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Increasing Patients' Knowledge in Transmission of Bacterial Vaginosis and its Treatment

Regimens

by

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BS in Nursing, University of Missouri - St. Louis, 2002

A DISSERTATION

Submitted to the Graduate School of the

UNIVERSITY OF MISSOURI- ST. LOUIS In partial Fulfillment of the Requirements for the Degree

DOCTOR OF NURSING PRACTICE

in

NURSING

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Abstract

Research has shown bacterial vaginosis to be one of the most common vaginal disorders in women of child bearing age (Chen, Tian, & Beigi, 2009; Centers for Disease Control, 2012; Menard, 2011). Each year many women are seen by their gynecologist, sexually transmitted infection (STI) clinics, and emergency rooms (ER) for complaints of having malodorous discharge (Bradshaw, et al., 2005). Several STI's and adverse pregnancy outcomes have been attributed to women having bacterial vaginosis (Bradshaw, et al, 2005; Chen, et al.2009; Elkins, & Mayeaux, 2010). Women are predisposed to bacterial vaginosis by the use of wearing non cotton underwear, douching, having multiple sex partners, not using condoms, or not adhering to or complying with the recommended treatment regimens. Each year non- adherence to medications cost the US billions of dollars.

Purpose

This project was to (a) evaluate patients' knowledge regarding bacterial vaginosis prevention and treatment regimens, (b) and attempt to increase patients' knowledge as a result of training of providers.

Methods

A quasi-experimental approach was utilized using a comparative change model at two different Planned Parenthood health centers. The project was conducted Monday through Saturday enrolling 50 women diagnosed with bacterial vaginosis. One clinic was randomly selected for providers to receive the 45 minute in-service training, and the other clinic's providers did not receive the in-service training. Subjects were asked to complete two surveys. The first survey consisted of 6 questions which were administered after their diagnosis for bacterial vaginosis and consent obtained which took no longer than 3-4 minutes to complete. Nine to 14 days after the initial visit a second survey was administered by phone by the researcher and assistants.

Results

The intervention group has a lower median adherence score compared to the control group (p<.002) which indicates that the intervention group has better adherence to their Flagyl and Metro Gel medication.

Adherence of wearing thong and cotton underwear was assessed as a yes/no variable by intervention status using Fisher's Exact Test instead of Pearson's Chi-Square given small cell size.

There was no significant difference between the intervention and control group (p>0.05) in regards to thong or cotton underwear adherence.

Conclusion

There was an increase in patients' knowledge regarding adhering to treatment regimens; however, there were no significant change in behavior.

Acknowledgement

The completion of a project of this magnitude takes time, commitment, and perseverance. I could not have completed this project alone but needed to recruit the help of others. It is for that reason that I take time to recognize those who made this project possible.

My committee members were a wealth of knowledge and they kept me abreast of deadlines and other necessary commitments. I don't know how they were able to keep it all together and still have time for me, but they did it! I would like to thank Dr. Susann Farberman, Director of the program and my committee co-chair. Dr. Farberman served as a personal compass through this project. Without her guidance and direction I am not sure where I would be. I would like to thank Dr. Rick Zimmerman for his help as I progressed through my project under his leadership. I would also like to thank Dr. Claudia Valentine for her assistance as my committee member. Next there is Sue Kendig who presented with exponential expertise and was always there when I needed her invaluable feedback.

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Introduction

Research has shown bacterial vaginosis to be one of the most common vaginal disorders in women of child bearing age (Chen, Tian, & Beigi, 2009; Centers for Disease Control, 2012; Menard, 2011). Each year many women are seen by their gynecologist, sexually transmitted infection (STI) clinics, and emergency rooms (ER) for complaints of having malodorous discharge (Bradshaw, et al., 2005). Several STI's and adverse pregnancy outcomes has been attributed to women having bacterial vaginosis (Bradshaw, et al, 2005; Chen, et al.2009; Elkins, & Mayeaux, 2010). The etiology of bacterial vaginosis continues to be misunderstood. Approximately 45% of all women seen and diagnosed with symptomatic abnormal vaginal discharges are due to this clinically mild disease. Koumans, Sternberg, Bruce, McQuillan, Kendrick, Sutton, & Markowitz, 2007; Menard, 2011; Elkins & Mayeaux, 2010 have stated that many women self- medicate their vaginal discharge with anti-fungal medications.

Statement of Purpose

The purpose of this project was to evaluate patients' knowledge regarding bacterial vaginosis prevention and treatment regimens, and attempt to increase patients' knowledge as a result of training of providers. Specifically, there will be a greater effect on the intervention group receiving education from the health care providers who have received additional in-servicing regarding bacterial vaginosis compared with standard patient care with patients receiving discharge instructions from the educators or nurse practitioner but who have not received additional training.

Significance of Study

Research and data statistics from the National Health and Nutrition Examination Survey showed that the United States continues to linger in healthcare when it comes to decreasing the recurrence of bacterial vaginosis. (Koumans et al., 2007). Data from the 2001-2002 showed bacterial vaginosis to be very common among women of child bearing ages (Koumans et al., 2007; Allsworth, & Peipert, 2007). Annually in the United States (U.S.) and Canada the prevalence rates are approximately 4-23% of private gynecological patients (higher in lower incomes and African American race), 10% to 30% of pregnant women and 12% to 61% of women are seen at clinics for vaginal discharge or sexually transmitted diseases (Yuden, & Money, 2008), "Research shows women diagnosed with bacterial vaginosis have an overgrowth of vaginal anaerobes or Gran – negative bacterial", (Menard, 2011, p. 295). Research has shown that more than fifty percent of women diagnosed with bacterial vaginosis are asymptomatic (Donders, 2010; Menard, 2011). Microbiological diagnostic testing method is necessary, such as Nugent's scoring system, which is considered the gold standard for diagnosis of having bacterial vaginosis (Donders, 2010; Menard, 2011). According to the CDC 2012 many women diagnosed with bacterial vaginosis often have complaints of having a malodorous discharge, pain with intercourse, itching, and/or burning (CDC, 2012; Menard, 2011). Untreated bacterial vaginosis can lead to several unfavorable patient outcomes such as increased risk of sexually transmitted infections (HIV, Chlamydia, Gonorrhea, and herpes), preterm labor, and premature infants or births (Menard, 2011; CDC, 2012; Koumans et al, 2007; Allsworth, & Peipert, 2007)

Project Rationale

Providers have voiced concerns about seeing patients multiple times for recurrent bacterial vaginosis. At the end of each patient's health visit they are given an approved handout from the health clinic, clinician or health educator. Many patients seen at the health centers have been diagnosed and treated several times for recurrent bacterial vaginosis. Many patients have voiced concerns as to receiving written materials but no one has educated them verbally on ways to decrease or change behavioral practices that increase their risk for acquiring bacterial vaginosis. Written and verbal instructions remain to be two of the most common forms of communication when relaying drug information to patients (Pharm, Pierce, & Muhlbaier, 2013). Research has proven that many "patients don't understand the written instructions given to them with their prescriptions" (Pharm, Pierce, & Muhlbaier, 2013, p 1). There are several reasons cited by the patients for recurrence such as non-adherence to treatment regimens and/or behavioral practices. In 2011, Brown, & Bussell reported that 50 percent of patients don't take their medications as ordered.

Project Purpose

The purpose of the project was to evaluate patients' knowledge regarding bacterial vaginosis prevention, treatment regimens, and attempt to increase patients' knowledge as a result of training of nurse practitioners and health educators. Specifically, it was hypothesized that there would be a greater reduction in risk behaviors related to bacterial vaginosis (increased condom use, reduced wearing of thongs, less frequent douching, less use of scented tampons or pads) and more consistent adherence to the medication regimens in women whose providers received an additional in-service. Several studies have been conducted relating to ways to increase adherence to treatment regimens. Today just about everyone has access to computers, cell phones or the internet. In 2014 Lunny and colleagues concluded that text messaging can play a substantial important role in notifying patients of doctors' appointments, STI retesting, provisions of STI results, and help improve and facilitate patient communication among patients and health care providers. In 2006, the Institute of Medicine (IOM) wrote a report emphasizing the importance of educating patients regarding the importance of adhering to their prescribe regimen. Annually approximately 1.5 million people are affected by adverse effects of medications simply due to misunderstanding drug information and the importance of adherence to treatment regimens (Pharm et al., 2011). A statement issued by the World Health Organization (WHO) in 2003, characterized poor adherence to treatment as a worldwide problem affecting developing, as well as developed countries (Brown, & Bussell, 2011). It is estimated that one third to one half of patients are not taking their medications as prescribed (Kirpalani, Yaom, & Hayes, 2007; Haynes, .et al, 2005). Annually, the US loses approximately \$100-\$289 billion due to patients being non-adherent to medication (Ho, 2009; Levine, 2013). World Health Organization considers adherence to be the single modifiable factor that compromises treatment outcomes across diseases (Brown, & Bussell, 2011; Au-Yeung, 2011). Patients have shared several reasons to their health care providers for not taking, adhering to or completing prescribed medications, including"(1) forgetfulness (30%), (2) other priorities

(16%), (3) deliberate decision to omit doses (11%), (4) lack of information (9%), and (5) emotional factors (7%)" (Au-Yeung, 2011, p 277).

Review of Literature

This section included a comprehensive review of the literature related to treating bacterial vaginosis and medication adherence. A literature search was done with multiple search engines that included full texted articles from Cumulative Index of Nursing and Allied Health Literature (CINAHL), OVID, and MEDLINE. Key words used in the literature search included etiology, bacterial, vaginosis, treatment, metronidazole, clindamycin, adherence, and recurrence. No restrictions were given to dates; all articles were written in English and published in peer reviewed journals.

Etiology of Bacterial Vaginosis

The cause of bacterial vaginosis continues to raise questions and remains to be poorly understood (Marrazzo, Thomas, Fiedler, Ringwood, & Fredricks, 2010; Chen et al., 2009; Koumans et al., 2007; Menard, 2011; CDC, 2012). Bacterial vaginosis is a synergistic infection involving multiple bacteria. (Marrazzo et al., 2010: Menard, 2011). Patients diagnosed with bacterial vaginosis commonly have complaints of malodorous discharge and an increase in vaginal pH flora (Koumans et al., 2007, Elkins, & Mayeaux, 2010.) The exact reason for the rise in the pH remains a mystery to researchers (Kumer et al., 2011). The vagina continues to be a complex system making women prone to bacterial vaginosis (Kumer et al., 2011). Many researchers have classified bacterial vaginosis as a sexually transmitted infection (Turovskiy, Sutyak, & Chikindas, 2011, Menard, 2011; Cherps, Hillier, Meyn, Busch & Krohn, 2008). Socioeconomic status, multiple sex partners, same sex relationships, douching, smoking, medications, and lack of condom use are several factors which predispose women to bacterial vaginosis (Klebanoff et al., 2010; Koumans, et al., 2007; CDC, 2012; Menard, 2011).

Diagnosis of Bacterial Vaginosis

The diagnosis of bacterial vaginosis is made if three of four of the following symptoms known as Amsel's criteria are present: "a thin homogenous vaginal discharge, vaginal pH greater than 4.5, fishy amine odor when vaginal discharge is mixed with a 10% potassium hydroxide solution (a positive whiff test), and presence of clue cells which are epithelial cells with Gram negative polymorphic-bacterial rods attached to their surface on microscopic examination" (Menard, 2011, p 297; Donders, 2010; Nugent, Krohn & Hillier, 1992). Bacterial vaginosis can be asymptomatic in about 50% of women, and for that reason microbiological diagnostic method is necessary, such as Nugent's scoring system (Menard, 2011: Donders, 2010: Nugent, et al., 1992). Bacterial vaginosis is diagnosed using a score applied to gram stains of vaginal fluid and the Nugent criteria or scoring system. The gold standard for microscopic evaluation of vaginal discharge for the diagnosis of bacterial vaginosis is Nugent's scoring system. (Nugent et al., 1992, Elkins, & Mayeaux, 2010). Menard (2011, p 297) stated there must be a certain number of lactobacilli and associated bacterial morphotypes required to create a scale of clear abnormality ranging from normal (score = 0 to 3) through intermediate (score = 4 to 6) to frank bacterial vaginosis (score = 7 to 10)". Nugent's scoring system must equal 7 or greater for the diagnosis of bacterial vaginosis to be given (Menard, 2011).

Treatment Regimens Antibiotic Therapy

This review of the literature continues found that currently, intra-vaginal and oral formulations of the antibiotics clindamycin and metronidazole continues to be the recommended formulations for the treatment of bacterial vaginosis (Chen et al., 2009; Bradshaw, Morton, & Hocking, 2006; Menard, 2011; CDC, 2012). However, oral metronidazole remains the drug of choice among clinicians and the CDC due to its efficacy (CDC, 2012). However, most practitioners are aware of the common gastrointestinal side effects when prescribing systemic metronidazole (CDC, 2012).

Metronidazole Treatment

Since the early 1980s, metronidazole has been used widely in the treatment of bacterial vaginosis with good clinical results. The CDC has recommended metronidazole as the first line of treatment for bacterial vaginosis (CDC, 2012: Menard, 2011). Metronidazole is the drug of choice among clinicians and recommended by the CDC protozoa infections and other aerobic infections (Lofmark, Edlund, & Nord, 2010). Oral and vaginal preparations of Metronidazole and Clindamycin have been studied extensively for the treatment of bacterial vaginosis (Chen et al., 2009; Menard, 2011; Bunge, Beigi, Meyn, & Hiller, 2009).

Hanson et al., 2000 and Ransom et al., 1999, compared the efficacy of oral metronidazole (500 mg) take by mouth twice daily and vaginal metronidazole gel 5 grams 0.75 %, both studies showed the treatments to be similar with vaginal preparation to have fewer side effects than oral treatments regimens. Hanson et al., 2000 & Menard, 2011 studies discussed the criteria for what defines cure and treatment failures for

bacterial vaginosis. Several studies have shown that 31% of patients treated with vaginal preparations for bacterial vaginosis have fever gastrointestinal side effects compared to 52% or oral treatment regimens (Hanson, et al., 2000, Menard, 2011).

The cure rate for the treatment using clindamycin and metronidazole (Flagyl) has been shown to achieve cure rates of 91-92 % in cases after two weeks of treatment (Oduyebo et al., 2009). In 2007 Schwebe and colleagues discovered that treatment utilizing 2 gram of metronidazole for the treatment of bacterial vaginosis had the lowest cure rates and is no longer recommended. A more recent review also concluded that the "seven day regimen of metronidazole is superior to the single dose regimen leading authors to recommend it as the first line regimen in the treatment of bacterial vaginosis" (Menard, 2011, p 297). Metallic taste, gastrointestinal symptoms nausea, vomiting and candida infections have been associated with the use of oral metronidazole (CDC, 2012; Menard, 2011; Oduyebo, Anorlu, Ogunsola, 2009). Vaginal preparations of metronidazole (Metro gel) have fewer side effects than oral metronidazole (Menard, 2011).

Clindamycin Treatment

The second line of antimicrobial medication used for the treatment of bacterial vaginosis is Clindamycin (Faro & Skokos, 2005; Menard, 2011). Clindamycin regimens have several preparations for the treatment of bacterial vaginosis including oral and vaginal preparations (cream and ovules) (Faro & Skokos, 2005; Menard, 2011). Only one study was found that evaluated the use of oral clindamycin versus vaginal clindamycin. Treatment using oral clindamycin of 450 mg three times a day and vaginal clindamycin

cream had similar cure rates (Faro & Skokos, 2005). In a recent Cochrane review five gram 2% clindamycin vaginal cream (5 gr) at bedtime for seven days; 100 milligram (mg) ovule daily for three days or 500 mg oral clindamycin twice daily for seven days appears to have equivalent efficacy to 500 mg oral clindamycin twice daily for seven days or topical five gram 0.75% metronidazole gel daily for seven days (Oduyebo et al., 2009, p). However, topical clindamycin tends to cause lower adverse effects (metallic taste in the mouth, nausea, and vomiting), than oral metronidazole (Menard, 2011). Clindamycin creams and ovules are oil based which interferes with condom and diaphragm safety (Menard, 2011).

Recurrence of Bacterial Vaginosis

Several studies have shown that relapse is frequent after antibiotic therapy (Chen et al., 2009; Reichman, et al. 2010; Bunge, et al., 2009). The treatment of asymptomatic women or their sexual contacts will not reduce the transmission of bacterial vaginosis and is not currently recommended (CDC, 2012; Menard, 2011). The recurrence rate of bacterial vaginosis can be as high as 30% in 3 months to 58% 12 months after oral metronidazole therapy in some cases (Reichman et al., 2010; Chen et al, 2009, Menard, 2011). Several reasons were cited for treatment failure using oral metronidazole: (a) "resistance to the drug of choice, (b) survival of bacteria on the vaginal epithelium (c) possible re-infection from not abstaining from sex or using condoms during treatment" (Menard, 2011, p. 302-303). Kirpalani et al., (2007) the rate of non- adherence of patients not complying with treatment regimens may has been estimated to be 20% to 50 %. Non-adherence can lead to increase hospitalizations, antibiotic resistance, worsening of

diseases, and health care cost (Osterberg & Blaschkle, 2005). Adherence or compliance has been called "the key mediator between medical practice and patient outcomes" (Kirpalani et al. 2007, p. 540). Increasing communication between patients and health care professionals with simple interventions have been discussed to improve patient adherence (Kirpalani et al., 2007). In a recent Cochran review database, several simple interventions appeared to improve adherence with short term regimens (Kirpalani et al., 2007). Several measures or interventions such as pill counting, electronic pill bottle caps, and patient diaries to improve medication use for chronic conditions have been studied and appear to be less effective (Kirpalani et al., 2007). Several studies have been conducted regarding barriers related to patients adhering to medication treatment regimens and HIV antiviral treatment adherence (Brown, & Bussell, 2011; Russell, et al., 2007; Flaks et. al 2003). The transmission of HIV continues to be a worldwide epidemic (Mayer et al, 2012). Despite education and highly active antiviral HIV and AIDS treatment (HAART), which has been shown to decrease or slow the spread of HIV by decreasing the infectiousness of those treated, the spread of HIV in the US alone has remained unchanged during the past decade (Mayer, 2012). HIV treatment calls for strict adherence to antiviral medications. Non-adherence to antiviral medications can lead to many unfavorable out comes. Research has shown that text messaging can play a role in notifying patients of doctors' appointments, STI retesting, provisions of STI results, and help improve and facilitate patient communication among patients and health care providers (Lunny et al., 2014).

Methods

A quasi-experimental approach was utilized using a comparative change model at two different Planned Parenthood health centers. The project was conducted Monday through Saturday until the total number of participants reached 50. The project enrolled 50 women, ages 18-45 seen for vaginal discharge and given a diagnosis of bacterial vaginosis with the ICD 9 code 616. The control group: Clinic A enrolled 25 women, aged 18-45 of child bearing ages, seen for vaginal discharge and given a diagnosis of bacterial vaginosis with the ICD 9 code 616. These women were seen by providers and educators who had not received a 45-minute in-service training that covered information about behavior change related to type of underwear worn, type of tampons/pads worn, condom use, and medication adherence. The intervention group: Clinic B enrolled 25 women, aged 18-45 of child bearing ages, seen for vaginal discharge and given a diagnosis of bacterial vaginosis with the ICD 9 code 616. These women were seen by providers and educators who had received a 45-minute in-service training that covered information about behavior change related to type of underwear worn, type of tampons/pads worn, condom use, and medication adherence. One clinic was randomly selected for providers to receive the 45 minute in-service training, and the other clinic's providers did not receive the in-service training. Subjects were asked to complete two surveys. The first survey was administered after their diagnosis for bacterial vaginosis and consent obtained (Appendix A). The initial survey consisted of six questions which took no longer than 3-4 minutes to complete (Appendix B). Nine to 14 days after the initial visit a second survey was administered by phone by the researcher. The second survey took less than 10 minutes and asked about medication adherence and the same

behavioral changes as survey one (Appendix C). All project material was kept under lock and key in the health center's managers' office. Approximately two weeks into the project the primary investigator followed up with health center personnel for any questions and concerns regarding the project. Data was entered and analyzed using the SPSS program. Data was presented as frequency and percent for categorical variables and mean and standard deviation (or median and interquartile range where appropriate) and range (minimum –maximum) for continuous variables. Data was checked for normal distribution using the Kolmogorov-Smirnov (K-S) Test and visually examined histograms which revealed that all the continuous variables were skewed.

Eligibility Criteria

Participants between the ages of 18 and 45; who had vaginal discharge; must not had been treated for bacterial vaginosis within the last month or be currently under treatment for bacterial vaginosis or taking any antibiotics; were not pregnant; were not allergic to the treatment medications; and could read and speak English were eligible to be in the study.

Stakeholders

The stakeholders for this pilot project consisted of patients, health center clinicians, educators and insurance companies. The World Health Organization (WHO) has adopted different views as to what constitutes a disparity. Ethnicity, sex and quality of and/or access to care when treating patients were several disparities discussed by the World Health organization (American College of Physicians, 2010). Major stakeholders such as health care providers and insurance companies agreed that such disparities are unjust and need to be addressed by (American College of Physicians, 2010). Medical and clinical outcomes were affected by all of the stakeholders involved when treating bacterial vaginosis. Increased health care cost, death and worsening of disease have been attributed to non-adherence of medication treatment regimens (Osterberg & Blaschkle, 2005). All stake holders were important in increasing patient knowledge regarding the transmission of bacterial vaginosis and its treatment regimens. Advanced Practice Nurses provided evidence based treatment regimens and education to the patients they serve. Accountably is ultimately up to patients to adhere to medication and treatment regimens (Osterberg, & Blaschkle, 2005). As stated by the former Surgeon General C. Everett Koop "drugs don't work if patients don't take them" (Osterberg, & Blaschkle, 2005, p 487). When patients adhere to medication regimens patients are healthier and there is a decrease in hospital costs and admissions.

Challenges to Project

The challenges to the project were the small sample size and conducting the project only within two Midwest Health Care Centers. Lower social economic status and/or population, educational level, age and race were additional challenges to the project. Other challenges the project faced when measuring outcomes included the use of female feminine products (pads or tampons), the association of bacterial vaginosis with birth control methods, types of underwear (cotton or silk), and menstrual cycles (Klebanoff et al., 2010; Menard, 2011: Koumans et al., 2007). Another challenge

the providers regarding taking their medications or their sexual and hygiene behaviors. Several rationales to results obtained from the project may be related to (1) Are the clinicians and health educators using pre/post questionnaires the same way all the time? (2) Are all clinicians and health educators receiving the same education and are they educating their patients in similar ways? (3) How will new employees be educated? (4) How will the investigator track the movement of employees within the establishments?

Application to Practice

The results of this project will be disseminated and discussed with the Advanced Practice Nurses and health center directors involved in the project. This project will be helpful for the Advanced Practice Nurses when discussing drug regimens and plans of care by increasing the patients' knowledge and education regarding the transmission of bacterial vaginosis. This project encouraged positive changes by both the providers and patients by using evidence based discharge sessions. Behavioral changes made by the patients involved in the study will inevitably increase medication adherence and decrease the risk of acquiring bacterial vaginosis. This clinical project had an inter-professional collaboration among providers APRNs and stake holders by using evidence based practice and education which helped increase patient's knowledge regarding bacterial vaginosis and its treatment regimens.

Theoretical Framework

Many people are apprehensive to change. However, change can bring out the best in individuals. There were many ways of implementing change throughout this clinic project. Kurt Lewins' theoretical framework 'Change Theory'' guided this clinical project. Schifalacqua et al. (2009) and his colleagues state that Lewins' changed method will be adapted, when there is a plan, a purpose, and collaboration among those involved. Lewin's Change theory addressed how and why change occurs. In 1951 Kurt Lewin explained that in order for change to take place there are three steps the agent must go through (Figure 1).



Fig.1 Lewin's Theory of Change

Unfreezing was the 1st step: change was needed. The advanced nurse practitioners and health center educators were in-serviced on up to date evidence based practices on

bacterial vaginosis. In the unfreezing phase the advanced practice nurse and health center educators challenged patients beliefs ("scented tampons or pads") will make sure I won't have a vaginal odor while on my menses"), attitudes ("I don't have to use condoms 100 %") and norms "(it's normal to douche: everyone douches after their menstrual cycle"). Moving/Change is the second step of the Change Theory: change had been initiated. In order for the change to be successful patients believed change was needed. Advanced nurse practitioners and health center educators reevaluated their teaching by giving patients a post questionnaire by phone call between days 9-14 after their initial visits. Medical providers educated patients on ways to decrease or minimize their risk on acquiring bacterial vaginosis ex. (a) increasing condom usage (b) reducing the use of scented feminine products during their menstrual cycles, (c) decreasing douching and (d) increasing the percentage of wearing cotton underwear throughout the month. Refreezing took place after equilibrium had been established, which was the last phase or step to the Change Theory. Patients understood with behavioral changes such as no douching, no thongs or non-cotton type underwear, 100% usage of condoms, and 100% compliance with medication would decrease their risk of acquiring or having a recurrence of bacterial vaginosis.

Gaps in Nursing Science

As discussed by Marrazzo, et al. (2010, p. 740) there were several outstanding questions that warrant further investigation: (a) "What is normal clinically, microbiologically, and immunologically? (b) What was considered normal for the human vagina? (c) Which bacterial or bacterial community types were associated with bacterial vaginosis?" A major limitation of several studies of the vaginal microbiota is their failure to use any objective method such as Amsel's or Nugent criteria to assess for bacterial vaginosis (Marrazzo et al., 2010). No studies or reviews were found that discussed medication adherence when treating bacterial vaginosis. However, there were several studies regarding medication adherence when treating HIV, chlamydia and gonorrhea infections (Lunny et al, 2014). There appeared to be gaps in nursing research regarding compliance when treating bacterial vaginosis.

Research Question

The research question to be answered was there a greater increase in patients' knowledge and behaviors in the intervention group regarding bacterial vaginosis and medication adherence, as compared to the comparison group?

Project Design

Instruments /Tool Development

There are no programs at the present to follow, therefore an appropriate instrument to measure clinicians and patients' knowledge was adapted and modified to questions by the lead investigator. Medication adherence was measured using a questionnaire modified by the primary investigator, Patients' Medication Adherence Questionnaire (see Appendix D). All surveys developed were written on at or below fourth grade level. The medication adherence questionnaire was modified to be appropriately used with the project for timing of data collection and constraints to the project. Validity was assessed by making sure all goals and objectives were clearly defined. Staff members were surveyed and asked to look over the questionnaires for troublesome wording, readability and/or understanding, comments, concerns and/or suggestions.

Data Analysis

A total of 50 women participated in the study which included pretest, posttest, and adherence questions analyzed at first with Univariate analysis. Data were presented as frequency and percent for categorical variables and mean and standard deviation (or median and interquartile range where appropriate) and range (minimum -maximum) for continuous variables. Data were checked for normal distribution using the Kolmogorov-Smirnov (K-S) Test and visually examining histograms which revealed that all the continuous variables were skewed. Thus the Mann Whitney test, ranks data from low to high, rather than using exact values, was used instead of the independent samples t-test. The group with the highest mean rank has the highest scores and vice versa. The median measure was used for the adherence score given the skewed nature as indicated by the significant K-S test. A p-value of 0.05 was considered statistically significant. Since only 5% of the study participants had menstrual cycles since their last visit, not enough data was available to analyze usage of scented feminine products. Since 30% of the study population reported sexual activity since their last visit, not enough data was available to analyze condom usage. The distribution of adherence score is the same across categories of the intervention using the Mann-Whitney U Test (non-parametric equivalent of the Students t-test). All data was analyzed using SPSS statistical package (version 20.0, SPSS Inc., Chicago, IL, USA).

	Contro	Interventio
	l	n
Question	(n=25)	(n=25)
In the Past 3 months how often have you used condoms?		
Always	3(12)	4(16)
Sometimes	10(40)	7(28)
Never	12(48)	13(52)
Last time you had sex did you use condoms? (yes)	6(24)	7(28)
During last menstrual cycle did you use any scented feminine tampons or pads? (yes)	6(24)	3(12)
In last 30 days, how many days did you wear thong underwear? †	0(0)	0(0)
Range (days)	0-20	0-15
In last 30 days, how many days did you wear cotton underwear? [†]	30(0)	30(2)
Range (days)	10-30	15-30
In last 30 days, how many days did you douche? †	0(0)	0(1.50)
Range	0-3	0-4

Table 1. Pre-Test Univariate Analysis by Intervention Status (n=50)

Results are presented as Frequency and Percent unless denoted. † Results presented as median and interquartile range.

	Control	Intervention
Question	(n=25)	(n=25)
Have you had sex since your visit to the health clinic? (yes)	6(24)	8(38)
How many times?	2.00(2.50)	2.00(0.50)
Range (days)	1-4	2-4
How often did you use a condom?		
Always	1(17)	2(29)
Sometimes	3(50)	4(14)
Never	2(33)	1(14)
Have you had a menstrual cycle? (yes)	1(4)	2(8)
Did you use any scented feminine tampons or pads? (yes)	1(100)	0(0)
How many days have you worn thong underwear? [†]	0(0)	0(0)
Range (days)	0-9	0-2
How many days have you worn cotton underwear? [†]	9(0)	9(0)
Range (days)	0-9	7-9
Have you douched since your last visit to the health clinic?		
(yes)	1(5)	4(20)
How many times have you douched? †	0(0)	0(0)
Range (days)	0-2	0-2

Table 2. Post-Test Univariate Analysis by Intervention Stat	tus (n=50). All Questions
pertain to the last 9-14 Days	

† Results presented as median and interquartile range. Adherence of wearing thong and cotton underwear was assessed using Fisher's Exact Test. Numbers do not add up to 50 due to loss at follow up.

Status (11-75).		
	Control	Intervention
Question	(n=20)	(n=25)
In the last 9-14 days since your visit to health center have you forgotten to take your Flagyl or Metro gel? (yes)	16(64)	6(24)
Over the past 7 days, were there any days when you did not take your Flagyl or Metro Gel Medicine?(yes)	16(64)	6(24)
Have you ever stopped or cutback on taking your Flagyl or Metro Gel without telling your healthcare provider because it made you feel worse? (yes)	25(100)	17(71)
Did you take all of your doses of Flagyl or Metro Gel yesterday? (yes)	22(88)	23(92)
When you feel like your symptoms are under control, do you sometimes stop taking your Flagyl or Metro Gel medicine? (yes)	25(100)	19(79)
Do you sometimes feel hassled about sticking to your treatment plan? (yes)	25(100)	20(83)
How often do you have difficulty remembering to take all of your Flagyl or Metro Gel?		
Never/Rarely	0(0)	4(17)
Once in a while	4(16)	6(25)
Sometimes	10(40)	7(29)
Usually	6(24)	3(13)
All the time	5(20)	4(17)
Total Score [†] (median, SD, max, min)	7(2)	5(3)*
Range (points)	5-7	0-7
Low Adherence	25(100)	19(76)**

Table 3. Post-Test Adherence Univariate Analysis by InterventionStatus (n=45).

Results are presented as Frequency and Percent unless denoted.

[†] Results presented as median and interquartile range.

Number does not equal 50 due to 5 participants were lost due to follow up. Control Group (median = 7.00, SD = .943, Min = 5, max = 7, p < .002) Intervention Group (median =5.00, SD = 2.219, min = 0, max = 7, p > .035)

*p-value for Mann-Whitney U < .002

**p-value for chi-square = .035

Results

The control group showed a lower range on three of the questions relating to wearing of cotton or thong underwear and douching before in-servicing was provided to the intervention group of Advanced Nurse Practitioners and health care providers (see table #1).

The intervention group had a lower median adherence score as calculated in the Mann-Whitney U test, compared to the control group (p<.002). The intervention group had better adherence to their Flagyl and Metro Gel medication. The median measure was used for the adherence score given the skewed nature as indicated by the significant K-S test. A p-value of 0.05 was considered statistically significant (see table #3).

Adherence of wearing thong and cotton underwear was assessed as a yes/no variable by intervention status; differences between the two groups were assessed using Fisher's Exact Test instead of Pearson's Chi-Square given small cell size. There was no significant difference between the intervention and control group (p>0.05) in regards to wearing of thong or cotton underwear (see table #2).

Only 5% of the study participants reporting having had a menstrual cycle since their last visit, not enough data were available to analyze usage of scented feminine products. With only 30% of the study population reporting sexual activity since their last visit, not enough data was available to analyze condom usage.

Post- Test Adherence Intervention Status

Data analysis of the adherence was analyzed by their clinic allocation (intent to treat analysis) following analysis of the post -test adherence, seven of the nine questions retained to the primary investigators null hypothesis that there would be a greater effect on the intervention group receiving education from health care providers. The analysis of the total score and low adherence between the control and intervention group reject the null hypothesis were evaluated with Mann-Whitney U and chi-square, respectively, with as both have a p value <.05 (p < .002 and p =.035, respectively). The median adherence score for the control group was 7, and the median adherence score for the intervention group adhered significantly more than the control group.

Conclusion

The project showed that after an educational in-service with the Advanced Practice Nurses and health educators there was an increase in patients' knowledge regarding the transmission of bacterial vaginosis and adherence to treatment regimens, as compared to the control group, whose providers had not received the in-service. The lead investigator will disseminate the findings to the medical director, lead clinician, and health center staff. The findings of the study will be submitted as a poster presentation at the national Family Planning conference. This project can be replicated in the other family planning facilities or similar health centers by in-servicing the health care providers and educators on current evidence based practice, developing protocols for treatment of bacterial vaginosis and educating patients' on behaviors associated with increased chances of contracting bacterial vaginosis. Increasing clinician and patient knowledge regarding bacterial vaginosis, behavioral changes, and medication adherence were important key factors for the success of this project.

Essentials to DNP Practice

The development of a professional doctorate program for nursing has been in the works for decades (Chism, 2010). Many have raised the question since the development of the DNP program, what exactly is the Doctor of Nursing Practice (DNP) degree? (Chism, 2010). As stated by Chism (2010) the "Doctoral education in nursing is connected to our past and influences the directions we may take in the future", (Chism, 2010 p. 3). Doctoral prepared clinicians will be better prepared to handle the more critically ill and underrepresented patients and provide higher quality care utilizing evidence based measures. As nurse practitioners further their education and clinical practice, they will help to bring such process bring about positive changes in health status which affects practice and education at the doctoral level. Such positive changes help to increase patients' knowledge regarding behavioral and changes to help decrease their risk of acquiring bacterial vaginosis and improving medication adherence. The DNP essentials used to guide this project were the "Scientific Underpinnings for Practice and Inter-professional Collaboration for Improving Patient and Population Health Outcomes and Clinical Scholarship and Analytic Methods for Evidence –Based Practice (Chism, 2010). DNP Essential I, Scientific Underpinnings for Practice and Inter-professional Collaboration for Improving Patient and Population Health Outcomes were met by collaboration among the primary investigator and other health clinicians to help patients

improve medication adherence when treating bacterial vaginosis and identifying behavioral changes to decrease the risk of acquiring bacterial vaginosis. DNP Essential III was met by incorporating evidence based literature and discharge instructions to patients and in-servicing health care providers on up to date treatment regimens. The project main goals were met by increasing medication adherence and encouraging positive behavioral changes by patients.

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Appendix A

Consent Form

Study Title:	Increasing Patients Knowledge in Transmission of			
	Bacterial Vaginosis and its Treatment Regimens			
Principal Investigator:	Debra Pikes, BC-FNP			
Address:	Planned Parenthood	Planned Parenthood		
	West County Health Center	North County		
	Stonegate Center #1	2796-98 N. Hwy 67		
	Manchester, MO 63088	Florissant, Mo. 63033		

Introduction: You are being asked to participate in this clinical project to assess patient's knowledge regarding bacterial vaginosis and medication adherence. After reading this form, you can decide to be in the project or you can decide not to be in the project. Either choice is OK.

Participants Status: This project is strictly voluntary and I may stop participation at any time.

Study Goals: The project will evaluate patients' knowledge regarding behavioral changes and adherence to medications when treating bacterial vaginosis.

Sample collection: Collection of vaginal discharge using a clean unlubricated speculum and evaluation of vaginal discharge by microscope will be performed by a trained nurse practitioner.

Procedures: All patients participating in the project will be asked to complete a pre and post questionnaire regarding their knowledge pertaining to behavioral practice, treatment

regimens of bacterial vaginosis and medications prescribed. Patients will be followed up with a phone call at approximately 9-14 days after their visit.

Confidentiality Pledge: All information will be kept confidential and only shared with those involved in analyzing the questionnaires, Midwest Health Centers Directors and Advanced Nurse Practitioners and the University of Missouri Committee members. The Electronic medical records will be accessed only to retrieved data for the project. All project participants will be identified by their medical record number.

Compensation: I agree that if I participate in this project I will not be compensated for my time.

Potential Risk: The potential risk involved in this project may be discomfort while receiving a pelvic exam, increase risk for infection or potential false positive test results.

Participant Selection: If you agree to take party in this project, you will be one of about 50 subjects taking part at two family planning clinics. To be included in this project, you must currently have vaginal discharge; must be at least 18 years of age but no older than 45 years old, must not have been treated for bacterial vaginosis within the last month or currently under treatment or taking any antibiotics, not pregnant, allergic to the treatment medications, able to read and speak English.

Contact Information: If at any time during this study you have any questions or concerns the investigator may be reached at: DP469@umsl.edu

Subject Signature

Date

Signature of Witness/Investigator

Date

Appendix B

Bacterial Vaginosis Pre-Questionnaire

MRN_	Date of Service					
	1. In the past 3 months how often have you used condoms?					
		(a) always	(b) sometimes		(c) never	
	2.	Last time you had	l sex did you us	e condo	oms?	
			(a) yes	(b) no		
	3.	During your last i	nenstrual cycle	did you	use any scented feminine tampons or	
		pads?	(a) yes	(b) no		
	4.	In the last thirty (30) days, how r	nany da	ys did you wear thong underwear?	
	5.	In the last thirty (30) days, how r	nany da	ys did you wear cotton underwear?	
	6.	In the last thirty (30) days, how r	nany tin	nes did you douche?	

Appendix C

Bacterial	Vaginosis	Questionnaire
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MRN_____ Date of Service_____

Post follow up date _____

1. In the last 9-14 days have you has sex since your visit to the health clinic?

(a)yes (b) no

- 2. If yes, how many times? And how often have you used condoms with sex?
 - (a) always (b) sometimes (c) never
- 3. In the last 9-14 days have you had a menstrual cycle?

(a) Yes (b) no

4. If yes, did you use any scented feminine tampons or pads?

(a) yes (b) no

- 5. In the last 9-14 days since your visit to the health clinic how many days have you worn thong underwear?
- 6. In the last 9-14 days since your visit to the health clinic how many days have you worn cotton underwear?
- 7. In the last 9-14 days have you douched since your visit to the health clinic?

(a) yes (b) no

8. If yes, how many times have you douched?

Appendix D

MRN_					
Patien	t Post medicatio	on Questionna	iire		
Date o	f Follow up				
Quest	ion		Patient Answer		Score
			(Yes / No)	$\mathbf{Y} = 1$	$\mathbf{N} = 0$
1.	In the last 9-14 take your Flag	4 days since y yl or Metro g	our visit to the health el medication?	center have you forgott	en to
2.	People someti Thinking over Flagyl or Metr	mes miss taki the past 7 day to Gel medicin	ng their medicines for ys, were there any day ne? Yes/ No	reasons other than forg s when you did not take	etting. 9 your
3.	Have you even without telling	t stopped or cu g your health c	ut back on taking your care provider because Yes/No	Flagyl or Metro Gel m it made you feel worse?	edication
4.	Did you take a	all of your dos	ses of Flagyl or Metro Yes/No	Gel yesterday?	
5.	When you feel taking your Fl	l like your syr agyl or Metro	nptoms are under con Gel medicine? Yes/No	trol, do you sometimes	stop
6.	At times takin sometimes fee	g medication I hassled abou	can be a real inconver at sticking to your trea Yes /No	nience for some people. htment plan?	Do you
7.	How often do Gel? A=0	you have diff B-E=1	iculty remembering to	take all of your Flagyl	or Metro
A	Never/rarely	221			
B.	Once in a while	e			
C.	Sometimes				
D.	Usually				
E. A	All the time				

Total Score: Scores: >2 = low adherence 1 or 2 = medium adherence 0 = high adherence