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Cynthia Kuehner

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Program Evaluation of an Easy Access Clinic for Effective  
Contraception for U.S. Active Duty Women in Okinawa, Japan

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## Abstract

*Background:* Unintended pregnancy in the United States (U.S.) is a significant health problem that takes on additional magnitude in the context of military service. Young, active duty women have higher unintended pregnancy rates compared to the general population, secondary to non-use of contraception or selection and use of the least effective methods (condoms and oral contraceptive pills). The literature validates the problem, identifies access barriers to highest-efficacy contraception options in primary care settings, and offers evidence-based, best practice opportunities to impact this public health challenge. *Purpose:* The purpose of this project was to evaluate access, utilization, effectiveness, and patient satisfaction of the newly-implemented Walk-in Sexual Health (WiSH) clinic for contraception services delivery at a military health clinic in Okinawa, Japan. *Methods:* The widely-used RE-AIM (Reach-Effectiveness-Adoption-Implementation-Maintenance) framework was employed to analyze the impacts of this health promotion initiative in the community. Data were collected to determine access to contraceptive clinic services, changes in high risk (age 18-24) female population use of long-acting reversible contraception (LARC), and baseline patient satisfaction, comparing 12-month periods, pre- and post-WiSH clinic implementation. *Results:* LARC utilization increased among all demographic groups (women, age 18-53), but most substantially among populations of interest, namely high risk (18-24 years of age) active duty and non-active duty women. Patients reported very high baseline satisfaction with the clinic's services. *Conclusion:* The WiSH clinic eliminated known barriers to the most effective contraception options (LARC) and demonstrated its acceptance, utilization, and value in the community, according to the RE-AIM domains for health promotion.

**Keywords:** LARC, unintended pregnancy, contraception, barriers, long-acting reversible contraception, U. S. military women, family planning, access to primary care, RE-AIM

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### **Introduction**

Unintended pregnancy among female service members in the U.S. military presents an important problem for military readiness. Pregnancy precludes deployment, and women who become pregnant while deployed must return from most operational settings. While all branches of the military remain predominately male, the number of women serving is on an upward trajectory. The percentage of women in military service has increased from 11% in 1990 to 15% in 2015 (Parker, Cilluffo, & Stepler, 2017), with continuous growth anticipated. In spite of free health care for active duty service members, real barriers impede easy access to the most efficacious contraceptive care options, namely long-acting reversible contraception (LARC), for active duty females in military treatment facilities (MTFs). Implementation of evidence-based practice guidelines for quality family planning services is indicated to enhance the availability of safe, highly effective contraceptive options and reduce the many and complex burdens of unintended pregnancy among military females. Evaluation of the of these clinical service efforts is important for ensuring that the targeted population's contraception needs are met, for validating progress toward reducing unintended pregnancy in the military, and for ensuring stewardship and efficiencies in federally-funded clinical resources.

### **Background**

Unintended pregnancy is a national problem that has specific and unique ramifications for female service members in the U.S. military. Finer and Zolna (2014) identified that 51% of U.S. pregnancies were unintended in 2008, with the highest percentages reflected in younger age groups. The rate of unintended pregnancy in the general population was 52/1000 women. In

comparison, Grindlay and Grossman (2015) identified a much higher rate of unintended pregnancy (72/1000 women) among active duty women in 2011. The Office of Disease Prevention and Health Promotion (2018) has set a Healthy People 2020 target to increase the percentage of *intended* pregnancies from 51%, at baseline in 2001, to 56% by 2020, over a 19-year period. MacDonald (2013), reporting on the Navy and Marine Corps Public Health Center's Sexual Health and Responsibility (SHARP) program initiatives, identified the same target (56% intended pregnancy rate) for SHARP 2020 goals, which would be an ambitious increase for Navy enlisted women, since 64% of pregnancies among this demographic were unintended, and only 36% were intended in 2012.

Prevention of unintended pregnancy among the active duty female population is especially important because of the implications for military readiness degradation, inability to complete operational missions, potential for negative career impacts, suboptimal access to timely prenatal care or abortion services (not authorized in military facilities), and elevated risks to mothers and babies, secondary to military hazards and environmental exposures. Adams (2017) quantified avoidable costs of unintended pregnancy to include the financial costs of publicly funded maternity care (\$12,770), a non-deployable status for 17 months, and 84 lost duty days per pregnancy. Various studies have identified that unintended pregnancy among military women and women in general is largely due to non-use of contraceptives; and among contraceptive users, the least effective methods (condoms and oral contraceptives) are most commonly employed (Goyal, Borrero, & Schwartz, 2012; Grindlay & Grossman, 2015; Rabie & Magann, 2013).

Some of the factors that may influence military women's contraceptive use include individual desires to maintain privacy regarding *prohibited* sexual activity (while deployed or if

unmarried), poor reproductive health knowledge, including awareness of LARC and emergency contraception, lack of provider knowledge or experience with all forms of contraception, especially in overseas or deployed settings, inadequate options for pregnancy termination, and difficulty managing contraception over time (Grindlay & Grossman, 2015; Rabie & Magann, 2013). All of these variables may be magnified in the common military contexts of demanding operational tempo, travel between time zones, irregular work and personal schedules, harsh environmental conditions, inadequate hygiene and toileting facilities, lack of privacy, and inconsistent access to prescription services or supplies.

In addition to the active duty female, patient-centric issues already identified, there are numerous barriers to contraceptive care imposed by the structures and common practices of the military health care system, the placement of clinical providers, the variability of clinician knowledge and skills, and the timely, convenient access and availability of contraceptive resources. Heitmann, Hammons, and Batig (2017) evaluated the knowledge and skills of frontline military clinicians stationed in troop clinics or unit-based settings and determined that many were inadequately trained to provide the full spectrum of contraception options, and most were only comfortable prescribing the least effective methods; fewer than half had been trained in LARC options. In the broader community, many studies have identified the lack of LARC training among primary care providers, clinics that do not support same-day LARC administration, and clinician bias and attitudes are common barriers that prohibit best practice contraception access and availability (Biggs, Arons, Turner, & Brindis, 2013; Nisen, Peterson, Cochrane, & Rubin, 2016; Philliber, Hirsch, Brindis, Turner, & Philliber, 2017).



**Problem Statement**

Unintended pregnancy among active duty female service members is identified by a higher rate (72/1000) than the U.S. general population (52/1000) and results from inadequate access to the most efficacious contraceptive options, including long-acting reversible contraception (LARC), in primary care clinics in the military health system, which has the potential to degrade individual, unit, and military readiness.

The MTF project site selected for evaluation recently implemented a Walk-in Sexual Health (“WiSH”) clinic that was deliberately established to address the problem of unintended pregnancy in the active duty population on Okinawa by effectively removing the identified barriers and comprehensively addressing the factors that contribute to its occurrence. The full-service sexual health and contraception clinic, staffed by properly trained primary and specialty care clinicians, is capable of educating patients on contraception and sexual health prevention and treatment options and delivering all available contraceptive and family planning services, with the exception of elective pregnancy termination. The clinic offers the most effective LARC methods for pregnancy prevention during a walk-in, easy-access, single clinic visit, in the absence of any clinical contraindications. To date, the WiSH clinic has introduced highly-effective contraception services in an easy-access setting, removed known barriers, and concentrated resources. However, prior to this project, the MTF’s WiSH clinic had not yet been evaluated for its effectiveness or impacts. This project was initiated to systematically evaluate the clinic’s access and utilization, with a specific focus on LARC utilization among high-risk patient demographic groups, as indicators for public health impact toward reducing unintended pregnancy in the military community of Okinawa. Additionally, the project collected baseline patient satisfaction data in response to WiSH clinic services.

### **Organizational “Gap” Analysis of Project Site**

Unintended pregnancy is a well-recognized, significant problem in the U.S. When embedded in the context of active duty service members, the problem takes on additional significance. Unintended pregnancy among active duty females imposes a significant disruption for the individual and for the unit in which she serves. Rendered non-deployable, the pregnant female is personally impacted, *and* she impacts unit readiness and the ability to complete the mission. If the pregnancy is unplanned and unexpected, the disruption can have significant individual and military mission consequences. Unintended pregnancy among active duty service women is preventable. Active duty women have access to free contraceptive services. However, barriers remain. The delivery systems for most-effective contraceptive options in the military health system are suboptimal. There are needless barriers to walk-in and same day LARC procedures. Military clinicians on the frontlines of primary care are inadequately trained in LARC methods and assigned to clinics without consideration of their training and competence for this in-demand primary health service.

As a result of the concerns for a high rate of unintended pregnancy among military women, there has been a heightened interest across the Department of Defense (DoD) in developing solutions to address the problem (Adams, 2017). In the Navy, a walk-in contraception clinic opened at the Naval Medical Center, San Diego in February, 2016. Since then, an additional seven, similar clinics have been established, with the project site being among the most recent to open, in February, 2018.

The ease of access and availability of family planning services, to include long-acting reversible contraception (LARC), for active duty female service members is an important topic in military healthcare delivery. Grindlay and Grossman (2015) found that rates of unintended

pregnancy are higher among military women than in the general population and these rates have increased between 2005 and 2008, from ten percent to eleven percent. Additionally, rates among Marine Corps and Navy females are higher than other branches of the service. The predominant services represented in Okinawa are Marine Corps and Air Force, followed by Navy and Army. A breakdown of females among the island wide demographic is not available, but all active duty females are eligible for care and services at the U.S. Naval Hospital Okinawa. The impact of unintended pregnancy in the military is significant, because of the potential to compromise military readiness. Because Okinawa is considered a “forward-deployed” location for active duty personnel, identifying and eliminating barriers to contraceptive services is a critical imperative for clinics and practices that serve all active duty women, but especially in this overseas, high operational tempo location.

The community of interest and stakeholders for this project, identified in the gap analysis, include the targeted patient population, the available staff to provide services and the physical geographic resources and services on the island. The targeted patient population consists of the active duty female population, who are primarily of childbearing age on the Island of Okinawa. The staff include the available primary and specialty care staff specifically trained to administer LARC options, including general medical officers, family medicine and obstetric-gynecologic physicians, nurse practitioners, and physician assistants. The physical resources include the main hospital WiSH clinic site and a future potential for additional branch health clinic locations which will best promote ease of access for the population, in addition to configuration of clinician schedules, support staff, equipment, and supplies to deliver the services optimally (see Appendix A).

The availability of qualified staff and the distribution across the island's medical resources, including the Naval Hospital Okinawa, the Air Force Clinic on Kadena Air Field, the Navy's Branch Health Clinics, and the U.S. Marine Corps' medical aid stations are assigned without consideration of specific capabilities or liabilities in relation family planning services. Currently, clinics and staff are generally distributed according to active duty and military family population centers and their corresponding demand for primary and specialty services. This distribution is without regard to specific requirements or needs of sub-populations within the military demographic, such as female Sailors and Marines. Prior to the WiSH clinic opening, there was no deliberate placement of providers holding credentials and privileges for LARC placement; nor were there the structural and support mechanisms (schedule templates, supplies, equipment) in place to enable same-day, walk-in family planning and LARC contraceptive services at any of these clinical sites. In recognition of these shortfalls, the deliberate concentration of appropriate resources to enable the recent establishment of the site MTF's Walk-in Sexual Health ("WiSH") clinic was facilitated to address the issue of unintended pregnancy, specifically targeting the military population. The aim of this project was to evaluate its success and effectiveness in addressing the identified gaps by analyzing WiSH clinic services and outcomes.

## **Review of the Literature**

### **Literature Review Strategy**

Separate searches were performed to narrow the focus for each of three themes in this review. The dominant themes included incidence and consequences of unintended pregnancy among active duty women, barriers to contraceptive care in primary care and military clinic settings, and evidence-based application of current guidelines for family planning services. Each

search was initiated in the comprehensive Power Search interface of the Uniformed Services University of the Health Sciences (USUHS, 2017) remote Learning Resource Center. This interface allows a single starting point for all of the library's references and searches 18 different databases, which include the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, PsycInfo, JAMAevidence, and many others. After initially entering search words and phrases as a starting point, all searches were narrowed to full-text online, scholarly/peer reviewed and journal articles; searches were further limited to the disciplines of nursing, medicine, and public health. These common steps enabled a quick reduction of high volume results.

The first search began with the terms "unintended unplanned pregnancy active duty military females". This yielded 1,143 results. After the common filters were applied, 30 studies remained. Initially these results were limited to the last five years, which produced nine articles. After reviewing these, eight were eliminated, so the date range was adjusted to the past ten years, which produced 22 articles. Six exclusions were made due to lack of focus and specificity. Five were eliminated because they studied non-applicable populations (veterans and adolescents). Four were either non-scientific or obsolete (a case study, an editorial, a qualitative review, and an outdated (1990-2010) literature review). Two were excluded because they studied foreign militaries. Five articles remained for this theme.

The second search proved to be more difficult, as there is a paucity of information specific to barriers to contraceptive access exclusively focused on military primary care settings for female service members. Multiple searches were initiated, using the following terms in various combination: "education and practice, barriers, long acting reversible contraception, LARC, same day, access, U.S., primary care, physician, nurse practitioner, military women".

Available results were refined and scanned with each modification, applying the common filters and preferentially selecting those within the past five years. Once filtered to a reasonable number of articles (37), only one was selected, excluding all others for non-applicability, foreign studies, wrong demographic, qualitative studies, outdated, or primarily abortion-focused. Returning to the previous search (88 articles), another two were extracted. As a result of poor yield, the approach was modified to targeting the reference lists from the three articles selected and, through this effort, another three applicable studies were identified and individually located in the remote UMass Library system.

The third search focused on evidence-based practice and ease of contraceptive access, including LARC in primary care settings, based on current clinical practice guidelines and other supporting evidence. The Clinical Practice Guideline, titled *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* is relevant and was selected (Gavin, et al., 2014). The remote database search started with the terms “increasing long acting reversible contraception LARC primary care”, which yielded 405 results. The common filters were applied and limited to publications in the last ten years. This reduced the number of articles to 147. Adding “military” to the search reduced the number to six; one article was considered relevant, and “military” was removed again. The number was reduced to forty-three by further subject refinements of “United States, unintended pregnancy, reversible contraception”. From these, exclusions were applied to 35, including 11 foreign, six abortion-focused, six which lacked focus or specificity, seven for the wrong demographic, and four that studied adolescents. Eight articles remained for additional review and possible inclusion.

Eighteen peer-reviewed, original research articles of various methodologies, including retrospective, and mixed methods, one clinical practice guideline, and one professional

committee opinion paper were selected for review and consideration for inclusion in this literature review. Several appeared on all of the searches as the most relevant and specific to the identified area of interest. The Johns Hopkins Nursing Evidence-based Practice Rating scale (Newhouse, Dearholt, Pohl, Pugh, & White, 2005) was used to critique select articles and is based on strength of evidence (Level I-V) and quality of the evidence (from high to low, A-C). For details, see Appendix B.

### **Unintended Pregnancy in the Military**

Unintended pregnancy in the military is a significant issue that negatively impacts military readiness. Military women are unable to deploy and must be returned early from operational settings if pregnancy occurs, and both the woman and her unit may be negatively impacted by risks to individual health and mission accomplishment (Goyal, Borrero, & Schwartz, 2012; Grindlay & Grossman, 2015; Heitmann, et al., 2016; Rabie & Magann, 2013). Rabie and Magann (2013), using survey data from 7,225 active duty navy participants from 2005 and 2008 (Level III B) found that the unintended pregnancy rate among military women (105 per 1000 women) had increased between 2005 and 2008 and was fifty percent higher than the general population (52 per 1000 women). Grindlay and Grossman (2015) made similar conclusions (Level III B) that the military rate of unintended pregnancy in 2011 (72/1000 women) remained higher than the general U.S. population (52/1000 women). Both studies showed higher rates among married or cohabitating women and among enlisted women in the Navy and Marine Corps than in the Air Force. Both showed no differences between deployed or non-deployed females. Heitmann, et al. (2016), whose study was limited to Army sites (Level III B) found that rates were higher among (mostly Army soldiers) single enlisted active duty

women (229/1000 and 68% of respondents) and that rates were higher than for married members (70/1000) or for the general population, identified as 51%.

### **Barriers to Most Effective Contraceptive Options in Primary Care**

Barriers to contraceptive options exist in primary care settings accessible to both civilian and military females. Barriers were identified by several studies (all are Level III B studies) and included the lack of on-site services or multiple patient visits for LARC placement options (Beeson, et al., 2013; Biggs, et al., 2013; Nisen, Peterson, Cochrane, & Rubin, 2016). Other systemic barriers were identified, including costs, clinician attitudes, and lack of current education and training (Heitmann, et al., 2017; Philliber, et al., 2017; Witkop, Webber, Chu, & Clark, 2017). Heitmann, et al. (2017), while limited by sample size, identified key gaps specific to military primary care settings, determining that less than half of the frontline clinicians surveyed were trained to provide LARC, even though 97% cared for active duty women in their clinical settings (Level III B).

### **Evidence-based Practice: Verification of Chosen Option**

The best available evidence is the practice guideline titled *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs* published by the National Guideline Clearing House (2014). The source for the guideline content is attributed to Gavin et al. (2014). This comprehensive guideline is graded as 6/7 utilizing the Appraisal of Guidelines for Research and Evaluation (AGREE) Instrument (Agree, 2017). The guideline emphasizes ready access to contraceptive options and the elimination of barriers. The guideline is supported by the American College of Obstetricians and Gynecologists (2015) expert committee opinion (Grade IV B). Ample research studies (all Level III B) demonstrate strategies and innovations to implement the practice guideline into primary care



clinical settings (Hathaway, Torres, Vollett-Krech, & Wohltjen, 2014; Kelly, Cheng, Carlson, Witt, 2017; Pace, Dolan, Tishler, Gooding, & Bartz, 2016), including specific application in the military healthcare system (Chiles, Roberts, & Klein, 2016).

### **Project Rationale**

This literature review and evidence synthesis make a compelling case for addressing the problem associated with unintended pregnancy among active duty military women. The problem is well defined. Unintended pregnancy rates are higher in the military than in the general population and have the potential to negatively impact military readiness and successful mission completion. Barriers to the most effective forms of contraception (LARC) are abundant in primary care settings. These include patient and provider attitudes, knowledge and skill deficits, and delays and loss to follow-up by unnecessary imposition of multiple visits for LARC insertion. The evidence indicates that LARC and other forms of contraception should be readily available, during same day, single-site visits. Military settings especially may have gaps that pair eligible patients seeking contraceptive services with providers who lack the capacity (systems issues, knowledge deficits, lack of experience/competence, etc.). Finally, there is compelling evidence that comprehensive family planning services focused on reducing the high rates of unintended pregnancy can be effective and are shown to reduce unintended pregnancy, when approached systematically and identified barriers are eliminated.

### **RE-AIM Framework for Impact Evaluation**

The model which served as the foundation for this project is the RE-AIM framework developed originally by Glasgow, Vogt, and Boles (1999). RE-AIM offers a systematic approach for planning and evaluating health care initiatives and has been widely utilized and accepted as the standard for disseminating findings from public health research, application of

evidence-based intervention, and community-based health promotion programs. The RE-AIM framework has five distinct components or dimensions, as originally described and subsequently evolved (RE-AIM.org, 2018). The dimensions include Reach, Effectiveness (or Efficacy), Adoption, Implementation, and Maintenance, as illustrated in Appendix C. The original model suggested potential for application at the individual, clinic or organization, and community levels. A core tenet of the RE-AIM framework is that overall impact of an intervention results from the cumulative effects of all five dimensions, consistent with systems-based models. Although the RE-AIM model was not specifically employed for the preparation and planning of the WiSH clinic in Okinawa, the model was considered to be a best-fit for both initial and continuous (future) evaluation of the clinic's impact within the Okinawan military beneficiary community. The scope of this project was to use the RE-AIM framework to establish a baseline evaluation of this newly-implemented health care initiative. A description of each of the five RE-AIM dimensions follows.

### **Reach**

The *Reach* measure of the RE-AIM framework is measured at the individual level for the community health intervention. Reach targets the patient or the employee and can be easily expressed as a percentage or ratio, reflecting the numerator (number of actual participants) over the denominator (number in the population) as long as both variables can be quantified. Reach also delineates the demographics or characteristics of both the participants and population, as well as the same features for the *non*-participants. By evaluating the demographics, in addition to the numeric data, an evaluation of *representativeness* can be made for the participants within the community of interest. In public health initiatives, this is an important distinction, because frequently participants may over-represent individuals who least *need* the intervention, i.e. they

may not be the intended target of the community health intervention (Glasgow et al., 1999). Therefore, this project sought to evaluate reach by collecting and analyzing data for the targeted population / stakeholders (i.e. women who access or use the clinic services). The project also sought to identify feedback in terms of any identified barriers and facilitators (ease of access, hours of clinic, ability to obtain necessary information, etc.) of the clinic / program from the aforementioned stakeholders.

### **Effectiveness**

*Effectiveness* (or Efficacy) is the degree to which the health care initiative improves (reduces) a health disparity or produces a desired health outcome. It is also recommended that any unintended, or negative outcomes are identified and evaluated. Common outcome measurements have historically concentrated focus on biologic measures, but current use of the RE-AIM framework suggests that it is also important to consider behavioral outcomes as well as life quality or satisfaction outcomes (Glasgow et al., 1999). As the RE-AIM framework has evolved since its inception, additional measures of effectiveness are recommended for comprehensive incorporation and evaluation. These include both direct and broader outcomes and ideally, incorporation of qualitative data collection and interpretation, in order to more fully understand the impact of interventions on the community and population of interest (Kessler et al., 2013). This project evaluated the impact of the clinic by analyzing access and utilization of contraceptive services, the types of contraceptives chosen, with relative comparison of SARC to LARC options, and patient satisfaction for newly provided services. Additionally, feedback for marketing effectiveness and suggestions for improvement were solicited from clinic users.

**Adoption**

In the RE-AIM framework, *adoption* references the willingness of organizations within the community to adopt the program and the proportionality or representativeness of their participation. Adoption addresses the settings in which participation occurs and also addresses barriers to participation from clinics/settings/individuals that opt-out or choose not to participate. From a who, what, when, where, how and why perspective, Adoption answers *where* the program was applied, and by *whom* - individually and organizationally (Glasgow & Estabrooks, 2018). This project enabled baseline evaluation of concentrated resource allocation (staffing, clinic structures of time and space, overall patient satisfaction), and collected feedback from patients to determine their knowledge of the clinic and its services regarding contraception access and the full spectrum of options for pregnancy prevention.

**Implementation**

In the original RE-AIM framework, Glasgow et al. (1999) describe *implementation* as an evaluation of whether and to what extent a program or protocol meets its intended plan for delivery. At both the individual and at the setting levels, adherence by both participants and staff members, respectively, to the intended implementation, is quantified and evaluated.

Implementation gets at the *how* questions for the program or intervention, including consistency with original planning, adaptation (if any), and costs. If available, an analysis of resources and returns on investment may be identified and evaluated (Glasgow & Estabrooks, 2018).

Originally, the WiSH clinic was established at a single site with the intention of enhanced and ease of access to care. This project enabled baseline analysis of whether the WiSH clinic was meeting the focused intent, whether contraceptive services concentration increased access and

utilization, and whether expansion (portability to additional sites and/or extended WiSH clinic hours) should be considered for the future.

### **Maintenance**

Maintenance, like other elements of the RE-AIM framework can be evaluated at both the individual and at the organization/community levels. Maintenance references the sustainment of behavior change and is evaluated on the merits of longevity, or whether the health promotion activity becomes a part of the routine practice and endures over time. Maintenance implies stability and integration as the intervention becomes *normal* in both individual behavior, community standards, and cultural acceptance (Glasgow et al., 1999). Modern RE-AIM framework considerations describe *maintenance* further, adding other examples of operationalization, including the degree to which the intervention becomes integral to policies, resource commitments over time, position descriptions, and even performance evaluations (Glasgow & Estabrooks, 2018). At the local level this project demonstrated its potential for sustainability and integration through ongoing access, use and effectiveness data. Further, the project provided opportunities to identify future direction for the existing program and a benchmark for evaluating similar clinics considered by the military.

### **Goals, Objectives and Expected Outcomes**

The overarching goal of this project was to use the well-established RE-AIM framework to evaluate the preliminary/baseline impacts (utilization and outcomes) of the recently-established Walk-in Sexual Health (WiSH) clinic within an active duty and family member military community in Okinawa. The WiSH clinic applied evidence-based, best-practice interventions for both contraception management and delivery, as well as elimination of known

barriers for family planning services, including non-delayed, same-day service for prescription and placement of the most efficacious contraceptive options (LARC).

The RE-AIM framework provides a model for evaluation of evidence-based community health programs and initiatives. While this is perceived to be a best-fit framework for evaluating the newly-established WiSH clinic at the project site, it is recognized that not all dimensions of RE-AIM are fully mature. It is acknowledged that this preliminary evaluation will be most able to target *reach*, *effectiveness*, and *adoption* and that objectives and outcomes for *implementation*, and *maintenance* will be in preliminary review and require additional, follow-on evaluation for accurate determination of the WiSH clinic's impact within the active duty female (target) and larger patient population in the military community on Okinawa. Full program maturity is anticipated to evolve over the next 12-24 months. Additional evaluation will be indicated and is recommended. Based upon initial implementation of the WiSH clinic and preliminary evaluation, specific objectives with expected outcomes were delineated in the following table (Table 1).

**Table 1 – Objectives and Expected Outcomes Using RE-AIM Framework**

	<i>Objectives</i>	<i>Expected Outcomes</i>
<b><i>Reach</i></b>	1. The total number of potential contraception participants will be identified as the total number of women (all demographic categories) eligible for care at the naval hospital and branch clinics between the ages of 18-52.	1. The total number of women who access contraception management services at the WiSH and other clinics will be quantified and evaluated by demographic category between two periods (pre-WiSH, including February 2017 – January 2018 and post-WiSH,

<p><i>Effectiveness</i></p>	<p>2. Improved access to care and availability of walk-in contraceptive services will result in higher utilization of contraceptive service provision within the population of interest.</p> <p>1. Patients pursuing contraception services at the MTF between February 1, 2018 and January 31, 2019 will opt for LARC, vice short-acting reversible contraception (SARC) with greater frequency than baseline (retrospective data collected for the 12 months, prior to WiSH clinic initiation (February 2017 – January 2018)).</p> <p>2. Clinic staff will offer patients a single page feedback/satisfaction survey form at each visit, consistent</p>	<p>including February 2018 – January, 2019).</p> <p>2. A comparison of ICD-10 CPT codes for contraception access and utilization will be identified according to patient demographic (active duty female, civilian, etc.) with comparison of pre-intervention utilization rates.</p> <p>1. CPT codes for contraception (SARC vs. LARC) will demonstrate a ratio over time (at least six months of data collection, March – December 2018) favoring LARC over SARC, with a target decreasing (toward &lt;1) SARC/LARC ratio (indicating a higher preference for LARC) over time).</p> <p>2. Feedback will reflect high patient satisfaction (scored “yes” and “Excellent” or “Good” on options)</p>
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	<p>with clinic use at other Navy sites.</p> <p>Data will be collected/compiled between September 1, 2018 - January 31, 2019.</p>	<p>with clinic convenience, access, availability of desired service, and staff knowledge and interaction.</p>
<b><i>Adoption</i></b>	<p>1. A focused, single-site access to care for walk-in contraception services was the initial goal for the WiSH clinic at the clinical site (without any plan for elimination of services at other clinics; i.e. a Primary Care Manager (PCM) in the family medicine clinic could still prescribe oral contraception or place LARC). Preliminary evaluation will describe the access to care and utilization of the WiSH clinic since inception.</p>	<p>1. Analysis of expansion opportunities, including expanded hours or additional clinical sites (and capability of organization to adapt to demand), will be described. Any persistent barriers (as identified in the literature and locally) will be identified and evaluated. These will be described with respect to potential for future expansion, relocation, continuation, etc. by completion of this evaluation.</p>
<b><i>Implementation</i></b>	<p>1. Staff education (contracted and follow-on clinically supervised) will be utilized to increase available, trained, (and credentialed/privileged) primary care providers in proprietary LARC administration by July 1, 2018 to</p>	<p>1. Clinic staff at newly-established walk-in contraception clinic will be able to provide same-day services for all available clinic-based contraception, including LARC without needing to refer to specialty care or schedule additional</p>



	<p>adequately staff walk-in contraception clinic in Okinawa, Japan.</p> <p>2. MTF public affairs officer to advertise walk-in contraception clinic to Okinawan military community using social media and radio spots prior to opening of clinic (February 2018) and regularly (monthly) indefinitely. Posters and flyers will be distributed throughout MTF and clinics.</p>	<p>appointments. Adequacy of clinic staffing and services will be determined by utilization data and patient feedback at conclusion of program evaluation.</p> <p>2. Through the use of available advertising and social media options, the walk-in contraception clinic will see upward trends in utilization over time, demonstrating its return on investment during duration of the evaluation.</p>
<p><b><i>Maintenance</i></b></p>	<p>1. Preliminary goal was the initial resourcing (staff and materiel resources) to initiate the WiSH clinic.</p>	<p>1. Baseline evaluation using the RE-AIM framework will provide the foundation for ongoing resource commitment and continuation, including indicators for expansion (hours, sites) or termination (if analysis fails to demonstrate expected outcomes and benefits to population).</p>

### **Project Design**

The design of this project was a systematic evaluation of a recently-implemented clinical practice intervention based upon best-practice evidence. Comprehensive, patient- and population-centered strategies to reduce unintended pregnancy are described in the literature and endorsed by professional practice groups and organizations. The WiSH clinic in Okinawa was implemented with the intent of managing available resources and mitigating barriers to effective contraception access and options for the female beneficiary population as the island's first walk-in contraception management clinic at an overseas MTF. Utilizing the RE-AIM framework, the implemented program was evaluated for its preliminary impacts in the community. The setting was a wellness-based care clinic, embedded in the Public Health Directorate at a military hospital in Okinawa. Evaluation of successful implementation and intervention employed quantitative methods to determine pre- and post- WiSH clinic LARC utilization for the beneficiary population on Okinawa. Quantitative methods were used to determine effectiveness of the intervention by measuring LARC utilization by specific demographic groups, with an expectation that LARC utilization would trend upwards as SARC utilization trended downward.

### **Project Site and Population**

The site for implementing the proposed project was a wellness-based public health clinic at a MTF in Okinawa, Japan. The geographic location was on the main hospital campus, within walking distance (across a parking lot) of the main hospital building. A long-term potential is to export the clinic's capabilities to one or more branch clinics, even closer to the active duty population centers. The identified MTF patient population consists of the active duty military, family members and Department of Defense (DoD) eligible beneficiaries, as well as space available personnel. In the direct care system, there are approximately 40,000 patients eligible

for care. The project had the potential to provide all eligible females same day, walk-in contraceptive services. The sub-population of high-risk active duty women, age 18-24 (the target population for this project) was the demographic of greatest interest. From the eligible females, it was recognized that not all would be pursuing contraceptive services; some would be planning pregnancy or were pregnant. The MTF in Okinawa performs > 90% of the deliveries in Okinawa for the eligible population and averages approximately 80-100 deliveries monthly. Among these deliveries, it is unknown how many births resulted after an unintended pregnancy. Pregnancy termination services are not authorized at federally-funded facilities (Performance of Abortions: Restrictions, 10 U.S.C. §1093, 1996). It is unknown how many women pursue pregnancy termination in Okinawa.

Staffing for the WiSH clinic was derived from available clinical resources (ob-gyn physicians, midwives, family medicine physicians, nurse practitioners and physician assistants) who were trained/privileged to provide LARC services. There was strong command support from the hospital administration, and further commitment for this project in the higher (external) echelons of Navy Medicine's bureaucracy and chain of command. Successful "Process Improvement for Non-delayed Contraception" (PINC) clinics have been initiated at other Navy Medicine sites. The comprehensive sexual health services clinic in Okinawa was the first of its kind at a Navy overseas MTF serving predominantly an overseas Navy and Marine Corps population. The WiSH clinic incorporated the expertise from a team comprised of multidisciplinary (family medicine, nursing, obstetric-gynecologic, and public health/preventive medicine) professionals. While this clinic was new and newly-established, it did not demand entirely new capabilities; i.e. LARC and SARC contraception were already available at the hospital and branch clinics, with varying processes and individual, non-specific provider skill

sets. The clinic provided new capacity and concentrated resources to meet the evidence-based tenets for best practice contraception delivery. It was deemed to be important and consistent with Navy Medicine objectives to evaluate the effectiveness of these resource investments and allocations.

### **Setting Facilitators and Barriers**

There were numerous facilitators in place for the proposed project, which were considered accelerants and enablers toward success. Specific facilitators for the proposed project implementation included enthusiasm, commitment, and support from the Commanding Officer, the executive board, and the specific clinical directorate involved in launching the clinic as described. The command has always had the capabilities in place to deliver LARC services on a referral basis through specialty care appointing. Some primary care providers were also already trained in LARC delivery. The command was budgeted for the equipment, supplies and pharmaceuticals necessary to sustain the newly-implemented clinic. The command had ample space in the targeted location for implementation and could support the clinic for one half day per week, with the potential for future expansion (time, days, and additional sites). Clinical staff leaders were motivated to succeed and were connected professionally to the sites in the continental U.S. that have launched walk-in contraception clinics at military treatment facilities. Early data were already available validating the successes of same-day, walk-in contraception clinics at other Navy facilities. Education and counseling resources were already developed and were adapted for local use. The MTF has a robust public affairs capability, including access to social media, the hospital's website, and local Armed Forces Network (AFN) radio advertising. The target population was physically located on the island. Their medical care service access

was mostly limited to the MTF and branch clinics, with occasional access to unique medical care capabilities through Host Nation (Okinawan) suppliers.

Barriers to continuation and ongoing evaluation were deemed to be few and could be managed and overcome. The requirement for contracted services to train clinical staff in proprietary LARC procedures (e.g. Nexplanon® insertion) imposed budget considerations for initial training and sustainment. Clinical staff in Okinawa turn over every two to three years, with only sparse continuity exceeding this rotation. The greatest instability in continuity existed among the clinical staff most in need of LARC training and capability; these were (are) the frontline clinicians, including general medical officers, physician assistants, nurse practitioners and family medicine physicians. Because readiness remains of paramount importance in the Okinawan “forward deployed” geography, the MTF invested in funding for LARC administration training with an open invitation of participation by all available clinic staff. They were motivated to obtain the training, because continuing medical education (CME and CE) was offered, and they would be able to apply for supplemental clinical privileges for LARC, once deemed competent. Another, easily-overcome barrier was the need for clinic template modification and commitment to staffing the clinic (maintenance). This change did not require any degradation to clinical access, and in fact was perceived to enhance primary care providers’ schedules which didn’t previously accommodate procedures such as LARC placement. Finally, active duty women’s work requirements, support for pursuing health care, and operational demands/deployment schedules were considered variables affecting successful implementation (reach). Impact and outcomes, utilizing the widely accepted RE-AIM framework were evaluated and monitored for unexpected barriers and obstacles to overcome.

## Methods

A comprehensive understanding and application of project management, inclusive of resource allocation and stewardship, budgeting, strategic goal alignment, leadership buy-in, consensus building, team leadership, trust, delegation, prioritization, communication, dedication, and commitment, within the context of Navy Medicine health care delivery, were all prerequisites to successful program evaluation of quality improvement initiatives within the MTF. Consistent with the RE-AIM framework for public health initiatives, desired improvements and outcomes were dependent upon the ability to address and affect each of the five dimensions of RE-AIM. Success of the recently-established WiSH clinic was predicated on enabling factors, as well as the availability of the trained personnel to deliver on the tasks. Foundationally, these features were available and managed accordingly for successful continuation and evaluation. Serving in a role as the commanding officer of the MTF, the DNP candidate/author was responsible for and held the ultimate accountability for resource management, sustainment, and ongoing program evaluation.

## Measurement Instruments

In order to evaluate effectiveness of the WiSH clinic, measurements established by the Bureau of Medicine and Surgery (BUMED) for previously-established walk-in contraception clinics in the Navy were attempted to be duplicated. Adams (2017) and the Reef Point Group (2017) presented data collection and analysis procedures that were to be implemented for consistency across Navy Medicine sites. For the purpose of this project, in consideration of time constraints, the preliminary focus for evaluation were the RE-AIM dimensions of *reach*, *effectiveness*, and *adoption*. The tenets of *implementation* and *maintenance* will require more time for mature evaluation and will be recommended as a follow-on to this project. Plans to

measure impact included measures of clinic access and utilization, patient satisfaction, historic rates of LARC usage among demographic groups, LARC to SARC ratios, and adequacy of services.

### **Data Collection Procedures**

Retrospective review of contraception types (LARC and SARC) were collected by the DNP student from the staff in the MTF's healthcare business office. Requests for specific data, coordinated with the business office staff, were made after project approval. The healthcare business office provided retrospective coding information specific to contraceptive CPT and ICD-10 codes consistent with previous Navy Medicine analytics. The data demonstrated baseline (pre-project implementation) contraceptive utilization among active duty and other eligible women in the twelve months (February 2017 – January 2018) preceding WiSH clinic implementation, compared with the twelve months post WiSH clinic implementation, between February 2018 through January, 2019.

A performance tracker was utilized to collect data on patient demographics and contraceptive selection for women presenting to the WiSH clinic. The tracker allowed internal-clinic monitoring of clinic demand, utilization, types of services provided, and patient demographics. The purpose of this tracker was to inform resource considerations, to include adequacy of pharmaceuticals (types of SARC and LARC), staffing requirements, indications for clinic expansion (hours, days, etc.). A model of this tracker is represented in Appendix D. Additionally, patient feedback was collected to capture the patient experience of care. A standardized satisfaction questionnaire was developed for implementation across Navy Medicine walk-in contraception clinics. The questionnaire is included in Appendix E. This feedback form was be offered to patients who presented for walk-in contraception. Surveys were anonymous,

voluntary and collected by the WiSH clinic staff and stored in a locked cabinet. This DNP candidate collected a total of 59 surveys bi-monthly between August 2018 and January 2019. Data (patient satisfaction scores) were entered into an SPSS database. Handwritten remarks were reviewed and coded by the DNP student for systematic evaluation.

### **Data Analysis**

Evaluation employed a number of tools and methods. Historic contraceptive use among active duty and general population females, including SARC and LARC options, and SARC to LARC ratios were extracted from de-identified outpatient medical record coding data, using capabilities of the business office analytics staff. These data were filtered and analyzed and are depicted in both tables and graphs in the results section of this project. Previous data collected from Navy Medicine walk-in contraception clinics have included similar descriptive analytics and served as a model for comparable data collection and display (Reef Point Group, 2017; Adams, 2017).

It was anticipated that the SARC to LARC ratio would decrease as an outcome of improved provider and patient education, effectiveness of the evidence-based implementation of same-day walk-in contraceptive services, and that trend data over time would demonstrate the shift (decrease) in the ratio with effective clinic implementation and utilization. Raw data were entered into SPSS and descriptive analytics were utilized to define population characteristics, such as active duty or civilian, and types of contraception delivered, specifically SARC and LARC options. LARC insertion rates post WiSH clinic initiation (both etonogestrel subdermal implants/ Nexplanon® and all forms of Intrauterine Devices/IUDs) were compared with pre-WiSH clinic rates of LARC initiation among comparable patient demographics.



Patient feedback tools were useful in presenting satisfaction data that will help to inform indications for quality improvement adjustments during evolution of the clinic's use and effectiveness over time. Descriptive analytics were employed to demonstrate satisfaction and feedback statistics. Because patient satisfaction was not previously measured specific to MTF contraceptive management, patient satisfaction statistics from this project established baseline data for the WiSH clinic so that responsive enhancements may be implemented in the future, with the aim of continuous process/quality improvement.

### **Cost-Benefit Analysis/Budget**

The cost-benefit analysis provides best information available. Access to contraceptive services at military health facilities is provided at no direct cost to eligible beneficiaries. Resources, such as trained and available staff, all prescription modalities, location for services, equipment and supplies are already available at the Naval Hospital Okinawa and are included in current staffing plans, formulary inventory, and supply budgets. In preparation for initiating walk-in contraception clinics at other Navy facilities, the Reef Point Group (2017) analyzed costs and cost avoidance for pregnancy, unintended pregnancy, and contraception utilization in the Navy. Per their analysis, the average cost for prenatal care and delivery per patient was \$15,725. Pregnancies at sea, resulting in medical evacuation from the fleet platform are estimated to cost an additional \$5,600. It was estimated that the costs of unplanned pregnancies in the Navy in 2012 exceeded \$52.8 million. Cost avoidance can be achieved by successful implementation of walk-in contraception clinics as demonstrated by the work product of the Reef Point Group (2017). Graphics demonstrating calculated costs, benefits and cost avoidance are illustrated in Appendix F. The illustration of comparable Clinics was utilized, as these clinics are similar in

population and patient demographic to the project MTF. It is estimated that costs and benefits for this project would be similar.

### **Timeline**

The clinic opened and began seeing patients in February 2018, was opened one half day per week, and delivered contraceptive intervention, including LARC and SARC, as well as sexual health counseling and sexually transmitted infection (STI) screening, according to plan. The clinic is capable of doing Point of Care (POC) testing for pregnancy and can collect specimens for STI testing. The clinic staffing included two providers (one ob-gyn and one family medicine), preventive medicine staff, support staff (medical assistants or Navy Hospital Corpsmen assigned to each provider), and clerical / administrative support (which was previously in place for the other services provided in the clinic spaces).

The evaluation of success of the WiSH Clinic was the focus of this capstone project. Appendix G details the timeline for all of the components for the project's implementation, subsequent to the original planning and initiation of the WiSH clinic. The Institutional Review Boards at both UMass at Amherst and the Naval Medical Center San Diego (the IRB assigned for the project site MTF) approved the project proposal and the MTF site for implementation of this quality improvement project. Retrospective data collection included ICD-10 and CPT codes for LARC/SARC contraceptive services. Data for the project site were collected for the twelve months preceding WiSH implementation, for historic baseline, and then for the twelve months post-WiSH implementation to evaluate community health impacts post-WiSH clinic implementation. These data were organized to enable historic and current information and analysis using SPSS-generated descriptive statistics.

### **Ethical Considerations/Protection of Human Subjects**

The University of Massachusetts, Amherst (UMass) Institutional Review Board (IRB) approval was obtained prior to initiating the data collection elements of the DNP project (see Appendix H). Additionally, IRB review and approval was pursued from the Naval Medical Center San Diego, as required prior to project implementation at the selected MTF (see Appendix I). The evaluation of the WiSH clinic was deemed to be a performance improvement, quality improvement project, categorized as not-human subjects research and as such was waived from full IRB oversight, as there were no new clinical interventions, and the DNP candidate used only de-identified data for program evaluation. Evaluation of the WiSH clinic's effectiveness is consistent with building patient-centered models of care delivery while deriving resource efficiencies and meeting the readiness aims of military medicine. Patients were offered usual contraceptive services in accordance with all governing standards of practice by licensed, privileged clinical staff and fully trained support personnel.

All staff who interfaced with patients, assisted with data collection, documented in the clinic tracker or collected satisfaction surveys in the clinical setting were bound by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 regulatory requirements. No patient identifiers will be used for any of the data collection or files (spreadsheets). There were no privacy breaches during the course of this project. Data were reported in aggregate form only. Patient satisfaction and WiSH clinic intake forms were collected by WiSH clinic support staff. The intake forms data for populating the clinic tracker were entered into an Excel spreadsheet. No protected health information was included in the spreadsheet. The spreadsheet was maintained in a write-protected file on a project site internal drive. Access was granted on a need to know basis by the hospital IT staff, with application and justification maintained by the

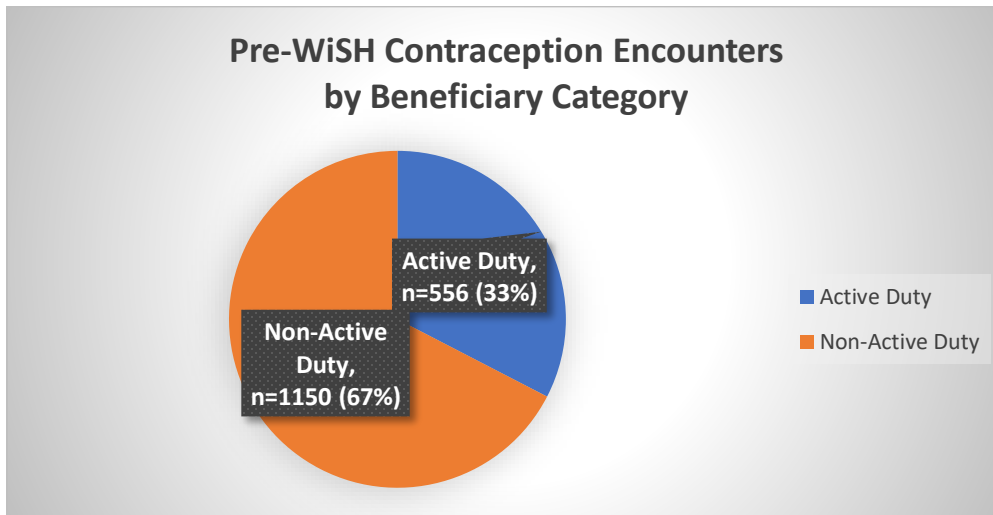
IT department in accordance with MTF privacy policies. Access to all hospital computers and data are Common Access Card (CAC) enabled with unique (embedded chip) identifiers and individual password requirements. Patient satisfaction forms were collected at the conclusion of WiSH clinic encounters. A folder with paper entries were locked in the WiSH clinic for collection by the DNP student. No protected health information (PHI) was included on the forms.

### **Results**

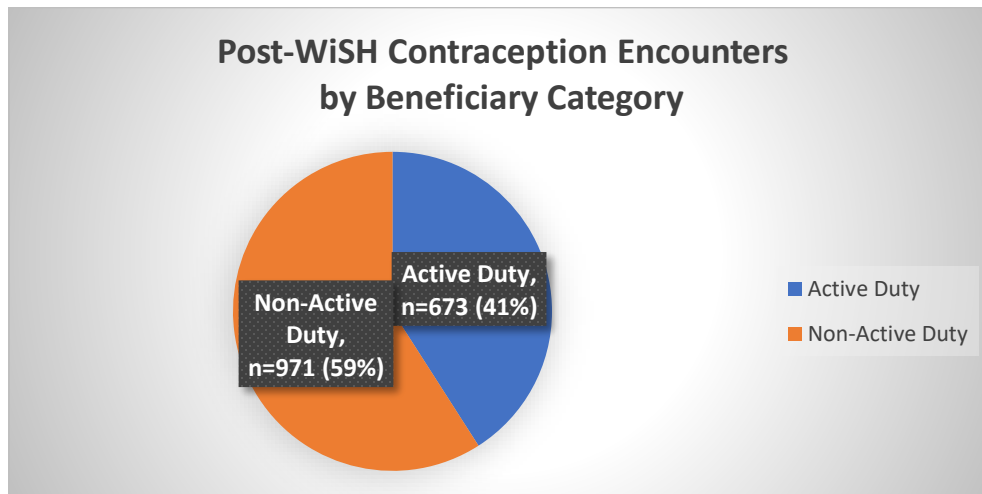
Access to the comprehensive menu of WiSH clinic services is open to all eligible beneficiaries in Okinawa. All of the available services (STI testing and treatment, prescriptions for emergency contraception, insertion and removal of LARC types, etc.) are provided at variable additional sites (branch clinics, the emergency department, or the main hospital). For the purposes of this project, data were filtered to include (female only) patients who accessed contraception services in Okinawa (both SARC and LARC) in the age range, 18-53. Data were compared between the twelve months preceding the WiSH clinic implementation (February, 2017 – January 2018), described as “Pre-WiSH” and the twelve months after WiSH clinic implementation (February, 2018 – January, 2019), described as “Post-WiSH”. Additional discriminators were identified, including service branch (U.S. Marine Corps, Navy, Air Force, and Army), military affiliation (active duty or non-active duty), and age-group ranges for populations of interest.

The age range 18-24 was specifically analyzed for Pre-WiSH and Post-WiSH contraception utilization, as this age range (especially among active duty service women) is known to be “high risk” for unintended pregnancy. This high-risk age category was the sub-population of interest specific to this quality improvement project. Figures 1 and 2 illustrate

basic characteristics of active duty and non-active duty female contraceptive utilization, pre- and post-WiSH clinic implementation, illustrating a 21% increase in contraception encounters for active duty females between the respective 12-month periods, pre- and post-WiSH clinic implementation.



*Figure 1.* Contraception encounters by beneficiary category (active duty military females or non-active duty females) age 18-53 in the 12-month period (February, 2017 – January, 2018) preceding WiSH clinic implementation.



*Figure 2.* Contraception encounters by beneficiary category (active duty military females or non-active duty females) age 18-53 in the 12-month period (February, 2018– January, 2019) following WiSH clinic implementation, illustrating a 21% increase in Active Duty contraception encounters.

Figure 3 illustrates a side-by-side comparison of contraception utilization by age demographics for all females (active duty and non-active duty) pre- and post-WiSH implementation.

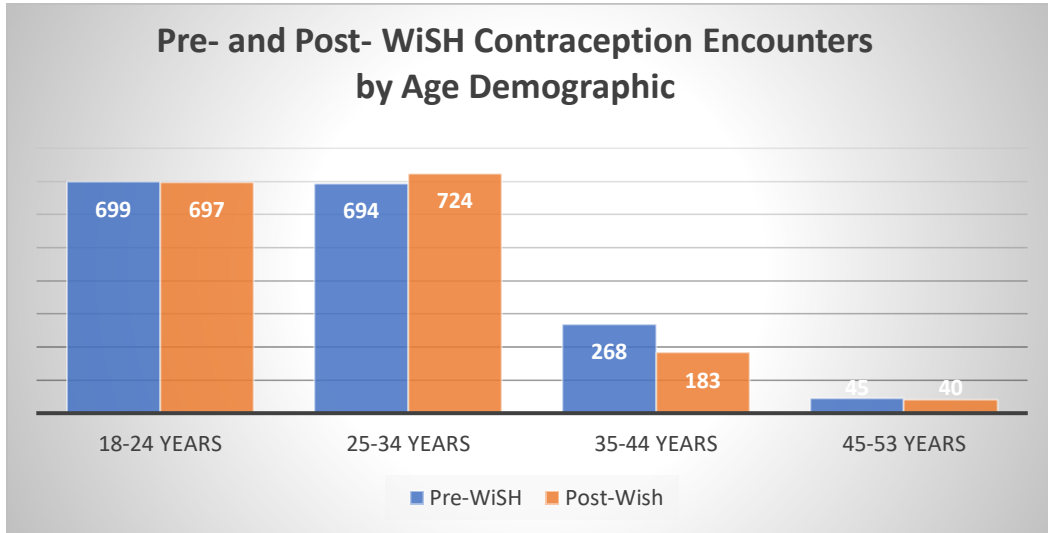


Figure 3. Pre- and post-WiSH contraception encounters by age range

Figure 4 illustrates the distribution by service (U.S. Marine Corps, Navy, Air Force, and Army) of the active duty women who accessed contraception and the numeric changes pre- and post-WiSH clinic implementation.

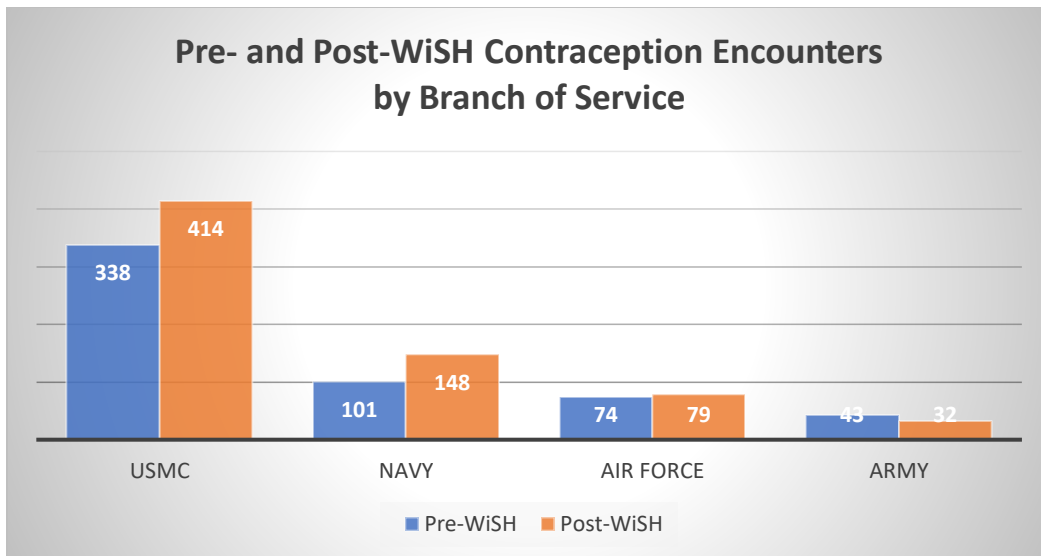


Figure 4. Pre-and post-WiSH clinic implementation encounters by service branch

Table 2 (below) illustrates a crosstabulation of both SARC and LARC utilization for each demographic group in the pre- and post-WiSH time periods. The side-by-side data compare actual contraception demand by demographic category, as well as the respective percentage changes in from pre- and post-WiSH time periods.

**Table 2**

*Crosstabulation of Patient Category and Contraception Method (SARC or LARC)*

Patient Category	Type of Contraception	
	SARC	LARC
	Pre-WiSH / Post-WiSH	Pre-WiSH / Post-WiSH
All Active Duty (AD) Military	314 / 343 (9.24)	240 / 332 (38.33)
High-risk AD (age 18-24)	206 / 227 (10.14)	161 / 245 (51.85)
All Non Active Duty	829 / 602 (-27.38)	320 / 370 (15.63)
High-risk Non AD (age 18-24)	226 / 99 (-56.19)	107 / 127 (18.69)
All females (age 18-53)	1143 / 945 (-17.32)	560 / 702 (25.36)

*Note:* These data represent contraception utilization by type (SARC and LARC) and by patient category in both the pre-WiSH clinic implementation (February, 2017 – January 2018) period and post-WiSH clinic implementation (February 2018 – January, 2019) period. The percentage change for each category is included in the parentheses. LARC data and percentage changes are presented with confidence. However, SARC data may not fully represent ALL SARC prescriptions issued (see Discussion).

The overall outcomes of the WiSH clinic implementation data are presented in Table 2. The results demonstrated the important influence of the WiSH clinic on the community (population) of interest for this project. Most noteworthy were the increases in LARC usage among both active duty and non-active duty females in the high-risk age demographic. All

patient categories demonstrated increases in LARC utilization, indicating improved access, acceptability, and utilization of LARC by the eligible female beneficiary population in Okinawa.

A graphic portrayal of these data are presented in Figure 5.

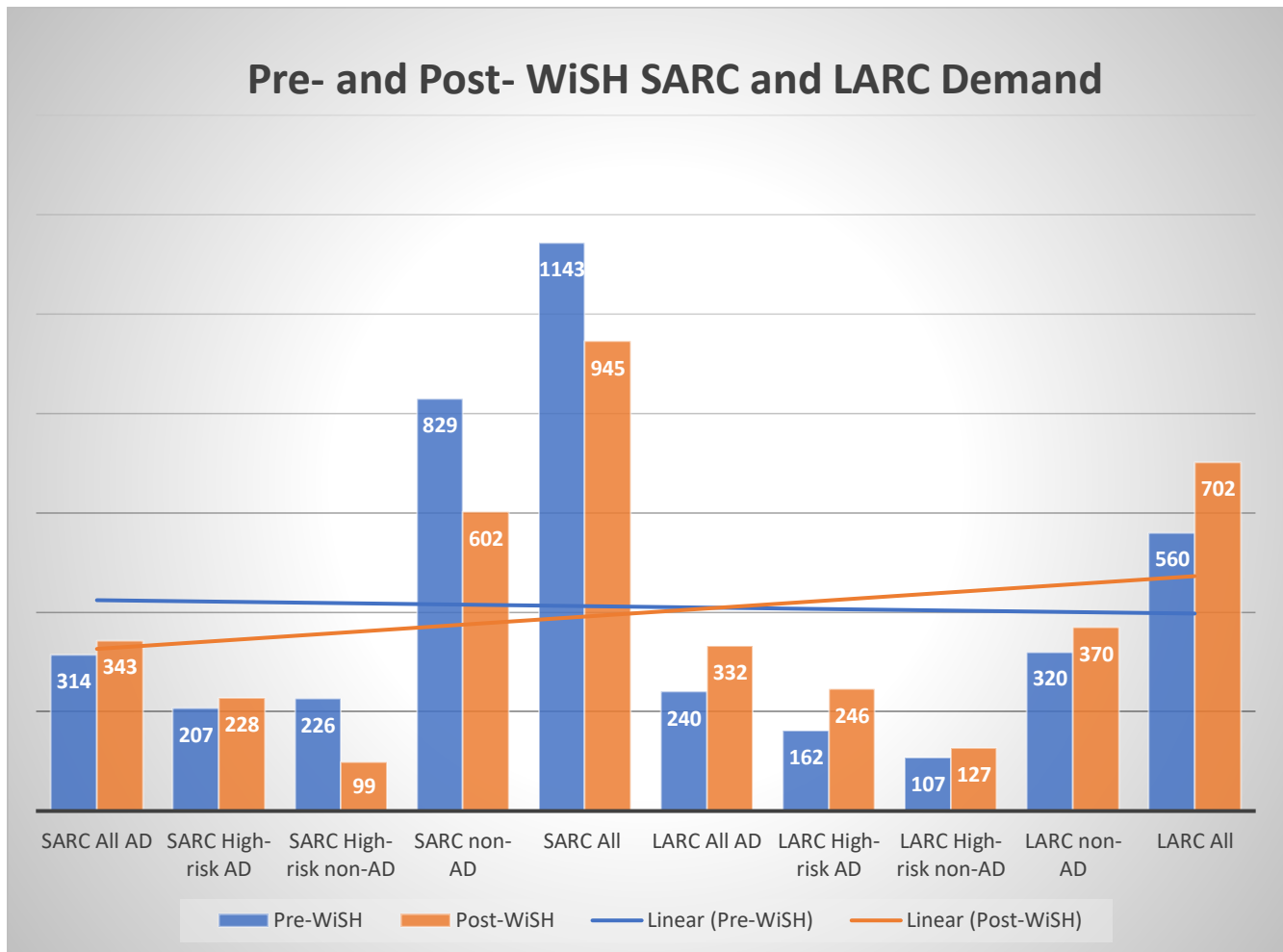


Figure 5. This side-by-side comparison demonstrates the pre-WiSH (February, 2017 – January, 2018) utilization of both SARC and LARC types compared with post-WiSH (February, 2018 – January, 2019) SARC and LARC utilization.

While the SARC data (Figure 5) may under-represent actual SARC prescriptions (see Discussion section for additional explanation), the LARC data were considered reliable and suggest a shifting preference toward LARC utilization, with the greatest appreciable changes noted in the specific target communities of interest, namely high-risk females age 18-24.

Increases in LARC utilization were noted in all of the patient categories. These data findings



were consistent with measures of success for project evaluation, especially in the *reach* and *effectiveness* domains.

Figure 6 demonstrates net LARC increases by demographic groups with adjustments applied for actual population changes, by demographic. It is clear from these data that LARC use increased (post-WiSH clinic implementation) in every group, with substantial increases in the highest risk populations, both active duty and non-active duty females, age 18-24 with net increases of 44% (active duty) and 19% (non-active duty), respectively.

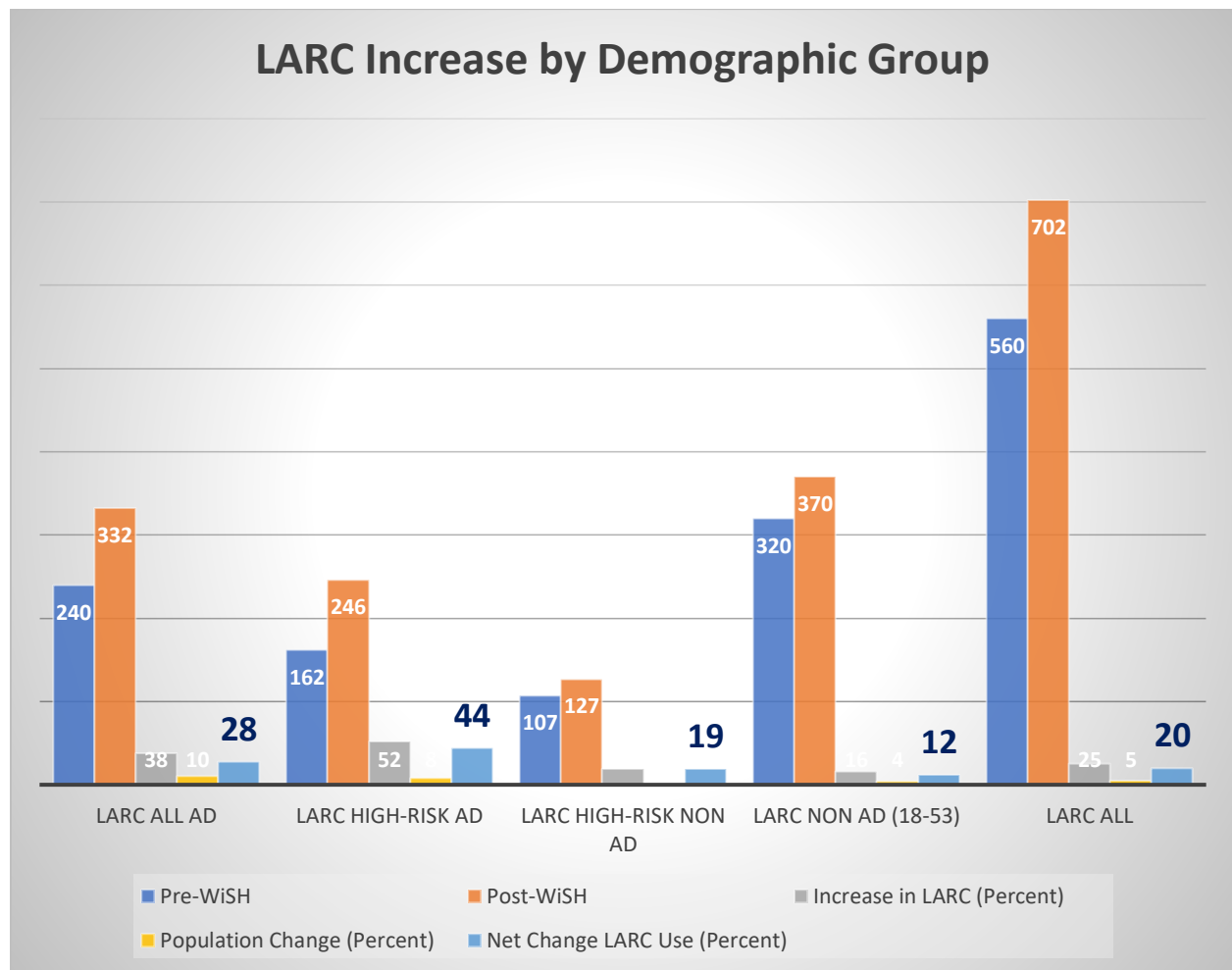


Figure 6. This figure represents LARC increases by specific demographic groups, demonstrating the net percent change (adjusted for population changes) for LARC usage, with the most substantial changes occurring in the high risk population groups, females, age 18-24. Active duty LARC use in this demographic increased 44% between pre- and post-WiSH users.

Additional analysis was performed specific to the active duty high-risk population, in order to determine whether there was a statistical difference between pre-WiSH and post-WiSH contraception utilization in this targeted population of interest. Table 3 represents these results.

**Table 3**

*Results of Chi-square Test and Descriptive Statistics for LARC Choice by WiSH Status*

LARC Choice	Pre-WiSH	Post-WiSH
Chose LARC	161 (44%)	245 (52%)
Did not choose LARC	206 (56%)	227 (48%)

*Note.*  $\chi^2(1) = 5.341^*$ ,  $df = 1$ . Numbers in parentheses indicate column percentages.

\* $p < .05$

A chi-square test for association was conducted between pre-WiSH and post-WiSH active duty females in the high risk (age 18-24) age group and LARC selection as the contraception choice (represented in Table 3). All expected cell frequencies were greater than five. There was a statistically significant association between post-WiSH status and preference for LARC  $\chi^2(1) = 5.341$ ,  $p = .021$ . Although the strength of the association was considered very weak, ( $\phi = 0.08$ ,  $p = .021$ ), the preliminary post-WiSH data suggest that active duty females in the highest risk category may be trending toward a preference for LARC.

The WiSH clinic was accessible on Tuesday mornings for a half day each week and cancelled only for inclement weather (typhoons) or federal holidays. Figure 7 demonstrates the apparent influence of WiSH clinic operations on both Tuesday and other days of the week for contraceptive access. While the measurable/quantified influence of the WiSH clinic on Tuesday access and utilization was not completely clear, the data suggested that Tuesday was an effective day to offer contraception services (both in and outside of WiSH clinic operations).

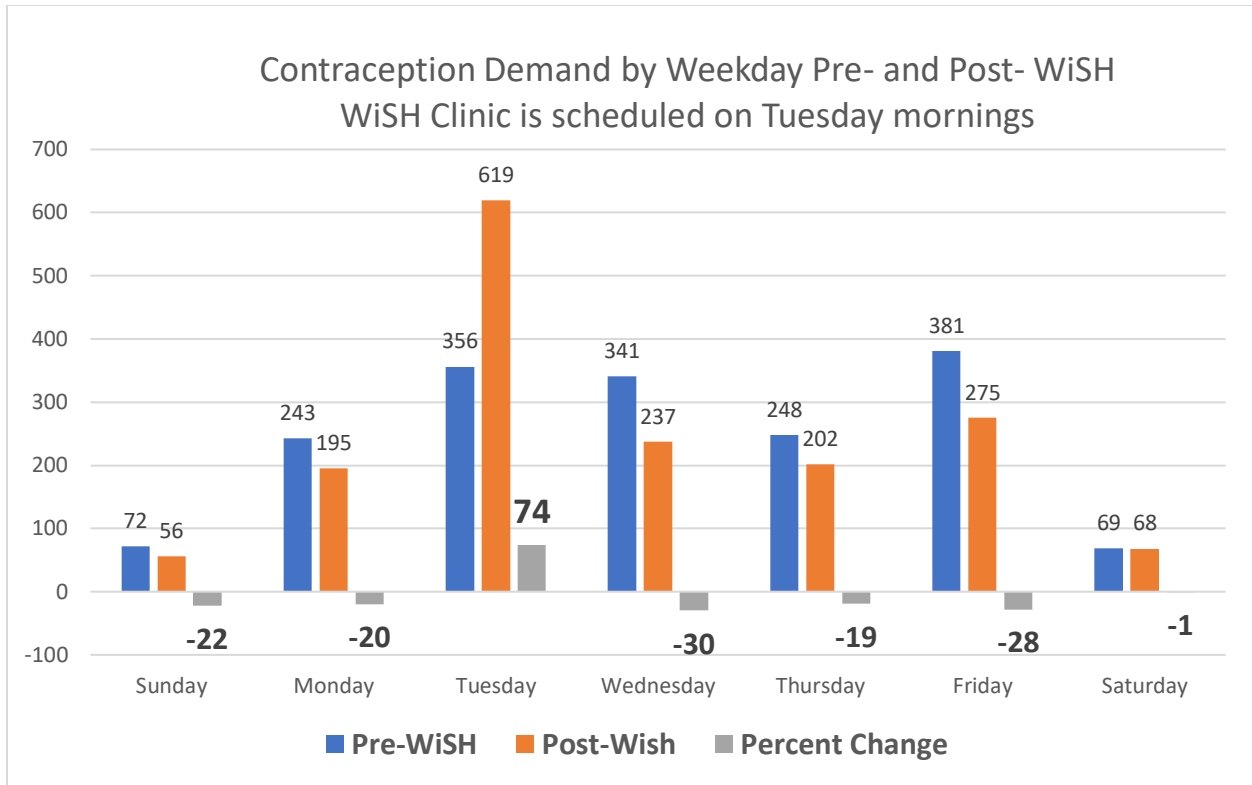


Figure 7. Tuesday a.m. WiSH clinic scheduling positive influence on contraception access

Patient satisfaction was reported according to answers provided by 59 users of contraception services in the WiSH clinic reported between August, 2018 and January, 2019. Patients expressed high levels of satisfaction. Very few patients made any suggestions for improvement, and the only suggestions were for increased capacity (additional days or hours availability). Only one person identified a desire for a scheduled appointment (as opposed to the deliberate, same-day, walk-in structure of the WiSH clinic). Patient satisfaction response data are illustrated in Figures 8, 9, and 10. Figure 8 illustrates respondent answers to yes/no and range responses to satisfaction questions. Figure 9 delineates patient feedback pertaining to marketing effectiveness (“How did you hear about the WiSH clinic?”). Figure 10 delineates patient feedback for suggested improvements (“Do you have any suggestions for changes or improvement?”). Write-in answers were categorized and coded for these two questions.

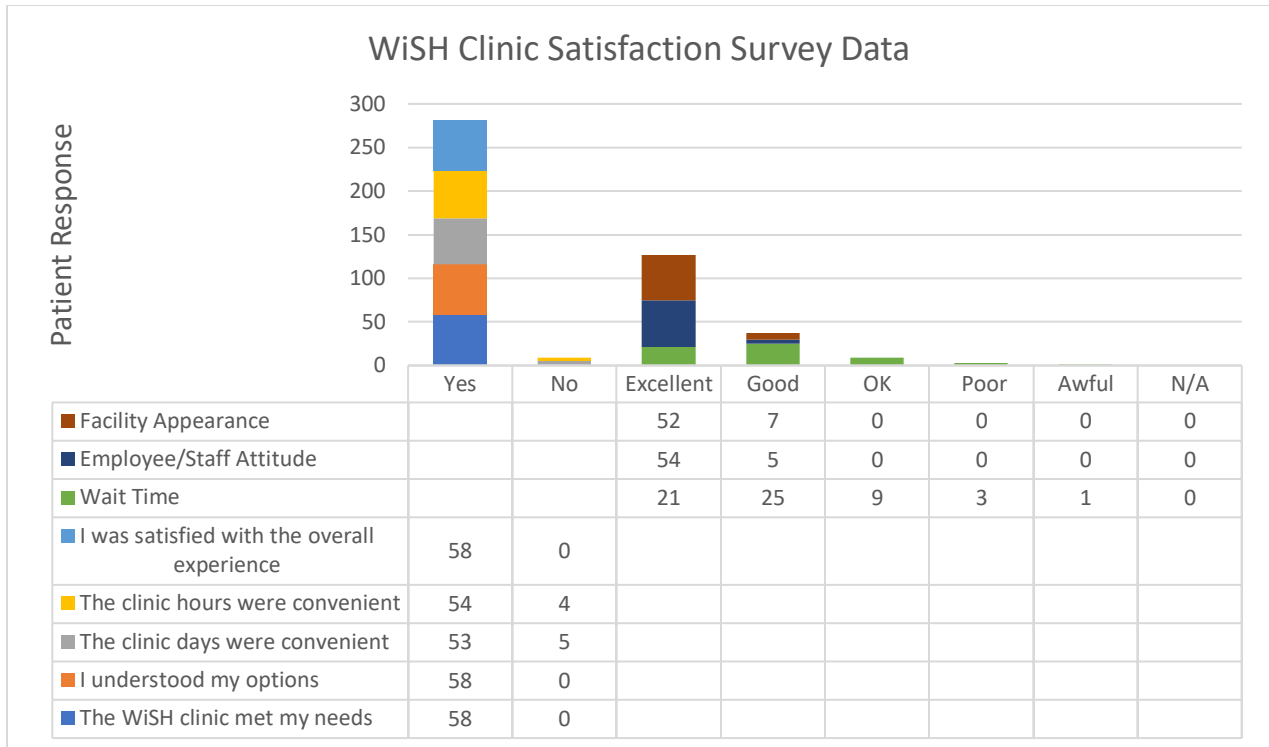


Figure 8. Patient satisfaction responses

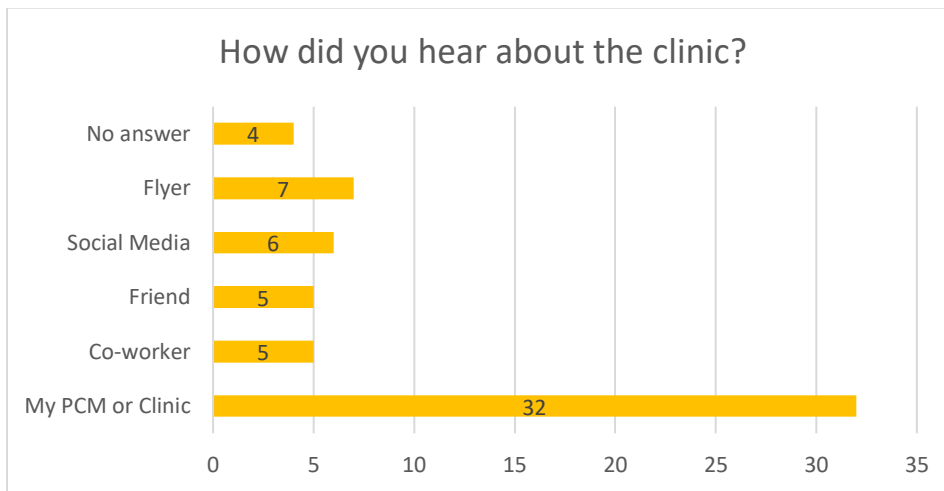
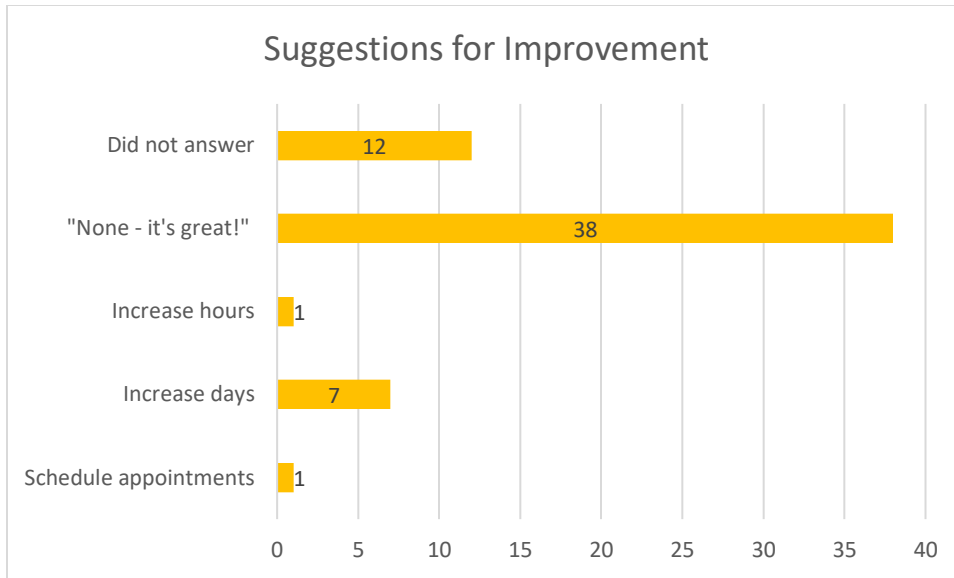


Figure 9. Marketing effectiveness.

Patient feedback data were considered important baseline indicators and suggested overall high satisfaction with WiSH services and indicated that PCM or clinic referral or recommendation was the strongest influence in directing patients to the WiSH clinic.



*Figure 10.* Most respondents were completely satisfied. There was a low – moderate amplitude signal to increase capacity, with eight respondents suggesting increasing additional days or hours

### **Discussion/Interpretation**

Results of this project reveal important preliminary findings. Absolute LARC utilization increased dramatically between pre-WiSH and post-WiSH timelines, especially in the population of interest, namely high-risk (age 18-24) females in both the active duty and non-active duty beneficiary populations. Tuesday proved to be an effective day of the week for contraception access and demand. The addition of the WiSH clinic hours on Tuesdays for half-days each week (cancelled only for weather emergencies or federal holidays) appeared to be beneficial and was well-utilized. Additionally, high patient satisfaction was confirmed by survey participants and suggested only minimal opportunities for improvement.

Planning for this project was ambitious, but data collection proved problematic in a few key areas, necessitating some design modification and limitations on results reporting. During original planning for this project, it was anticipated that detailed data over time (month-to-month) specific to SARC and LARC utilization would be available, enabling an analysis of

trends and specific ratios of LARC to SARC utilization in the pre- and post- periods of WiSH clinic operations. These analytics have been applied at other MTF sites by fully-staffed, contracted analytics services employed by Navy medicine headquarters.

Unfortunately, duplication of these data collection capabilities proved elusive at the project site. The SARC data were difficult to measure and quantify with local software and reports generation. The SARC utilization data would ideally include oral contraceptive pills, medroxyprogesterone acetate injections, contraceptive patches, and rings (diaphragms are not available through site clinics, and condom use is unknown). Project site reports were unable to quantify (with full confidence) unique-patient SARC prescription starts (separate from refills) filtered for pre- and post-WiSH utilization. CPT codes for injections were the only exception, as these were easily extractable data and *are included* in the project site's SARC data. As a result, LARC:SARC ratio data and SARC-specific utilization should be interpreted with caution. SARC data were pulled and filtered by the appropriate and applicable ICD-10 diagnostic and CPT procedural codes and were analyzed *consistently* pre- and post-WiSH implementation. However, it is considered *likely* that SARC use (with the exception of injections) may be *under-represented* by this problematic methodology. Efforts to cross-check between WiSH clinic SARC utilization and pharmacy dispensing data were made but did not resolve data confidence specific to SARC utilization. For ongoing analysis and accuracy of SARC utilization, future coordination with the headquarters for duplication of methodology, or remote, standardized data pulls will be necessary.

Additionally, it was projected that "pure" WiSH data could be fully discriminated from other utilization data. It was realized late during project implementation (December, 2018) that the unique "code" for the WiSH clinic was unable to be separated from the MTF's ob-gyn clinic

“code” (a data system flaw, requiring a manual work-around). Consequently, filtered *WiSH-only* data were not possible to distinguish from all-site data. As a result, the pure positive effects of the WiSH clinic are somewhat *buried* (obscured) in overall changes in contraception utilization data. However, the specific LARC utilization by age and military duty status, day-of-week contraception access/utilization, and baseline patient satisfaction data were extracted consistently for pre- and post-WiSH timelines. Reported overall results for LARC utilization may be regarded with confidence, but are unable to be aligned specifically to the WiSH clinic, because contraceptive services were not suspended at other sites or fully shifted to the WiSH clinic. The Tuesday contraception utilization data is likely the most suggestive (albeit indirect, non-specific) of the influence of the WiSH clinic on overall contraceptive access and utilization. Analysis of contraception access/utilization demonstrated a by-day decrease in services on every day of the week, with the exception of Tuesday (WiSH clinic day) between pre- and post-WiSH implementation comparisons. Manual entry by schedulers went into effect in January 2019, enabling future extraction, filtration, and evaluation of WiSH-only data.

This project addressed important themes from the literature surrounding contraception access and utilization for active duty women. These themes included higher rates of unintended pregnancy in the military, numerous barriers to effective contraception in primary care, and evidenced based recommendations for family planning services. Establishment of easy-access contraception clinics across navy medicine MTFs has become more prevalent over the past three years. This project systematically evaluated a specific, newly-established service at an overseas Navy MTF in Okinawa Japan. Specifically, this project addressed the second and third themes, by evaluating whether the clinic has been successful in addressing the gaps and barriers in availing access to the most effective forms of contraception (specifically long-acting reversible

contraception, or LARC) to active duty women in accordance with best-evidence, best-practice literature and guidelines.

Examples of barriers to effective contraception for the patient community of interest are abundant, including requiring multiple appointments to obtain contraception, lack of available and trained staff at the clinic site when contraception is requested, fragmented and varied adherence to best-evidence guidelines, and systemic issues such as costs, clinician knowledge and attitudes. This project demonstrated successful elimination of known barriers and reflected successful patient, clinic, and staff outcomes as a result.

The framework chosen for this project was the RE-AIM (*reach, effectiveness, adoption, implementation, and maintenance*) model, which has been widely utilized and accepted as the standard for disseminating findings from public health research, application of evidence-based intervention, and community-based health promotion programs (Glasgow, et al., 1999). The RE-AIM framework was useful for evaluation of the WiSH clinic, although it is recognized that the preliminary findings (the scope of this project) best addressed the first two elements, *reach* and *effectiveness*. Although mentioned here, ongoing evaluation will be able to further evaluate the other three dimensions (*adoption, integration, and maintenance*) as the clinic matures, evolves, and adapts.

Specifically, the first dimension *reach* has to do with whether the targeted intervention reached the intended population. For this project, the population of interest was high-risk (age 18-24) active duty women, who experience a higher-than-expected unintended pregnancy rate. This demographic (especially young, enlisted, U.S. Marine Corps and Navy women, respectively) comprise a significant portion of the eligible beneficiaries in Okinawa. Although the WiSH clinic was open to *all* eligible beneficiaries, data analysis revealed high utilization of



contraception services and a dramatic increase in LARC use, post-WiSH clinic implementation by the specific community of interest, implying successful reach of the targeted population by the public health intervention (availing easy access, walk-in, same day LARC services).

*Effectiveness* describes the degree to which the targeted intervention achieved a desired outcome. The effectiveness domain also considers qualitative information (e.g. patient satisfaction, acceptance by staff, etc.) and considers any negative or untoward outcomes resulting from an intervention. In the case of the WiSH clinic, effectiveness was clearly demonstrated. The WiSH clinic was established to reduce barriers to contraception and sexual health services. Increased utilization of contraception services by the population of interest, and especially the increased preference of LARC by the same demographic revealed demonstrable effectiveness.

Further, patient satisfaction data illustrated very high patient satisfaction with the WiSH clinic's baseline services in all domains. The only area suggested for improvement from collected patient satisfaction data was in clinical capacity. There was an apparent demand signal for additional hours and days by several respondents. This finding is an area of opportunity for ongoing evaluation, additional targeted feedback and a potential indication that resource allocation (different sites, additional hours, or days) could be adjusted to better accommodate patients' needs and preferences. Marketing data indicated that the most-likely source of patient knowledge about the WiSH clinic was from other MTF clinics and clinic staff. These findings would suggest that the WiSH clinic effectiveness has similarly been enhanced by acceptance and endorsement by internal stakeholders (staff) as well as patients.

*Adoption* has to do with whether the community or the demographic of interest accepts and utilizes the intervention, in this case, the services of the WiSH clinic. Although considered preliminary, descriptive data analysis indicated that adoption was good during the first twelve

months of WiSH clinic utilization. Improvements in both contraception use and type (LARC) suggest that the products and services offered by the WiSH clinic are acceptable and desired by the community (both staff and patients).

In order to fully apply the RE-AIM model for this quality improvement initiative, additional and ongoing evaluation and analysis is warranted. The additional dimensions of RE-AIM include *implementation* and *maintenance*. Both dimensions require analysis that was beyond the scope of this project. Future evaluation of implementation has the potential to suggest reasonable adjustments to the WiSH clinic resource allocation. For example, site-specific detailed data analysis may demonstrate that portability of WiSH services could expand the clinics reach even more by opening a second half day at another branch clinic site. Maintenance, similarly, will need additional time to evaluate and analyze. An initial surge of interest and utilization (demonstrated by this project) may taper over time. Personnel, staffing, patient demographics, and even enthusiasm are likely to change over time. It will be important to continue to evaluate the utilization and effectiveness of the WiSH clinic for appropriate resource allocation and effective stewardship. Additionally, distant (headquarters level) evaluation of the WiSH clinic, in comparison to other comparable sites across the Navy or the DoD military health system is warranted and will likely endure, but was beyond the scope of this project.

### **Conclusion**

The evaluation of walk-in contraception at the project site using the well-established RE-AIM framework offered an exciting opportunity to ensure improved contraceptive access for active duty women in the community, consistent with evidence-based, patient-centered models already established in other Navy medical facilities. The commitment of personnel and materiel

resources eliminated barriers and resulted in measurable (desired) outcomes, including enhanced access to care, and improved delivery of best-practice, evidence-based contraception services to both active duty and other eligible beneficiaries in Okinawa Japan. An analysis of historic contraception usage and post-WiSH utilization demonstrated successful impact among the populations of interest as well as high patient and staff acceptance and satisfaction. Additional and ongoing evaluation of WiSH clinic services use and efficiencies is recommended and will enable the site MTF to continue to deliver patient-centered family planning services consistent with current evidence-based recommendations.

Consistent with tenets of continuous process improvement and quality assurance, the WiSH clinic should continue to be evaluated and modified as indicated, to enhance, expand, or re-locate services accordingly, as this quality improvement project matures over time. Improved and sophisticated analytics applied to long-term data collection from the WiSH clinic site, compiled with standardized big data from similar MTF sites in the Navy and DoD, has the potential to demonstrate an actual reduction in the occurrence of unintended pregnancy among the active duty female population.

In summary, the U.S. national defense strategy prioritizes military operational readiness as the most important variable in our military mission set. Even one unintended pregnancy has the potential to degrade individual and unit readiness and interfere with successful mission accomplishment. This capstone project has addressed the relevant issues surrounding ease of access to best-evidence contraception resources. The results were considered positive and demonstrated the preliminary successes of a significant quality improvement initiative targeting contraceptive care needs specific to the active duty female population on the island of Okinawa.

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Appendix A

Gap Analysis

Best Practice Solution/s	Best Practice Strategies	How the Community and Clinical Site Differ From Best Practice	Potential Barriers and Facilitators that can overcome the Barriers to Best Practice Implementation
<p>1. Providing quality family planning services: Recommendations of the CDC and U.S. Department of Population Affairs. (CDC, 2014, April 25).</p>	<p>a) “Provide contraception to help women and men plan and space births, prevent unintended pregnancies and reduce the number of abortions;</p>	<p>a) This service is available, albeit NOT <b>BEST PRACTICE</b> (as updated in ACOG recommendations)</p>	<p>a) Although service exists, until recently it was not centrally located, readily accessed by the community of interest (COI), or strategically positioned for demand and best return on investment (e.g. prevention of unintended pregnancy and enhanced military readiness)</p>
	<p>b) Offer pregnancy testing and counseling;</p>	<p>b) This service is available. No gap.</p>	<p>b) Determine whether Point of Care testing is available at all sites with immediate results.</p>
	<p>c) Help clients who want to conceive” (CDC, 2014, April 25)</p>	<p>c) This service is available through referral, but not necessarily at all points of primary care.</p>	<p>c) Referrals to specialty obstetric services are available and CPGs for primary care infertility workup and intervention are used.</p>
<p>2. Increasing access to contraceptive implants and intrauterine devices to reduce unintended pregnancy. (ACOG, 2015).</p>	<p>a) “Provide long-acting reversible contraception (LARC) methods on a same day basis, whenever possible, if pregnancy can reasonably be excluded.</p>	<p>a) Insufficiently trained primary care staff in clinical settings to place LARC at point of service</p>	<p>a) Recruitment and offering of on-site training and subsequent competency sustainment for primary care providers in LARC modalities</p>
		<p>a.i) Insufficient time and staff support in currently-designed primary care clinic templates to meet the needs of active duty service members for same day service.</p>	<p>a.i) Clinical template analysis to determine best resource utilization for managing service (i.e. meeting demand capacity without compromising access to care in other clinical settings).</p>
	<p>b) Screen for STIs at the time of IUD insertion; if positive, treat without removing IUD.</p>	<p>b) STI testing is available at all clinical sites.</p>	<p>b) Ensure no knowledge deficit among clinical providers regarding maintenance of IUD in the setting of TREATED STI.</p>
<p>c) Offer the copper IUD as the most effective method of emergency contraception” (ACOG, 2015).</p>	<p>c) Service is available, but may be delayed secondary to gaps in trained providers, gaps in knowledge</p>	<p>c) Ensure knowledge currency among clinical providers; ensure availability of copper IUD device and insertion capability at point of service for women desiring this intervention vice hormonal alternatives.</p>	

Appendix B

Johns Hopkins Nursing Evidence-based Practice Rating Scale

**JHNEBP EVIDENCE RATING SCALES**

<b>STRENGTH of the Evidence</b>	
<b>Level I</b>	Experimental study/randomized controlled trial (RCT) or meta analysis of RCT
<b>Level II</b>	Quasi-experimental study
<b>Level III</b>	Non-experimental study, qualitative study, or meta-synthesis.
<b>Level IV</b>	Opinion of nationally recognized experts based on research evidence or expert consensus panel (systematic review, clinical practice guidelines)
<b>Level V</b>	Opinion of individual expert based on non-research evidence. (Includes case studies; literature review; organizational experience e.g., quality improvement and financial data; clinical expertise, or personal experience)

<b>QUALITY of the Evidence</b>		
<b>A High</b>	Research	consistent results with sufficient sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence.
	Summative reviews	well-defined, reproducible search strategies; consistent results with sufficient numbers of well defined studies; criteria-based evaluation of overall scientific strength and quality of included studies; definitive conclusions.
	Organizational	well-defined methods using a rigorous approach; consistent results with sufficient sample size; use of reliable and valid measures
	Expert Opinion	expertise is clearly evident
<b>B Good</b>	Research	reasonably consistent results, sufficient sample size, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
	Summative reviews	reasonably thorough and appropriate search; reasonably consistent results with sufficient numbers of well defined studies; evaluation of strengths and limitations of included studies; fairly definitive conclusions.
	Organizational	Well-defined methods; reasonably consistent results with sufficient numbers; use of reliable and valid measures; reasonably consistent recommendations
	Expert Opinion	expertise appears to be credible.
<b>C Low quality or major flaws</b>	Research	little evidence with inconsistent results, insufficient sample size, conclusions cannot be drawn
	Summative reviews	undefined, poorly defined, or limited search strategies; insufficient evidence with inconsistent results; conclusions cannot be drawn
	Organizational	Undefined, or poorly defined methods; insufficient sample size; inconsistent results; undefined, poorly defined or measures that lack adequate reliability or validity
	Expert Opinion	expertise is not discernable or is dubious.

*\*A study rated an A would be of high quality, whereas, a study rated a C would have major flaws that raise serious questions about the believability of the findings and should be automatically eliminated from consideration.*

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## Appendix C

**RE-AIM Framework**

<b>Dimension</b>	<b>Definition</b>
<b>Reach</b>	The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative.
<b>Effectiveness (Efficacy)</b>	The impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes.
<b>Adoption</b>	The absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program.
<b>Implementation</b>	At the setting level, implementation refers to the intervention agents' fidelity to the various elements of an intervention's protocol, including consistency of delivery as intended and the time and cost of the intervention. At the individual level, implementation refers to clients' use of the intervention strategies.
<b>Maintenance</b>	The extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies.

**Source:** RE-AIM.Org (2018, July 1). Frequently asked questions. Available at <http://www.re-aim.org/about/frequently-asked-questions/#validation>

Appendix D

Walk in Contraception Performance Tracker

1	Beneficiary Type				LARC								
2	Week of	Active Duty and Reserve	Dependant Spouse	Dependant Daughter	Other	Turned Away	Hormonal IUD Insertion	Hormonal IUD Removal	ParaGard Insertion	ParaGard Removal	Nexplanon Insertion	Nexplanon Removal	OC Rir
3	1-Oct												
4	8-Oct												
5	15-Oct												
6	22-Oct												
7	29-Oct												
8	5-Nov												
9	12-Nov												
10	19-Nov												
11	26-Nov												
12	3-Dec												
13	10-Dec												
14	17-Dec												
15	24-Dec												
16	31-Dec												
17	7-Jan												
18	14-Jan												
19	21-Jan												
20	28-Jan												

1	SARC			Emergency Contraception		Weekly Total						
2	ParaGard Removal	Nexplanon Insertion	Nexplanon Removal	OCP, Patch, Ring, Depo	Plan B or ella	ParaGard	Counseling	Total Served	LARC Insertions	LARC Removals	SARC Prescriptions	Emergency Contraception
3								0	0	0	0	0
4								0	0	0	0	0
5								0	0	0	0	0
6								0	0	0	0	0
7								0	0	0	0	0
8								0	0	0	0	0
9								0	0	0	0	0
10								0	0	0	0	0
11								0	0	0	0	0
12								0	0	0	0	0
13								0	0	0	0	0
14								0	0	0	0	0
15								0	0	0	0	0
16								0	0	0	0	0
17								0	0	0	0	0
18								0	0	0	0	0
19								0	0	0	0	0
20								0	0	0	0	0

Source: Reef Point Group. (2017). *Navy medicine walk-in contraception quick start guide*. Report product for U.S. Navy Bureau of Medicine and Surgery, Contract N00189-17-D-Z013, Task Order N00189-17-F-Z078.

Appendix E

Walk-in Contraception Clinic Patient Feedback

**Walk-In Contraception Clinic Patient Feedback**

*Please circle one option for the questions below:*

Did the walk-in contraception clinic meet your needs?	Yes	No
Did you understand your options for contraception?	Yes	No
Were the clinic days convenient?	Yes	No
Were the clinic hours convenient?	Yes	No
Were you satisfied with your overall experience?	Yes	No

*Please circle one option for the topics below:*

Wait Time	Excellent	Good	OK	Poor	Awful	N/A
Employee/Staff Attitude	Excellent	Good	OK	Poor	Awful	N/A
Facility Appearance	Excellent	Good	OK	Poor	Awful	N/A

*Please provide as much detail as possible for the questions below:*

How did you hear about the walk-in contraception clinic?

Do you have any suggestions for changes or improvements to the walk-in contraception clinic?

Would you like to recognize military and/or civilian clinic personnel for providing outstanding service?

Do you have additional feedback you would like to share?

*Thank you for your feedback!*

Appendix F

Cost/Benefit Analysis Graphs

Minimum Recommended LARC Inventory Levels for a Walk-In Contraception Clinic						
Clinic Population of Enrolled Females Age 12-52	Nexplanon	Kyleena	Liletta	Mirena	Skyla	ParaGard
2,500	5	2	2	3	2	2
Average Cost per Unit	\$498.73	\$530.00	N/A*	\$410.56	\$403.57	\$444.90

Clinic Population of Enrolled Females Age 12-52	Clinic Days	Dedicated or Shared Front Desk Clerks	Dedicated Medical Assistants	Point-of-Care Testing Personnel	Nurse Educator	Prescribing Provider Trained for all LARCs
2,500	2.5	1	1	1	1	1 + 1 Backup

Site Name	Documented LARC Insertions in One Month	Predicted Increase for LARC Insertions in One Month Based on NMCS D Trends	Predicted Increase for LARC Insertions for One Year Based on NMCS D Trends	Predicted Number of Unintended Pregnancies Prevented (each 5% Increase in LARC Insertions Prevents 225 Navy Medicine Pregnancies)
BHC VA Beach	41	82	984	72

Site Name	Predicted Increase for LARC Insertions for One Year Based on NMCS D Trends	Predicted Cost to Insert LARCs (Navy Medicine Cost for Each Mirena IUD is \$405.56)	Predicted Number of Unintended Pregnancies Prevented (each 5% Increase in LARC Insertions Prevents 225 Navy Medicine Pregnancies)	Predict Cost to Navy Medicine for Unintended Pregnancies (\$15,725 for prenatal care and delivery, per pregnancy)	Predicted Cost Savings for Navy Medicine
<b>BHC (VA Beach)</b>	<b>984</b>	<b>\$77,867.52</b>	<b>72</b>	<b>\$1,051,407.62</b>	<b>\$735,342.45</b>

Source: Reef Point Group. (2017). *Operation PINC: Process improvement for non-delayed contraception: Analysis and recommendations*. Report product for U.S. Navy Bureau of Medicine and Surgery, Contract N00189-17-D-Z013, Task Order N00189-17-F-Z078.

## Appendix G

## Timeline for Capstone Project Implementation

Task	July 2018	August 2018	September 2018	October 2018	November 2018	December 2018
Incorporate proposal draft feedback / Finalize draft	X					
IRB review and agreements for MTF/UMASS		X	X			
Collect WiSH clinic satisfaction surveys		X	X	X	X	X
Collect retrospective chart data (CPT codes) from Healthcare Business Office						X

Task	January 2019	February 2019	March 2019	April 2019	May 2019
Manage Data in SPSS	X	X			
Process Data - Analyze Outcomes	X	X	X		
Review results with Chair/Mentor	X	X	X		
Submit Capstone Report			X	X	
Present Results (UMass at Amherst Scholarship Day, May 9, 2019)					X

## Appendix H

## UMass at Amherst IRB Approval Memorandum



University of Massachusetts Amherst  
Human Research Protection Office  
Mass Venture Center  
100 Venture Way, Suite 116  
Hadley, MA 01035

**Office of Research Compliance**  
voice: (413) 545-3428  
fax: (413) 577-1728

**Memorandum – Not Human Subjects Research Determination**

**Date:** August 24, 2018

**To:** Cynthia Kuehner, College of Nursing

**Project Title:** Program Evaluation of an Easy Access Clinic for Effective Contraception for U.S. Active Duty Women in Okinawa, Japan

**IRB Determination Number:** 18-160

The Human Research Protection Office (HRPO) has evaluated the above named project and has made the following determination based on the information provided to our office:

The proposed project does not involve research that obtains information about living individuals [45 CFR 46.102(f)].

The proposed project does not involve intervention or interaction with individuals OR does not use identifiable private information [45 CFR 46.102(f)(1),(2)].

The proposed project does not meet the definition of human subject research under federal regulations [45 CFR 46.102(d)].

**Submission of an Application to UMass Amherst IRB is not required.**

Note: This determination applies only to the activities described in the submission. If there are changes to the activities described in this submission, please submit a new determination form to the HRPO prior to initiating any changes.

A project determined as “Not Human Subjects Research”, must still be conducted in accordance with the ethical principles outlined in the Belmont Report: respect for persons, beneficence, and justice. Researchers must also comply with all applicable federal, state and local regulations as well as UMass Amherst Policies and procedures which may include obtaining approval of your activities from other institutions or entities.

Please do not hesitate to call us at 413-545-3428 or email [humansubjects@ora.umass.edu](mailto:humansubjects@ora.umass.edu) if you have any questions.

A handwritten signature in cursive script that reads "Iris L. Jenkins".

Iris L. Jenkins, Assistant Director  
Human Research Protection Office



## Appendix I

## Naval Medical Center San Diego IRB Approval Letter



DEPARTMENT OF THE NAVY  
NAVAL MEDICAL CENTER  
34805 BOB WILSON DRIVE  
SAN DIEGO, CALIFORNIA 92134-5000

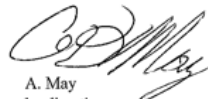
IN REPLY REFER TO:  
22 Aug 18

From: Commanding Officer, Naval Medical Center San Diego  
To: UMass at Amherst, Institutional Review Board

Subj: INSTITUTIONAL REVIEW BOARD REVIEW AND DETERMINATION OF  
QUALITY IMPROVEMENT PROPOSAL NMCSO.QI.2018.0035

Encl: (1) Approved Performance Improvement / Quality Assurance Project

1. The Quality Improvement project proposal submitted by Cynthia A. Kuehner, CAPT, USN, titled, "Program Evaluation of an Easy Access clinic for Effective Contraception for U.S. Active Duty Women in Okinawa, Japan" (NMCSO.QI.2018.0035) has been approved as a Performance Improvement / Quality Assurance Project.
2. Enclosure (1) provides a record of the Naval Medical Center, San Diego Institutional Review Board (IRB) determination. This project *meets* all of the required elements for a Quality Improvement project (see page 8, of enclosure) and does *not* qualify as human subject research. The data will be used for the site's purposes rather than for research. Approved as a Quality Improvement project, the project is exempted from full IRB submission or review.
3. The approved Quality Improvement proposal is supported by both the Naval Medical Center San Diego (IRB authority) and the U. S. Naval Hospital Okinawa (the implementation site).
4. For any questions or concerns, my POC in this matter is Elisea Avalos-Reyes, PhD, MPH at [Elisea.e.avalos-reyes.civ@mail.mil](mailto:Elisea.e.avalos-reyes.civ@mail.mil) or (619)-279-0470.

  
A. May  
by direction