Targeted Counseling to Prevent Occurrence of Bacterial Vaginosis

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Abstract

Background: Bacterial vaginosis (BV) is the most common gynecological infection among reproductive-aged women, and the most common complaint among deployed women. Of the many women affected, at least half will experience a relapse. Without treatment, BV leads to an array of physical and psychological complications. Limited studies show that behavioral modification to improve self-care behaviors may reduce frequency of acquiring BV.

Purpose: Determine incidence of BV, examine current practice among women's health providers, develop a behavioral education intervention to target women ages 18-40, and create educational resource in efforts of reducing occurrence of BV.

Project Design: A retrospective chart review was conducted to evaluate incidence of BV and assess if management practices coincided with current best evidence. A behavioral change intervention was designed from current evidence and application of The Health Belief Model. Providers were educated on best management methods, while patients received individual counseling, followed by dissemination of an evidence-based educational handout during routine clinic visits. Post-intervention analysis was done using SPSS software and results disseminated to leadership and clinic staff.

Analysis of Results: A total of 227 female beneficiaries met inclusion criteria. Prior to intervention, there was an incidence rate of 2.95% and 22.4 BV cases per provider. At the three-month follow-up, the incidence rate for BV was 2.88% and 12.8 BV cases per provider, thus representing a 43% reduction in BV. This reduction increased clinic appointment access by five days.

Organizational Impact: Implementing targeted behavioral counseling and dissemination of self-care resources empowers women to take efficacious health actions that will reduce occurrence of BV. Timely diagnosis, treatment, and knowledge awareness of BV prevents morbidity associated with misdiagnosis and overtreatment. As a result, health outcomes are improved and health care costs is decreased.

Introduction

Bacterial vaginosis (BV) is the most common reproductive tract infection in women, characterized by shifts in vaginal flora where Lactobacillus is replaced by overgrowth of anaerobic bacteria. Lactobacillus plays the important role of sustaining the acidic environment within the vagina, thus inhibiting growth of other bacterial agents (CDC, 2015; Turovisky, Noll, & Chikindas, 2011). Discovered in the 1950's, Gardnerella vaginalis was the sole anaerobe responsible for the presence of BV. Currently there have been over 25 microbes (e.g., Prevotella, Mobilincus, Mycoplasma) connected with the pathogenesis of BV, and the list continues to expand (Onderdonk, Delaney, & Fichorova, 2016). BV can manifest whether one overactive microbe is responsible or if polymicrobes are present. The greater the bacterial content, the greater damage caused to the female reproductive tract. Complications manifested from BV range from mild to severe in nature, especially in pregnant women.

With the disruption of vaginal flora that BV creates allows unfavorable bacteria to ascend up the genital tract, invading the cervix, uterus, and fallopian tubes. Pelvic inflammatory disease (PID), infertility, endometritis, chronic pelvic pain, and increased susceptibility to other sexually transmitted infections (STIs) can ensue if BV is not treated or persists. In pregnant women, the cascade of inflammatory events demonstrated by BV can lead to preterm labor, premature rupture of membranes, and delivery of low birth-weight infants due to chorioamnionitis thus adversely affecting healthcare cost (Kumar et al., 2011). Persistent BV also damages a woman's psychosocial health by inducing depression, low self-esteem, and relationship problems (Bilardi et al., 2013). The experiences of women with BV vary greatly, but the impact on their health is significant. Although the exact cause of BV is unknown, there

are multiple determinants that increase a woman's risk of acquiring this infection, namely sexual activities and behaviors.

BV is not considered a sexually transmitted infection (STI), but is highly associated with sexual behaviors and activities. Frequency of unprotected sexual intercourse, new partners, and use of sex toys disturb the ecosystem of the vagina by introducing new pathogens and altering the pH (Hay, 2005; Marrazzo, Thomas, & Ringwood, 2011). Female hormones play their role in the development of BV. Fluctuating hormones that occur throughout a woman's menstrual cycle creates a temporary favorable environment for bacteria to grow due to elevations in pH and decreased Lactobacilli (Kumar et al., 2011). The lists of concomitant risk factors associated with BV are exhaustive, hence why management is complicated and increased frustration among women.

Prevalence of BV is highest among women of childbearing age, thus affecting the armed forces community. An estimated 2.2 million females represent the total U.S military population. Surprisingly, 85% of this population is of ages 18-40 (Militaryonesourse, 2012). Reproductive health is important to all women, but especially servicewomen who face unique challenges that predisposes them to certain reproductive tract infections (RTIs) such as BV. Timely diagnosis, treatment, and knowledge awareness of BV is of the essence in preventing morbidity that could impact quality of life and mission readiness.

Women often mistake symptoms of BV for those of other vaginal infections. Clinical presentation of BV consists of milky whitish-gray or yellow homogenous vaginal discharge, accompanied by an offensive "fish-like" odor and vaginal irritation. However, many women are asymptomatic (CDC, 2015). Accuracy of diagnosis requires careful evaluation of vaginal discharge via physical exam or self-collected, though syndromic and self-assessment methods

continue to be exercised (Nwankwo, Aniebue, & Umeh, 2017). Amsel's criteria and Nugent's gram stain system are the two most common diagnostic tools utilized; however other commercialized tools are being explored. Medical management of RTIs is highly dependent on the causative organism (e.g., yeast vs. bacteria) so that overtreatment, resistance, and recurrence can be minimized.

Treatment for BV consists of oral and intravaginal antibiotics. Metronidazole and clindamycin are common pharmacologic treatments that have been in use for over two decades, and have side effects, including gastrointestinal upset and hepatotoxicity. The recurrence rate of BV is up to 70% within 12 months, conveying that either compliance or effectiveness of these medications has diminished (Vujic, Knez, Stefanovic, & Vrbanovic, 2013; Brotman, 2007). Complementary therapies such as probiotics, boric acid suppositories, and essential oils have also been suggested for persistent BV. Above all pharmacologic and non-pharmacologic therapies, primary and secondary prevention have a crucial role in minimizing infection in vulnerable women.

Vaginal infections are a top concern among women and healthcare providers, warranting greater awareness. Despite the various methods for analyzing vaginal secretions to accurately detect BV, empiric treatment based on patient's history and present symptoms alone remains problematic, leading to misdiagnosis and over treatment of BV (Carr, Rothberg, Friedman, Felsenstein, & Pliskin, 2005). Furthermore, misdiagnosis and careless use of antibiotics contributes to standard therapy resistance and recurrence of infection. To prevent a disservice to patients, healthcare providers must stay abreast on the most current evidence available in the management of BV as well as predisposing factors. Patients have the responsibility of caring for

self. If they are aware of the behaviors and health threats that may increase their risk of acquiring vaginal infections, they may be willing to change their behaviors to prevent infection.

Significance of the Problem

Bacterial vaginosis is the most prevalent-type of vaginal infection, affecting 1 in 4 women and accounting for over 10 million office visits annually. The direct cost of treating BV estimates to roughly $1 billion annually, including medical office visits and self-treatment (Bradshaw & Brotman, 2015). The indirect cost associated with BV, secondary to complications and lost wages from work absenteeism is far greater. In fact, the average lifetime cost of caring for a preterm infant is estimated to be $26 billion. Maternal care, early intervention, and special education services are also included in this overage costs (IOM, 2007). Further impact that BV causes to women cannot be measured in terms of money, but quality of life. Stress associated from persistent infection can take a mental toll on women, potentially placing a strain on work productivity, intimate relationships, and self-image. Appropriate methods for diagnosis are critical to ensure appropriate treatment of BV.

Screening and Diagnostics

Advancements in technology have sharpened the detection of BV, but the efficacy of current therapies is unchanged. Amsel's and Nugent's criteria are the two most common diagnostic tools utilized, with the latter recognized as the gold standard for BV diagnosis. Other commercial diagnostic tests include BD Affirm VPIII microbial identification, OSOM BV Blue, and Polymerase chain reaction (PCR) and yields fast and easy to read results. Obtaining a thorough history, physical examination, and careful analysis of vaginal secretions is key to accurate diagnosis and treatment of BV. Self-diagnosis is not recommended, as BV can co-exist with other causes of abnormal vaginal discharge.

Nugent's Gram Stain

Nugent's criteria utilize gram stain microscopy to evaluate characteristics and quantity of vaginal smear (e.g., Gram-negative rods, Gram-positive cocci, Gardnerella), thus a calculated score of 7-10 is consistent with BV. This method is costly, time consuming and requires highly skilled personnel, as well as additional resources (Hainer, & Gibson, 2011). Due to rapid changes in healthcare, the gram stain method is rarely used in clinical settings and is now primarily reserved for research studies.

Amsel's Criteria

Amsels's criteria evaluates characteristics of vaginal fluid: pH > 4.5, clue cells, homogenous whitish grey appearance, and positive whiff test after exposure to 10% potassium hydrochloride (KOH). Three of the four criteria must be met and can be analyzed at the point of care, if a microscope and skilled personnel are available (Kampan, et al., 2011). This method is widely utilized, however has low validity (i.e., 69% sensitivity, 93%, specificity) and reliability is dependent on the expertise of interpreter (Hainer, & Gibson, 2011). These two conventional diagnostic methods have been in use for over 60 years. However manning, resources, and experience are required. Analysis of results can vary from minutes to hours causing delays in treatment. Furthermore, not every facility will have access to a microscope, especially in deployed locations, hence why other commercialized methods should be explored.

Other Commercial Methods

BD Affirm

The BD Affirm VPIII simultaneously detects DNA from microbial agents responsible for the most common vaginal infections from a single swab of vaginal fluid. This molecular system features automated processing, delivering readable visual results within 45 minutes (BD, 2018;

Hainer & Gibson, 2011). The Affirm is shown to be more sensitive in detection of BV compared to conventional methods, yielding a sensitivity of 95% and specificity of 100%.

OSOM BV Blue Test

The OSOM BV Blue is a rapid point of care test (POCT) used to evaluate presence of BV in vaginal fluid. Yielding results within 10 minutes, BV Blue identifies enzymatic (i.e., sialiadase) activity that is produced when harmful bacteria are invading and destroying tissue (Kampan et al., 2011; Hainer et al., 2011). The accuracy and reliability of BV Blue rapid test kit, compared to Amsel's and Nugent's criteria have been studied in at least three studies yielding an average sensitivity and specificity of 97% and 96% respectively.

Polymerase Chain Reaction (PCR)

Lastly, the PCR is a molecular photocopy technique used to amplify copies of Deoxyribonucleic acid (DNA) found in vaginal specimens. Not only does PCR detect specific types of bacteria associated with vaginal infections, but also quantifies them and yields a higher validity with a positive predictor value of 100% (Hainer et al., 2011; Malaguti, Bahls, Uchimura, Gimenes, & Consolaro, 2015). Although, rapid PCR is the most sensitive, it is also the most expensive.

The BD Affirm VPIII and rapid PCR test has sensitivity to all three vaginal infections, while the OSOM BV Blue test is only sensitive to BV. They all involve automated processes, require minimal equipment, personnel, and deliver quick results, thus taking the guesswork out of diagnosing vaginal infections. The increase cost of these advanced diagnostic tools may offset the costs of under or over treated infections and its complications from recurrences.

In reference to vaginal smear collections, self-collected vaginal specimens are just as feasible as provider-collected specimens (Madhivanan et al., 2013). This method allows for

disentanglement of busy providers, enhanced privacy, and quicker access to care; method may also support deployed women where pelvic exams are inaccessible. This alternative method may also be useful for women in refusal of a pelvic examination, and walk-in clinics where a speculum examination is not required. The use of available diagnostics provides rapid and reliable results, which warrant recommended antibiotic therapy.

Pharmacologic Treatment Modalities

Treatment modalities should be selected based on type of bacteria present, however the CDC recommends first-line agents Metronidazole and Clindamycin for the treatment of BV. Both are similar in effectiveness and can be delivered via intravaginal or oral route. Regardless of delivery route, the choice of medication is based on availability, patient preference, side effects, and cost. Oral medication is more convenient, but associated with a higher rate of systemic side effects compared to vaginal administration. If neither metronidazole nor clindamycin are available, either tinidazole or secnidazole are reasonable oral alternatives.

Metronidazole

The CDC (2015) recommends specific prescriptive first-line medications to treat symptomatic women with BV, which include Metronidazole or Clindamycin. Oral Metronidazole is to be prescribed 500 mg orally twice a day for 7 days or Metronidazole gel 0.75%, one full applicator intravaginally, once a day for 5 days per the CDC (2015). Metronidazole therapy in both forms is equally effective in the treatment of BV according to the CDC (2015) with a 70% cure rate. Healthcare providers are to discuss medication administration options as well as potential side effects while on the medication. For example, National Center for Biotechnology Information (NCBI) reported Metronidazole tablets may leave a metallic taste in about 10 out of 100 women (2015). Another a serious side effect is a disulfiram-like reaction

will occur if a patient consumes alcohol during the medication regimen and up to 24 hours after completion of therapy. Patients are advised to avoid alcohol due to reduce the likelihood of undesired effects.

Clindamycin

Besides the use of Metronidazole, Clindamycin is also an acceptable treatment option for BV. Per the CDC (2015), Clindamycin cream is to be ordered as 2%, one full applicator intravaginally at bedtime for 7 days or as an alternative treatment as Clindamycin 300 mg orally twice daily for 7 days. Oral clindamycin has been noted to have 85% cure rate (CDC, 2015). Patients are to be counseled that the Clindamycin cream contains an oil-based product, which may weaken latex condoms and diaphragms for 5 days after use with and may result in an unintended pregnancy. The National Center for Biotechnology Information (NCBI) (2015) reports that clindamycin and metronidazole are equally effective with over 90 out of 100 women without symptoms after treatment, regardless of drug administered. A common side effect of antibiotics include the development of a vaginal yeast infection, 10 out of 100 women experience symptoms (NCBI, 2015). For optimal management, women should be advised to continue medication regardless of improvement of symptoms, refrain from sexual activity or use condoms consistently and correctly during the treatment regimen.

Tinidazole

First-line treatment for BV is provided by the CDC (2015) however, alternative medications are also discussed for curative therapy. Tinidazole is prescribed as 2 g orally once daily for 2 days or 1 g orally once daily for 5 days (CDC, 2015). Currently, there is limited data to evaluate the effectiveness of the medication. Patients must be aware of the possibility of a

disulfiram-like reaction, the CDC (2015) recommends abstaining from alcohol use for 72 hours after completion of tinidazole.

Secnidazole

The Food and Drug Administration has recently approved a new medication to assist in the treatment of BV. Secnidazole or brand name Solosec, is the first and only single dose oral medication on the market. According to Symbiomix Therapeutics (2017) Solosec 2g oral granules is composed of a 5-nitroimidazole antimicrobial agent indicated for the treatment of bacterial vaginosis in adult women. Patient education on administration involves the entire contents of Solosec packet to be sprinkled onto foods such as applesauce, yogurt or pudding and consumed once within 30 minutes without chewing or crunching the granules (Symbiomix Therapeutics, 2017). The most common adverse events reported from Symbiomix Therapuetics (2017) included: vulvovaginal candidiasis, headache, nausea, dysgeusia, vomiting, diarrhea, abdominal pain, and vulvovaginal pruritus. BV treatment adherence will likely increase due to a single dose therapy compared to 50 percent compliance rate (Symbiomix Therapuetics, 2017) with current therapy.

Complementary and Alternative (CAM) Therapies

Vaginal infections can have a recurrence rate ranging from 30%-70% within one year. Overzealous use of over the counter medications, decreased treatment compliance, and inaccurate diagnosis, contributes to standard therapy resistance and recurrences, thus warranting consideration of alternative agents (Secor & Coughlin, 2013). As conventional methods used to treat BV has been declining in effectiveness, the use of complementary therapy has been on the rise. It is important for providers to be aware of the common CAM therapies on the market.

Vitamin C

Previous studies suggest Vitamin C vaginal tablets are effective against BV relapse. In a randomized-controlled, double-blinded study, 142 women were given a monthly dose of ascorbic acid for six months. At the completion of study, Vitamin C was shown to halve BV recurrence rate from 30% to 16% (Krasnopolsky, 2013). Another study comparing the effectiveness of Vitamin C against standard therapy Metronidazole, showed no significant difference between the two therapies as both were effective against BV (Zahra, Fateme, & Mohamadreza, 2010). The only adverse reactions noted were localized skin irritation.

Vitamin D

Recent studies suggest a relationship between Vitamin D deficiency and BV. Vitamin D deficiency is prevalent among African American women, as well as BV. As part of a randomized controlled study, Vitamin D 2000IU given to women over a period of 15 weeks showed efficacy against asymptomatic BV (Taheri, Baheiraei, Foroushani, Nikmanesh, & Modarres, 2015). Inversely, another study where high-dose Vitamin D (50,000IU) was given to women over a 14-week period showed no efficacy in recurrence, but did result in elevated Vitamin D serum levels (Turner et al., 2014).

Probiotics

Probiotics inhibit colonization of the gut by pathogenic bacteria, and has been useful in preventing antibiotic-associated diarrhea. Probiotics show promising effects against BV prevention, as some are able to produce metabolic products that have antibacterial effect. However, not all probiotics are created equal. In vitro studies demonstrate that Lactobacilli strains can invade biofilms caused by polymicrobes, causing destruction to BV related organisms and reestablishing normal vaginal environment (Huang, Zhao, & Song, 2014; Hamayoui et al.,

2013). However validity of probiotic use should be further studied. Also, the adverse effects associated with probiotics have not been well established.

Boric Acid

Boric acid is a white, odorless powder that has historically been used as a topical antiseptic, and a form of treatment of vulvovaginal candidiasis and trichomonas vaginalis. Vaginal boric acid has bacteriostatic and fungistatic properties. The exact mechanism of action is unknown, but is thought to create an acidic environment, which prevents colonization of pathogenic organisms associated with BV. The BASIC (Boric Acid, Alternate Solution for Intravaginal Colonization) study is a new and first of its kind trial underway that will determine if boric acid is a superior treatment compared to Metronidazole. The study is currently in its enrollment phase (Bradshaw & Sobel, 2016). Boric acid as part of a six-month triple-phase maintenance regimen for preventing recurrence of BV showed minimal effectiveness, as treatment compliance and participants lost to follow-up served as limitations (Reichman, 2009). Adverse reactions include localized itching, burning, dyspareunia, and respiratory irritation.

Tea Tree Oil and Garlic

In vitro studies show that tea tree oil, Melaleuca alternifolia, and crushed garlic have antibacterial and antifungal properties. Tea tree oil disrupts the cell membrane, thus disbanding bacteria. Fresh crushed garlic contains the active ingredient "allicin" which possess antimicrobial effects, however loses potency when dried, powdered, or extracted (Kessel, Assefi, Marrazzo, & Eckert, 2003). Currently, the use of first-line antibiotic therapy is the standard in treatment of BV with on-going studies to evaluate alternate methods of therapy. In addition to recommended therapies, patients should be provided education on specific behaviors that may increase their risk of developing BV.

Predisposing Factors

Patients and healthcare providers must be aware of risk factors that may contribute to the development of BV to minimize long-term complications. Li et al. (2014) conducted a study to determine the risk factors for BV of women in China. The results showed that a husband of older age, greater than 35 days between menstrual cycles, menses less than 3 days, dysmenorrhea and use of an intrauterine device (IUD) placed women at a greater risk of developing BV. Similarly, to other published studies, Joesoef et al. (2001) had significant findings where BV was common among IUD users. However, women with a higher education, lower frequency of pre-washing vaginal area before sexual intercourse, as well as a higher frequency of sexual intercourse per month may be protective factors for BV. Bradshaw et al. (2014) conducted a study in Australia of women ages 16-25 and established that sexual exposure to new partners was influential in the development of BV while the use of estrogen-containing contraceptives was associated with a reduced risk. The literature also demonstrates that women who have sex with women (WSW) have a higher prevalence of BV. Marrazzo et al. (2011) discussed factors to support the increased prevalence among this population to include: higher lifetime number of female sex partners, shared use of a vaginally inserted sex toy, oral–anal sex, and having a female sex partner with BV.

Another study aimed to review the psychosocial factors that contribute to the recurrence of BV. Payne et al. (2010) reported that women experienced feelings of shame and embarrassment, which caused them to engage in hypervigilant routines of hygiene that negatively impacted their professional, personal, and intimate relationships. Brown et al. (2016) reviewed the motivation of women to perform intravaginal practices, which increases the risk for bacterial vaginosis (BV), sexually transmitted infections (STI), and HIV. These specific

practices consisted of a variety of behaviors, to include wiping, cleansing, douching, or the insertion of over-the-counter products, such as sexual lubricants, into the vagina (Brown et al., 2016). The results of the study showed that women performed intravaginal practices for good hygiene, to cleanse after a sexual encounter or at their partner's request. Self-cleansing may also be a cultural practice as many women are educated by their mothers or self-taught to cleanse intravgianlly for good hygiene. Douching is another behavior that many women practice to self-cleanse, however it can disrupt the vaginal flora and put women at risk of developing BV. Cottrell (2010) discusses how douching is also associated with serious gynecologic outcomes, including increased risk of cervical cancer, pelvic inflammatory disease, endometritis, and increased risk for sexually transmitted infections, including HIV. Without proper education and advice from healthcare providers, continuation of behavioral practices will lead to a recurrence of BV.

Education

An evidence-based educational intervention provided to patients as well as to the healthcare team is critical to reduce BV recurrence. Studies have demonstrated an increased association between BV recurrence and intravaginal practices. Esber et al. (2015) conducted a 12-week behavior change intervention to encourage cessation of intravaginal practices among 85 Zimbabwean women to affect the prevalence of BV. The intervention entailed a 15-min semi-scripted counseling message on cessation of intravaginal practices targeted to the participant's stage of change. At time of participant enrollment, 100% of women practiced intravaginal practices with a significant reduction at the end of the study with 8% continuing their previous behavior. Unfortunately, the authors were unable to have an effect on the rates of BV, which were sustained throughout the study.

Alcaide et al. (2017) performed a randomized pilot study to reduce intravaginal practices and BV among HIV infected women during a 12-month period. At baseline, all participants received an individual education session on the risk of engaging in intravaginal practices, advice to discontinue intravaginal practices, and tips for healthy vaginal hygiene, with emphasis to avoid intravaginal practices and replacement of those practices with external vaginal cleansing. The experimental arm of the study obtained the baseline education as well as a 45-minute group-based intervention. This particular session consisted of risks associated with intravaginal practices, symptoms of vaginal infections, vaginal health, women's experience with alternative methods for vaginal care, and communication with partners about vaginal health and the risks associated with intravaginal practices. The findings of the study demonstrated that both the standard of care and experimental group decreased the use of intravaginal practices and BV, with greatest reduction in the participants who attended the group session.

Initiation of an evidence-based targeted education project starts with meeting clinic leadership to discuss the purpose and planned implementation within their setting. After receiving approval from the clinic and the Institutional Review Board (IRB) the project team members conducted a four-month retrospective chart review. The significance of the medical records review was to determine if BV is problematic within this particular population and to obtain co-founding factors (demographics, contraception type, concomitant STI etc.) that may have an effect on BV. Next, team members developed a provider and patient education resource to be disseminated within the clinic. Completion of a literature review and published guidelines recommendations resulted with limited evidence, which specifically discusses how to successfully implement an education intervention to reduce BV occurrence. The findings from

Alcaide et al. (2017) study demonstrated that individual in addition to a group educational session on reduction of intravaginal practices produced significant results to reduce BV.

An educational brief was conducted at a staff meeting that entailed symptomatology, diagnostic criteria, and treatment recommendations. Many studies have demonstrated an association of intravaginal practices towards the development of BV and creation of a patient resource may benefit women by providing education on BV definition, transmission, symptoms, diagnosis, treatment and how to reduce the risk of BV. The patient resource was developed after review of current guidelines from organizations such as the CDC, American Academy of Family Physicians (AAFP), American College of Obstetricians and Gynecologists (ACOG) and other creditable sources, see Appendix A for chart comparison of the content. The informational handout was to be disseminated throughout the clinic and placed in exam rooms. Prime opportunities to discuss BV were presented during well woman exams and patient encounters for abnormal vaginal discharge while providing patients an evidence-based resource to re-enforce BV teaching. Patient and provider awareness of diagnostic criteria, symptoms, and appropriate treatment may reduce the incidence and recurrence of BV.

Military Relevance

Women represent 15% of active duty population, as well as 18% of active guard and reservists (Women's Health Department of Veterans Affairs, 2013). Bautista, Wurapa, Sateren, Morris, Hollingsworth, and Sanchez, (2016) reported prevalence of BV was 27 percent among female military recruits to the US Marine Corps between 1999 and 2000. Although BV is not defined as a sexually transmitted infection (STI), it is closely associated to common STIs such as gonorrhea and chlamydia. New recruits are at a higher risk of contracting sexually transmitted infections compared to general population (Goyal, Mattocks, & Saddler, 2012) due to most

recruits tend to be young and unmarried. Furthermore, new female trainees may likely participate in unsafe practices such as inconsistent contraception usage, multiple sexual partners, and binge drinking (Goyal et al., 2012). Data from the US Defense Medical Surveillance System indicates that between 2004 and 2013, 149,666 (15,000 cases per year) BV cases were reported in women in the US military (Bautista et al., 2016). Servicewomen are unique compared to their civilian counterparts, as they are required to maintain deployment readiness at all times.

Military deployments pose another risk for vaginitis, as urinary tract infections and vaginitis are the most common complaints among deployed women (AFHSC, 2014). Stress, oral contraceptives, menstrual blood, and the use of feminine products (e.g. soaps, sprays, douches, etc.) can disrupt vaginal pH leading to bacterial overgrowth and symptoms of vaginitis. The physical impact of vaginitis includes external dysuria and vulvar pruritus, pain, swelling, and redness, vulvar edema, fissures, excoriations, and thick curdy vaginal discharge with or without an odor, but clinical presentations vary depending on the causative agent (CDC, 2015). The aforementioned conditions and austere environments during deployments challenge health maintenance practices among women and can exacerbate gynecologic disorders (Trego, 2011).

According to a medical report from Armed Forces Health Surveillance Center (2014), 1 in 10 women are diagnosed with a gynecologic disorder at least once during deployment; one in 20 will be evacuated out of theater, thus representing 384 women in a six-year surveillance period. Without treatment, vaginitis leads to decreased comfort, concentration, and can compromise the member's ability to perform duties. Absence from work is critically important to the military services, as every individual is needed for mission readiness. In addition to annual medical expenses and time off work, vaginitis can impact unit effectiveness and overall organizational mission (Trego, 2011). Healthcare providers must ensure member readiness and

preventative care maintenance before, during, and after deployment (AFHSC, 2014) as well as awareness of predisposing factors.

In summary, if BV is left untreated, the CDC (2015) reports women are at an increased risk of contracting sexually transmitted diseases, including chlamydia, gonorrhea, herpes, trichomaniasis and HIV. The sequelae associated with untreated vaginitis include pelvic inflammatory disease (PID), ectopic pregnancy, infertility, and long-term pelvic/abdominal pain (CDC, 2014). Vujic et al. (2013) have also stated possible outcomes of untreated infections: Endometriosis and pregnancy complications of chorioamnionitis, premature rupture of membranes, and preterm labor. Overzealous use of over the counter medications, decreased treatment compliance, and inaccurate diagnosis, contributes to standard therapy resistance and recurrences, thus warranting consideration of alternative agents (Secor & Coughlin, 2013). Awareness of BV prevention education for providers and patients can potentially reduce recurrence rates and significantly impact the health and well being of the patient.

Clinical Question

In non-pregnant, reproductive aged, female military beneficiaries between the ages 18-40, how does targeted health promotion counseling affect the incidence of bacterial vaginosis?

Focus Areas

Primary focus areas include assessing severity of vaginitis at a large military treatment facility (MTF) located in San Antonio, Texas. The DNP project was specifically targeted at the Women's Health Clinic within the MTF, which serves an estimated population of 7,520 of eligible female beneficiaries. The initial step in implementing an evidence-based project is to engage key players early in the planning process to discuss goals, expectations, and potential barriers are paramount. Once approval is obtained from the clinic's leadership, project team will

begin the implementation process. The role of the investigators is to educate the providers and patients within the clinics on the risk factors, diagnosis and management of bacterial vaginosis. This will ensure that the healthcare providers are all provided a foundational informational brief on BV prior to project implementation. From the readings, providers are knowledgeable on BV, but without implementation of an evidence-based project their awareness on the subject may not be as heightened.

Initially, the project team will identify the incidence and recurrence rates of BV as well as additional co-founding factors via a four-month retrospective chart review. An evidence-based educational intervention will be presented to the healthcare providers on the recommended guidelines, diagnostic criteria, and treatment. The BV educational brief will be presented to all clinic staff during their scheduled morning meeting. In addition, a patient handout will be created to have available in exam rooms as a resource for patients to facilitate and reinforce vaginitis education. Lastly, a post-intervention four-month retrospective chart review will be conducted and analyzed to measure the effect of the educational intervention on BV incidence and recurrence rates. Due to the focus areas discussed, creation of short and long-term goals were identified.

Project Short and Long Term Goals

Short and long-term goals are an important factor to consider with project implementation. A diagnostic gap exists between providers where there is no standardization in diagnosis of BV. Providers are treating patients based on a patient's symptoms, use of laboratory specimens or clinic microscopy. Short, immediate project goals consist of increasing provider and consumer awareness regarding management of vaginal infections, to include assessment, diagnosis, treatment, and preventative measures. While long term goals include

policy integration into primary care clinics in addition to decreased health care spending. By reinforcing recommended diagnosis and treatment among providers, they will be able to offer appropriate counseling to patients to prevent recurrent vaginal infections, the major strategic goal this project wishes to achieve.

Primary preventative measures are aimed at changing behaviors that increase risk of developing BV. While secondary preventative measures aim towards educating women on the risk factors associated with BV, and the application of self-care interventions that will reduce the incidence and reoccurrence (Youngkin & Lester, 2010). Overall long-term commitment is to implement standardized evidence-based clinical guidelines along patient education pamphlets to reduce the incidence of disease. Advance practice nurses are at the forefront of influencing policy and driving change in health care organizations. Integration of an evidence-based targeted educational BV counseling into local policy (i.e. SOP) at the local MTF is just a starting point, with hopes of expanding policy to other MTF's in the region. BV policy can then be adopted by civilian organizations and then become the mainstream method of provider and patient education.

Anticipated Global Impact

Global impact of project is in accordance with military health system's (MHS) quadruple aim: Readiness, population health, patient experience, and healthcare costs. Vaginitis is the most frequent diagnosis among gynecologic disorders among women of childbearing age, and accounts for 75% of gynecologic appointments (AFHSC, 2014). Inaccurate diagnosis and treatment may result in an increase of BV recurrence. Absence from work is critically important to the military services, as every individual is needed for mission readiness. When service

members have absenteeism from multiple medical appointments, they can have a detrimental impact on the mission.

Many clinics have under-utilized resources, such as the microscope to obtain a diagnosis. Microscopy utilization provides rapid results as well as increases satisfaction of the patient's experience. Standardization in practice of clinic's microscope and the laboratory department provide fast, accurate results to deliver patient centered quality care. Ensuring that women are accurately diagnosed and treated efficiently as well as, conducting a BV prevention education improves the care of female beneficiaries, while promoting disease awareness. The implementation of an educational evidence-based project via the use of a health promotion theoretical framework may reduce the incidence and recurrence of BV.

Organizing Framework

Elicited health behaviors are essential to health promotion and disease prevention. The Health Belief Model (HBM) by Hochbaum, Rosenstock, and Kegels will be utilized as a framework to develop educational intervention. HBM examines how individual perception of health risks impact their involvement in various health practices and identifies factors (i.e. attitudes/beliefs) that influence their behavior towards said health practices. HBM consists of six constructs: perceived susceptibility, perceived threat, perceived benefits, perceived barriers, cues to action, and self efficacy. Essentially, health behaviors (i.e. willingness to change) is dependent upon his/her perception of their chances of actually acquiring a disease, seriousness of particular disease, positive outcomes if behavior is adjusted to mitigate health risk, roadblocks that may affect behavior change, individual motivation, and confidence (Hayden, 2014; Bishop, Baker, Boyle, & Mackinnon, 2015). In addition, there are several interpersonal variables that may influence a person's attitude regarding behavioral change (e.g. religion, culture, knowledge,

experiences, etc.). The HBM will be foundational to the health-promoting education interventions that will be implemented to reduce BV incidence.

Five out of the six constructs will be emphasized: perceived susceptibility, perceived threat, perceived benefits, perceived barriers, and self-efficacy. *Perceived susceptibility* will include discussing prevalence and risk factors associated with BV (i.e., unprotected sex, smoking, improper vaginal hygiene). Explanation of symptoms and sequelae (i.e., pelvic inflammatory disease, pregnancy complications) related to untreated BV or other vaginal infections would address *perceived threat*. Integrating the most current evidence from the health care literature to explain *perceived benefits*, treatment and preventative measures to prevent recurrence of BV will be described (i.e., condom use, lifestyle management). Assessing patient obstacles that may hinder behavior change (i.e., money, time, and partner conflict) will emphasize *perceived barriers*. Finally for fulfillment of *self-efficacy*, a patient education pamphlet will be provided at the end of the visit to reiterate provider-facilitated discussion. The sole purpose of applying behavior interventions based on HBM is to motivate and empower women to take efficacious health actions that will reduce occurrence of BV and improve outcomes.

Project Design

Evidence Evaluation

Four common databases for nursing and allied health professionals were used to search the literature: PowERsearch; Public/Publisher Medical Literature Analysis and Retrieval System Online (PubMed); EMBASE; and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). All databases were accessed through the Uniformed Services University of the Health Sciences Learning Resource Center. PowERsearch key terms were (Vaginosis, Bacterial)

AND (Patient Education as Topic) AND (Prevention Education). PubMed search utilized the Medical Subject Heading (MeSH) terms: "Vaginosis, Bacterial" AND "primary prevention" OR "prevention education." EMBASE used key terms: (bacterial vaginosis); (bacterial vaginitis); (prevention and education); (clinical education); (adult education); (allied health education). CINAHL used Boolean term "bacterial vaginosis."

There were a total of 360 peer-reviewed articles obtained: 303 articles from PowERsearch; 24 from PUBMED; 60 from EMBASE; and 16 from CINAHL. The search was limited to articles dated 2007-2017, English language, random controlled trials, and systematic reviews. Exclusion criteria were articles related to in vivo studies, pregnant women, pediatrics, expert reviews, menopause, and co-infections.

The selected articles were evaluated via the use of an evidence appraisal form template provided by faulty. Utilization of this tool involved critiquing the design type, sample size, outcomes, measures, findings and limitations of the studies. A hierarchy of evidence rating system modified from Melnyk and Fineout-Overholt (2011) assessed the level of evidence while the level of quality was measured by the use of a tool modified from Johns Hopkins Nursing Quality of Evidence Appraisal (n.d.). After appraising the literature, the studies were divided into a total of (a) one, level-two study; (b) two, level-four studies; and (c) three, level-six studies. The Levels of evidence were categorized into one randomized control trial, a retrospective study, two retrospective comparative studies, and one case series. All six articles were determined to be of "good" level of quality. A total of 18 duplicate articles were removed. After reviewing titles and abstracts, 367 articles were excluded based on relevance to clinical question (See Appendix B). An additional 12 articles were discarded based on full text and irrelevancy to clinical question. A total of 6 articles were retained for inclusion in literature synthesis.

In reference to consistency, the studies found were homogenous throughout with diagnostic criteria, population characteristics, and positive effects of a targeted education. Clinical criteria (e.g. Amsel's diagnostic criteria) and Gram staining are considered the gold standards for diagnosing vaginitis (CDC, 2015). The sample populations consisted of women at high-risk of developing bacterial vaginosis due to intravaginal practices and high-risk behavior.

Setting

The project was conducted in the women's health clinic at Wilford Hall Ambulatory Surgical Center (WHASC). This specialty care clinic offers expansive obstetrical and gynecological services and is accessible to all women beneficiaries. WHASC is located at Joint Base Lackland Air Force Base in San Antonio, Texas with an estimated population of 1.4 million. This fast-growing, metropolitan area has a tri-service military presence of over 200,000 active duty personnel and veterans (MVCC, 2016), making our data collection applicable to all branches. The primary focus area will be the women's health clinic with a goal of expanding to all primary care clinics. The large number of beneficiaries empaneled to these clinics allows for an enlarged number of participants to be affected from expansion of clinician knowledge base

Procedural Steps

Approval to initiate project activities was granted through the Institutional Review Board (IRB) at Joint Base Lackland Air Force Base. A retrospective chart review, based on BV International Classification of Diseases code10 (ICD-10), from January 2017 through March 2017 was conducted to identify the incidence rate of BV among female patients ages 18-40, and to assess if diagnostic and treatment practices coincided with current best evidence. Other confounding variables affiliated with BV acquirance (i.e., contraception use, pregnancy history, sexually transmitted infections, race) were also assessed. Applying the Health Belief Model

(HBM), a health promotion intervention consisting of supported recommendations, guidelines, diagnostic criteria, treatments, and preventative measures were composed.

Prior to patient counseling, providers and clinic staff were briefed during weekly staff meetings on what was to be expected during the implementation of project. Briefing consisted of an overview of BV management and how targeted counseling to educate women on self-care practices may reduce recurrence of the nuisances associated with BV. Starting Jan 1, 2018, women ages 18-40 received counseling during annual wellness exams or acute visits for vaginal complaints. Counseling consisted of explaining how and why BV occurs, symptoms associated with BV, diagnosis and treatment of BV, and how to reduce risk of acquiring BV. Approximately 20% of appointment visit was spent counseling and educating patients. Following counseling session, women were provided a health maintenance resource, at the end of visit to reiterate what was previously discussed. Refer to Appendix C to review education pamphlet. Additionally, education resources were placed in exam rooms and in the waiting area of the clinic to facilitate greater access.

Post-Intervention Analysis

A retrospective chart review was performed from January through March 2018 to assess if individual counseling per provider had an impact on incidence rate of BV. The statistical package for the social sciences (SPSS) version 23 was used to input and analyze data. In addition to incidence rates, tests included unpaired t-test, chi-squared test, and Levene's test to determine equality of variances and means. $P < 0.05$ was considered statistically significant.

HIPAA Concerns (IRB)

During the various phases of project assessment, implementation and re-evaluation, confidentiality and privacy was maintained. Patients who met inclusion criteria were

selected based on ICD 10 code. Patient's health information was confidentially collected from electronic health records (EHR), which was secured and password protected. Data could only be assessed at the medical treatment facility via use of a common access card (CAC), which is necessary to assess any government-owned electronic data systems. For further safeguarded measures, information was de-identified and no surveys were administered. The information from the records was documented in a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. No physical copies of data collection were retained to minimize data breach. As a result of protecting health information, there was no Health Insurance Portability and Accountability Act of 1996 (HIPAA) concerns throughout the development of the project.

Project Results

Participants

A total of 227 female participants met inclusion criteria. The sample population was homogenous, consisting of active duty (44%) and dependent military beneficiaries (56%). Members of other or unknown race made up the majority of the participants (56%), followed by Caucasians (24%), African-Americans (18%), and Asians or Pacific Islanders (2%). Although the age groups studied were 18-40, the average age of the participants were 29. Majority of women were multiparous, using no known method of contraception, oral contraceptives and intrauterine devices (IUDs) were associated with 42% of BV incidences. Sexually transmitted infections (STIs) were not a contributing factor to BV. Complete baseline characteristics of women are provided in Table 1.

Inclusion Criteria

Between the two study periods (Jan - Mar 2017; Jan-Mar 2018), 227 women were diagnosed with BV. The ICD codes used for diagnosis were acute vaginitis, other specified non-inflammatory disorder of vagina, or other specified bacterial agent as the cause of disease classified elsewhere. The most common complaints reported amongst women were vaginal discharge and odor. Methods of diagnosis were primarily done via point-of-care or bedside testing using microscopy and Amsel's criteria, whereas 25% of women were diagnosed and treated based on patient history of symptoms. Metronidazole "Flagyl" therapy alone was the dominant form of treatment. There were few mixed infections in which Metronidazole and an antifungal agent were prescribed. Full description of the methods of BV management is described in Table 2.

Incidence Rate

The incidences of BV did not significantly change between 2017 and 2018. $P< 0.05$ was considered statistically significant. The BV incidence rate were 2.95% in 2017, and respectively 2.88% in 2018 ($P<0.64$). However, when looking at BV incidences per provider, there was a considerable difference. There were 22.4 cases of BV per one provider in 2017, compared to 12.8 cases in 2018. This represents a 43% reduction in BV cases per provider. As a result, this reduction has opened up approximately 70 additional clinic appointments, thus providing greater access to care.

Discussion

This study, involving multi-ethnic female military beneficiaries, demonstrated that behavioral counseling targeted to at-risk populations was marginally effective in reducing incidence of BV. Although current clinic practice was aligned with recommended clinical

guidelines, there were few women who were empirically diagnosed and treated for BV. There were a small number of participants who had other non-inflammatory vaginal conditions, but were incorrectly coded as having BV, and therefore received other forms of treatment therapies. Our results were comparable to similar studies.

Esber et al. (2014) used a transtheoretical model (TTM)-based behavior change approach on Zimbabwean women to decrease intravaginal practices (IVP), and subsequently prevent bacterial vaginosis. Participants received 15 minute, semi-scripted counseling for 12 weeks. At completion, self-reported intravaginal practices declined, however there was no significant decline in episodes of BV. Sivapalasingam et.al, (2014) also utilized group-based behavioral counseling in African American women in essence of reducing HIV risks and other vaginal infections. Following three-month intervention, self-report IVP declined from 95% to 0%, but again no significant changes to vaginal microbiota. Results following the HIV Prevention Trials Network, Kasaro et al. (2017) described the impact of targeted counseling on reducing IVP, and its effect on BV. During quarterly visits, over 3,000 predominantly African-American participants received individualized counseling regarding HIV/STI risk reduction and against vaginal hygiene practices. Following 12 months, intravaginal practices did decline over time, but still did not have impact on prevalence of BV.

Another at-risk population for acquiring BV is women who have sex with women (WSW). This population tends to participate in activities involving exchange of vaginal fluids (i.e., multiple female partners, sharing of sex toys, digital penetration), thus increasing their risk of disturbing vaginal ecosystem and developing BV. In a trial conducted by Marrazzo et al., (2011), 108 women who reported having sex with women were randomized to receive either HBM-based counseling to reduce sharing of vaginal fluid, or general STI education. The

intervention proved to have a positive effect on sexual behaviors and activities, however BV was still persistent.

Empowering women to take control of their health by assisting them with modifying certain behaviors and offering self-care interventions to prevent BV was the main goal of this study. This concept was originally learned from Youngkin et al., (2011), who utilized HBM-based counseling to encourage women to seek early diagnosis and treatment of BV, following use of a home self-screening kit, in efforts of preventing secondary complications. This intervention proved to be very effective. All of the women who perceived to have BV, based on scoring system used with the self-screening kit, did seek additional medical attention within 10 days following symptoms, which improved health promotion and secondary disease prevention.

Lastly, a lifestyle improvement educational intervention was conducted on reproductive-aged Iranian women. Parsapure et. al., (2016) counseled women on various lifestyle modifications, such as adequate nutrition, physical activity, and stress reduction in relation to vaginal health and infection prevention. Not only, did the intervention group receive 30 minutes of individualized counseling, but also provided a pamphlet, follow-up telephone calls or texts, and access to various electronic resources. This intervention proved beneficial in improving lifestyle changes that promote optimal vaginal health. In review, all studies demonstrated positive effects of behavioral interventions on changing sexual behaviors, improving attitudes, and improving lifestyle skills. However, there was little to no effect on minimizing BV, thus suggesting that behavioral counseling alone may not be sufficient enough to prevent BV occurrence, or that intravaginal practices may not be as big of a culprit as perceived.

Limitations

Although the authors rigorously attempted to maintain authenticity of this study, there were a few limitations noted. Our sample population was small and consisted of a predominantly healthier population, and therefore cannot be generalized. BV incidences in our population were approximately 3%, compared to an estimated 30% of women in the general public whom are affected by BV. This also suggests that BV is not as problematic as once thought to be. Due to time constraints, our study only looked at three out of the twelve months of the calendar year, so it is possible that more women could be affected by BV and captured in our data analysis. Demographics, sexual behaviors, or intravaginal practices could not be thoroughly assessed due to being a retrospective study, and women were not personally asked these questions. Most of the literature provided 15-20 minutes of counseling at more than one clinic visit, whereas women in our study received approximately 3-5 minutes of a single individualized counseling session. Furthermore, these women were not directly followed to assess if educational intervention was beneficial to them or not.

Other limitations included the use of incorrect ICD codes to diagnose other disorders of the vagina. For example, providers were using code “acute vaginitis” for women who complain of vaginal dryness or other irritation, and were treated with premarin cream versus the recommended treatment for BV, thus offsetting the results and analysis of the study. The Health Belief Model had its own limitations as well. The model does not account for a person's attitudes, beliefs, or other individual determinants that dictate a person's acceptance (or avoidance) of a health behavior. It does not account for behaviors that are habitual and may impact the decision-making process to accept a recommended action (e.g., use of tampons, feminine wipes, smoking). The model also does not account for environmental or economic

factors that may prohibit or promote recommended actions. HBM is thought to be more descriptive than explanatory, and therefore does not provide a clear strategy of changing health-related actions. To optimize use of HBM, this model should be integrated with other models that account for environmental or other social elements, and promote other strategies for change.

Organizational Impact

After analyzing the results of our interventions, team members were able to determine their impact on the organization. The ultimate goal for the Military Health System (MHS) is the focus on the Quadruple Aim. Project members represent the MHS leadership's commitment to delivering value to all they serve and is aligned with the MHS strategic goals: better health and better care at a lower cost while improving readiness. The implementation of an evidence-based project supports the MHS goals by synthesizing the literature and applying into current practice to make improvements. Utilization and familiarization of clinic microscopy provides patient-centered care by providing rapid diagnostic results, but also saves the MTF healthcare related costs as well as increases clinic access. The readiness requirement of the quadruple aim is met by ensuring that women are medically ready to deploy with minimal impact on mission readiness. Standardization of clinic processes is critical for recommended BV diagnostics in addition to treatment to reduce recurrence.

Future Directions

Completion of the evidence-based BV project has initiated implications to practice to better care for patients. The development of a BV Support Staff Protocol (SSP) is one way the clinic can continue to provide quality care while improving access. Ideally, a standard algorithm would be created with exclusion criteria. Women not meeting the inclusion criteria would be given an appointment with a provider while the other women will be screened by the nurses or

medical technicians. Patients can then self-swab and provide the laboratory the sample to identify BV. The provider, acting as consultant, can prescribe the recommended therapy and the patient can then obtain the medication at pharmacy. By implementing a SSP process, women are being screened, diagnosed, and treated without exhausting an already constricted clinic.

Similarly to the above SSP, women in deployed settings may also benefit from point of care testing. BV Blue is a highly accurate and reliable test that rapidly identifies BV. Minimal resources are required; women will self-swab and return sample to lab for diagnosis. Women can be treated appropriately while minimizing the impact of the mission. One in twenty women are evacuated out of theater for a gynecological disorder and implementation of BV rapid testing may reduce the frequency of medical evacuations.

Conclusion

Bacterial vaginosis remains the most common gynecological infection among women of reproductive age with high recurrence rates. If not appropriately diagnosed and treated, women may experience long-term complications as well as decreased quality of life. The recommended diagnostic methods have been available for many years without variation. During the course of the evidence-based project, clinic microscopy use versus specimens reviewed by the laboratory was the primary techniques to diagnose BV. Healthcare providers assigned to a MTF should familiarize themselves with their specific clinic and laboratory capabilities, as other diagnostic methods are available. Point of care testing can improve access to care by accurately diagnosing a patient’s symptoms as well as prescribing the recommended therapy to reduce recurrence. Patient education on altering behaviors that increase their risk of developing BV in conjunction with treatment may also minimize the recurrence of BV. Team members recommend future

studies be conducted at larger community facilities with varying patient demographics to evaluate BV education on incidence rates.

References

Alcaide, M. L., Chisembele, M., Malupande, E., Rodriguez, V. J., Fischl, M. A., Arheart, K., & Jones, D. L. (2017). A bio-behavioral intervention to decrease intravaginal practices and bacterial vaginosis among HIV infected zambian women, a randomized pilot study. BMC Infectious Diseases, 17 doi:10.1186/s12879-017-2436-3

Anhang, R., Goodman, A., & Goldie, S. J. (2004). HPV communication: Review of existing research and recommendations for patient education. CA: A Cancer Journal for Clinicians, 54(5), 248-259. 10.3322/canjclin.54.5.248

Armed Forces Health Surveillance Center (AFHSC). (2014). Gynecologic disorders diagnosed during deployment to southwest/central Asia, active component females, U.S. armed forces, 2008-2013. *Medical Surveillance Medical Report, 21*(8), 7.

Bautista, C., Wurapa, E., Sateren, W., Morris, S., Hollingsworth, B., & Sanchez, L., (2016). Bacterial vaginosis: a synthesis of the literature on etiology, prevalence, risk factors, and relationship with chlamydia and gonorrhea infections. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4752809/

Becton, Dickinson and Company (BD). BD affirm test. Retrieved from https://www.bd.com/en-us/offerings/capabilities/molecular-diagnostics/molecular-systems/bd-affirm-vpiii-microbial-identification-system

Bilardi, J. E., Walker, S., Temple-Smith, M., McNair, R., Mooney-Somers, J., Bellhouse, C., Bradshaw, C. (2013). The Burden of Bacterial Vaginosis: Women's Experience of the Physical, Emotional, Sexual and Social Impact of Living with Recurrent Bacterial Vaginosis. PLoS ONE, 8(9), e74378. http://doi.org/10.1371/journal.pone.0074378Bi

Bishop, A. C., Baker, G. R., Boyle, T. A., & MacKinnon, N. J. (2015). Using the health belief model to explain patient involvement in patient safety.Health Expectations, 18(6), 3019-3033. doi:10.1111/hex.12286

Board on Health Sciences Policy, Institute of Medicine, & Committee on Understanding Premature Birth and Assuring Healthy Outcomes. (2007). Societal costs of preterm birth. (pp. 398-429) National Academies Press.

Bradshaw, C. S., & Brotman, R. M. (2015). Making inroads into improving treatment of bacterial vaginosis - striving for long-term cure. BMC Infectious Diseases, 15(1), 292. 10.1186/s12879-015-1027-4

Bradshaw, C. S., & Sobel, J. D. (2016). Current treatment of bacterial vaginosis-limitations and need for innovation. Journal of Infectious Diseases, 214(4), S14.

Braun, L. A., Kennedy, H. P., Womack, J. A., & Wilson, C. (2016). Integrative literature review: U.S. military women's genitourinary and reproductive health. Military Medicine, 181(1), 35. 10.7205/MILMED-D-15-00242

https://www.nichd.nih.gov/health/topics/vaginitis/conditioninfo/risk

Brotman, R. M., Erbelding, E. J., Jamshidi, R. M., Klebanoff, M. A., Zenilman, J. M., & Ghanem, K. G. (2007). Findings associated with recurrence of bacterial vaginosis among adolescents attending sexually transmitted diseases clinics. Journal of Pediatric and Adolescent Gynecology, 20(4), 225–231. http://doi.org/10.1016/j.jpag.2006.11.009

Brown, H. L., Fuller, D. D., Jasper, L. T., Davis, T. E., & Wright, J. D. (2004). Clinical evaluation of affirm VPIII in the detection and identification of Trichomonas vaginalis, Gardnerella vaginalis, and Candida species in vaginitis/vaginosis. Infectious Diseases in Obstetrics and Gynecology, 12(1), 17–21.

Brown, J. M., Poirot, E., Hess, K. L., Brown, S., Vertucci, M., & Hezareh, M. (2016). Motivations for intravaginal product use among a cohort of women in los angeles. Plos One, 11(3), e0151378. doi:10.1371/journal.pone.0151378

Carr, P. L., Rothberg, M. B., Friedman, R. H., Felsenstein, D., & Pliskin, J. S. (2005). "shotgun" versus sequential testing: Cost-effectiveness of diagnostic strategies for vaginitis. Journal of General Internal Medicine, 20(9), 793-799. doi:10.1111/j.1525-1497.2005.0188.x

Centers for Disease Control and Prevention. (2014). Genital/Vulvovaginal candidiasis statistics. Retrieved from: http://www.cdc.gov/fungal/diseases/candidiasis/genital/statistics.html

Centers for Disease Control and Prevention. (2015). Bacterial vaginosis. Retrieved from https://www.cdc.gov/std/tg2015/bv.htm

Cottrell, B. H. (2010). An updated review of of evidence to discourage douching. MCN, the American Journal of Maternal/Child Nursing, 35(2), 102-107. doi:10.1097/NMC.0b013e3181cae9da

Esber, A., Moyo, P., Munjoma, M., Franci, S., Van De Wijgert, J., Chipato, T., & Turner, A. N. (2015). Cessation of intravaginal practices to prevent bacterial vaginosis: A pilot intervention in zimbabwean women. Sexually Transmitted Infections, 91(3), 183-188. doi: 10.1136/sextrans-2014-051764

Friedman, A. J., Cosby, R., Boyko, S., Hatton-Bauer, J., & Turnbull, G. (2011). Effective teaching strategies and methods of delivery for patient education: A systematic review and practice guideline recommendations. Journal of Cancer Education, 26(1), 12-21. 10.1007/s13187-010-0183-x

Foxman, B., Barlow, R., D'arcy, H., Gillespie, B., Sobel, J. (2000). Candida vaginitis self-reported incidence and associated costs. *Sexually Transmitted Diseases*: 27: 230–235. doi: 10.1097/00007435-200004000-00009.

Hainer, B. L., & Gibson, M. V. (2011). Vaginitis: Diagnosis and treatment. American Family Physician, 83(7), 807-815.

Hay PE. Bacterial Vaginosis as a Mixed Infection. In: Brogden KA, Guthmiller JM, editors. Polymicrobial Diseases. Washington (DC): ASM Press; 2002. Chapter 7. Available from: https://www.ncbi.nlm.nih.gov/books/NBK2495/

Hayden, J. (2014). Introduction to health behavior theory. Burlington, MA: Jones & Bartlett.

Huang, H., Song, L., & Zhao, W. (2014). Effects of probiotics for the treatment of bacterial vaginosis in adult women: A meta-analysis of randomized clinical trials. Archives of Gynecology and Obstetrics, 289(6), 1225-1234. 10.1007/s00404-013-3117-0

Homayouni, A., Bastani, P., Ziyadi, S., Mohammad-Alizadeh-Charandabi, S., Ghalibaf, M., Mortazavian, A. M., & Mehrabany, E. V. (2014; 2013). Effects of probiotics on the recurrence of bacterial vaginosis: A review. Journal of Lower Genital Tract Disease, 18(1), 79-86. 10.1097/LGT.0b013e31829156ec

Joesoef, M. R., Karundeng, A., Runtupalit, C., Moran, J. S., Lewis, J. S., & Ryan, C. A. (2001). High rate of bacterial vaginosis among women with intrauterine devices in manado, indonesia. Contraception, 64(3), 169-172. doi:10.1016/S0010-7824(01)00246-3

John Hopkins Nursing Quality of Evidence Appraisal. (n.d.). Johns hopkins nursing evidence-based practice appendix e: Research evidence appraisal tool. Retrieved from John

Hopkins Nursing Quality of Evidence Appraisal. (n.d.). Johns hopkins nursing evidence-based practice appendix e: Research evidence appraisal tool

Kampan, N. C., Suffian, S. S., Ithnin, N. S., Muhammad, M., Zakaria, S. Z. S., & Jamil, M. A. (2011). Evaluation of BV ® blue test kit for the diagnosis of bacterial vaginosis. Sexual & Reproductive Healthcare, 2(1), 1-5. doi:10.1016/j.srhc.2010.11.002

Kasaro, M. P., Husnik, M. J., Chi, B. H., Reid, C., Magure, T., Makanani, B., Guffey, M. (2017). Impact of targeted counseling on reported vaginal hygiene practices and bacterial vaginosis: The HIV prevention trials network 035 study. International Journal of STD and AIDS, 28(5), 467-475. doi: 10.1177/0956462416653001

Melnyk, B. M., & Fineout-Overholt, E. (2011). Evidence-based practice in nursing & healthcare: A guide to best practice. Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins.

Van Kessel, K., Assefi, N., Marrazzo, J., & Eckert, L. (2003). Common complementary and alternative therapies for yeast vaginitis and bacterial vaginosis: A systematic review. Obstetrical & Gynecological Survey, 58(5), 351-358. doi:10.1097/01.OGX.0000068791.04785.8D

Krasnopolsky, V. N., Prilepskaya, V. N., Polatti, F., Zarochentseva, N. V., Bayramova, G. R., Caserini, M., & Palmieri, R. (2013). Efficacy of Vitamin C Vaginal Tablets as Prophylaxis for Recurrent Bacterial Vaginosis: A Randomised, Double-Blind, Placebo-Controlled Clinical Trial. Journal of Clinical Medicine Research, 5(4), 309–315. http://doi.org/10.4021/jocmr1489w

Krulewitch, C. J. (2016). Reproductive health of active duty women in medically austere environments. Military Medicine, 181(1 Suppl), 63-69. 10.7205/MILMED-D-15-00221

Kumar, N., Behera, B., Sagiri, S. S., Pal, K., Ray, S. S., & Roy, S. (2011). Bacterial vaginosis: Etiology and modalities of treatment - A brief note. Journal of Pharmacy and Bioallied Sciences, 3(4), 496-503. 10.4103/0975-7406.90102

Li, X. -., Wang, C. -., Zhang, X. -., Gao, G. -., Tong, F., Li, X., . . . Sun, Y. -. (2014). Risk factors for bacterial vaginosis: Results from a cross-sectional study having a sample of 53,652 women. European Journal of Clinical Microbiology & Infectious Diseases, 33(9), 1525-1532. doi:10.1007/s10096-014-2103-1

Madhivanan, P., Ravi, K., Wilcox, M., Niranjankumar, B., Shaheen, R., Srinivas, V., Krupp, K. (2013). P2.003 feasibility and acceptability of self-collected vaginal swabs for diagnosis of bacterial vaginosis among pregnant women in a community setting in rural mysore, india. Sexually Transmitted Infections, 89(Suppl 1), A88-A88. 10.1136/sextrans-2013-051184.0268

Malaguti, N., Bahls, L. D., Uchimura, N. S., Gimenes, F., & Consolaro, M. E. L. (2015). Sensitive detection of thirteen bacterial vaginosis-associated agents using multiplex polymerase chain reaction. BioMed Research International, 2015, 645853.

Marrazzo, J. M., Thomas, K. K., & Ringwood, K. (2011). A behavioural intervention to reduce persistence of bacterial vaginosis among women who report sex with women: Results of a randomised trial. Sexually Transmitted Infections, 87(5), 399-405. doi:10.1136/sti.2011.049213

Menard, J., Fenollar, F., Raoult, D., Boubli, L., & Bretelle, F. (2012; 2011). Self-collected vaginal swabs for the quantitative real-time polymerase chain reaction assay of atopobium vaginae and gardnerella vaginalis and the diagnosis of bacterial vaginosis.

European Journal of Clinical Microbiology & Infectious Diseases, 31(4), 513-518. 10.1007/s10096-011-1341-8

National Center for Biotechnology Information (NCBI), U.S. National Library of Medicine (2015). Pub Med Health. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0078015/

Nwankwo, T. O., Aniebue, U. U., & Umeh, U. A. (2017). Syndromic diagnosis in evaluation of women with symptoms of vaginitis. Current Infectious Disease Reports, 19(1), 1-9. 10.1007/s11908-017-0558-9

Nyirjesy, P. (2014). Management of persistent vaginitis. *Obstetrics & Gynecology, 124*(6), 1135-1146. doi:10.1097/AOG.0000000000000551

Oberg, E., Guarneri, M., Herman, P., Walsh T., & Wostrel, A. (2010). Integrative health and medicine: Today's answer to affordable healthcare. Retrieved from http://www.ihpc.org/wp-content/uploads/IHPC-CE-Booklet-March2015.pdf

Okumus, F., & Demirci, N. (2016). Vaginal douching cessation in rural turkish women with vaginitis. International Journal of Caring Sciences, 9(1), 236.

Onderdonk, A. B., Delaney, M. L., & Fichorova, R. N. (2016). The human microbiome during bacterial vaginosis. Clinical Microbiology Reviews, 29(2), 223-238. 10.1128/CMR.00075-15

Malaguti, N., Bahls, L. D., Uchimura, N. S., Gimenes, F., & Consolaro, M. E. L. (2015). Sensitive detection of thirteen bacterial vaginosis-associated agents using multiplex polymerase chain reaction. BioMed Research International, 2015, 1-10. 10.1155/2015/645853

Military and Veteran Community Collaborative. (2016). 2016 military city usa needs assessment. Retrieved from http://mvcc-sa.org/images/upload/2016%20MVCC%20Needs%20Assessment.pdf

Parsapure, R., Rahimiforushani, A., Majlessi, F., Montazeri, A., Sadeghi, R., & Garmarudi, G. (2016). Impact of health-promoting educational intervention on lifestyle (nutrition behaviors, physical activity and mental health) related to vaginal health among reproductive-aged women with vaginitis. *Iranian Red Crescent Medical Journal,* 18(10) doi:10.5812/ircmj.37698

Payne, S. C., Cromer, P. R., Stanek, M. K., & Palmer, A. A. (2010). Evidence of african-american women's frustrations with chronic recurrent bacterial vaginosis. Journal of the American Academy of Nurse Practitioners, 22(2), 101-108. doi:10.1111/j.1745-7599.2009.00474.x

Reichman, O., Akins, R., & Sobel, J. D. (2009). Boric acid addition to suppressive antimicrobial therapy for recurrent bacterial vaginosis. Sexually Transmitted Diseases, 36(11), 732-734. 10.1097/OLQ.0b013e3181b08456

Secor, M., & Coughlin, G. (2013). Bacterial vaginosis update. Advance for NPs & PAs, 4(8), 23-26.

Sivapalasingam, S., McClelland, R. S., Ravel, J., Ahmed, A., Cleland, C. M., Gajer, P., Kurth, A. E. (2014). An effective intervention to reduce intravaginal practices among HIV-1 uninfected kenyan women. *AIDS Research and Human Retroviruses*, 30(11), 146-1057. doi:10.1089/aid.2013.0251

Symbiomix Therapeutics. (2017). FDA approves symbiomix therapeutics' solosec (secnidazole) oral granules for the treatment of bacterial vaginosis in adult women. Retrieved from:

https://symbiomix.com/fda-approves-symbiomix-therapeutics-solosec-secnidazole-oral-granules-treatment-bacterial-vaginosis-adult-women/

Taheri, M., Baheiraei, A., Foroushani, A. R., Nikmanesh, B., & Modarres, M. (2015). Treatment of vitamin D deficiency is an effective method in the elimination of asymptomatic bacterial vaginosis: A placebo-controlled randomized clinical trial. *The Indian Journal of Medical Research*, 141(6), 799-806. 10.4103/0971-5916.160707

Trego, L. L. (2011). Advanced practice nursing intervention: Improving women's health in the combat zone. Journal of Obstetric, Gynecologic & Neonatal Nursing, 40, S91-S92. doi:10.1111/j.1552-6909.2011.01243_9.x

Turner, A. N., PhD, Carr Reese, P., MPH, Fields, K. S., RN, Anderson, J., MPH, Ervin, M., MT(ASCP), Davis, John A., MD, PhD, . . . Jackson, R. D., MD. (2014). A blinded, randomized controlled trial of high-dose vitamin D supplementation to reduce recurrence of bacterial vaginosis. American Journal of Obstetrics and Gynecology, 211(5), 479.e1-479.e13. 10.1016/j.ajog.2014.06.023

Turovskiy, Y., Noll, K. S., & Chikindas, M. L. (2011). THE ETIOLOGY OF BACTERIAL VAGINOSIS. Journal of Applied Microbiology, 110(5), 1105–1128. http://doi.org/10.1111/j.1365-2672.2011.04977.x

United States Census Bureau. (n.d.). Quickfacts: San antonio, texas; united states. Retrieved from https://www.census.gov/quickfacts/fact/table/sanantoniocitytexas,US/PST045216

Van Kessel, K., Assefi, N., Marrazzo, J., & Eckert, L. (2003). Common complementary and alternative therapies for yeast vaginitis and bacterial vaginosis: A systematic review. Obstetrical and Gynecological Survey, 58(5), 351-358. 10.1097/00006254-200305000-00024

Ventola, C. L. (2010). Current issues regarding complementary and alternative medicine (CAM) in the united states: Part 1: The widespread use of cam and the need for better-informed health care professionals to provide patient counseling. *Pharmacy and Therapeutics, 35*(8), 461–468.

Vujic, G., Knez, A., Stefanovic, V., & Vrbanovic, V. (2013). Efficacy of orally applied probiotic capsules for bacterial vaginosis and other vaginal infections: A double-blind, randomized, placebo-controlled study. *European Journal of Obstetrics & Gynecology and Reproductive Biology, 168*(1), 75-79. doi:10.1016/j.ejogrb.2012.12.031

Weissenbacher, E., Donders, G., Unzeitig, V., Martinez de Tejada, B., Gerber, S., Halaska, M., Spacek, J. (2011). A comparison of dequalinium chloride vaginal tablets (fluomizin) and clindamycin vaginal cream in the treatment of bacterial vaginosis: a single-blind, randomized clinical trial of efficacy and safety. *Gynecologic and Obstetric Investigation.*

Witt, A., Kaufmann, U., Bitschnau, M., Tempfer, C., Özbal, A., Haytouglu, E., Kiss, H. (2010). Monthly itraconazole versus classic homeopathy for the treatment of recurrent vulvovaginal candidiasis: A randomized trial. *Obstetrical & Gynecological Survey, 65*(1), 26-27. doi:10.1097/01.ogx.0000367513.03170.41

White, K. & Dudley-Brown. (2012). Translation of evidence into nursing and health care practice. Springer Publishing Company, LLC: New York, NY.

Women's Health Department of Veterans Affairs. (2013). A profile of women veteran's today. Retrieved from https://www.womenshealth.va.gov/WOMENSHEALTH/docs/ProfileSheet_073113_508c .pdfmv

Youngkin, E. Q., & Lester, P. B. (2010). Promoting self-care and secondary prevention in women's health: A study to test the accuracy of a home self-test system for bacterial vaginosis. *Applied Nursing Research*, 23(1), 2-10. doi:10.1016/j.apnr.2008.02.002

Zahra, A., Fateme, G., & Mahamadreza, A. (2010). Comparison of the effectiveness of vitamin C vaginal tablet with metronidazole vaginal gel in the treatment of bacterial vaginosis. *African Journal of Pharmacy and Pharmacology,* 4(7), 484-489.

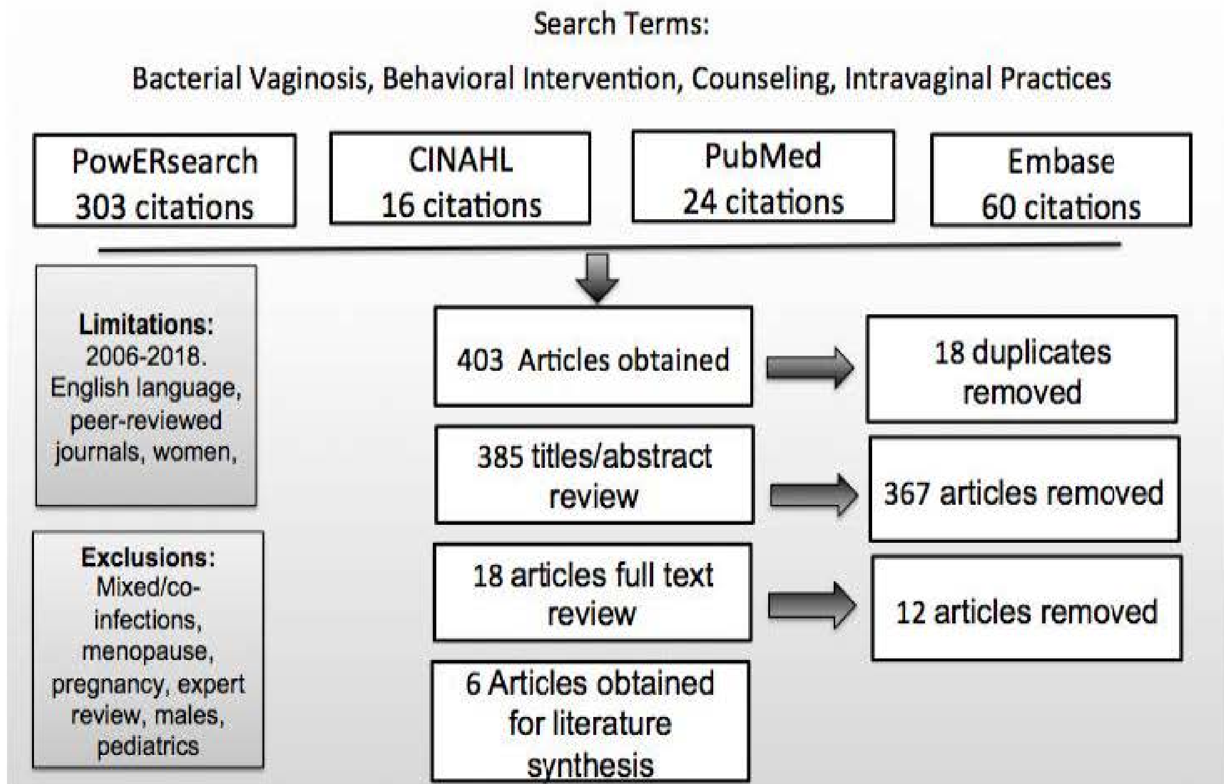
Zeron Mullins, M., & Trouton, K. M. (2015). BASIC study: is intravaginal boric acid non-inferior to metronidazole in symptomatic bacterial vaginosis? Study protocol for a randomized controlled trial. Trials, 16, 315. http://doi.org/10.1186/s13063-015-0852-5

Appendix A

Chart comparison of credible sources used to design patient education document.

STUDY, Year	Discussions	Written Materials	Verbal	Group	Individual	Structured	General Information	Pt Specific
Anhang et al. (2004)	x	x	x		x	x		
Alcaide et al. (2017)	x		x	x	x			
Esber et al. (2015)	x		x		x	x		x
Okumus et al. (2004)	x	x	x	x	x	x		
Paraspure et al. (2016)		x	x	x	x		x	

Appendix B



Appendix C
Patient Education Handout

Bacterial Vaginosis
Frequently Asked Questions

What is Bacterial Vaginosis (BV)?

- An imbalance between good and bad bacteria
- Vagina normally contains a lot of "good" bacteria called Lactobacillus, but can also have "bad" bacteria (*G. Vaginallis*), resulting in infection
- The exact cause BV is unknown (Family Doctor, 2017).

low do you get BV?

- Participating in vaginal, oral, or anal sex.
- Male or female partners.
- BV is the most common vaginal infection in women ages 15 to 44 (CDC, 2017).

'ou may be **more at risk** for BV if you:

- Have a new or multiple sex partners
- Douche
- Do not use condoms
- Are pregnant
- Have sex with other women
- Are African-American
- Have an intrauterine device (IUD)
- Cigarette Smoking
- Stress (Secor & Coughlin, 2013)

What are the symptoms?

Many women have no signs or symptoms. If you do have symptoms, they may include (Women's Health, 2015):

- Unusual vaginal discharge. The discharge can be white (milky), gray, foamy or watery.
- Some women report a strong fish-like odor, especially after sex.
- Burning when urinating
- Itching around the outside of the vagina
- Or other vaginal discomfort (Women's Health, 2015)

How is BV diagnosed?

- Collection of vaginal discharge via cotton swab.
- Sample will be observed under a microscope to see if too much bad bacteria is present (Family Doctor, 2017).
- Laboratory tests can also be used to determine if BV is present.

What are the treatments for BV?

- Prescribed antibiotics: oral medications, intravaginal gel or cream (NIH).
- Even if symptoms improve, complete the entire course of medications due to the likelihood of recurrence (NIH).
- Remember to abstain from vaginal intercourse until completion of treatment.

How can I lower my risk of BV?

- Use only warm water to clean the outside of your vagina. You do not need to use soap (Women's Health, 2015)
- Always wipe front to back (Women's Health, 2015)
- Do not douche. Douching removes some of the normal bacteria in your vagina that protects you from infection
- Be sure to clean toys used during sex after each use
- Practice safe sex with the use of condoms, being monogamous, and limiting your number of sex partners (Women's Health, 2015)
- Oral or intravaginal probiotic bacteria (L. acidophilus, L. rhamnosus GR-1, and L. fermentum RC-14) when administered for 2 months can normalize the vaginal flora (Homayouni, A. et al, 2013).

ADDITIONAL RESOURCES

American Congress of Obstetrics and Gynecologists (ACOG): https://www.acog.org/Patients/FAQs/Vaginitis
Centers for Disease Control and Prevention (CDC): https://www.cdc.gov/std/bv/default.htm
Women's Health: https://www.womenshealth.gov/a-z-topics/bacterial-vaginosis
National Institutes of Health (NIH): https://www.nichd.nih.gov/health/topics/bacterialvag/Pages/default.aspx
Family Doctor: https://www.nichd.nih.gov/health/topics/bacterialvag/Pages/default.aspx

Table 1
Basic Characteristics of Participants

Variables	Jan-Mar 2017 (N = 112)	Jan-Mar 2018 (N = 115)
Mean Age	29.0±6.5	28.9±5.9
Status (%)		
Active Duty	46%	43%
Dependents	54%	57%
Retiree	< 1%	< 1%
Race (%)		
Other/Unknown	60%	52%
African American	21%	14%
Caucasian	18%	30%
Asian/Pacific Islander	1%	4%
Gravida		
G0	39%	35%
G1	15%	26%
> G1	46%	39%
Contraceptive Type (%)		
No method	26%	21%
Oral Contraceptive Pill (OCP)	21%	20%
Intrauterine Device (IUD)	19%	23%
Condoms	7%	6%
Implant	7%	8%
Patch	4%	2%
Tubal Ligation	4%	3%
Partner Vasectomy	8%	3%
NuvaRing	2%	3%
Sexually Transmitted Infection		
None	91%	95%
Chlamydia	4%	3%
Other	5%	2%
Incidence Rate (P<0.64)	2.95%	2.88%
Incidence rate/provider	22.4	12.8

Table 2

Current Clinic Management of BV

Management Methods	Jan-Mar 2017 (N = 112)	Jan-Mar 2018 (N = 115)
Diagnostic (%)		
Point-of-care-test (POCT)	79%	67%
Symptoms	21%	29%
Laboratory	< 1%	3%
Deferred Exam	< 1%	< 1%
Treatment (%)		
Metronidazole	61%	65%
Clindamycin	3%	4%
Metronidazole + Antifungal	23%	10%
Clindamycin +Antifungal	2%	2%
Other treatment unrelated to BV	4%	14%
Counseling/ No medical treatment	6%	5%

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Monique Battle (ID: 4988583)
- **Email:** monique.battle-stallworth@usuhs.edu
- **Institution Affiliation:** Uniformed Services University of The Health Sciences (ID: 395)
- **Institution Unit:** Nursing
- **Phone:** 240-888-9773

- **Curriculum Group:** OUSD P&R Human Research (Current)
- **Course Learner Group:** Biomedical Investigators and Research Study Team
- **Stage:** Stage 1 - Biomedical Investigators

- **Report ID:** 16977510
- **Completion Date:** 08/24/2015
- **Expiration Date:** 08/23/2018
- **Minimum Passing:** 80
- **Reported Score*:** 92

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Records-Based Research (ID: 5)	08/21/15
Vulnerable Subjects - Research Involving Children (ID: 9)	08/22/15
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	08/22/15
FDA-Regulated Research (ID: 12)	08/23/15
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	08/23/15
Informed Consent (ID: 3)	08/23/15
History and Ethics of Human Subjects Research (ID: 498)	08/23/15
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	08/23/15
Genetic Research in Human Populations (ID: 6)	08/24/15
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	08/24/15
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	08/24/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	08/24/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	08/24/15
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	08/24/15
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	08/24/15
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	08/24/15

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

CITI Collaborative Institutional Training Initiative at the University of Miami

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Tialicka Johnson (ID: 4988627)
- **Email:** tialicka.johnson@usuhs.edu
- **Institution Affiliation:** Uniformed Services University of The Health Sciences (ID: 395)
- **Institution Unit:** GSN
- **Phone:** 301-295-0000

- **Curriculum Group:** OUSD P&R Human Research (Current)
- **Course Learner Group:** Biomedical Investigators and Research Study Team
- **Stage:** Stage 1 - Biomedical Investigators

- **Report ID:** 16977476
- **Completion Date:** 08/23/2015
- **Expiration Date:** 08/22/2018
- **Minimum Passing:** 80
- **Reported Score*:** 98

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Records-Based Research (ID: 5)	08/21/15
Vulnerable Subjects - Research Involving Children (ID: 9)	08/21/15
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	08/21/15
FDA-Regulated Research (ID: 12)	08/21/15
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	08/22/15
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Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	08/23/15
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	08/23/15
Cultural Competence in Research (ID: 15166)	08/23/15

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CITI Program
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Phone: 305-243-7970
Web: https://www.citiprogram.org

CITI Collaborative Institutional Training Initiative at the University of Miami

USUHS FORM 3202N
DANIEL K. INOUYE GRADUATE SCHOOL OF NURSING
EVIDENCE-BASED PRACTICE/PERFORMANCE IMPROVEMENT PROPOSAL

VPR Date Stamp

Project Number: T0619346 (VPR will assign)
Project Title: Best Practices to Managing Vaginitis

SECTION A: STUDENT POC INFORMATION

1. Name (Last, First, MI): **Battle-Stallworth, Monique N** Student E-mail: **monique.battle-stallworth**

SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION

3. Name (Last, First, MI): **Korkosz, Jennifer**
4. Telephone: **301-295-1881** Fax: E-mail: **jennifer.korkosz@usuhs.edu**
5. USUHS Building/ Room No.: **Bldg E Rm 1054**

SECTION C: PROJECT INFORMATION

6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? ☐Yes ☒No
   If yes, complete below; if no, proceed to Part 8.
   Project Number: ____________
   Project Title:
   Project Start Date: ____________ Project End Date: ____________
8. Anticipated period of performance: Project Start Date: **May 2017** Project End Date: **May 2018**
9. Performance Site(s): **Wilford Hall Ambulatory Surgical Center, Lackland AFB, TX**
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) ☐Yes ☒No
11. Do you have a funding source for this project? ☐Yes ☒No ☐NA
    If yes, specify the funding agency and the amount provided:

SECTION D: SIGNATURES

The following signatures attest to the validity of the above information:

Student (Project Point of Contact for the Group)	5 May 2017 (Signature and Date)		5May17 (Signature and Date)
Chair/Program Director	14Sep17 (Signature and Date)	Chair/Program Director	(Signature and Date)
DNP Project Director or PhD Director	10 May 2017 (Signature and Date)	Associate Dean for Academic Affairs, GSN	21 Sep 2017 (Signature and Date)
Associate Dean for Research, GSN	19 Sept 2017 (Signature and Date)	Dean, DKI Graduate School of Nursing	19 Sept 2017 (Signature and Date)

In light of the above signatures, the project is approved.

______________________ ____________
USUHS Vice President for Research Date

USUHS Form 3202N (VPR) - Revised Sep 2015 v1.2
Previous versions are obsolete

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Johnson, Tialicka, Capt 59 MDW/SGVT	3. GME/GHSE STUDENT: ☐ YES ☒ NO	4. PROTOCOL NUMBER: FWH20170110N

5. PROTOCOL TITLE: (**NOTE:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)
Targeted Counseling to Reduce Incidence of Bacterial Vaginosis

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:
Targeted Counseling to Reduce Incidence of Bacterial Vaginosis

7. FUNDING RECEIVED FOR THIS STUDY? ☒ YES ☐ NO FUNDING SOURCE: USU

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
☐ YES ☒ NO **NOTE:** If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☐ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)

☒ 11b. PUBLISHED ABSTRACT (List intended journal.)
USU Research Week 2018, May 14-18, Bethesda, MD

☒ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)
USU Research Week 2018, May 14-18, Bethesda, MD

☐ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)

☐ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?
☐ YES ☒ NO ASSIGNED FILE # ____________ DATE ____________

13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE
April 30, 2018

14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	15. DUTY PHONE/PAGER NUMBER
Kittelson, Brian, D, brian.d.kittelson.mil@mail.mil	292-6893

16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Battle-Stallworth, M.	Maj	59 MDW/SGVT	
b. Johnson, T.	Capt	59 MDW/SGVT	
c.			
d.			
e.			

17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? ☐ YES ☒ NO

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

18. AUTHOR'S PRINTED NAME, RANK, GRADE	20. DATE
Johnson, T. Capt/O-3	April 04, 2018
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	23. DATE
Brian D. Kittelson, Lt Col, Director DNP Phase II Site	April 04, 2018

59th Medical Wing (59th MDW)
Institutional Review Board (IRB)
59th Clinical Research Division/SGVUS/(210) 292-7143
2200 Bergquist Dr, Bldg 4430, Lackland AFB, TX 78236-5300

17 August 2017

FINAL DETERMINATION – NOT RESEARCH

Determination Date: 17 Aug 2017

Project Lead: Maj Monique Battle-Stallworth/SGVT

Reference Number: FWH20170110N

Project Title: Targeted counseling in females aged 18-30 to minimize risk of vaginal infections

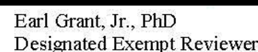
You may begin your project, as you would any other clinical or operational activity, with the approval and sponsorship of your leadership.

Your activity was determined on 17 Aug 2017 to be considered **not research** as defined by DoD regulation **32 CFR 219 and FDA regulation 21 CFR 56**. Continued IRB oversight for this activity is not required. The proposed activity is not funded by DHHS/DoD as research; is not a systematic investigation to test a hypothesis and permit conclusions to be drawn; is not designed to develop or contribute to generalizable knowledge; and the purpose is not to investigate the safety or effectiveness of a drug, medical device or biologic.

Since the IRB does not have regulatory oversight for your study, it is the investigator's responsibility to validate the study's scientific merit and research design and to ensure the conduct of the study is upheld by the highest ethical standards, as required by the Wing. Should you require assistance in reviewing the scientific merit and research design of your study, please contact the Protocol Office. Protection of subjects' rights safety and welfare and responsibility for protecting PHI/PII and research data now fall on the investigator and their commander.

In accord with DoDI 6000.08 any intramural funding of this study as research or as a clinical investigation may continue to be received or sought regardless of this IRB determination.

Your study has received a one-time research determination. If the goals and/or activities of the project change during the course of the project, or if new activities are proposed that would constitute human subjects research, re-contact the Protocol Office, so that a regulatory expert may determine whether or not the revised plan involves human subject research activities.



Earl Grant, Jr., PhD
Designated Exempt Reviewer

Appendix J: Daniel K. Inouye Graduate School of Nursing
DNP Project Completion Verification Form

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled: Targeted Counseling to Prevent Occurrence of Bacterial Vaginosis was completed at Wilford Hall Ambulatory Surgical Center at JBSA Lackland AFB, San Antonio, TX by the following student(s):

(type student name)	*(signature)*	*(date)*
Monique N. Battle-Stallworth		30 April 2018
Tialicka B. Johnson		30 April 2018

The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report.

Verified by:

(type name)	*(signature)*	*(date)*	
Lt Col Jennifer Korkosz		2 May 2018	Senior Mentor
Col Candy Wilson		9 May 2018	Team Mentor
N/A		N/A	Team Mentor
Lt Col Brian Kittelson		2 May 2018	Team Mentor & Phase II Site Director

***For RNA Students only** - add the following additional signature for final verification of project completion:*

RNA Project Director *(type name)*	*(Signature)*	*(Date)*

Form Version: 26 Aug 2017