dearholt, 2017). Lastly, articles selected were organized in a summary table (see Appendix A).



**LARC uptake.** A landmark study, known as the Contraception CHOICE Project, examined the effect of reducing barriers to LARC methods, with a larger goal of reducing unintended pregnancies (Birgisson, Zhao, Secura, Madden & Peipert, 2015). Over 9,000 women of reproductive age received tiered contraceptive counseling to increase their knowledge and awareness of LARC methods and were then provided free contraception of their choosing. When barriers, including education, cost, and access, were reduced, 75% of women selected a LARC option (Birgisson et al., 2015). Interestingly, the authors also found that women who selected a LARC were more likely to report continuation at 12 and 24 months than those who had selected other methods (87% versus 57%; 77% versus 44%, respectively). Birgisson et al. (2015) demonstrated that women prefer long-acting contraception and are more likely to continue use than with other non-LARC methods when provided contraception counseling with barrier reduction.

After implementing a standardized provider training, Gibbs et al. (2016) explored the effect of contraception counseling among nulliparous and adolescent women. A total of 1,500 young women ages 18 years to 25 years were enrolled in either an intervention or a control clinic in a cluster randomized trial, with 12-month follow-up. Among the intervention group, women were more likely to receive contraceptive counseling and were nearly twice as likely to select a LARC than the control group (Gibbs et al., 2016). Notable findings included that nulliparous women were less likely to receive contraceptive counseling from healthcare providers (adjusted odds ratio [aOR]=.57; 95% confidence interval [CI]: .42-.79) or select a LARC (aOR=.53; 95% CI: .37-.75) than women who had given birth (Gibbs et al., 2016). However, when older adolescents were compared with young adult women, they had similar rates of counseling (aOR=.85; 95% CI: .63-1.15), LARC selection (aOR=.86; 95% CI: .64-1.17), and utilization

(adjusted hazard ratio [aHR]=.94; 95% CI: .69-1.27). Gibbs et al.'s findings highlight the effectiveness of contraceptive counseling on LARC selection among young women. However, the results also suggest that parity may influence a provider's engagement in contraceptive counseling regarding LARC methods.

Harper et al. (2015) evaluated the influence of evidence-based training for providers regarding counseling and IUD insertion on LARC uptake. The cluster randomized trial was performed among 40 clinics throughout the United States and included 1,500 enrolled women ages 18 years to 25 years. Provider training at the intervention clinics included method knowledge, counseling, and placement, while control clinics received no training. In the intervention group, 71% of women reported their provider discussed LARC, compared to only 39% in the control group (Harper et al., 2015). Long-acting contraception was selected by 27.9% of women in the intervention group, compared with 16.8% in the control group (Harper et al., 2015). Again, the results of this study support effective contraceptive counseling on increased LARC uptake.

**Continuation rates.** Contraceptive counseling has also been suggested to influence rates of IUD continuation. Reasons for discontinuation of an IUD include irregular menstrual bleeding, cramping and pelvic pain, expulsion, systemic effects, or desired pregnancy. Discontinuation rates were evaluated through the Contraceptive CHOICE Project. Hormonal IUDs were noted to have 7.3% discontinuation within the first six months, compared with 8.0% for the Cu-IUD (Grunloh, Casner, Secura, Peipert, & Madden, 2013).

Raifman, Barar, and Foster (2017) investigated the effect of counseling regarding IUD self-removability on IUD uptake, satisfaction, and continuation. The six-month study was divided in two phases. During the first three months, the counselor provided standard

contraceptive counseling, with the addition of IUD self-removal counseling during the last three months. Women who selected an IUD were then compared among the control and intervention group for differences in the previously mentioned outcome variables. There were no significant differences in IUD uptake, satisfaction, or discontinuation rates among women who had received counseling that included self-removal compared with those who had not received this counseling (Raifman et al., 2017). Yet, knowledge of self-removability was high prior to intervention in both groups (27% control, 43% intervention). An additional finding was that one-third of women who had considered IUD removal reported barriers to removal, such as provider discouragement and appointment availability (Raifman et al., 2017). Self-removal is an important topic to consider in contraceptive counseling, especially when a woman expresses concern over contraceptive control or barriers to removal.

While satisfaction with LARC methods is higher than other methods of birth control, with comparatively high rates of continuation, the role of intensive contraceptive counseling on discontinuation rates was undetermined. Intensive and non-intensive counseling were evaluated for effect on discontinuation rates of three LARCs due to bleeding problems (Modesto, Bahamondes, & Bahamondes, 2014). Participants included 297 women who had received either a hormonal IUD, non-hormonal IUD, or implant. No significant differences were seen in discontinuation rates due to bleeding disturbances in women who had received intensive counseling compared with standard counseling (Modesto et al., 2014). Premature discontinuation of an IUD may lead a woman to choose a less effective form of birth control and increase her risk for unintended pregnancy. Although intensive versus standard counseling did not reduce the already low rates of discontinuation attributed to bleeding disturbances, counseling about what to expect following LARC initiation is an important strategy to prevent premature discontinuation.

## Rationale

### Conceptual Framework

The conceptual framework guiding this project is the Clinical-Community Relationships Evaluation Roadmap. Patients, clinics/clinicians, and community resources, and their interplay in delivering clinical preventative services, are at the center of this framework (Agency for Healthcare Research and Quality [AHRQ], 2013). There are three didactic relationships, which are the clinic/clinician-patient relationship, clinic/clinician-community resource relationship, and patient-community resource relationship (AHRQ, 2013). The purpose of the roadmap is to design and implement relationships, with the goal of providing clinical preventative services specifically through the clinical-community relationship (AHRQ, 2013). The roadmap was developed initially for primary care clinics to expand their linkages with community resources in providing preventative services, but it is applicable in a broader context, as well (AHRQ, 2013).

The clinic/clinician provides accessibility of reproductive services to appropriately identified patients. As a result, barriers to access are mitigated. The interrelationship between clinician and patient is influenced by trust, shared decision-making, and support of patient self-management (AHRQ, 2013). There are currently three healthcare providers on site, including a medical doctor, nurse practitioner, and physician's assistant, who are well-equipped to provide contraceptive counseling and services. Both the clinic stakeholders and clinicians recognize the need for women with SUD to have increased access to family planning services. Expanding on the currently offered initial screening of contraception use, the addition of contraceptive counseling and same-day LARC services act as both a valuable community resource and a clinical preventative service.

Patients in the roadmap are the clients admitted for residential or outpatient treatment. Clients requesting medication-assisted or residential treatment require medical evaluation and clearance in the on-site clinic, providing the prime opportunity for the incorporation of family planning services. Patient perceptions and attitudes impact contraceptive preference and attitudes, with the potential to affect the patient-community resource relationship (Matusiewicz et al., 2017). Patient barriers, including limited or incorrect knowledge, are addressed through counseling that is effective, efficacy-centered, and respectful of patient autonomy.

The relationship between clinic and community resource is traditionally affected by a referral process, collaboration among providers, and feedback mechanisms between the two site entities (AHRQ, 2013). Due to the incorporation of the community resource within the clinic, referral processes and collaboration between external entities for the services are limited. The framework was utilized to develop a project intervention to enhance the delivery of a clinical preventative resource by the existing providers on site due to the rural location and lack of outside community resources.

The project intervention included a LARC training workshop for providers, with evidence-based clinical practice recommendations on LARC methods and a skills portion for IUD and implant procedures. The aim of the intervention was to enhance the providers' knowledge and procedural skills for LARC counseling and initiation in preparation for offering services on site. Provider training was selected to target the relationship between provider and client to increase uptake of LARC utilization through contraceptive counseling. Multiple studies have demonstrated LARC barrier reduction, including contraceptive counseling, to increase LARC uptake among women with underutilization (Birgisson et al., 2015; Gibbs et al., 2016; Harper et al., 2015).

The integration of contraceptive services within an addiction medicine center highlights the need for effective relationships among patients, clinic/clinicians, and community resources in addressing high rates of unintended pregnancy. This DNP project utilized the Clinical-Community Relationships Evaluation Roadmap to identify and address a crucial clinical preventative service lacking for women with SUD. Barriers to patients and providers were considered in the design of this project to improve the key didactic relationships among the clinic/clinician, community resource, and the patient. An intervention to improve the key didactic relationships was implemented through a LARC provider training workshop to enhance provider knowledge and skill in providing contraceptive services. Outcome evaluation was assessed through a pre/post assessment on provider confidence and readiness for providing contraceptive services at the clinic. With increased confidence in LARC knowledge and procedural skill, the providers will be adequately prepared to enhance utilization of LARC methods on site.

### **AIM Statement**

The primary aim of this quality improvement project is to reduce rates of unintended pregnancy among women with SUD through the development of a pilot project to integrate contraceptive services in addiction medicine treatment. Emphasis was placed on effective contraceptive counseling to increase uptake of highly-effective contraceptive methods.

### **Project Goals**

1. Research and design a pilot program for the delivery of contraceptive counseling and LARC services at Granite Wellness Centers.
2. Plan for a future pilot program rollout of contraceptive services at Granite Wellness Centers.

**Project Objectives**

1. Conduct a feasibility analysis, to include an evaluation of the current literature regarding contraceptive counseling methods on LARC uptake and continuation; perform a site evaluation to determine resource readiness; conduct a women's focus group to assess current attitudes, beliefs, and needs regarding contraception; and identify two possible funding sources for pilot initiation.
2. Design and provide an interdisciplinary LARC training workshop for the medical staff at Granite Wellness Centers to enhance readiness for service integration.
3. Present all findings of the feasibility study to the board members at Granite Wellness Centers. The presentation will include recommendations for contraceptive services derived from the feasibility analysis, a proposed timeline for implementation when funding is obtained, and a financial analysis including a proposed budget and return on investment.

### Section III: Methods

#### Context

There is an unmet need to enhance access of contraceptive services to women with an SUD. Offering contraceptive services concurrently with substance use treatment, with same-day services, provides the greatest opportunity to eliminate potential barriers to contraceptive use. Ultimately, birth control methods, known as LARC, are ideal for this patient population due to the highest rates of efficacy among all birth control options.

The selected site for this DNP project is Granite Wellness Centers, a non-profit in the city of Grass Valley. The clinic is located in a rural area of northern California. The stated mission includes, “to provide a full spectrum of programs focused on reducing the social, health, and financial impact on our families and children from all types of drug abuse” (Granite Wellness Centers, 2019, para. 2). The site provides comprehensive addiction treatment services, including residential, outpatient, and medication-assisted treatment. Presently, contraceptive services are not offered on site, and patients are referred out to their primary care provider or other community resource for healthcare needs outside of substance use treatment (see Appendix B. Gap Analysis).

While contraceptive services are largely covered by private and public insurance providers, the clinic site is not currently contracted for billing and reimbursement for medical services outside of substance use treatment. The clinic was actively in the process of expanding services provided on campus. Therefore, it was mutually agreed upon by the site stakeholders that priority should first be placed on conducting a feasibility analysis, and a letter of support was issued by the organization (see Appendix C). The goal of the feasibility evaluation was to determine readiness for the integration of LARC services in preparation for a future pilot project,



when services and related costs are covered or a funding source is available. In addition to the feasibility analysis, this DNP student designed and executed an interdisciplinary LARC training workshop. The training was conducted in part by IUD and implant device representatives to provide hands-on skills training for the medical providers and education about their respective products. The pharmaceutical representatives provided their time and training at no cost.

### **GANTT**

The timeline of this DNP project is detailed through the use of a GANTT chart (see Appendix D). This DNP project occurred over an 11-month period from February 2019 until December of 2019. Following the conceptual phase and project approval was the design phase. Details of the design phase included design of the surveys for the current client focus group, provider training pre- and post-engagement assessment, and staff readiness for change survey, which occurred in August and September of 2019. The women's focus group and site assessment were then conducted, while funding sources and other resources were explored. The main intervention included the two-part provider LARC workshop offered in November and December of 2019. A final presentation was prepared and delivered to the board members at Granite Wellness Centers, including a summary of findings and recommendations for a pilot project. Lastly, the project evaluation was closed with the final report preparation. Further project details were organized in a work breakdown structure and communication matrix (see Appendix E and Appendix F).

### **Strengths, Weaknesses, Opportunities, Threats**

The strengths, weaknesses, opportunities, and threats of this project were acknowledged to aid in the identification of potential external and internal influences (see Appendix G).

**Strengths.** The internal strengths of this project include the on-site medical clinic with patient rooms. The clinic has two patient rooms available for providers to offer contraceptive counseling and services during medical appointments. There are three providers on site with prior experience in IUD insertion. Also, the mission of Granite Wellness Centers is in line with the aim of this project to reduce healthcare disparities among women with SUD. Lastly, the staff are regularly engaged in process improvement meetings and aware of organizational change.

**Weaknesses.** There are also internal weaknesses to this project. An initial pilot project requires a funding source or internal medical billing changes at the clinic, which involves continued communication with the billing department and a search for potential funding opportunities. Also, co-occurring service expansion places additional strain on the clinic and its resources, with the potential to halt pilot initiation until the other service expansions are completed. Potential weaknesses that will require continued evaluation are the upfront supply cost and time factors related to same-day contraceptive initiation. The healthcare providers are responsible for all residential admissions, overseeing group medication-assisted treatment meetings and requested appointments from both residential and medication-assisted treatment clients. Issues and appointments related to substance use will be prioritized and may affect the ability to deliver LARC services when requested.

**Opportunities.** This quality improvement project provides anticipated external benefit, as well. The first potential opportunity is the ability to reduce rates of unintended pregnancy among women seeking substance use treatment. Adverse maternal and fetal outcomes associated with unplanned pregnancy will also be reduced. There is an additional opportunity for women to receive comprehensive, evidence-based contraceptive counseling. Women utilizing LARC methods have higher satisfaction with method choice and greater control over family planning

due to the highest efficacy rates. With success of the pilot initiation of integrated services at the Grass Valley campus, expanded services may be added to other campuses in northern California.

**Threats.** The potential inability to obtain external reimbursement for services rendered is the largest threat, as the clinic is not currently set up to bill for medical services outside of substance use treatment. If medical reimbursement is obtained, another external threat is the repeal of the Affordable Care Act. The Affordable Care Act is responsible for expanding coverage of contraceptive services to patients without cost-sharing. The cost of an IUD alone is substantial and can range from \$400 to \$700, which would be prohibitive to patients without coverage. Another external threat is the development of other clinics or sites offering competing services, with the potential to reduce client acquisition at the site.

### **Cost-Benefit Analysis**

The proposed budget for the pilot rollout is detailed here for a three-month estimate. Operational expenses of this project include employee salary and benefits, medical supply costs, and laboratory testing supplies and fees. Contraceptive services are largely reimbursable through changes made by the Affordable Care Act, ensuring coverage for contraceptive services without cost-sharing to individuals. Supply costs for IUD insertion include a speculum, lubricant, tenaculum, antiseptic, uterine sound, scissors, sterile gloves, ring forceps, gauze, cotton swabs, chucks, sanitary napkins, and sterile drapes (University of California San Francisco, Bixby Center for Global Reproductive Health [UCSF], 2015). The average IUD cost is \$629.75 when purchased from the manufacturer and disposable insertion kit price is \$44.21 (UCSF, 2015). Training time (2.5 hours to 3 hours) and provider time to complete screening, education, documentation, insertion, and follow-up are estimated to be at a minimum 60 minutes per patient (\$51.15 hourly). Laboratory testing for basic STI screening is \$55 and \$1.60 per test for urine

pregnancy testing. Performing pelvic examination and IUD insertion also requires specialized equipment. Fixed asset purchases include stirrups (\$1,395) and an illumination system (\$299). Total costs expected over a three-month pilot project, including the operational and fixed asset costs for 15 patients, are \$17,390. However, as previously mentioned, these services are reimbursable. Reimbursement may be obtained for the IUD and other supply costs, insertion, surveillance, and an evaluation and management visit for time spent counseling patients (UCSF, 2015).

Due to the high rate and commensurately high costs associated with unintended pregnancy, there has been a large national initiative to improve the reimbursement rates of LARC methods. The majority of clients receiving care at Granite Wellness Centers have state-funded insurance through the Medi-Cal Program. Reimbursement rates currently listed on the Department of Healthcare Services(2019) site are itemized as \$166.20 for insertion, \$808.50 for the Cu-IUD and \$953.51 for the five-year levonorgestrel-containing IUD, a \$12 dispensing fee, \$57.20 for contraceptive counseling encounter and follow-up encounter, \$31.17 for each chlamydia and gonorrhea testing, and \$2.80 for a urine pregnancy test.

### **Return on Investment**

A return on investment (ROI) is traditionally calculated by dividing the net projected benefit by total program cost and then multiplying by 100. Upon pilot initiation, finalized program costs can be appreciated and included in the ultimate calculations. Projected benefit with initiation of contraceptive services is considered in the avoidance of unintended pregnancy. Current cost avoidance estimates, including prenatal care, birth, and the first year of life care, are \$12,770 (Sonfeld & Kost, 2015). Additional costs, including medical treatment for unintended pregnancy-related adverse outcomes in women with SUD, should also be considered. The

average cost for the Cu-IUD and hormonal IUDs are \$1,136.84 and \$995.02, respectively. For each dollar spent on IUD services, there is an expected \$5 cost savings for the Cu-IUD and \$4.89 for the hormonal IUD (Foster et al., 2013). Therefore, for each woman who receives an IUD for contraception, there is an expected cost savings of \$5,330. Cost savings can be achieved with the prevention of one unintended pregnancy (see Appendix H).

## **Interventions**

### **Feasibility Analysis**

A feasibility analysis was conducted to determine site preparedness for a contraceptive service integration pilot project. Components of the feasibility analysis included a site survey to develop a comprehensive inventory list and identification of additional supplies required, a women's focus group exploring current attitudes to contraception, staff readiness for change survey, and identification of possible funding sources. In preparation for the anticipated pilot project, necessary resource documents were identified and used with permission from the Reproductive Health Access Project to cover the establishment of new policies and procedures (see Appendix I), consent forms, billing resources, documentation aids, supply lists, and patient education materials (see Appendix J).

**Site survey.** The site survey was performed utilizing the site readiness checklist (Reproductive Health Access Project, n.d.; see Appendix K). Issues and requirements assessed included considerations for the facility and administrative and clinical areas. The site presently met the facility requirements for storage space for devices, sterile equipment and non-sterile equipment, and sterilization of equipment using an autoclave. It was noted that a policy and procedure was not currently established for the use of the autoclave, but one was being developed. Administrative considerations included chart note templates for IUD insertion and

removal, up-to-date billing and coding codes, system appointment for scheduling, and system for ordering and tracking supplies. The site had two active medical supply vendors with the capability to order LARC supplies. Clinical considerations met were the establishment of an IUD protocol and procedure, consent forms, patient education materials, patient aftercare information, and malpractice coverage. Also, a patient satisfaction survey was developed by this DNP student to aid with quality assurance when the pilot is initiated (see Appendix L).

There were some requirements not met or completed at the time of site survey. The site has two exam rooms with exam tables. Unfortunately, the exam tables are not height adjustable and do not have foot holders contained within them to allow lithotomy positioning. However, the clinic had budgeted to purchase a new exam table and were working towards obtaining one with the aforementioned requirements. Also, the site did not have IUD insertion and removal supplies on site. A supplies list was obtained as a reference guide for pilot initiation. As previously mentioned, billing practices were not established for medical services.

**Women's focus group.** Current female clients of Granite Wellness Centers were included in a focus group on contraception and participated in a survey of current attitudes, knowledge, and concerns regarding contraception. This DNP student provided a comprehensive, efficacy-based, contraceptive educational session, with time allowed for additional questions. Each birth control method was briefly reviewed, starting with LARC methods and ending with the least effective methods. Side effects, adverse effects, mechanism of action, and efficacy were discussed. A paper survey was administered to each participant to collect additional information, including barriers to contraception, concerns regarding birth control, existing knowledge, and interests and concerns regarding the addition of family planning services within substance use treatment (see Appendix M).

**Staff readiness.** Staff buy-in is a vital component to organizational change. Therefore, an intervention to assess staff readiness for the integration of contraceptive services on site was utilized to make appropriate recommendations to the board committee. A staff survey was designed to address the five major organizational components of change, including the need for change, leadership and management, attitudes to change, communication, and preparation for change (see Appendix N).

**Funding sources.** Funding sources were explored through a grant database search. Grants were evaluated for applicability and appropriateness of the pilot project to meet the listed grant criteria. Grant organizers were contacted when additional information was required. Contraceptive services met the criteria of multiple open grants; however, they did not have an open application cycle at the time the research was conducted. Also, the process for medical contracting was actively pursued by the organization. The practice manager submitted a contractual application in September 2019. In anticipation of future medical reimbursement, billing and reimbursement were further investigated through a cost-benefit analysis and estimated ROI.

### **LARC Interdisciplinary Training Workshop**

A staff training course was created to provide the healthcare providers and medical staff a review of current best practice recommendations regarding LARC utilization, skills on IUD insertion with vaginal simulators, contraceptive counseling, and Nexplanon training and certification. This DNP student coordinated with the representatives of Bayer, CooperSurgical, and Nexplanon to provide a hands-on component to the workshop for skill practice and development. The training was provided on two separate dates due to clinical providers' time constraints and the availability of the representatives.

The first training date was provided by this DNP student and a Bayer representative. The Bayer representative included an overview of their available levonorgestrel-containing devices (i.e., Mirena, Skyla, and Kyleena), with a combined skills portion on vaginal simulators for IUD insertion. The Bayer representative provided patient clinical education resources, noted the ability to stock devices without upfront costs to the clinic, and the ability to obtain replacement devices without additional cost if insertion failure occurs. This student presented evidence-based practice recommendations regarding LARC use, safety and efficacy, and contraceptive counseling through a PowerPoint presentation (see Appendix O). This DNP student also provided a folder containing applicable resources for each attendant that included a billing codes tool, birth control efficacy chart, IUD insertion and removal note templates, IUD consent form, an IUD patient take-home sheet, and copy of presentation slides (see Appendix P). All medical staff discussed and identified their role in enhancing contraceptive awareness through contraceptive counseling. The nursing staff recognized opportunities to provide and reinforce patient teaching within the residential treatment center. Additional topics discussed were consequences of unintended pregnancy and barriers to contraceptive use in the general population, as well as in women with SUD. A pre- and post-test were utilized to assess provider confidence and readiness in providing contraceptive counseling and IUD insertion with the Bayer products (see Appendix Q).

The second training date was conducted by a representative from Nexplanon on the subdermal implant. The Nexplanon representative offered a two-hour training course regarding the subdermal implant and removal procedure. Upon completion, the providers were given a certification for Nexplanon insertion and removal. A pre- and post-test were utilized to assess provider confidence and readiness in providing the Nexplanon device. Upon completion of the



training, a training evaluation form was administered to each participant to gather information regarding participant satisfaction and training quality and relevance (see Appendix R). Practice kits, including an arm simulator and two implant injectors, were also given to the healthcare providers to keep for additional practice following the training.

### **Presentation**

The project culminated with a presentation to the board members at Granite Wellness Centers. The final presentation included recommendations for contraceptive services derived from the feasibility analysis, a proposed timeline for project implementation when funding is obtained or billing practices are established, and a financial analysis including a proposed budget and ROI. Data obtained from the women's focus group, staff readiness for change survey, and provider training were included in the project recommendations.

### **Study of the Methods**

The long-term goal of this project is to prevent unintended pregnancy through the addition of contraceptive services within substance use treatment, emphasizing LARC methods. However, due to the current inability to bill for medical reimbursement at the clinic location, short-term outcomes were established to prepare the clinic for future pilot initiation. The short-term goals established to evaluate this quality improvement project were to conduct a feasibility analysis of the site, develop an interdisciplinary LARC training workshop, and to present findings of the feasibility analysis to the board committee in preparation for future pilot initiation. Surveys were administered to the women at the focus group, providers pre/post the LARC training workshop, and medical staff to determine readiness for change. Survey data were collected and analyzed with Microsoft Excel analysis tools and Survey Monkey. All data

collected were used to summarize findings and make appropriate recommendations for pilot program initiation to the board members.

### **Measures and Methods of Evaluation**

For this project, outcome measures were completing the components of the feasibility analysis, LARC interdisciplinary training workshop, and final presentation with recommendations for pilot project.

The feasibility analysis included a literature review, site assessment, women's focus group, staff readiness for change survey, and funding source identification. A survey of the clients attending the women's focus group was administered to gather more information from the current clients regarding contraceptive use, attitudes, and knowledge to include in the board committee presentation. The women's focus group survey included three open-ended questions and four multiple choice items. Questions included: 1. What barriers do you experience in obtaining birth control/contraceptive services? 2. What are your concerns regarding birth control? 3. What community organizations are you aware of that provide free/low cost birth control? 4. What resources regarding contraceptive care would benefit you the most? 5. Would you utilize birth control if offered at no cost while receiving treatment? 6. Have you ever received comprehensive contraceptive counseling regarding all birth control options available to you? 7. Which birth control options would you be most interested in receiving?

The staff readiness for change survey was administered to all medical staff following the LARC training workshop. Readiness was assessed through agreement in responses to 16 statements corresponding to different areas of organization change. Likert-type responses ranged from 1 for *strongly disagree* to 5 for *strongly agree*. Statements were as follows: 1. There is need for organizational change to expand services to include contraceptive services. 2. I am aware of

the reasons why change is needed within the organization. 3. Expanding the services provided to the clients is appropriate and achievable. 4. I am aware that the organization is considering expanding services offered to include contraceptive services. 5. I understand the need to include contraceptive services in the services offered in all clinical visits including intake appointments and follow-ups. 6. Management is committed to providing support to staff during periods of change. 7. I am able to discuss changes with leadership and management. 8. Providing contraceptive services will benefit the organization. 9. I am supportive of the integration of contraceptive services into clinic appointments. 10. I know how my role can help make the expanded services successful. 11. There is adequate consultation with staff when change occurs. 12. Staff communication is reliable and well-timed. 13. I am adequately trained to offer contraceptive services within my role and scope of practice. 14. I have the resources I need to provide contraceptive services within my role. 15. I am confident in my ability to provide contraceptive services to all clientele. 16. Overall, I believe contraceptive services will be advantageous for the clientele participating in substance use treatment and the larger community.

The interdisciplinary LARC training workshop was designed to enhance readiness and confidence for providing contraceptive counseling and LARC procedures among medical staff. The outcome of the LARC training workshop was assessed through an identical pre- and post-engagement survey administered to the healthcare providers. Readiness and confidence regarding contraceptive counseling and IUD insertion were measured through an eight-item assessment, based on a 5-point Likert scale. Possible responses assessed agreement with posed confidence and readiness statements and included: *strongly agree* (5), *agree* (4), *neutral* (3), *disagree* (2), and *strongly disagree* (1). There was also a comment section included at the end of each survey to obtain additional information from participants. Outcomes for the LARC provider

workshop were evaluated based on the following statements: 1. I am comfortable providing comprehensive contraceptive counseling consistent with current practice recommendations. 2. I am confident in identifying all LARC eligible candidates. 3. I feel prepared to counsel patients about LARC effectiveness and safety. 4. I feel confident in counseling patients about LARC insertion and follow-up. 5. I feel comfortable with IUD insertion. 6. I am adequately prepared to insert an IUD. 7. I have sufficient previous experience with IUD insertion. 8. Hands-on skills training is an effective method to prepare for IUD insertion.

The outcome of the second LARC training workshop was similarly assessed through an identical pre- and post-engagement survey administered to the healthcare providers. Readiness and confidence regarding Nexplanon counseling, insertion, and removal were assessed through a four-item assessment, based on a 5-point Likert scale. Possible responses assessed agreement with posed confidence and readiness statements and ranged from *strongly agree* (5) to *strongly disagree* (1) with additional comment section at the end. Outcomes for the second LARC provider workshop were evaluated based on the following statements: 1. I feel comfortable with Nexplanon insertion and removal. 2. I am adequately prepared to provide Nexplanon counseling, insertion, and removal. 3. I have sufficient previous experience with providing the subdermal implant. 4. Hands-on skills training is an effective method to prepare for Nexplanon insertion and removal.

Methods for assuring data quality and accuracy included a post-training follow-up survey with statements about training relevance, effectiveness, satisfaction, and quality. The first section assessed satisfaction with different aspects of the training. Likert scale responses were *very satisfied* (5), *satisfied* (4), *neutral* (3), *dissatisfied* (2), and *very dissatisfied* (1). Possible Likert scale responses to posed statements regarding training content, relevance, organization, quality,

and time included: *strongly agree* (5), *agree* (4), *neutral* (3), *disagree* (2), and *strongly disagree* (1). A comments section was also available for additional information.

### Analysis

The women's focus group data were analyzed utilizing Survey Monkey. Paper surveys were disseminated to all women in attendance. The women's focus group survey responses were manually entered into SurveyMonkey for analysis. Summary statistics, including frequencies and means, were calculated. Responses to open-ended questions were ranked categorically for similarity, with subsequent ranking by frequency. *Select all that apply* formatted questions were categorized by frequency of response. Mean responses were calculated for questions with one answer selection.

For evaluation of the LARC training workshop, qualitative data were collected through a pre- and post-assessment survey for both training sessions. The Likert scale responses were numerically categorized ranging from *strongly disagree* (1) to *strongly agree* (5). The responses assessed agreement with confidence and readiness-based questions surrounding contraceptive counseling and LARC utilization. Responses were manually entered into Excel, where the mean response was calculated for each of the seven questions on the pre- and post-surveys. The mean percent change (delta  $\Delta$ ) was calculated between the pre- and post-assessment responses to measure the impact of the LARC workshop for medical providers. A post-training evaluation was administered to all staff to evaluate training content, relevance, and delivery.

The staff readiness for change survey was administered at the LARC workshop to the medical staff. The survey consisted of 16 statements, with Likert scale responses ranging from *strongly agree* (5) to *strongly disagree* (1). The responses assessed agreement with posed statements assessing different aspects of the change process as related to this quality

improvement project. Survey responses were manually entered into Excel. Summary statistics including the mean (*M*) and standard deviation (*SD*) were calculated for each statement.

### **Ethical Considerations**

The University of San Francisco DNP department determined that this project met the criteria for an evidence-based practice change project, as outlined in the DNP project checklist, and was approved as non-research (see Appendix S). The primary Jesuit value of *Men and women for and with others* is represented in this project. The project intends to expand currently offered services to women in substance use treatment. This project identified a critical healthcare disparity, with a goal to work with the current client population to reduce healthcare disparities and barriers to care.

Ethical principles considered in this project include beneficence and respect for autonomy. Beneficence refers to promoting the patient's wellbeing. The goal of this project is to help motivate patients to take control of their reproductive health and engage in contraceptive planning. There is an increased risk of poor maternal outcomes associated with unplanned pregnancies. Medical providers in addiction medicine are primed for the opportunity to address contraceptive use when contact is frequent and closely monitored. Respect for autonomy is also imperative in this project. It is essential for the client to make her own informed decision when participating in birth control selection, once provided with all available options and information. It is the provider's responsibility to provide comprehensive contraceptive counseling free from any potential bias and to respect the choice of the client.

## Section IV: Results

Qualitative data were collected through surveys disseminated at the women's focus group and LARC provider training workshop. The results from the surveys are discussed in detail here.

### Women's Focus Group

The women's focus group was a 60-minute session held in the residential treatment program building at Granite Wellness Centers in September 2019. All women in attendance were participating in inpatient substance use treatment. Only 10 of the 13 participants completed surveys, and it was noted that three of the women were post-menopausal. Regarding barriers to obtaining contraception, interestingly, six of 10 respondents did not feel they currently had any barriers, noting, "none," "N/A," and "none at this time." The most common contraception concerns were identified by participants from a *select all that apply* question, which included side effects, fertility, access, ease of use, hormones, bleeding patterns, cost, effectiveness, and other. Most commonly selected were side effects (7/10), hormones (4/10) and access (3/10). Ease of use, bleeding patterns, and cost were less frequently reported concerns. All respondents had knowledge of an existing community resource that offered contraception for free or at a reduced cost. Interestingly, the community resource identified by nine of the 10 participants was Planned Parenthood, but the nearest available clinics were approximately one hour away. When asked what resources regarding contraceptive services would be most beneficial, respondents most commonly selected STI testing (3/10) and free birth control (3/10). Nine of the 10 participants reported they would utilize birth control if offered at no cost while receiving substance use treatment. An unexpected finding was that six of the 10 women reported they had never previously received comprehensive contraceptive counseling regarding all birth control options, one respondent was unsure, while the remaining three respondents reported they had received

contraceptive counseling. Lastly, the women reported which birth control options they would be most interested in receiving from a *select all that apply* question, with the hormonal IUD, non-hormonal IUD, emergency contraception, condoms, birth control pills, Depo-Provera shot, Nexplanon (implant), and other listed. The non-hormonal IUD was selected most often (5/10), followed by condoms (3/10), hormonal IUD (2/10), and birth control pills (2/10).

### LARC Training Workshop

#### Part 1

Two providers (physician's assistant and family nurse practitioner) of the three medical providers at the site attended the LARC training workshop with hands-on skills training. Both participants had previous experience with IUD insertion. Results of the pre and post mean data are displayed in Table 1.

Table 1

#### Survey Results

Survey	S1	S2	S3	S4	S5	S6	S7	S8
Pre-Survey Mean	3.0	3.0	2.5	3.0	2.5	2.5	3.0	3.5
Post-Survey Mean	4.5	4.5	4.5	4.5	4.0	4.0	3.5	4.5
% Change	33.33	33.33	44.44	33.33	37.50	37.50	14.20	22.22

Note. S denotes survey statement number.

There was a 33.33% increase in provider comfort with providing contraceptive counseling, confidence in identifying LARC eligible candidates, and confidence in counseling clients about the LARC insertion procedure and follow-up. Statement 3 showed the greatest improvement, with a 44.44% increase in provider preparedness in providing counseling regarding LARC safety and efficacy. Both providers stated they agreed with statements of feeling comfortable and prepared for IUD insertion following training, with a 37.5% increase. Provider attitude on whether hands-on skills training was an effective method to prepare for the



procedure increased 22.22% following the training. No additional comments were given on the assessments.

## Part 2

Four providers attended the LARC training workshop with hands-on skills training. Two providers were from outside clinics and medical settings. It was noted that one attendee had previously been certified in Nexplanon insertion in 2014 and was attending the training as a training update and refresher. Results of the pre and post mean data are displayed in Table 2.

Table 2

### *Survey Results*

Survey	S1	S2	S3	S4
Pre-Survey Mean	2.0	3.5	3.0	3.75
Post-Survey Mean	4.75	4.75	4.0	5.0
% Change	57.89	26.31	25.0	25.0

*Note.* S denotes survey statement number.

The greatest increase was exhibited in provider comfortability with Nexplanon insertion and removal post training. Statement 2 reflected a 26.31% increase in provider preparedness to provide Nexplanon specific counseling, insertion, and removal. Provider attitude on whether hands-on skills training was an effective method to prepare for the procedure increased 25.0% following the training. There was similarly a 25.0% increase in agreement with the posed statement, “I have sufficient previous experience with providing the subdermal implant”. No additional comments were given on the assessments. Inferential analysis was not conducted due to limitations from the small sample sizes.

### **Readiness for Change Survey**

Ancillary medical staff attended the in-service, including the practice manager, two medical assistants, one licensed vocational nurse, and one registered nurse. Following the

training, all medical staff were administered a survey to assess readiness for change. Ratings from the staff members are displayed in Figure 1.

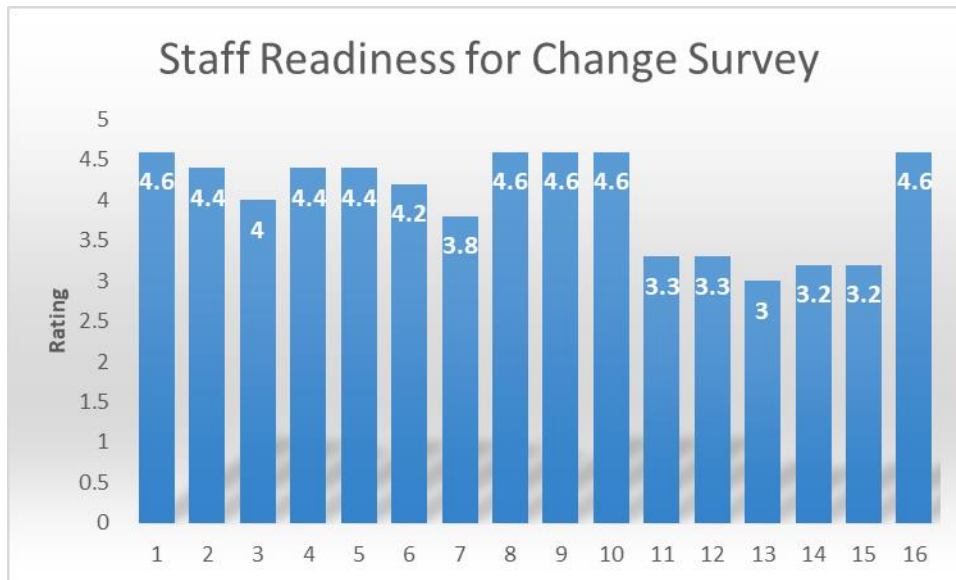


Figure 1. Staff readiness for changes results.

Statements 1, 2, 3, 4, and 5 assessed staff recognition for the need for change to integrate contraceptive services within the organization, with largely favorable responses in agreement or strong agreement. Statements 8, 9, 10 and 16 had the most favorable responses ( $M = 4.6$ ,  $SD = 0.55$ ), indicating strong agreement in the area of attitude to change and client benefit from the addition of services. Responses to Statement 7 and Statement 8 pertained to leadership and management in the change process, with responses ranging from *neutral* to *strongly agree* ( $M = 3.8$ ,  $SD = 0.84$ ;  $M = 4.6$ ,  $SD = 0.55$ , respectively). The lowest rated responses occurred in Statement 11 through Statement 15; these statements related to areas for communication and preparation for change, which averaged between *neutral* and *agree* (3.0 – 3.3). Statement 13 had the least agreement ( $M = 3.0$ ,  $SD = 0.71$ ), representing a *neutral* response to the statement, “I am adequately trained to offer contraceptive services within my role and scope of practice.” One

additional comment was provided from a respondent, stating, “Communication between staff can be improved.”

### **LARC Training Evaluation**

Four attendees completed the LARC training evaluation following the second training session. One of the providers attended both trainings. All providers rated training satisfaction as *very satisfied* regarding overall training quality, quality of instruction, training materials, and the training experience. Providers rated strong agreement with all statements regarding training organization, job applicability, instructor knowledge and preparedness, benefit and utilization of training, and appropriate training length. One additional comment stated, “Great experience”.

## Section V: Discussion

### Summary

The aim of this project was to design and prepare for a pilot project for initiation of contraceptive services at an addiction treatment center, with a larger goal of reducing rates of unintended pregnancy. Advanced practice providers (APP) in the community recovery setting are provided a prime opportunity to address reproductive health needs, to assess current barriers to effective contraceptive use, and to integrate contraceptive services within substance use treatment. The APP can identify any potential knowledge gaps and provide appropriate education regarding the available methods of birth control and their respective efficacies. Further, offering contraceptive services is within the scope of APP practice.

In preparation for anticipated service expansion, data were collected from current clients, healthcare providers, and medical staff for future pilot rollout of contraceptive services at the addiction treatment center. Key findings included feedback from current clients demonstrating the need and interest in contraceptive services, as well as the lack of prior comprehensive contraceptive counseling in the past. The most common client concerns cited regarding birth control methods were related to side effects and hormones. Regarding the healthcare providers readiness to offer contraception, respondents indicated they felt more prepared and confident to engage in contraceptive counseling that includes LARC safety and efficacy and more confident to perform IUD and Nexplanon insertion and removal procedures. Lastly, the medical staff indicated largely positive responses in terms of need for change, attitude for change, and leadership and management's role in the change process. However, the mean response was neutral, not in disagreement nor agreement, with being prepared to offer such services within their scope of practice.

### Interpretation

The expected outcomes of this project included an improvement in provider confidence and readiness with contraceptive counseling and LARC procedures following the training intervention. Research has shown that following additional training, providers have demonstrated increased efficacy-based contraceptive counseling that includes LARC methods (Birgisson et al., 2015; Gibbs et al., 2016; Harper et al., 2015). Findings of this LARC training intervention were consistent with previous research results.

Results from the client survey in the women's focus group showed a great interest and demand in the possibility of receiving contraceptive services within the substance use treatment program. Ninety percent of the women who completed surveys reported they would like to receive expanded services to include birth control services and STI testing, indicating consequences of unprotected sex is a concern. This number was higher than expected and perhaps represented the impact of the contraceptive counseling provided by this DNP student within the focus group. Approximately 50% of respondents reported interest in receiving the non-hormonal Cu-IUD, which was consistent with their most commonly reported concerns about side effects and hormones.

Additional outcomes included the completion of the feasibility analysis, with subsequent presentation to site board members. Based on the overall responses from the medical staff, there was confirmed interest in expanding services to include contraceptive services. The results from the staff readiness for change survey were largely favorable, but indicated areas for improvement within the organization, such as staff communication and further instruction on role development prior to future pilot rollout. Prior to pilot initiation, this DNP student can identify additional

training resources to prepare the ancillary medical staff with role-specific information and communication tools.

### **Limitations**

Limitations from the project intervention include the inability for providers who completed the training to immediately offer contraceptive services. With a delay from training to insertion-related procedures, provider confidence and readiness may regress. However, practice tools for insertion were obtained from the IUD representatives to keep on site to refresh skills for insertion and were given to each participant at the Nexplanon training. The product representatives also provided pocket instruction tools to review the sequence of procedural steps for IUD insertion. In addition, this DNP student created LARC training resource folders with hard copies of all information covered during the trainings.

The main barrier to implementation of a future pilot project is the current inability to bill for reimbursement of medical services at the project site. In order to overcome this barrier, regular meetings were held with the medical services coordinator and practice manager to monitor the medical reimbursement status. However, external funding resources, including grant opportunities, were recognized as a potential way to overcome this barrier. Two grant opportunities were identified by this DNP student in preparation for future pilot initiation, but were not currently accepting applications. Future monitoring of an open application cycle will be necessary to further explore grant funding. Other limitations include time availability to offer same-day contraceptive services. While there are three providers employed by the clinic, they have alternating schedules. Priority is placed on detox, follow-up visits, and medication-assisted treatment patients. Identifying a routine time and or day of availability to offer LARC specific services might be ideal to reduce the competing demands.

### Conclusions

Unintended pregnancy is a significant problem in women with SUD, with economic and health consequences. Both LARC methods have demonstrated safety and efficacy among various groups of women, including adolescents, nulliparous women, and those at high risk for STI (Foran et al., 2018; Jatlaoui, Simmons, & Curtis, 2016; Jatlaoui, Riley, & Curtis, 2017). Rates of unintended pregnancy can be greatly reduced through LARC utilization, which is considered the most effective reversible category of birth control other than abstinence. Methods for increased LARC uptake include efficacy-based contraceptive counseling and provider training (Birgisson et al., 2015; Gibbs et al., 2016; Harper et al., 2015).

Providing contraceptive services with an integrated approach, coinciding with substance use treatment, addresses barriers to access. Fragmented care and requiring multiple visits to receive LARC methods are known critical barriers to use (Higgins et al., 2018). Therefore, same-day contraceptive services further increase the likelihood of use, while reducing the likelihood of unintended pregnancy. Ultimately, routine offering of contraceptive services in substance use treatment is ideal to mitigate barriers in women with SUD. Implications for future practice are not limited to substance use treatment alone. Any healthcare practice with limited contraceptive services may benefit from additional provider training to further reduce barriers to access of contraception.

## **Section VI: Other Funding**

### **Funding**

There were no outside funding sources provided for this quality improvement project.

There are no conflicts of interest to disclose. The product representatives offered their time training at no cost.



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**Section VIII: Appendices**



**Appendix A. Evaluation Table**

Citation	Design/Method	Sample/Setting	Major Variables Defined	Data Analysis	Study Findings	Limitations
Birgisson et al. (2015)	Observational cohort study  Examined the effect of tiered contraceptive counseling on LARC uptake and continuation (with removal of barriers to access, cost and education).	9,000 women aged 14-45 years recruited through convenience sampling  St. Louis region	Intervention: Tiered contraceptive counseling provided by trained counselors based on efficacy  Contraceptive choice provided at no cost for 2-3 years  Outcomes: Contraceptive method choice and continuation	Descriptive analysis with summary statistics	75% chose a LARC method.  Higher continuation among LARC users compared with non-LARC users at 12 months (87% vs. 57%) and 24 months (77% vs 41%).	Variability among individual counselors  No comparison group  Services were provided at different sites and clinics  Contraception was provided at no cost  Generalizability

Harper et al. (2015)	Cluster-randomized trial  Examined the effect of clinic/clinician contraceptive and insertion training on patient LARC selection.	40 Planned Parenthood clinics in the USA  Eligible women were 18-25 years old  2-month recruitment process with paid incentives for participation	Intervention: Clinic training to improve providers' method-specific knowledge and counseling and placement skills  Outcomes: LARC selection and pregnancy rates	Analyses through intention to treat  Logistic regression to estimate intervention effect on LARC uptake  Life-table analysis and Kaplan-Meier survival estimates on pregnancy rates	Women were more likely to choose a LARC in the intervention group, intracluster correlation 0.05 (95 CI, 0.02 to 0.08).  Increase in the proportion of women using LARCs in the intervention compared to control group (2.3% vs 2.0%, coefficient for difference 0.0004, 95% CI 0.003-0.004).  Pregnancy rates were 15 per 100-person years in intervention group vs. 18.5 per 100 person-years in the control (hazard ratio 0.89, 95% CI 0.64-1.24).	Outside funding source  Variability among providers and clinics  Generalizability to clinics outside of Planned Parenthood  Un-blinded upon assignment of intervention  Additional patient education tools provided
Modesto et al. (2014)	Randomized-clinical trial 2011 to 2013  Brazil	297 women that selected either a 98 ENG-implant, 99 LNG-IUS, or 100 TCu380A IUD	Intervention: Intensive counseling at 45 days, 6 months, and 12 months following insertion  Comparison: Routine counseling  Outcomes: Continuation rates, reasons for discontinuation, user satisfaction at 12 months	SPSS version 20  ANOVA or Kruskal-Wallis test  Chi-squared test	Discontinuation rates due to expulsion were higher for the Cu-IUD ( $p = 0.008$ ), due to weight gain among ENG-implant ( $p = 0.022$ ).  There were no significant differences of women discontinuing the method due to bleeding in either group.  1-year continuation rate was 73% for Cu-IUD, 83% ENG-implant.  User satisfaction was 86% for the Cu-IUD and 90% for the LNG-IUS.	Standard counseling potentially already adequate  Possible patient information sharing in waiting room  External funding source

Raifman et al. (2018)	<p>Prospective cohort study</p> <p>Evaluated the effect on counseling containing IUD self-removal on uptake, satisfaction, and continuation.</p>	<p>361 women who selected IUD after contraceptive counseling</p> <p>Family planning clinics in Michigan, Missouri, New Jersey, and Utah</p>	<p>Intervention: Counseling, including IUD self-removal</p> <p>Outcomes: IUD uptake, satisfaction, and continuation</p>	<p>Descriptive analyses on effect of study group on adoption of the method, method satisfaction, continuation, reasons for discontinuation</p> <p>Multivariable discrete-time logistic survival model on relationship between study group and IUD discontinuation</p>	<p>No significant difference in IUD uptake rate by group (control 7% [95% CI, 6.8-7.8]; intervention 7% [95% ci, 6.4-7.5]).</p> <p>At the New Jersey site, uptake was higher among the intervention group (13% vs 8%; <math>p = 0.006</math>), but lower at another site (12% vs. 17%; <math>p = 0.044</math>).</p> <p>There were no differences in continuation rates by group or state.</p> <p>Control participants were more likely to consider discontinuation at 6 months (15% vs 7%: <math>p = 0.047</math>)</p>	<p>Pre-existing knowledge regarding self-removal</p> <p>Confounders related to time differences in recruitment for control and intervention group</p> <p>Small sample size</p> <p>Variation in sites</p>
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Gibbs et al. (2016)	Cluster randomized trial  Examined the effect of provider LARC training on LARC use.	1,500 sexually active women aged 18-25  20 intervention and 20 control clinics  Random allocation to intervention to control groups	Intervention: Provider LARC training  Outcomes: LARC counseling, LARC selection, LARC initiation	Stata version 14.0  Logistic regression  Cox proportional hazards model	Young adults and adolescents in the intervention group were more likely to select a LARC than the control (73% vs 41%, 66% vs 33%, respectively).  Initiation rates were higher among the intervention group.  Nulliparous women compared with parous women had lower rates of LARC counseling (.57; 95% CI: .42 - .79), lower LARC selection (adjusted Odds Ratio = .53; 95% CI: .37 - .75), and lower LARC initiation (adjusted Hazards Ratio = .65; 95% CI: .48-.90).	Participants aged 18-25 years only  Outside funding source  Generalizability  Variability among providers and clinics
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### Appendix B. Gap Analysis

Gap Analysis		
<b>Project Name</b>	LARC Method Appropriateness in Substance Use Treatment: A Quality Improvement Project for Integrated Care	
<b>Date</b>	May 2019	
<b>Project Aim</b>	The predominant aim of this quality improvement project is to reduce rates of unintended pregnancy among women with SUD through the development of a pilot project that integrates evidence-based contraceptive services, emphasizing highly effective methods.	
Current State	Best Practice	Proposed Solution
Unintended pregnancy rates are estimated to be 85% among women with a substance use disorder.	Recommend offering a LARC option, including: <ul style="list-style-type: none"> <li>• Same-day service when possible</li> <li>• Without delaying for the results of STI testing with normal examine findings and reasonable certainty that client is not pregnant</li> </ul>	A feasibility analysis will be conducted to design and develop a pilot project rollout of the incorporation of LARC services within substance use treatment appointments.
Client misperceptions regarding LARC methods and limited knowledge regarding side effects, efficacy, and potential adverse effects.	Recommend comprehensive contraceptive counseling including: <ul style="list-style-type: none"> <li>• Efficacy rates</li> <li>• Side effects</li> <li>• Potential adverse outcomes</li> <li>• Respect of patient autonomy</li> </ul>	Providers will be delivered a LARC-focused training that includes evidence-based recommendations regarding contraceptive counseling and hands-on skills training.
Contraceptive use screening in medical appointments for clients receiving inpatient and outpatient substance use treatment.	Recommend the integration of contraceptive services within substance use treatment.	Identify 2 possible funding sources, including grant opportunities, for the expansion of contraceptive services.

## Appendix C. Letter of Support



A Wellness-Focused Recovery Organization

Auburn | Grass Valley | Kings Beach | Lincoln | Roseville | Truckee |

February 1, 2019

To whom it may concern,

This letter of support signifies that Malia Johnson is authorized to complete her Doctor of Nursing Practice project at Granite Wellness Center in Grass Valley, California. The executive management team grants her permission to pursue her work here and use the name of Granite Wellness Center in her final manuscript and faculty presentation.

Thank you,

**Michelle Otten,**  
Medical Services Coordinator  
Granite Wellness Centers  
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**Appendix D. GANTT Chart**

		2019											
LARC Method Appropriateness in Substance Use Treatment		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
<b>Project Concept</b>													
	Literature review												
	Introduce project to site												
	Prepare business case												
	Obtain project approval												
	Project planning												
<b>Design</b>													
	Create staff survey												
	Create site survey												
	Create women's focus group survey												
	Design pilot study												
<b>Preparation</b>													
	Conduct women's focus group												
	Administer staff surveys												
	Identify funding sources												
<b>Implementation</b>													
	Prepare presentation for board members												
	Present findings at board meeting												
<b>Evaluation</b>													
	Data analysis												
	Final report preparation												

## Appendix E. Work Breakdown Structure

### 1.0 Design

- 1.1 Develop Project Scope
- 1.2 Needs Assessment/Gap Analysis
- 1.3 Develop Objectives
- 1.4 Identify Key Stakeholders
- 1.5 Develop Project Charter
- 1.6 Submit Project Charter

### 2.0 Plan

- 2.1 Identify Project Team
- 2.2 Discussion of Roles
- 2.3 Develop Project Plan
- 2.4 Develop WBS
- 2.5 Develop Surveys
- 2.6 Prepare Staff Training Protocol

### 3.0 Intervention

- 3.1 Feasibility Analysis
  - 3.1.1 Women's Focus Group
  - 3.1.2 Staff Survey
  - 3.1.3 Site Survey
- 3.2 Develop Policies and Procedures
- 3.3 LARC Training Workshop
  - 3.3.1 LARC Training 1
    - 3.3.1.1 Bayer Skills Training: Mirena, Skyla, Kyleena
    - 3.3.1.2 Best Practice Review
  - 3.3.2 LARC Training 2
    - 3.3.2.1 CooperSurgical Skills Training: ParaGard
    - 3.3.2.2 Nexplanon Training & Certification
- 3.4 Identify Funding Sources

### 4.0 Results

- 4.1 Present Results to the Board Committee
  - 4.1.1 Analyze Survey Findings
  - 4.1.2 Summarize Findings and Write Recommendations

### 5.0 Evaluation

- 5.1 Identify Student for Pilot Hand-Off
- 5.2 Review Training Feedback
- 5.3 Write Final Report
- 5.4 Dissemination
  - 5.4.1 DNP Paper
  - 5.4.2 DNP Presentation



**Appendix F. Communication Matrix**

Activity	Purpose	Responsible Person	Involved Stakeholders
Disseminate Project to Staff	Engage staff member involvement and obtain buy-in	Project Leader	Medical staff
Project Proposal	Gain approval for project implementation	Project Leader	Board members and medical director
Staff Meetings	Project updates, revisions, training, and evaluation	Project Leader Project Chair	All project members including clinical site participating staff
Feasibility Study	To gather data from appropriate stakeholders	Project Leader	Providers on site, medical staff, and current clients
Program Evaluation	Analysis and dissemination of results	All Project Team Members	Board members and clinical staff

### Appendix G. SWOT Analysis

<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>• Promoting patient involvement in care</li> <li>• Increasing access to community-based resources</li> <li>• Providing access to care</li> <li>• Providing contraceptive services</li> <li>• Providing patient education regarding contraceptive methods</li> <li>• Educating regarding common myths</li> <li>• Pre-existing on-site medical clinic</li> <li>• Two patient exam rooms</li> <li>• Three experience healthcare providers on staff</li> <li>• Regular staff process improvement meeting</li> </ul>	<p><b>Weaknesses</b></p> <ul style="list-style-type: none"> <li>• Cost</li> <li>• Inability to bill for reimbursement</li> <li>• Substance use appointments will take priority</li> <li>• Limited time available</li> <li>• Limited providers available</li> <li>• Patient misbeliefs and misperceptions</li> </ul>
<p><b>Opportunities</b></p> <ul style="list-style-type: none"> <li>• To reduce rates of and prevent unintended pregnancy</li> <li>• Reduce potential adverse maternal and fetal outcomes associated with unplanned pregnancy</li> <li>• Provide comprehensive, evidence-based contraceptive counseling</li> <li>• Increase client satisfaction in contraceptive method choice and increase greater control over family planning</li> <li>• To perform STI screening</li> <li>• To perform pregnancy screening</li> <li>• Extend contraceptive services to additional campuses within the organization</li> </ul>	<p><b>Threats</b></p> <ul style="list-style-type: none"> <li>• Clinic closure</li> <li>• Competing reproductive service sites</li> <li>• Patient attrition</li> <li>• Repeal of the Affordable Care Act</li> <li>• Lack of external funding source</li> </ul>

## Appendix H. Cost-Benefit Analysis

Costs	Pilot Study Cost (Initial 3 Months)	FY1	FY2
<b>Fixed Asset Start-Up Expenses</b>			
Medical Equipment	\$299.00	\$0	\$0
Furniture	\$1,395.00	\$0	\$0
<b>Total Fixed Asset Start-Up Expenses</b>	\$1,694.00	\$0	\$0
<b>Operating Expenses</b>			
Salaries and Wages (0.05 NP FTE )	\$3,799.80	\$15,199.2	\$15,487.96
Benefits at 30% of Employee's Salary	\$1,139.94	\$4,559.76	\$4,646.40
Medical Supplies	\$10,133.40	\$40,533.60	\$40,533.60
Contracted Services	\$825.00	\$3,300.00	\$3,300.00
Miscellaneous Costs (Support staff, Forms, etc.)	\$105	\$420	\$420
<b>Total Operating Expenses</b>	\$16,003.14	\$64,012.56	\$64,387.96
<b>Total Costs</b>	\$17,697.14	\$65,706.56	\$64,387.96
<b>Revenue</b>			
Projected billable revenue through Medi-Cal Reimbursement for contraceptive counseling, IUD, IUD Insertion, Dispensing Fee, Follow-up Visit, STI Testing)	\$17,490.90	\$69,963.60	\$69,963.60
<b>Total Gross Revenue</b>	\$17,490.90	\$69,963.60	\$69,963.60
<b>Net Revenue</b>	(\$206.24)	\$4,257.04	\$5,575.64

## Appendix I. IUD Policy and Procedure

Subject: Policy and Procedure for IUDs		Department: Clinical
Date:	Prepared by:	Approved by:

### I. Evaluation of insurance eligibility for IUDs

*Note: this should not be necessary in most cases, with the Affordable Care Act, which mandates coverage of all FDA approved contraceptives without co-pays or deductibles. Some grand-fathered plans will not be in compliance, and for those the following paragraph applies.*

The appropriate support staff will verify with the patient's insurance company to ensure the IUD is covered; this will preferably occur the day before the procedure. The results of this verification will be conveyed to nursing. Patients without insurance coverage should be referred to a case manager or entitlement counselor before their IUD insertions so that they can be enrolled in the appropriate health insurance plan or so that a patient assistance program with the appropriate pharmaceutical company can be applied for (Teva for the Paragard and Merck for the Mirena. Patient Assistance is currently not available for Skyla or Liletta.)

### II. The Procedure

In many cases, patients will be coming in first for contraceptive options counseling. They may or may not be making a decision during this visit about whether they elect to have an IUD. The Policy and Procedure statement that follows applies to the IUD insertion visit.

- **Arrival:** Patients who come for an IUD will enter the health center as do all patients. They will be registered and have vital signs performed. They will be called to the exam/treatment room in the order of their appointment.
- **Counseling and consent:** Each patient will have the opportunity to discuss all contraceptive options before the procedure. The patient will be carefully counseled on the side effects of each type of IUD, especially the changes in bleeding pattern and the cramping that will be experienced. The procedure consent form will be signed at this time.
- **Set up:** All equipment needed for the procedure will be stored in a supply room or closets where equipment for other procedures is stored. The proper IUD will be supplied to the clinician by the nursing staff, who will record the lot number and the expiration date of the IUD in the nursing notes in the medical record. The provider will offer the patient 800mg of ibuprofen to be given prior to the procedure and the nurse will administer it, if the patient agrees and is not allergic.
- **Procedure:** The clinician and a staff member or additional clinician will be with the patient during the procedure. The patient will undress from the waist down, be covered with a paper sheet, and lie in lithotomy position on the exam table. A bimanual exam will be performed. The speculum will be inserted and a Pap, **gc**, Chlamydia culture will be done, as medically indicated. The vagina will be dabbed with antibacterial solution. No-Touch Technique will be observed throughout the procedure: any instruments, or parts of instruments, that enter the uterus must be sterile. The provider may inject lidocaine at the tenaculum site. The cervix will be stabilized with a tenaculum and gentle traction to straighten the cervical canal. A sterile plastic sound will be used to measure the depth of the uterus. If the uterus sounds at a depth of 5 cm or less, the speculum and tenaculum will be tilted and re-positioned and the depth will be assessed again. If the sound still reaches only a depth of 5 cm, the IUD will not be inserted. If the depth is greater than 5 cm, the IUD will then be set to the proper depth and loaded under sterile conditions. The IUD will then be inserted and deployed correctly, according to the type of IUD. The loading device will be removed and the strings will be cut at 3 to 4 cm in length. The tenaculum and speculum will be removed and the patient's legs will be placed on the foot piece of the exam table while the patient rests and feels ready to get up. When the patient feels ready, the patient will get off the exam table and get dressed.

- **Recovery:** Patients will recover in the same exam room for a few minutes, under observation of medical and nursing staff. The IUD take-home information sheet will be reviewed with the patient prior to her leaving. When the patient is ready, and staff and provider confirm that the patient is stable, the patient may leave.
- **Discharge and follow-up:** The take home instructions, as well as the after visit summary will instruct the patient about when her IUD will need to be removed. She will also be given the clinic phone number so that she will have access to medical staff for any follow up concerns she may have.
- **Documentation:** The IUD health record template will be used by the clinician, with care given to mark off whether the IUD used was Mirena, Skyla, Liletta or Paragard.

### III. Quality Improvement

The Granite Wellness Center maintains a Quality Improvement committee, which consists of practice medical directors, trained clinicians, administrators and other staff. The committee will review the procedures and outcomes for important indicators on a regular schedule, and will report findings in committee minutes.

### IV. Facilities and equipment

#### 1. Facility

At the Granite Wellness Center, providers have private exam rooms, for both consultation and treatment. Providers currently perform other procedures in these rooms. Patients will have the IUD insertion in an exam/treatment room, and recover in the same room.

#### 2. Equipment

Sterile instrument trays will be made up of the following:

1 sponge stick/ring forcep  
Single tooth tenaculum  
One plastic uterine sound  
Sterile gauzes  
Medicine cup  
Scissors

Additional equipment for the procedure will be kept available:

10 cc syringes  
21 gauge 2" needles  
18 gauge 1" needles  
Denniston dilator size 5/6 or a set of ~~oa~~ finders  
Betadine  
Lidocaine  
Sodium Bicarbonate (1cc to be mixed with 3 cc of lidocaine)

#### 3. Disposal of medical waste and cleaning of instruments

The Granite Wellness Center has a procedure for the removal of medical waste such as blood and other infectious body fluids, as well as contaminated equipment. This procedure will continue to be followed.

### V. Staffing



All clinicians performing IUD insertion procedures at the Granite Wellness Center will have adequate training from either their clinical training program or from currently trained faculty. Nursing staff will assist the clinicians.

## Appendix J. Patient Education Materials



### IUD Information

What is the IUD?	The IUD (Intrauterine Device) is a plastic rod with 2 arms and a string. It is inserted into the uterus to prevent pregnancy. It is about the size of a quarter. There are 5 types of IUD in the US: the copper IUD and 4 progestin (hormone) IUDs. To choose the right one for you, see the "Which IUD Is Right for Me?" chart on the other side.
How well does the IUD work?	The IUD works better than the pill, the patch, the ring, and the shot. The IUD prevents pregnancy more than 99% of the time.
Is the IUD safe?	Yes. Serious problems with the IUD are rare, and most happen the first few days.
Can I get an IUD if I've never had a baby?	Yes. IUDs are a great choice even if you have not had a baby.
How is the IUD inserted?	After putting a speculum in your vagina, a health care provider inserts the IUD into your uterus. Many providers give pain medicine first. You may have cramps and spotting for a short time afterwards.
Does the IUD have side effects?	Yes. Most side effects improve after a few months. See other side for details.
Does the IUD cause infections?	No.
Does the IUD protect against HIV and other sexually transmitted infections?	No, the IUD does not protect you from sexually transmitted infections. Unless you and your partner have sex only with each other, you should use a condom every time you have sex, even with the IUD in place.
Do I need to check the IUD?	No. Schedule a visit with your provider if you have any questions, want to change your method, or would like to have your IUD removed.
Does the IUD cause an abortion?	No. The IUD works by preventing sperm from fertilizing eggs.
What happens when I want to get pregnant?	Your health care provider can remove your IUD at any time. You can get pregnant right after the IUD is removed.

## Which IUD Is Right For Me?

	<b>Copper IUD</b>  Paragard®	<b>Progestin IUDs</b>  Mirena®, Skyla®, Liletta®, and others
<b>Brand names</b>	Paragard®	Mirena®, Skyla®, Liletta®, and others
<b>When does the IUD start working?</b>	The copper IUD starts working right away.	The progestin IUDs start working 7 days after they are inserted. Use condoms or another back-up method of birth control for the first 7 days after the IUD is inserted to prevent pregnancy.
<b>How long can you use it?</b>	Paragard® works for 12 years. Your health care provider can remove your IUD at any time.	Works for 3 to 7 years, depending on which IUD you choose. Your health care provider can remove your IUD at any time.
<b>Does it contain hormones?</b>	No.	Yes. There is a low dose of progestin but no estrogen.
<b>Side effects</b>	Heavier periods Cramping for a few months after it is inserted Stronger cramps with your period Longer periods	Spotting Cramping for a few months after it is inserted Lighter periods or no periods after a few months – this is safe. Less common: bloating, nausea, headaches, breast pain



	<p><b>Copper IUD</b></p>  <p>Paragard®</p>	<p><b>Progestin IUDs</b></p>  <p>Mirena®, Skyla®, Liletta® and others</p>
<b>Benefits</b>	<p>No need to think about birth control before or during sex</p> <p>Private</p> <p>No need to buy refills every month</p> <p>Works better than the pill, the patch, the ring, or the shot</p> <p>Can be used while breastfeeding</p> <p>Can be used as emergency contraception: Prevents pregnancy when inserted up to 5 days after unprotected sex</p>	<p>No need to think about birth control before or during sex</p> <p>Private</p> <p>No need to buy refills every month</p> <p>Works better than the pill, the patch, the ring, or the shot</p> <p>Can be used while breastfeeding</p> <p>Can decrease heavy periods, cramps, PMS</p>
<b>Cost</b>	<p>The cost varies based on insurance coverage.</p> <p>Most insurance providers completely cover the cost the IUD.</p> <p>If the IUD is not covered by your insurance, it may cost up to several hundred dollars.</p>	<p>The cost varies based on insurance coverage.</p> <p>Most insurance providers completely cover the cost of the IUD.</p> <p>If the IUD is not covered by your insurance, it may cost up to several hundred dollars.</p>



### Appendix K. Site Assessment

Site Evaluation Site: Granite Wellness Centers	Completed by: Malia Johnson 10/10/2019
1. Adequate, private exam room with exam table	There are 2 exam rooms on site with exam tables. However, the exam tables do not have attached stirrups or similar equipment to appropriately position patient in lithotomy position. Exam table is not adjustable. However, the clinic has budgeted to purchase a new exam table.
2. Appropriate IUD/implant insertion and removal supplies  Resource: <a href="http://www.reproductiveaccess.org/wp-content/uploads/2015/01/IUD-Insertion-Setup-Supplies.pdf">http://www.reproductiveaccess.org/wp-content/uploads/2015/01/IUD-Insertion-Setup-Supplies.pdf</a>	The clinic does not currently have IUD implant and insertion supplies. A supplied list has been created with approximated costs. Supplies necessary include speculums, lubricant, lighting, uterine sound, swabs, tenaculum, curved scissors, ring forceps, betadine swabs, sterile gloves, chucks, sterile drapes, sanitary napkins, sterile gauze, Ibuprofen 600 mg, IUD. An exa
3. Space for storing IUD/implant devices	There is adequate storage in the clinic rooms for equipment and supplies.
4. Space for storing sterile and non-sterile equipment.	There is adequate storage spacing to store sterile and non-sterile equipment separately.
5. Sterilization of equipment <input checked="" type="checkbox"/> Onsite <input type="checkbox"/> Transport from offsite facility	Equipment sterilization would occur onsite. There is an existing autoclave at the facility. The policy and procedure is currently being developed for the process.
<b>Administrative Considerations</b>	
1. Chart note template for IUD insertion/removal visit  Resource: <a href="http://www.reproductiveaccess.org/resources/?rsearch=epic&amp;rtopic%5B%5D=46">http://www.reproductiveaccess.org/resources/?rsearch=epic&amp;rtopic%5B%5D=46</a>	Chart note templates have been obtained from <a href="http://www.reproductiveaccess.org">www.reproductiveaccess.org</a> Forms: "Sample IUD Insertion Note", "IUD Removal Note"
2. Chart note template for implant insertion/removal visit  Resource: <a href="http://www.reproductiveaccess.org/resources/?rsearch=epic&amp;rtopic%5B%5D=45">http://www.reproductiveaccess.org/resources/?rsearch=epic&amp;rtopic%5B%5D=45</a>	Chart note templates have been obtained from <a href="http://www.reproductiveaccess.org">www.reproductiveaccess.org</a> Forms: "Progestin Implant Insertion", "Progestin Implant Removal"

<p>3. Billing and coding codes up to date</p> <p>Resources:  <a href="http://www.reproductiveaccess.org/resources/?rsearch=epic&amp;rtopic%5B%5D=45">http://www.reproductiveaccess.org/resources/?rsearch=epic&amp;rtopic%5B%5D=45</a>  <a href="http://www.reproductiveaccess.org/resources/?rsearch=Coding&amp;rtopic%5B%5D=45">http://www.reproductiveaccess.org/resources/?rsearch=Coding&amp;rtopic%5B%5D=45</a></p>	<p>The administration is actively working towards obtaining processes for billing of medical services. Billing resources have been obtained from <a href="http://www.reproductiveaccess.org">www.reproductiveaccess.org</a>. The on-site providers have applied for contracting and are pending final approval. Forms: “Coding for Inserting and Removing IUDs”</p>
<p>5. System for appointment scheduling</p>	<p>There is an appointment scheduling system in place at the clinic. Microsoft appointment scheduling and AccuCare are currently being utilized. Athena EHR roll-out is anticipated for December 15<sup>th</sup>.</p>
<p>6. System for ordering/tracking supplies</p>	<p>The organization contracts with vendors to order necessary supplies. Mckesson and Henry Shein are the supply vendors.</p>
<p>Clinical Considerations</p>	
<p>1. IUD and implant protocols in place.</p> <p>Resources:  <a href="http://www.reproductiveaccess.org/resource/d-epo-provera-policy-procedures/">http://www.reproductiveaccess.org/resource/d-epo-provera-policy-procedures/</a>  <a href="http://www.reproductiveaccess.org/resource/iud-policy-procedure/">http://www.reproductiveaccess.org/resource/iud-policy-procedure/</a></p>	<p>A policy and procedure protocol has been obtained from <a href="http://www.reproductiveaccess.org">www.reproductiveaccess.org</a> Forms: “Policy and Procedure for IUDs”</p>
<p>2. Procedure for sterilizing equipment in place.</p>	<p>Autoclave is on-site for sterilization. Procedure is in process for sterilization.</p>
<p>3. IUD and implant consent forms available.</p> <p>Resources:  <a href="http://www.reproductiveaccess.org/resource/iud-consent-form/">http://www.reproductiveaccess.org/resource/iud-consent-form/</a>  <a href="http://www.reproductiveaccess.org/resource/progestin-implant-consent-form/">http://www.reproductiveaccess.org/resource/progestin-implant-consent-form/</a></p>	<p>Consent forms have been obtained from <a href="http://www.reproductiveaccess.org">www.reproductiveaccess.org</a> Forms: “IUD Insertion Consent Form”</p>
<p>4. Patient education materials available.</p> <p>Resources:  <a href="http://www.reproductiveaccess.org/resources/?rsearch=&amp;rtopic%5B%5D=46&amp;rtype%5B%5D=61">http://www.reproductiveaccess.org/resources/?rsearch=&amp;rtopic%5B%5D=46&amp;rtype%5B%5D=61</a>  <a href="http://www.reproductiveaccess.org/resources/?rsearch=&amp;rtopic%5B%5D=45&amp;rtype%5B%5D=61">http://www.reproductiveaccess.org/resources/?rsearch=&amp;rtopic%5B%5D=45&amp;rtype%5B%5D=61</a></p>	<p>Patient education materials have been obtained from <a href="http://www.reproductiveaccess.org">www.reproductiveaccess.org</a> Forms: “IUD Information”, “Which IUD is Right for Me”</p>

<p>5. Patient after care information available.</p> <p>Resources:  <a href="http://www.reproductiveaccess.org/resources/?rsearch=&amp;rtopic%5B%5D=45&amp;rtype%5B%5D=62">http://www.reproductiveaccess.org/resources/?rsearch=&amp;rtopic%5B%5D=45&amp;rtype%5B%5D=62</a>  <a href="http://www.reproductiveaccess.org/resources/?rsearch=&amp;rtopic%5B%5D=46&amp;rtype%5B%5D=62">http://www.reproductiveaccess.org/resources/?rsearch=&amp;rtopic%5B%5D=46&amp;rtype%5B%5D=62</a></p>	<p>Patient after care information has been obtained from <a href="http://www.reproductiveaccess.org">www.reproductiveaccess.org</a>  Forms: "IUD Take-home Sheet"</p>
<p>6. QA systems in place</p>	<p>A patient satisfaction survey has been developed to ensure quality assurance. Critical incident reports, complaints, IDT team.</p>
<p>7. Malpractice coverage</p>	<p>Malpractice coverage is provided by the organization.</p>

### Appendix L. Patient Satisfaction Survey

#### Patient Satisfaction Survey

Thank you for taking the time to complete this survey. Your feedback will be used to improve the services offered.

s	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Not Applicable
Receiving contraceptive services and counseling was helpful.						
Contraceptive counseling was provided by the healthcare provider that helped me make an informed decision.						
I was provided instructions regarding method choice and follow-up care.						
The provider gave me his or her attention.						
The provider understood and addressed my concerns.						
The provider answered my questions clearly.						
I am satisfied with my visit.						
I am satisfied with the quality of care I received.						
It was easy to schedule a follow-up appointment.						
I received the results of my lab tests in a timely manner.						
I did not have difficulty obtaining a contraception method of my choosing.						
I would recommend the services I received to other patients.						

What can we do differently in the future to make your experience more positive?

## Appendix M. Women's Focus Group Survey

### Women's Focus Group Survey Questions

1. What barriers do you experience in obtaining birth control/contraceptive services?

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2. What are your concerns regarding birth control?

- |                 |                      |
|-----------------|----------------------|
| a. Side effects | f. Bleeding patterns |
| b. Fertility    | g. Cost              |
| c. Access       | h. Effectiveness     |
| d. Ease of use  | i. Other             |
| e. Hormones     |                      |

Please explain/elaborate on your selection:

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3. What community organizations are you aware of that provide free/low cost birth control?

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4. What resources regarding contraceptive care would benefit you the most? (Some examples are pregnancy testing, STI testing, free birth control, access to a provider, same day services, pelvic exam, follow-ups)

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5. Would you utilize birth control if offered at no cost while receiving treatment?

- Yes
- No
- Unsure

6. Have you ever received comprehensive contraceptive counseling regarding all birth control options available to you?

- Yes
- No
- Unsure

7. Which birth control options would you be most interested in receiving?

- Hormonal IUD
- Non-hormonal IUD
- Emergency contraception
- Condoms
- Birth control pills
- Depo-Provera (shot)
- Nexplanon (subdermal implant)
- Other (vaginal ring, diaphragm, etc.)

### Appendix N. Staff Readiness for Change Survey

Staff Readiness Survey

Name (optional): \_\_\_\_\_

Position & Department: \_\_\_\_\_ Date: \_\_\_\_\_

**Contraceptive Service Integration: Staff Survey**

This survey is intended to gauge your interest and readiness for expanding the care offered at Granite Wellness Center to include contraceptive services. Proposed services will include contraceptive counseling, appropriate contraceptive choice selection, IUD insertion, pelvic exam, STI and pregnancy testing, prescription birth control methods, and appropriate follow-up.

Please select and check the appropriate rating for each question.

	Rating				
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
<b>Need for Change</b>					
There is a need for organizational change to expand services to include contraceptive services.					
I am aware of the reasons why change is needed within the organization.					
Expanding the services provided to the clients is appropriate and achievable.					
I am aware that the organization is considering expanding the services offered to include contraceptive services					
I understand the need to include contraceptive services in the services offered in all clinical visits including intake appointments and follow-ups.					
<b>Leadership and Management</b>					
Management is committed to providing support to staff during periods of change					
I am able to discuss changes with leadership and management					



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	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
<b>Attitude to Change</b>					
Providing contraceptive services will benefit the organization.					
I am supportive of the integration of contraceptive services into clinic appointments.					
I know how my role can help make the expanded services successful.					
<b>Communications</b>					
There is adequate consultation with staff when change occurs.					
Staff communication is reliable and well-timed.					
<b>Preparation for Change</b>					
I am adequately trained to offer contraceptive services within my role and scope of practice.					
I have the resources I need to provide contraceptive services within my role.					
I am confident in my ability to provide contraceptive services to all clientele.					
Overall, I believe contraceptive services will be advantageous for the clientele participating in substance use treatment and the larger community as a whole.					

Comments, concerns, or additional feedback:

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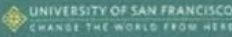


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Appendix O. LARC Training Workshop Presentation




**LARC Provider Workshop**

Malia Johnson MSN, RN  
November 7, 2019

1

**Learning Objectives**


- Explain consequences of unintended pregnancy
- Describe LARC efficacy and safety
- Outline barriers to contraception
- Discuss the available LARC options
- List key contraceptive counseling points
- Identify LARC eligible candidates
- Providers will have hands-on skills training with vaginal simulator



2

**Unintended Pregnancy**


- Approximately **45%**, or **2.8 million**, pregnancies per year are unplanned among women aged 15 to 44 years old (Finer & Zolna, 2016).
- Majority of unplanned births are paid for through public insurance (**68%**).
- Costs are estimated at **\$12,770 per pregnancy or \$21 billion** per year. (Sonfield & Kost, 2014)



3

**Women with Substance Use Disorder**

- Rates of unintended pregnancy in women with SUD are estimated to be **85%** (Heil et al., 2011).
- Overall **contraceptive use is lower and less effective methods are preferred** (Terplan, Hand, Hutchinson, Salisbury-Afshar, & Heil, 2015).




4

**Adverse Outcomes**

- Mothers are more likely to experience:
  - delay in receiving prenatal care
  - increased risk of depression
  - physical violence exposure while pregnant
  - less likely to breastfeed
- Neonates are at increased risk for:
  - Low birth weight
  - Increased rates of birth defects


(U.S. Department of Health and Human Services [HHS] & Office of Disease Prevention and Health Promotion [ODPHP], 2014)



**Adverse Outcomes Cont.,**

- Mothers with SUD are more likely to experience:
  - Mental health conditions
  - Poor nutrition
  - Use multiple substances while pregnant
  - Placental abruption
  - Lack of prenatal care
  - Intrauterine passage of meconium
  - Preterm labor/birth
- Neonates are at increased risk for:
  - Neonatal abstinence syndrome
  - Fetal death
  - Still birth

(Black & Day, 2016; Committee on Obstetric Practice & American Society of Addiction Medicine, 2017)





### Barriers to Contraception

- Cost
- Access
- Lack of awareness
- Transportation
- Clinic location and hours
- Knowledge
- Provider confidence or skill
- Provider's ability to identify LARC eligible candidate

(HHS & ODPHP, 2014)

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### Barriers to Women with SUD

- Past history of sexual abuse, fear of losing their existing custodial relationship as parents, and embarrassment regarding their substance use (Black & Day, 2016).
- Perceived lack of access to healthcare providers (Terplan, Lawental, Connah, & Martin, 2016).
- Concerns about side effects and lack of knowledge (Matusiewicz, Melbostad, & Heil, 2017).

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### LARC: Long-Acting Reversible Contraception

- Comprised of implantable and intrauterine devices (IUD)
- Non-hormonal: ParaGard IUD
  - Immediately effective
  - FDA approved as emergency contraception
- Hormonal: Liletta, Mirena, Kyleena, and Skyla.
  - Mirena IUD is FDA approved for menorrhagia.
- Implant: Nexplanon
- Failure rates are less than one in 100 women (Office of Population Affairs, 2019)
- Provide 3-10 years of safe contraception

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### LARC Options

Generic	Brand	Reservoir	Duration, y
ENG implant	Nexplanon <sup>®</sup>	50 mg TNB	4.5
LNG IUD 20 mcg/24 h	Liletta <sup>®</sup> Mirena <sup>®</sup>	52 mg LNG	5-5
LNG IUD 14 mcg/24 h	Skyla <sup>®</sup>	33.5 mg LNG	5.5
T380A copper IUD	ParaGard <sup>™</sup>	380 mm <sup>3</sup>	5.10

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### Guidelines: ACOG

- LARC methods should be routinely recommended as a first-line contraceptive method.
- Women who are nulliparous, adolescent, or considered to be of high-risk for sexually-transmitted infections are included in the recommendation for a LARC.
- Women at high-risk for sexually-transmitted infections should undergo STI testing, but insertion should not be delayed for test results.

(American College of Obstetrics and Gynecology, 2017)

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### Guidelines: NICE

- Even with use of a LARC method as short as 12 months, it is still more cost effective than oral contraceptives
- Increasing the utilization of LARCs will reduce the rate of unintended pregnancies
- The guideline aims to increase uptake of LARC methods through contraceptive counseling and education


(National Institute of Health and Care Excellence, 2019)

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**Guidelines: CDC & OPA**

- Contraceptive counseling that provides information regarding a broad range of birth control options and incorporates efficacy rates
- Advisees that substance use may be a factor in correct and consistent birth control use and should be considered by the provider
- Recommended strategies for providing contraception include keeping different methods available on-site so they may be offered at the time of visit

(Center for Disease Control and Prevention and the U.S. Office of Population Affairs, 2014)




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**Guidelines: AAP**

- Recommend counseling based on efficacy
- First-line contraceptive choice is LARC
- Know state and federal laws regarding disclosure of confidential information in minors
  - "A minor may consent to medical care related to the prevention or treatment of pregnancy." (Cal. Family Code 6925)
  - A minor may receive birth control without parental consent (Cal. Family Code 6925).
  - The healthcare provider is not permitted to inform a parent/legal guardian without minor's consent.


(American Academy of Pediatrics, 2014)



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**IUD Candidates**

- Age?
- Parity?
- STI risk?
- Time until desired pregnancy?
- Post-partum?
- Breastfeeding?




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**Identifying LARC Eligible Candidates**

U.S. Medical Eligibility Criteria for Contraceptive Use

**Absolute Contraindications:**


- Current PID or STI (IUD initiation only, may continue)
- Pregnancy
- Distorted uterine cavity
- Current breast cancer (levonorgestrel only)
- Cervical cancer awaiting treatment (IUD initiation only, may continue)
- Endometrial cancer (IUD initiation only, may continue)
- Copper allergy (Cu IUD) or Silver allergy (Skyla IUD)



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**Contraceptive Counseling**

- Start with one key question
  - "Would you like to become pregnant in the next year?"
- Efficacy based
- Recommend a LARC method if not planning to become pregnant within 1 year
- Consider typical use when making recommendations
- Discuss expected side effects to reduce premature discontinuation

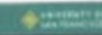


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**Reasonably Certain a Client/Patient is Not Pregnant**

No signs or symptoms of pregnancy in addition to meeting at least 1 of the following criteria:

- Is within 7 days of the start of normal menses
- Has not had sexual intercourse since the start of last normal menses
- Within 4 weeks postpartum
- Fully or near full breastfeeding, amenorrhoic, and <6 months postpartum
- Is within 7 days after spontaneous or induced abortion



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**References**

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Appendix P. LARC Training Folder Resources

## HOW WELL DOES BIRTH CONTROL WORK?


**Really, really well** (5 stars)

Works, hassle-free, for up to...

				
The Implant (Nexplanon)	IUD (Skyla)	IUD (Mirena)	IUD (ParaGard)	Sterilization, for men and women
3 years	3 years	5 years	12 years	Forever

*No hormones*

What is your chance of getting pregnant?








Less than 1 in 100 women

---

**Okay** (3 stars)

For it to work best, use it...

			
The Pill	The Patch	The Ring	The Shot (Depo-Provera)
Every. Single. Day.	Every week	Every month	Every 3 months



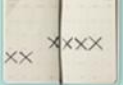



6-9 in 100 women, depending on method

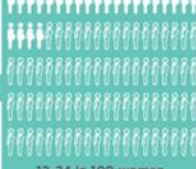
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**Not so well** (1 star)



For each of these methods to work, you or your partner have to use it every single time you have sex.


			
Withdrawal	Diaphragm	Fertility Awareness	Condoms, for men and women

*Needed for STI protection*  
*Use with any other method*



12-24 in 100 women, depending on method



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FYI, without birth control, over 90 in 100 young women get pregnant in a year.





### Coding for Inserting and Removing IUDs

The following codes can be used when inserting and removing contraceptive IUDs in an out-patient setting:

#### ICD-10 Diagnosis Codes (phased in by September 2014)

- Z30.014 Encounter for initial prescription of intrauterine contraceptive device (excludes insertion)
- Z30.430 Encounter for insertion of intrauterine contraceptive device
- Z30.432 Encounter for removal of intrauterine contraceptive device
- Z30.431 Encounter for routine checking of intrauterine contraceptive device (surveillance)
- Z30.433 Encounter for removal and reinsertion of intrauterine contraceptive device
- Z32.02 Pregnancy test/exam – negative

#### *Issues with IUDs*

- T83.31 Breakdown (mechanical) of intrauterine contraceptive device
- T83.32 Displacement of intrauterine contraceptive device
- T83.39 Other mechanical complication of intrauterine contraceptive device

For further guidance on coding difficult IUD cases see [Beyond the Pill's Quick billing guide](#).

#### Out-Patient Procedure Codes\*

- 58300 Insertion, intrauterine device
- 58301 Removal, intrauterine device
- 11702 Lidocaine
- 81025 Pregnancy test

#### Medication Administration Codes\*

- J7300: Intrauterine copper contraceptive (ParaGard® T-380A)
- J7297: Levonorgestrel-releasing intrauterine contraceptive system, 52 mg, 3 year duration (Liletta®)
- J7298: Levonorgestrel-releasing intrauterine contraceptive system, 52 mg, 5 year duration

August 2016 / [www.reproductiveaccess.org](http://www.reproductiveaccess.org)



Health Center:  
Address  
Phone:

## IUD Insertion Consent Form

I request a (circle one): Mirena / Skyla / Liletta / Paragard IUD

I understand the following:

I will have a pregnancy test before the IUD is inserted. If I had unprotected sex within the past 7 days the pregnancy test may not be accurate and may read negative when an early pregnancy is starting.

The Paragard may be used as Emergency Contraception for up to 5 days of after unprotected sex.

The Mirena protects against pregnancy for 5-7 years. The Skyla / Liletta protects against pregnancy for 3 years. The Paragard protects against pregnancy for 10-12 years.

The possible risks of IUD placement include infection, bleeding, allergic reaction, perforation of (poking a hole in) the uterus, and expulsion (falling out) of the IUD.

I may have irregular bleeding and cramping for the first 3 months after the IUD is inserted. Ibuprofen or a heating pad may help with these symptoms.

The IUD does not protect against STDs. I should use latex condoms to protect myself against STDs

With the Mirena, Skyla and Liletta IUDs my periods may get lighter or disappear and I understand that this is not dangerous.

With the Paragard IUD my periods may get heavier or last longer.

I have been given a patient information form to take home about the side effects to expect after the IUD is inserted.

I hereby consent that \_\_\_\_\_ insert the IUD for me.

Signature of patient: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of provider: \_\_\_\_\_ Date: \_\_\_\_\_

Witness: \_\_\_\_\_ Date: \_\_\_\_\_

July 2015 / [www.reproductiveaccess.org](http://www.reproductiveaccess.org)



### IUD Insertion Note

I have identified this pt. to be (PATIENT NAME). I have updated her Obstetrical and Gynecological history in (EHR).

(PATIENT NAME) is a (GxPx) presenting for an (Paragard/Mirena/Skyla/Liletta) IUD insertion. Number of elective abortions: (NUMBER). There (IS/IS NOT) a history of a prior cesarean section. The pap smear history has been reviewed. She (IS/IS NOT) due for a pap smear. She (HAS/HAS NOT) had unprotected sex since her last menstrual period.

I (DID/DID NOT) evaluate her contraindications to IUD placement: There is no current pregnancy, she is not postpartum within 6 weeks, there is no copper allergy for Paragard users, no progestin allergy for Mirena, Skyla and Liletta users, or no mucopurulent cervicitis.

We discussed the risks, benefits and alternatives to the IUD. The IUD is being placed as (post partum contraception <6months/post abortion contraception <3 months/routine contraception/emergency contraception/treatment for menorrhagia). I have answered all her questions about possible infection, complications and fertility after and during use. The risks we discussed included: bleeding and infection post procedure, risk for expulsion and the very small risk of pregnancy while using the IUD. (PATIENT NAME) has signed a consent and it is to be scanned into the record. Her most recent Pap smear results were reviewed, if applicable, and I evaluated the need to obtain a gonorrhea and chlamydia test.

#### Procedure Note:

Time out taken: (TIME)

Team: (NAME(s))

(PATIENT NAME) (DATE OF BIRTH) confirmed (YES/NO)

Procedure: IUD insertion

Confirmed by patient and team (YES/NO)

Position correct for procedure (YES/NO)

Equipment for procedure available (YES/NO)

A no touch technique was used throughout the procedure. A speculum was placed into vagina and cervix was cleaned with betadine. Approximately (NUMBER) cc of 1% lidocaine were injected into the 12 o'clock position of the cervix (YES/NO:63). A tenaculum was placed. A plastic sound was advanced through the external and internal os until it reached the fundus of the uterus, the depth was (number) cm. The use of os finders or dilators (WAS/WAS NOT) needed. The sound was then withdrawn. The IUD was loaded in a sterile manner and advanced into position. The string was visualized and cut to (NUMBER) cm. Patient (DID/DID NOT) tolerated the procedure well. (NO) complications were noted.

She was instructed that she may have intercourse without other birth control and verbalized understanding that the IUD does not protect against STI's. Pt. was instructed to return as needed for follow up care. I advised her to return sooner if any fever, pelvic pain or abnormal discharge developed. She clearly verbalized understanding of these instructions. I instructed her to take ibuprofen prn pain or cramping and that her first few menstrual cycles may be heavier than usual. She was given a detailed instruction sheet about her IUD.

Pap smear schedule (WAS/WAS NOT) reviewed. She (WAS/WAS NOT) offered Gardasil vaccine if age appropriate.

Mirena, Skyla and Liletta users are counseled to use condoms for the first 7 days post insertion. Paragard

March 2015 / [www.reproductiveaccess.org](http://www.reproductiveaccess.org)





### Intrauterine Device (IUD) Removal Note

I have identified this patient to be (PATIENT NAME). She presents today for the removal of her IUD due to (DESIRE FOR PREGNANCY/ABNORMAL BLEEDING/PAIN/DUE FOR REMOVAL/OTHER). The IUD (WAS/WAS NOT) placed at (NAME OF FACILITY). She has had the IUD in place for (LENGTH OF TIME). The IUD type is (PARAGARD/MIRENA/SKYLA/LILETTA). She (IS/IS NOT) up to date on her pap smear screening and sexually transmitted illness testing. She (DOES/ DOES NOT) have abdominal pain, fevers, dysuria, nor dyspareunia. Patient's last menstrual period was (DATE).

She would like to have another IUD inserted: (YES/NO).

#### Procedure Note:

A consent form was signed prior to the removal and is to be scanned into the record.

She appears well, in no apparent distress. Alert, pleasant and cooperative. Vital signs are as documented in vital signs section.

Time out taken: (TIME)

Following information identified:

Patient: (PATIENT NAME), (PATIENT DOB)

Procedure: IUD removal

Site (location and laterality): Intrauterine - per vagina

Pelvic exam: uterus (ANTEVERTED/RETROVERTED/MIDLINE). Cervix (ANTERIOR/POSTERIOR/MIDLINE). No cervical motion tenderness. No adnexal tenderness. No cervicitis.

Speculum placed. The IUD strings (ARE/ARE NOT) seen at external os and grasped with sterile ring forceps and removed (WITH/WITHOUT) difficulty. An IUD hook or other device (WAS/WAS NOT) needed. (PATIENT NAME) (DID/DID NOT) tolerate the procedure well. There (WAS/WAS NOT) a complication.

Plan: (PATIENT NAME) now chooses to use (CONTRACEPTION METHOD). She can start this as soon as today and needs 7 days of a back up method such as condoms before a hormonal method is effective. A handout was given for appropriate use of new contraceptive method.

If planning pregnancy she has been reminded to take folic acid daily and to follow up for preconception care.

She was offered Gardasil is age appropriate (YES/NO).

(PROVIDER NAME AND TITLE)

March 2015 / [www.reproductiveaccess.org](http://www.reproductiveaccess.org)



**Health Center:**  
**Address:**  
**Phone:**

### IUD Take-Home Sheet

[ ] **Copper-T IUD (Paragard<sup>®</sup>)**

- It begins working 2016 to prevent pregnancy.
- It can stay inside you for 12 years.
- Removal date \_\_\_\_\_ (12 years from today)

[ ] **Progestin IUD (Mirena<sup>®</sup>, Liletta<sup>®</sup>, Skyla<sup>®</sup>)**

- It begins working in 7 days to prevent pregnancy.
- You **MUST** use condoms for the first 7 days after your IUD was inserted. If you have sex without using a condom, you will need to take emergency contraception as soon as possible to prevent pregnancy.
- Mirena<sup>®</sup> can stay inside you for 7 years. Skyla<sup>®</sup> or Liletta<sup>®</sup> can stay inside you for 3 years.
- Removal date \_\_\_\_\_ (7 or 3 years from today)

Today you may go back to school or work after your visit. You must wait 24 hours after your IUD is put in before you can use tampons, take a bath, or have vaginal sex.

You may have more **cramps** or **heavier bleeding** with your periods, or spotting between your periods. This is normal. The cramping and bleeding can last for 3-6 months with the Mirena<sup>®</sup>, Liletta<sup>®</sup>, and Skyla<sup>®</sup> (hormone) IUDs. After 6 months, the cramping and bleeding should get better. Many women will stop having periods after 1 or 2 years with the Mirena<sup>®</sup>, Liletta<sup>®</sup>, and Skyla<sup>®</sup> (hormone) IUDs. If you have the Paragard<sup>®</sup> (copper) IUD, you may have more cramping and more bleeding with your periods as long as you have the IUD inside you.

**Ibuprofen** (also called Advil<sup>®</sup> or Motrin<sup>®</sup>) helps decrease the bleeding and cramping. You can buy Ibuprofen at any drug store without a prescription. You can take as many as 4 pills (800 mg) of Ibuprofen every 8 hours with food (each pill contains 200 mg). To prevent cramping, start taking Ibuprofen as soon as your period starts and keep taking it every 8 hours for the first 2-3 days of your period. You can also put a hot water bottle on your belly if you have bad cramps.

Your IUD may come out by itself in the first three months. If you can feel the strings, the IUD is in the right place. If your IUD comes out, you can become pregnant immediately. If you are not sure how to check the strings, we can help you (Our phone number is at the top of this paper.) Meanwhile, use condoms.

The IUD does NOT protect you against sexually transmitted infections. **ALWAYS use protection against sexually transmitted infections (male condoms, female condoms, dental dams) if you are at risk.** If you think you have been exposed to an STI, discuss testing with your healthcare provider. Most infections can be treated **WITHOUT** removing your IUD.

**WARNING SIGNS:**

**Within the first 3 weeks of the IUD insertion:**

- Fever (>101F)
- Chills
- Strong or sharp pain in your stomach or belly

**At Any Time (these are very rare):**

- Late period (for Paragard<sup>®</sup> users)
- Feeling pregnant (breast tenderness, nausea, vomiting)
- Positive home pregnancy test

If you develop any of the above warning signs, you see a healthcare provider. You can call this clinic at **XXX-XXX-XXXX**, or see your usual healthcare provider.

July 2015 / www.reproductiveaccess.org



## Appendix Q. LARC Workshop Pre- and Post-Engagement Surveys



### Long-Acting Reversible Contraception (LARC) Workshop Pre-engagement Survey

Question	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. I am comfortable providing comprehensive contraceptive counseling consistent with current guideline recommendations.					
2. I am confident in identifying all LARC eligible candidates.					
3. I feel prepared to counsel patients about LARC effectiveness and safety.					
4. I feel confident in counseling patients about the LARC insertion procedure and follow-up.					
5. I feel comfortable with IUD insertion.					
6. I am adequately prepared to insert an IUD.					
7. I have sufficient previous experience with IUD insertion.					
8. Hands-on skills training is an effective method to prepare for IUD insertion.					

Comments:



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SAN FRANCISCO

Long-Acting Reversible Contraception (LARC) Workshop Post-engagement Survey

Question	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
9. I am comfortable providing comprehensive contraceptive counseling consistent with current guideline recommendations.					
10. I am confident in identifying all LARC eligible candidates.					
11. I feel prepared to counsel patients about LARC effectiveness and safety.					
12. I feel confident in counseling patients about the LARC insertion procedure and follow-up.					
13. I feel comfortable with IUD insertion.					
14. I am adequately prepared to insert an IUD.					
15. I have sufficient previous experience with IUD insertion.					
16. Hands-on skills training is an effective method to prepare for IUD insertion.					

Comments:

### Appendix R. LARC Training Evaluation

#### LARC Training Evaluation Form

Please indicate which trainings you attended:

- November 7, 2019 LARC Part 1  
 December 12, 2019 LARC Part 2

Please rate your level of satisfaction for the following statements:

1. How satisfied are you with the overall quality of the training(s)?
2. How satisfied are you with the quality of instruction?
3. How satisfied are you with the training materials?
4. Overall, how satisfied are you with your training experience?

	Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied
1	1	2	3	4	5
2	1	2	3	4	5
3	1	2	3	4	5
4	1	2	3	4	5

Please indicate your agreement with the following statements:

5. The training was well organized.
6. The material was applicable to my job/role.
7. The instructors were knowledgeable about the subject matter.
8. The instructors were well prepared.
9. I expect to use the information gained from the training(s).
10. I expect the training(s) to benefit the clients.
11. The length of time allotted for the training(s) was appropriate.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
5	1	2	3	4	5
6	1	2	3	4	5
7	1	2	3	4	5
8	1	2	3	4	5
9	1	2	3	4	5
10	1	2	3	4	5
11	1	2	3	4	5

Comments and/or feedback:

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## Appendix S. DNP Statement of Non-Research Determination Form



### DNP Statement of Non-Research Determination Form

**Student Name:** Malia Johnson

**Title of Project:** LARC Method Appropriateness in Substance Use Treatment: A Quality Improvement Project for Integrated Care

**Brief Description of Project:** The proposed quality improvement project involves the integration of same-day IUD services within a substance use treatment center. Women of reproductive age will be screened for contraceptive use, provided education regarding different birth control methods, and offered same-day contraceptive service initiation.

**A) Aim Statement:** By December 13, 2019 implement contraceptive services, with an emphasis on LARC methods, for patients in substance use treatment to reduce rates of unintended pregnancy. Objective 1: Contraceptive services will be offered to all medically appropriate women of reproductive age newly admitted to residential treatment and those participating in medication-assisted treatment. Objective 2: Increase the rate of utilization of highly effective birth control methods in all women of reproductive age. Objective 3: Provide contraceptive counseling to increase awareness about available birth control methods and their safety and efficacy.

**B) Description of Intervention:** The proposed intervention includes the implementation of contraceptive services in coincidence with substance use treatment. On admission, the provider will screen the patient for contraception use. Education will be provided in a methodical manner prioritizing highly effective birth control methods. Contraception will be initiated at the time of request.

**C) How will this intervention change practice?** The routine offering of contraceptive services in substance use treatment is ideal to mitigate barriers to use. Long-acting reversible contraception is considered highly effective. Parity, STI risk, and age do not preclude women from being an appropriate candidate for an IUD. Same day contraceptive services further increase the likelihood of use. Women participating in substance use treatment are ideal candidates for LARC methods. Providing contraceptive services in an integrated approach, coinciding with substance use treatment, addresses barriers to access and implementation

**D) Outcome measurements:** 1. The number of IUD insertions completed through the integration of contraceptive services. 2. The number of women, of whom, documented contraceptive services were offered on admission/intake to substance use treatment. 3. The type of birth control utilized pre and post intervention.



To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used:  
<http://answers.hhs.gov/ohrp/categories/1569>

This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). Student may proceed with implementation.

This project involves research with human subjects and must be submitted for IRB approval before project activity can commence.

Comments:

**EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST \***



**Instructions: Answer YES or NO to each of the following statements:**

Project Title: LARC Method Appropriateness in Substance Use Treatment: A Quality Improvement Project for Integrated Care	YES	NO
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	X	
The specific aim is to improve performance on a specific service or program and is a part of usual care. ALL participants will receive standard of care.	X	
The project is NOT designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does NOT follow a protocol that overrides clinical decision-making.	X	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does NOT develop paradigms or untested methods or new untested standards.	X	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does NOT seek to test an intervention that is beyond current science and experience.	X	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	X	
The project has NO funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	X	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., not a personal research project that is dependent upon the voluntary participation of colleagues,	X	



students and/ or patients.		
If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: <i>"This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board."</i>	X	

**ANSWER KEY:** If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

\*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

**STUDENT NAME (Please print):** Malia Johnson

Signature of Student: *Malia Johnson* \_\_\_\_\_  
 DATE 04-29-19

**SUPERVISING FACULTY MEMBER (CHAIR) NAME (Please print):**

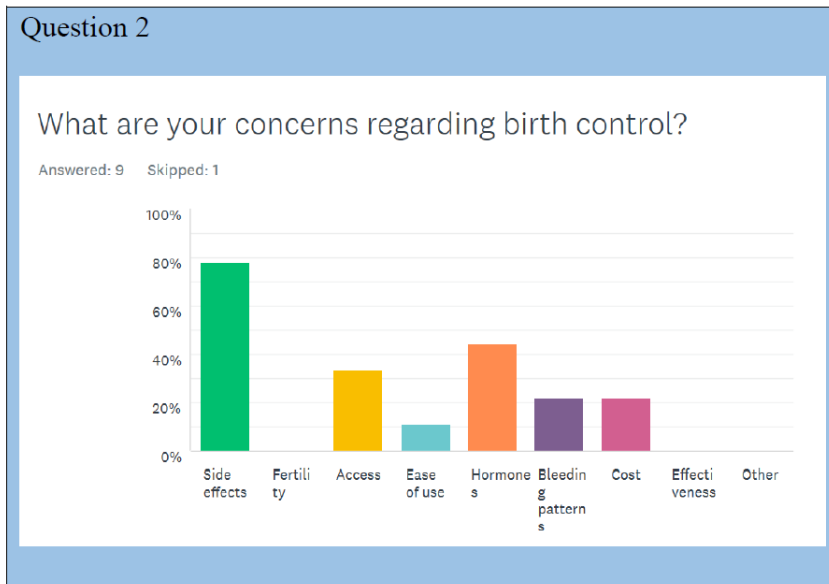
Signature of Supervising Faculty Member (Chair): \_\_\_\_\_  
 DATE \_\_\_\_\_





**Appendix T. Client Survey Results**

Question 1	What barriers do you experience in obtaining birth control/contraceptive services?
None	“NA”, “None. Post-menopausal”, “N/A. My tubes are tied”, “None at this time”, “None”, “None currently, I am pregnant”
Financial/Insurance	“Insurance coverage. They don’t want to pay for IUDs”, “No money to pay for the type I wanted”
Medical	“I do not have a primary care provider”, “No primary doctor”

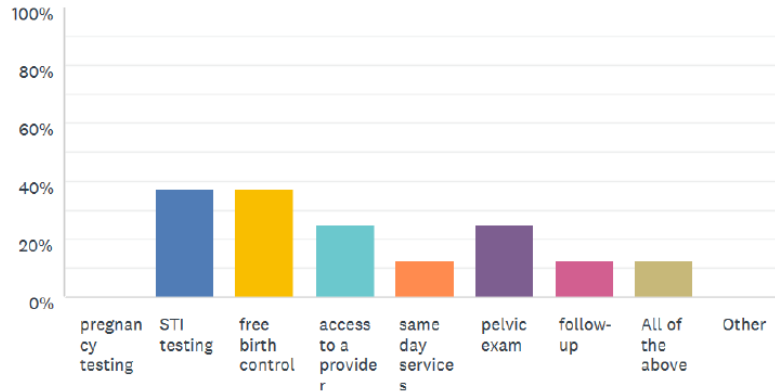


Question 3	What community organizations are you aware of that provide free/low cost birth control?
	<p>“Planned Parenthood and ER”</p> <p>“Planned Parenthood”</p> <p>“Planned Parenthood and community care”</p> <p>“Planned Parenthood”</p> <p>“Local wellness center, my OBGYN”</p> <p>“Free Clinic and planned parenthood”</p> <p>“Planned Parenthood”</p> <p>“Planned Parenthood”</p> <p>“Planned Parenthood”</p> <p>“Planned Parenthood”</p>

### Question 4

What resources regarding contraceptive care would benefit you the most?

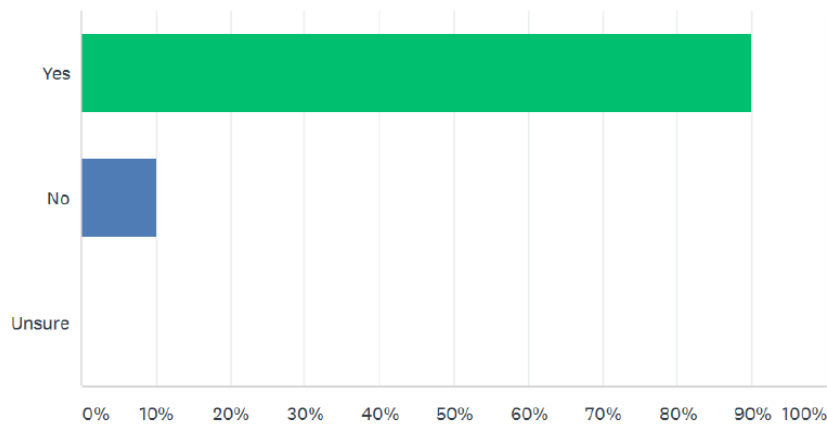
Answered: 8 Skipped: 2



### Question 5

Would you utilize birth control if offered at no cost while receiving treatment?

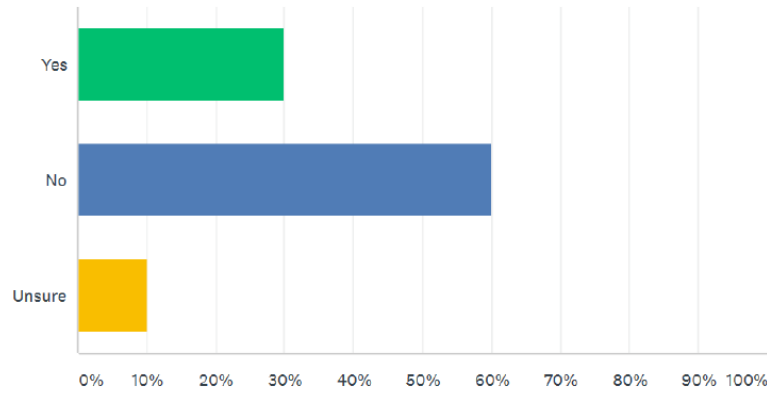
Answered: 10 Skipped: 0



Question 6

Have you ever received comprehensive contraceptive counseling regarding all birth control options available to you?

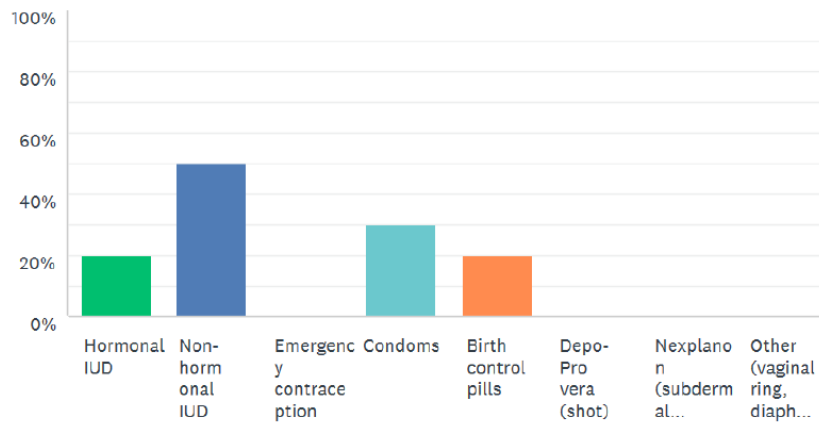
Answered: 10 Skipped: 0



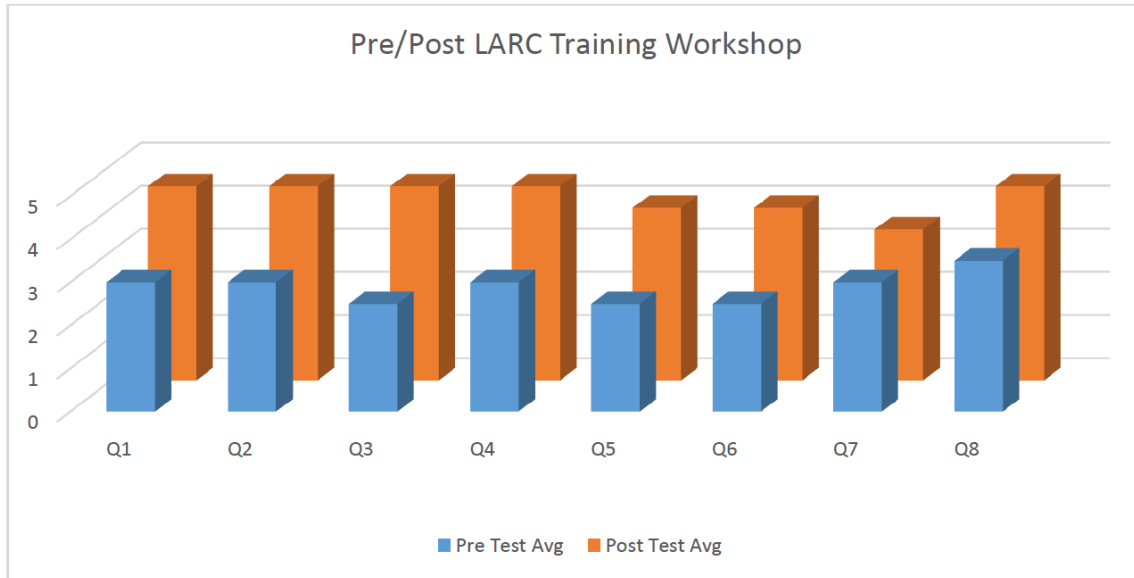
Question 7

Which birth control options would you be most interested in receiving?

Answered: 10 Skipped: 0



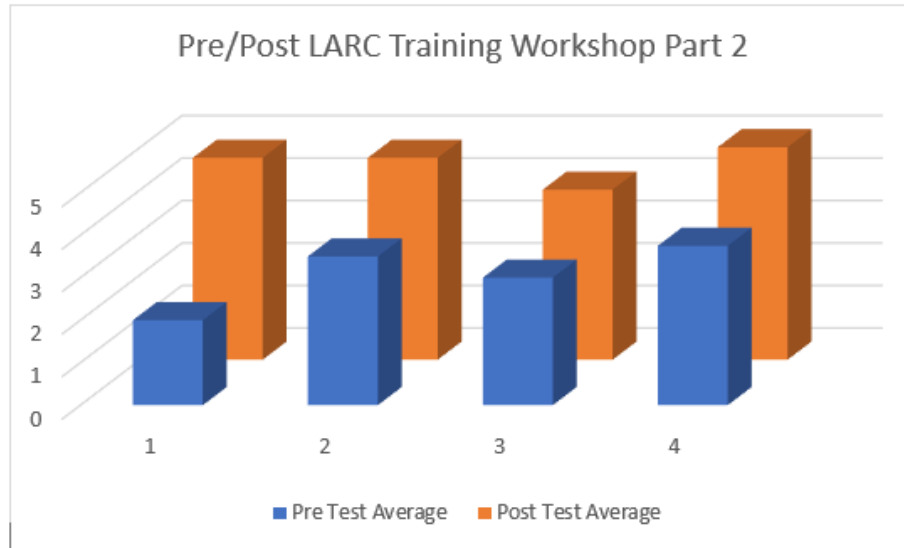
### Appendix U. Pre-Post LARC Training 1 Intervention Results



N=2

Q1	I am comfortable providing comprehensive contraceptive counseling consistent with current guideline recommendations.
Q2	I am confident in identifying all LARC eligible candidates.
Q3	I feel prepared to counsel patients about the LARC effectiveness and safety.
Q4	I feel prepared to counsel patients about the LARC insertion procedure and follow-up.
Q5	I feel comfortable with IUD insertion.
Q6	I am adequately prepared to insert an IUD.
Q7	I have sufficient previous experience with IUD insertion.
Q8	Hands-on skills training is an effective method to prepare for IUD insertion.
Key 1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree	

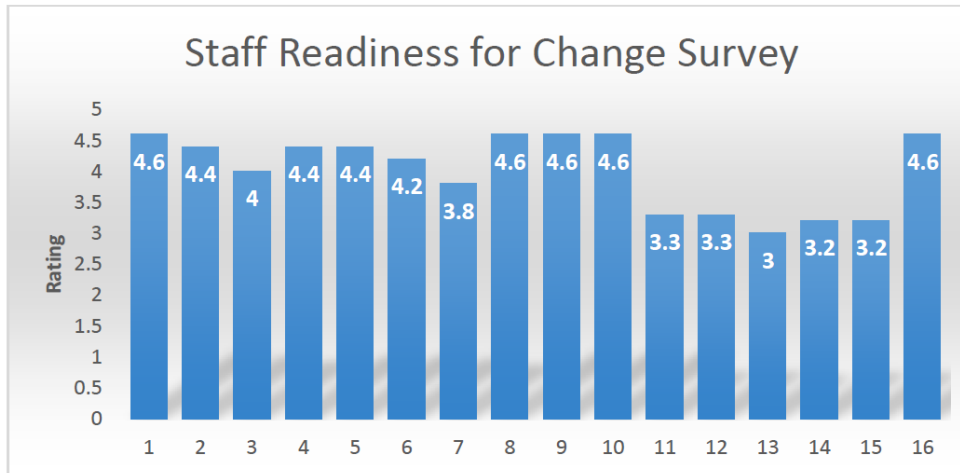
### Appendix V. Pre-Post LARC Training 2 Intervention Results



N=4

Q1	I feel comfortable with Nexplanon insertion and removal.
Q2	I am adequately prepared to provide Nexplanon counseling, insertion, and removal.
Q3	I have sufficient previous experience with providing the subdermal implant.
Q4	Hands-on skills training is an effective method to prepare for Nexplanon insertion and removal.
Key 1= Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree	

### Appendix W. Staff Readiness for Change Survey Results



N=5

1	There is a need for organizational change to expand services to include contraceptive services.
2	I am aware of the reasons why change is needed within the organization.
3	Expanding the services provided to the clients is appropriate and achievable.
4	I am aware that the organization is considering expanding the services offered to include contraceptive services.
5	I understand the need to include contraceptive services in the services offered in all clinical visits including intake appointments and follow-ups.
6	Management is committed to providing support to staff during periods of change.
7	I am able to discuss changes with leadership and management.
8	Providing contraceptive services will benefit the organization.
9	I am supportive of the integration of contraceptive services into clinic appointments.
10	I know how my role can help make the expanded services successful.
11	There is adequate consultation with staff when change occurs.
12	Staff communication is reliable and well-timed.
13	I am adequately trained to offer contraceptive services within my role and scope of practice.
14	I have the resources I need to provide contraceptive services within my role.
15	I am confident in my ability to provide contraceptive services to all clientele.
16	Overall, I believe contraceptive services will be advantageous for the clientele participating in substance use treatment and the larger community as a whole.
Key 1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree	