Recurrent Bacterial Vaginosis: An evidenced-based protocol for the improvement of patient outcomes final project

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Bacterial Vaginosis (BV) is the most frequent vaginal infection of women of childbearing age, with a prevalence of 10% to 50% (Parma, Vanni, Bertini, & Candiani). BV in women has been associated with pelvic inflammatory disease, post-surgical infections and preterm labor (Sanchez, Garcia, Thomas, Catlin, & Holmes, 2004). Women who suffer from recurrent BV can exhibit frustration, embarrassment, and changes in quality of life because of the condition (Payne, Cromer, Stanek, & Palmer, 2010). Researching better treatments and presenting a protocol to change the current practice at a large healthcare organization has the potential to help many women who suffer from recurrent BV, and was the focus of this project. There is potential for change at the microlevel of the organization where the clinicians interact with patients, as well as at the mesolevel and macrolevel as better treatment would likely translate into better patient satisfaction, and higher patient retention.

The PICO method is one way to frame clinical questions for nursing research (Meinyk & Fineout-Overholt, 2005). The PICO question developed for this project is: "For clinicians in a large not-for-profit healthcare system in Illinois, will the use of an evidenced based protocol for the treatment of recurrent bacterial vaginosis (BV) change the clinicians' practice?" This PICO question covers all four elements of the PICO method which include population of interest, intervention, comparison, out come and time. The practice issue was identified by clinicians at Planned Parenthood of Illinois (PPIL). Currently there is a wide variation in the treatment for recurrent BV. The development of an evidenced-based protocol would potentially change the practice of the clinicians at PPIL making it more consistent and efficacious for the patients.

Literature Review

A systematic review of the literature is an appropriate research methodology for use in developing treatment protocols (Polit & Beck, 2012). The systematic review was done on various studies found on bacterial vaginosis (BV). The DNP project involves changing clinicians' practices in treating BV by developing and presenting a protocol for treatment of recurrent BV. Several interesting facts came out of the systematic review. One fact is that BV is one of the most if not the most commonly diagnosed vaginal infections with rates reported as high as 50% of all vaginal infections (Shaaban et al., 2011). Another fact is that BV has a treatment failure rate of 48% using the currently accepted conventional treatment and a recurrence rate of greater than 50% within 6-12 months of treatment (Ya, Reifer, & Miller, 2010). One of the factors that makes BV so difficult to treat is that there is not one simple bacteria that causes the condition, but rather a shift in the vaginal flora that can involve a number or organisms (Muzny et al., 2013), (Petricevic & Witt, 2008).

In a survey of over 3700 women, done in the United States, results collected from self-collected swabs estimated the prevalence of BV to be 29% in the general female population aged 14 to 49 years and 50% in African American women (Parma et al., 2014). BV results from the breakdown of the equilibrium that exists in the vagina between lactobacilli (LB) and anaerobic and functionally anaerobic bacteria (Parma et al., 2014). During the childbearing years, healthy vaginal flora is dominated by Lactobacilli, mostly Lactobacillus crispatus, Lactobacillus jensenii, Lactobacillus iners and Lactobacillus gasseri (Parma et al., 2014). Lactobacillus in the vagina metabolizes glycogen that is secreted by the vaginal epithelial cells, producing lactic acid resulting in a normal vaginal pH of < 4 to 5 (Parma et al., 2014). The acid pH of the healthy vagina prevents the growth of many pathogens (Parma et al., 2014). The exact cause of BV

remains unknown, and returning the normal vaginal flora after treatment of BV can be difficult to achieve (Petricevic & Witt, 2008).

Having recurrent BV can cause distress in the individual as having a strong unpleasant vaginal odor is a key symptom of the condition; it can even cause ritualistic cleansing behaviors and impact quality of life for certain women (Payne, Cromer, Stanek, & Palmer, 2010). BV has also been associated with obstetric and gynecologic complications and increased risk for transmission of HIV 1 (Oduyebo, Anorlu, & Ogunsola, 2009). Having Herpes Simplex Virus Type 2 also increases a woman's risk of contracting the infection (Masese et al., 2013). It is clearly an important issue for both women and the clinicians who render their care.

The conventional treatment for BV is antibiotics. Many different combinations have been studied. After reviewing multiple studies including one meta-analysis it is clear that the conventional treatment for BV is inadequate (Oduyebo et al., 2009). Four of the studies reviewed compared different antibiotic regimens in women who were symptomatic for BV (Sanchez et al., 2004), (Shaaban et al., 2011), (Schwebke & Desmond, 2011) and (Oduyebo et al., 2009). Sanches et al found that metronidazole/nystatin vaginal capsules were more effective than metronidazole alone for the treatment of BV (2004), Shaaban et al found that metronidazole *in situ* gel was more effective than conventional metronidazole gel for preventing recurrence of BV (2011), Schwebke & Desmond came to the conclusion after their study that there is no difference in cure rates between metronidazole and tinidazole (2011), and the systematic review of antimicrobial therapy on bacterial vaginosis in non-pregnant women, Oduyebo et al found that clindamycin was comparable to metronidazole in cure rate but that the metronidazole had a higher rate of adverse effects (2009). The systematic review also found that triple sulfonamide cream and hydrogen peroxide douche was not as effective as a single 2 gm. dose of

metronidazole (Oduyebo et al., 2009). All of these studies looked at non pregnant symptomatic women, and each study had women of differing ethnic origins, including Peruvian women (Sanchez et al., 2004), Egyptian women (Shaaban et al., 2011), and American women (Schwebke & Desmond, 2011). The systematic review had several ethnicities represented (Oduyebo et al., 2009). No two studies looked at the same treatments, nor did they have the same methodology, interventions, data collection, or sample sizes. Each of these have to be reviewed based on their own merits and limitations.

Four of the studies included in the review addressed the use of probiotics in the treatment and prevention of BV (Parma et al., 2014), (Petricevic & Witt, 2008), (Ya, Reifer, & Miller, 2010), and (Oduyebo et al., 2009). All four studies concluded that probiotics given vaginally in one form or another can reduce BV recurrence (Ya et al., 2010), hinder vaginal bacterial growth after treatment with antibiotics (Parma et al., 2014), or given orally or vaginally can be an effective treatment for BV (Oduyebo et al., 2009). Petricevic and Witt concluded that exogenously applied *Lactobacillus casei rhamnosus* Lcr35 restores the vaginal flora after treatment with antibiotics (2008). Parma et al noted that none of the studies reviewed reported any side effects from the probiotic treatments (2014), and Oduyebo et al concluded that more information on the possible side effects of lactobacillus preparations are necessary (2009). Ya, Reifer and Miller concluded that short-term prophylaxis is well tolerated (2010). All of these authors looked at different probiotic preparations and different routes of administration (vaginal and oral) so comparing the findings from one study to another is inappropriate. Also the study conducted by Ya, Reifer and Miller was conducted with Chinese women exclusively making generalizability an issue (2010).

All of the studies reviewed defined BV differently from one another and all had different follow-up intervals and different populations of women. The ages, sexual preferences, socio-economic status and baseline health practices were heterogeneous in the studies reviewed. One study did telephone interviews as their long-term follow-up (Ya et al., 2010). In the other studies that looked at treatment of BV with antibiotics follow-up was done during office visits, or through the collection of vaginal swabs obtained by the patients themselves (Sanchez et al., 2004), (Schwebke & Desmond, 2011) and (Oduyebo et al., 2009).

One study added information to the complexity of the condition of BV by providing new information about the differences in the vaginal flora that cause BV (Muzny et al., 2013). The natural flora of the vagina undergoes numerous changes throughout a woman's lifetime (Parma et al., 2014). Muzny et al. found that the vaginal bacteria communities of all women in the study clustered into four taxonomic groups (2013). The bacterial makeup of BV was found to be different among women in different risk behavior groups; women who have sex with men (WSM) had the highest diversity of bacterial taxa (Muzny et al., 2013). This information can be instrumental in helping to understand why treatment failure rates are high and why treating recurrent BV can be so challenging. More studies would need to be done to explore how differences in the vaginal flora can affect the rate of cure using different treatment protocols.

The study done on vaginal douching cessation was a small study but it did add to the body of knowledge of risk factors for recurrent BV (Brotman et al., 2008).The findings from this small pilot study was that in a subgroup of women, douching cessation may help prevent recurrent BV (Brotman et al., 2008). It is also interesting to note that 5 of the ten studies reviewed also named unprotected sex as a risk factor for recurrent BV (Muzny et al., 2013), (Oduyebo et al., 2009), (Parma et al., 2014), (Sanchez et al., 2004), and (Schwebke & Desmond,

2011). A small pilot study which was a double –blind randomized study found that higher dose metronidazole treatment was more effective for recurrent BV, and that adding miconazole to the treatment regimen was not helpful (Aguin, Akins, & Sobel, 2014). This study was a pilot study and had limitations such as only 43 participants for 2 ethnic groups

The only qualitative study reviewed was pertinent to the clinical question in that it provided insight into the possible detrimental effects on women who suffer from recurrent BV (Payne et al., 2010). This study was small with only 23 participants who were all African American. There was no ethnic diversity and the women in the study were all well-educated (Payne et al., 2010). The lack of diversity of the participants limits its generalizability, but despite these limitations, the study does provide some insight into the psychological suffering as well as the physical suffering of women with BV. The study did show that quality of life was affected in a negative way by having recurrent, chronic BV (Payne et al., 2010). This study may help APNs to understand why examining the evidence to look for better treatment of recurrent BV is so important, and possibly assist APNs in understanding the need for changing current nursing practices.

Two reviews of the literature were included in the eleven studies reviewed. One review examined 69 studies relating to the use of various probiotics in the prevention of recurrent BV (Parma et al., 2014). This review described the clinical criteria and the microscopic assessment criteria for diagnosis of BV; and various studies on various probiotic treatments used to restore a normal vaginal flora including vaginal vitamin C (Parma et al., 2014). This review concluded that long term administration of Lactobacillus can be considered a an effective adjuvant treatment for recurrent BV (Parma et al., 2014). The larger of the two reviews focused on studies involving antimicrobial therapy for the treatment of BV in non-pregnant women and studied

randomized controlled trials comparing any two or more antimicrobial agents of antimicrobial agents with placebo or no treatment (Oduyebo et al., 2009). This review was exhaustive and concluded that the traditional forms of treatment for BV are effective and that lactobacillus given either orally or vaginally is also effective.

After completing this systematic review of the literature it is clear that there is no one treatment that has been clearly proven to be superior for preventing the recurrence of BV, meaning that more research needs to be done (Oduyebo et al., 2009). Since there were multiple different probiotic supplements studied both prescription and over the counter, and no one supplement or route of administration was clearly superior. The systematic review did consistently show that probiotics were effective in preventing BV. It therefore seems reasonable, based on the evidence from the systematic review, to add education on douching cessation and avoidance of unprotected intercourse as well as over the counter or prescription probiotics to a treatment protocol for recurrent BV to be presented to the clinicians at PPIL (Brotman et al., 2008), (Wang et al., 2010). Providing an evidenced based protocol for the treatment of recurrent BV can cause a positive change in the practice of the clinicians of PPIL and possibly in the practice of Planned Parenthood practitioners nation-wide.

Methodology and Implementation

The project involved the clinicians who consist mostly of APNs at PPIL which is an affiliate of Planned Parenthood Federation of America (PPFA). The clinicians at PPIL were asked to complete a questionnaire about their current practice regarding the treatment of patients with recurrent BV. They were then provided with a presentation about the review of the literature on the treatment of recurrent BV and presented with an evidenced-based protocol for the treatment of recurrent BV. After 3 to 4 weeks the clinicians were asked to complete a second

questionnaire. PPFA has 68 affiliates and over 700 health centers nation-wide, and has been providing health care in the United States for almost 100 years. PPIL is a Not-for-profit healthcare organization with 18 health centers located throughout the state. Each health care center has one or two advanced practice nurses (APNs) who see patients with reproductive health care needs including family planning, routine screening for breast and cervical cancers, diagnosis and treatment of sexually transmitted infections (STIs) and simple healthcare concerns such as urinary tract infections. Most of the APNs are family nurse practitioners, and the remaining APNs are certified in women's' health or midwifery. The protocol presented was part of an investigation and as such the clinicians were under no obligation to follow the protocol.

At a recent all staff, state-wide meeting, the APNs expressed concern over the lack of a formal treatment protocol for patients with recurrent bacterial vaginosis. There is a treatment protocol for treatment of bacterial vaginosis but when patients return to the health center after a treatment failure there is no set protocol to follow. This topic was presented as a concern by the clinicians.

The sample consisted of clinicians working at PPIL. Most of these clinicians are APNs with the remaining being physicians. Each clinician was asked to complete a questionnaire regarding current practice with regard to recurrent BV (Appendix B). After completion of the questionnaire, each clinician was provided with an evidenced-based protocol on the treatment of recurrent BV. After approximately 1 month another questionnaire was administered to assess change in practice (Appendix C). Data was collected on length of time in practice, and about current treatment practices, such as medications ordered, whether or not douching is routinely discouraged, condom use routinely encouraged, and whether or not probiotics either orally or vaginally is discussed or recommended. Questionnaires were evaluated for changes in practices.

Any changes in the questionnaires regarding practices in treating recurrent BV are attributed to orientation to and information regarding evidenced-based treatment of BV. It is anticipated there will be a change in practice toward treating recurrent BV using an evidenced-based protocol. The research results will be presented by the author to all PPIL clinical staff at a staff meeting date to be determined.

Protection of Human Subjects

This investigation used a pre-test-post-test self-report survey design to assess changes in practices of treatment of bacterial vaginosis after an educational intervention to change behavior towards more evidence-based practices. The investigation was approved by the Chamberlain College of Nursing Institutional Review Board on 12/05/2014 and conducted in accordance with the Declaration of Helsinki (Appendix D).

Analysis

The data analysis was completed with the expertise of a biostatistician. Data were entered into a Microsoft Excel(Katz, 2010) and saved into a comma-separated value format file. One-way frequency distributions were constructed for demographic variables. Two-way frequency distributions were constructed for variables related to the intervention and time. A chi-square test of independence was performed to test the association between the frequency of evidence-based practice and time. For example, was there a change in metronidazole prescribing after the educational intervention? *P* values were calculated for a Monte Carlo test with computed for a Monte Carlo (Hope, 1968) test with 1,000,000 replicates. Relative frequency bar charts were constructed to graphically display changes in frequency of use of evidence-based practice between pre-test and post-test. All analyses were done using R software (R Core Team, 2014).

Bar charts were constructed using ggplot2 (Wickham, 2009). (G. Gilbert, personal communication, March 26, 2015)

The demographics of the clinicians included their credentials, role, and years of experience. There were 25 clinicians qualifying. Only clinicians working for PPIL at the time of the study were eligible. Of the 25 clinicians 23 participated in the project. Of the 23 sets of returned questionnaire three sets were excluded from the project because of missing data. Of the 20 clinicians that fully participated in the project 13 identified themselves as Women's Healthcare Nurse Practitioners (WHNP), 3 as Certified Nurse Midwives (CNM), 2 as a Family Nurse Practitioner (FNP), 1 as a medical doctor (MD), and 1 as other which was a Clinical Nurse Specialist (CNS). There was a varying amount of experience in practice among the participants; 3 were in practice less than 1 year, 7 practiced for 1 to 5 years, 1 was in practice 6-10 years, 2 were in practice 11-15 years and 6 had been practicing greater than 15 years. In regards to their role in the organization 17 identified themselves nurse practitioners (NPs), 1 as an administrator and 2 as other. Both of the respondents who answered other refer to their role as "clinician". There were 15 participants that stated their specialty as obstetrics/gynecology, 2 identified as family practice (FP) and 3 as other which was public health, women's health, and gynecology.

Six aspects of treatment were studied: metronidazole gel 0.75% one full applicator (5g) intravaginally once daily for 5 days, clindamycin cream 2% one full applicator (5g) intravaginally at bedtime for 7 days, Counseling of probiotic use, Counseling of avoidance of douching, Counseling on condom use, and counseling on abstinence while on medications for BV. Each aspect was rated by the clinicians as being a practice Never, Rarely, Sometimes, or Always. The results for metronidazole were 2 never, 0 rarely, 16 sometimes and 2 always at time

1 and 1 never, 1 rarely, 17 sometimes and 1 always at time 2. The results for metronidazole between time 1 and time 2 were not significantly different. The results for clindamycin were 3 never, 12 rarely, 4 sometimes and 1 always at time 1 and 0 never, 12 rarely, 8 sometimes and 0 always for time 2. The results for clindamycin usage between time 1 and time 2 were not significantly different. The results for probiotics counseling were 3 never, 5 rarely, 4 sometimes and 8 always at time 1 and 3 never, 3 rarely, 7 sometimes and 7 always at time 2. Although more clinicians reported counseling on probiotic use at time 2 this difference did not reach a statistical significance. The results for counseling on avoidance of douching were 0 never, 0 rarely, 1 sometimes and 19 always for time 1 and 0 never, 0 rarely, 4 sometimes and 16 always at time 2. This result did not reach statistical significance. The results for counseling on condom use were 0 never, 1 rarely, 0 sometimes and 19 always at time 1 and 0 never, 1 rarely, 2 sometimes and 17 always at time 2. This result was not statistically significant. The results for counseling on abstinence while on medications for BV were 2 never, 3 rarely, 4 sometimes and 11 always at time 1 and 0 never, 2 rarely, 5 sometimes and 13 always at time 2. This result was not statistically significant. The following tables show the experience of the clinicians (table 1) as well as the results of the questionnaires for use of metronidazole (Table 2) and clindamycin (table 3).

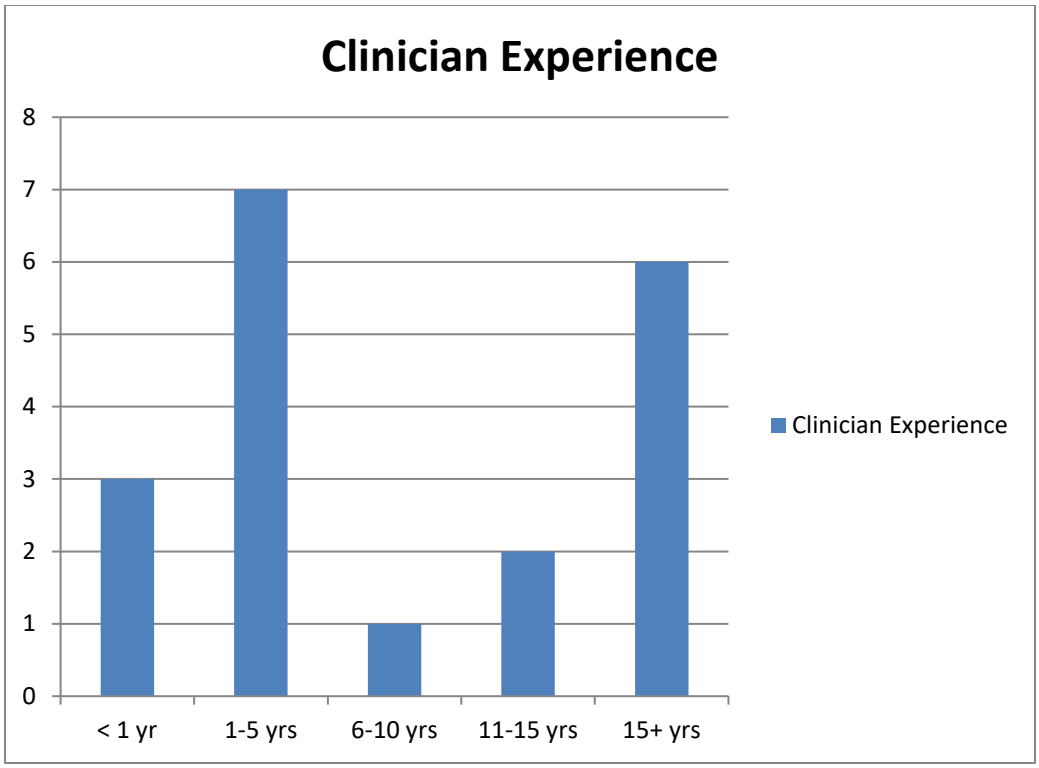
Clinician Experience
8
7
6
5
4
3
2
1
0
< 1 yr
1-5 yrs
6-10 yrs
11-15 yrs
15+ yrs
Clinician Experience

Table 1

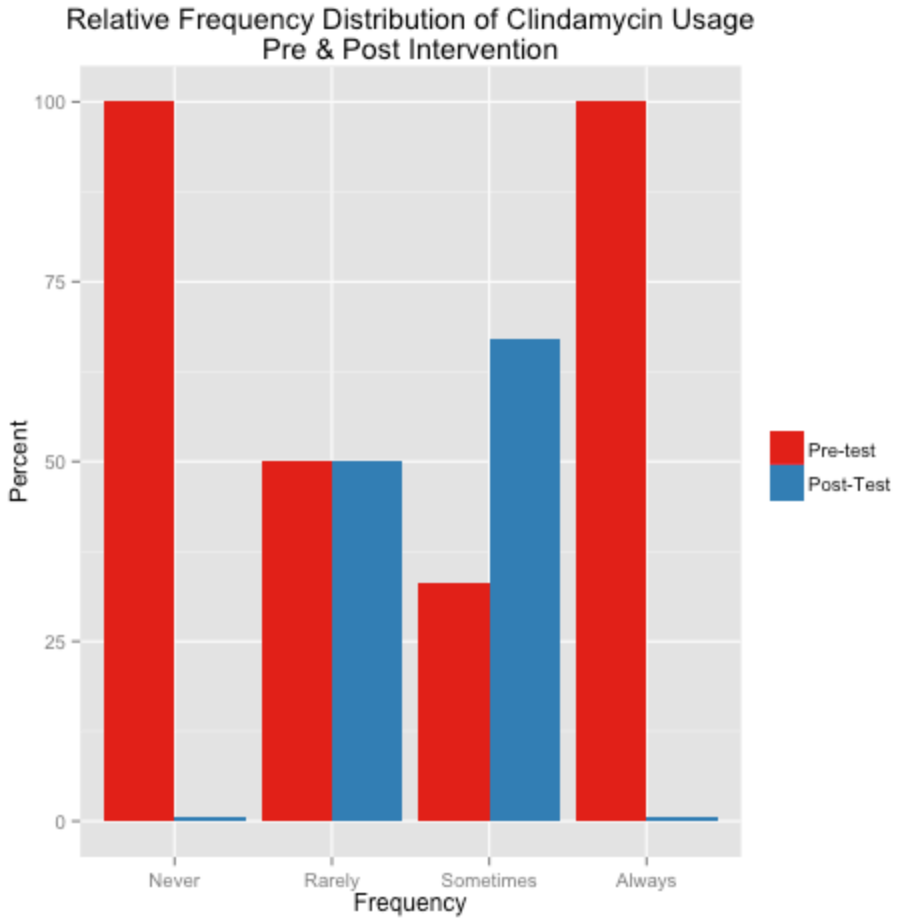
Relative Frequency Distribution of Clindamycin Usage
Pre & Post Intervention
100
75
50
25
0
Percent
Never
Rarely
Sometimes
Always
Frequency
Pre-test
Post-Test

Table 2

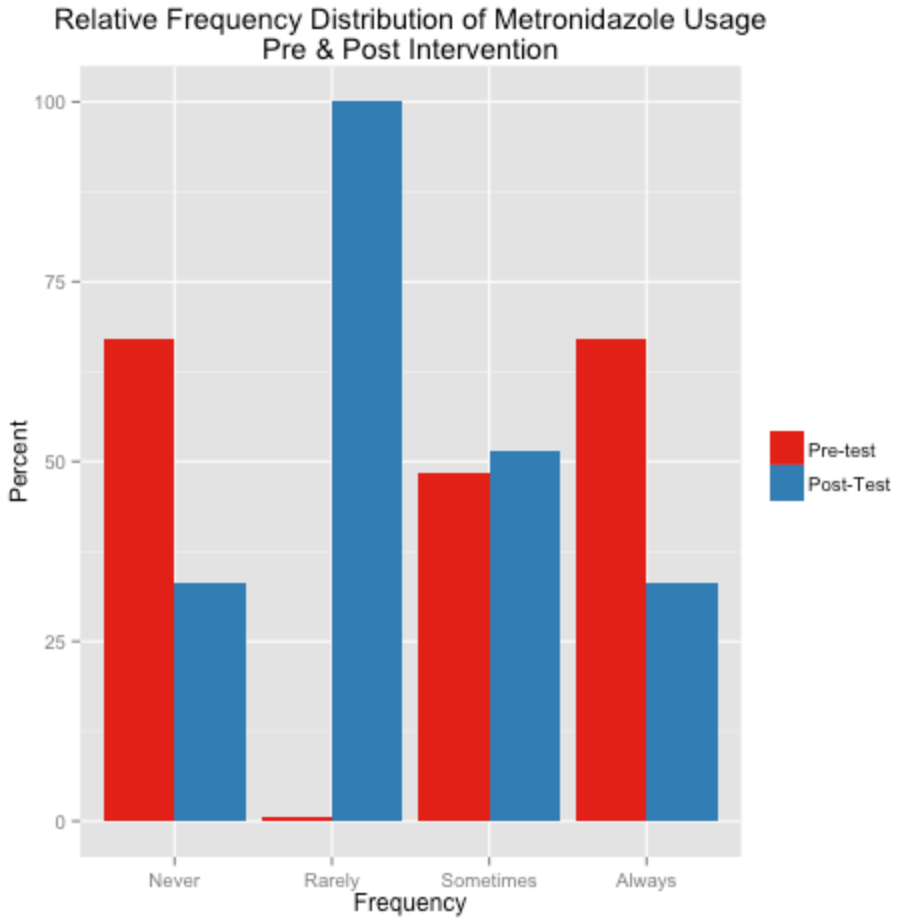
Relative Frequency Distribution of Metronidazole Usage
Pre & Post Intervention
100
75
50
25
0
Percent
Never
Rarely
Sometimes
Always
Frequency
Pre-test
Post-Test

Table 3

Solution

The findings of this project did not support the hypothesis that an evidenced-based protocol would effect a change in the practice of clinicians working at PPIL. There are many possible reasons for these findings. Nursing and other health care professions are in the process of changing from a tradition and intuition type of practice paradigm, to a more evidenced-based paradigm (Eizenberg, 2011). It may have been that the time between the pre and post questionnaires was not long enough to allow a change in practice. There is also the possibility that since the newly presented evidenced-based protocol was not mandatory; the clinicians chose to continue with their current practice. Another possible factor is that the use of probiotics can be expensive and some clinicians may have felt that their patients would not be able to afford the products. These findings point to the need for further research in the area of evidenced-based nursing. Further research is needed in order to investigate the impact of evidenced-based protocols on actual healthcare practice. The sample size was also quite small. The study could be repeated with a larger sample size by surveying all the clinicians at PPFA for example instead of just the clinicians at PPIL.

Microsystem Change

When dealing with a microsystem change there are 5 Ps that must be considered: Purpose, Patients, Professionals, Processes, and Patterns (Nelson, Batalden, Godfrey, & Lazar, 2011). This project has the potential to impact the clinical setting in a number of ways. The purpose of the project was to provide and evidenced-based protocol for APNs treating patients with bacterial vaginosis (BV). Having this new protocol will change their practice. This protocol directly affects patients in that they will be provided with the latest evidenced-based care and the

care will be more consistent among the clinicians. The professionals of the healthcare center will be impacted by the consistency and change in practice based on the protocol. The protocol directly affects the process of how the patients are treated. The clinical site operates based on protocols so the addition of a new protocol will affect the process of patient care directly. Having a new evidenced-based protocol for the treatment of recurrent BV may not change the overall patterns of how healthcare is administered since the current pattern is one of using evidenced-based protocols whenever possible. Translation of evidence into practice presents many challenges but can also be very rewarding (White & Dudley-Brown, 2012).

Dissemination

Dissemination of research findings is an important aspect of research (Eizenberg, 2011). The outcomes of this project will be disseminated to the management and staff of (PPIL). These stakeholders will be given the results of the project through email communication and through a presentation that will be given to an all-staff meeting. Parts of the project will be disseminated to different groups. The review of the literature will be submitted for publication to a scholarly journal and if accepted and published it will reach a greater number of people than the project as a whole. The actual evidenced-based protocol will be review by (PPFA), and possible incorporated into the national protocols. Adding to the body of knowledge for nursing is a goal of nursing research (Polit & Beck, 2012). There will also be some informal dissemination as the author has been asked to present the findings of the project to faculty at Chamberlain College of Nursing Addison Campus. There will also be informal discussions of the finding with the staff of PPIL. There is also the possibility that a poster presentation or a scholarly article about the project will be produced.

Appendix A

Treatment of Recurrent Bacterial Vaginosis (BV)

Protocol

1. Indications for treatment

   Symptomatic infection ("Centers for Disease Control and Prevention," 2010)

   Positive clinical criteria or confirmatory or commercially available tests ("Centers for Disease Control and Prevention," 2010)

2. Treatment – Except when otherwise noted, treatment regimens in current CDC guidelines or as recommended by your local/state health department must be used.

   Metronidazole 500 mg orally twice a day for 7days
   OR
   Metronidazole gel 0.75% one full applicator (5 g) intravaginally once a day for 5 days
   OR
   Clindamycin cream 2% one full applicator (5 g) intravaginally at bedtime for 7 days ("Centers for Disease Control and Prevention," 2010)

   Alternative Regimens include:

   Tinidazole 2 g orally once daily for 2 days
   OR
   Tinidazole 1 g orally once daily for 5 days
   OR
   Clindamycin 300 mg orally twice daily for 7 days
   OR
   Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days ("Centers for Disease Control and Prevention," 2010)

   May consider recommending the use of vaginal or oral probiotics containing lactobacilli. (Parma, Vanni, Bertini, & Candiani, 2014), (Petricevic & Witt, 2008), (Ya, Reifer, & Miller, 2010), (Oduyebo, Anorlu, & Ogunsola, 2009)

3. Client education includes:
   Recurrent BV is associated with having multiple sex partners, douching, and lack of lactobacilli. (Aguin, Akins, & Sobel, 2014), (Muzny et al., 2013), (Oduyebo et al., 2009), (Parma et al., 2014), (Sanchez, Garcia, Thomas, Catlin, & Holmes, 2004), & (Schwebke & Desmond, 2011)

   Women with recurrent BV are at increased risk for acquiring other sexually transmitted infections (STIs). ("Centers for Disease Control and Prevention," 2010)

   Vaginal clindamycin cream and ovules are oil-based and might weaken latex condoms for 5 days after use. ("Centers for Disease Control and Prevention," 2010)

   Avoid consuming alcohol during treatment with metronidazole (up to 24 hours after last dose) ("Centers for Disease Control and Prevention," 2010)

   It is important to stop behaviors that are associated with BV especially douching. Condom use may help prevent recurrences. (Brotman et al., 2008), (Aguin, Akins, & Sobel, 2014), (Muzny et al., 2013), (Oduyebo et al., 2009), (Parma et al., 2014), (Sanchez, Garcia, Thomas, Catlin, & Holmes, 2004), & (Schwebke & Desmond, 2011)

4. Refer – women with multiple recurrences.

Appendix B

Completion of questionnaire is implied consent for the study.

Treatment of Recurrent Bacterial Vaginosis
Study Questionnaire

I am conducting a study on the effects of an evidenced-based protocol for the treatment of recurrent bacterial vaginosis. The study involves completing a short questionnaire about current practices, followed by the introduction of an evidenced-based protocol for treatment of recurrent bacterial vaginosis. After one month the same questionnaire will be administered. There is no compensation for participating in this study and your participation is voluntary. You may withdraw from the study at any time without penalty. There is no penalty for not participating in this study. Filling out the questionnaire implies consent. Thank you.

What are your credentials?
CNM _____ DNP _____ FNP ____ MD ____ WHNP____ Other: please state _____

How many years have you practiced in your current field?
< 1 year _____ 1-5 years _____ 6-10 years _____ 11-15 years _____
> 15 years _____
What is your role in the institution?
Administrator Nurse Practitioner Physician Other (please specify) _____

Please circle or indicate your specialty in this organization:
Family Practitioner Internal Medicine OB/GYNE Pediatrics
Other (please specify): _____

How often do you prescribe/use the following for patients presenting with Recurrent BV?

	Never	**Rarely**	**Sometimes**	**Always**
Metronidazole gel 0.75% one full applicator (5g) intravaginally once a day for 5 days				
Clindamycin cream 2% one full applicator (5g) intravaginally at bedtime for 7 days				
Counseling on probiotic use				
Counseling on avoidance of douching				
Counseling on condom use				
Counseling on abstinence while on medications for BV				

Appendix C

Completion of questionnaires is implied consent for the study.

Treatment of Recurrent Bacterial Vaginosis

Study Questionnaire # 2

As part of my degree program I am conducting a study on the effects of an evidenced-based protocol for the treatment of Recurrent Bacterial Vaginosis. The study involves completing a short questionnaire about current practices, followed by the introduction of an evidenced-based protocol for treatment of recurrent bacterial vaginosis. After one month the same questionnaire will be administered. There is no compensation for participating in this study and your participation is voluntary. You may withdraw from the study at any time without penalty. There is no penalty for not participating in this study. Filling out the questionnaire implies consent. Thank you".

What are your credentials?

WHNP ____ CNM _____ FNP ____ MD ____ DNP____ Other: please state _____

How many years have you practiced in your current field?

<1 year _____ 1-5 years _____ 6-10 years _____ 11-15 years _____

greater than 15 years _____

What is your role in the institution?

Administrator Physician Nurse Practitioner Other (please specify) _____

Please indicate your specialty:

Family Practitioner Internal Medicine OB/GYNE Pediatrics

Other (please specify): _____

How often do you prescribe/use the following for patients presenting with Recurrent BV?

	Never	**Rarely**	**Sometimes**	**Always**
Metronidazole gel 0.75% one full applicator (5g) intravaginally once a day for 5 days				
Clindamycin cream 2% one full applicator (5g) intravaginally at bedtime for 7 days				
Counseling on probiotic use				
Counseling on avoidance of douching				
Counseling on condom use				
Counseling on abstinence while on medications for BV				

Where there any barriers identified to implementing the protocol? If yes please explain:

_____

_____

Do you have any suggestions for future evidenced-based practice projects?

_____

_____

Appendix D

Chamberlain College of Nursing
Institutional Review Board (IRB)
3005 Highland Parkway
Downers Grove, IL 60515-5799

Federal Registration: IRB00009799
Federal Wide Assurance: FWA00021986

12/5/2014

Dear **Barbara Meagher**:

This letter is to inform you that the Chamberlain College of Nursing (CCN) Institutional Review Board (IRB) for the Protection of Human Subjects has received and processed your proposal titled: **Recurrent Bacterial Vaginosis: An Evidenced-based protocol for improvement of patient outcomes.**. Your proposal was assigned IRB # **2014-11-15-EXM** which should be referenced in future communications.

The IRB has determined that your project is exempt from IRB oversight and continuing review since it meets the criteria indicated below as described in DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

_____ The proposed project does not include human subjects.
_____ The proposed project will not produce findings useful to external audiences or contribute to the knowledge base in a given field (broad definition of "research").
_____ The proposed project will be conducted in established or commonly accepted educational settings, involving normal education practices. (45.CFR.46.101[b][1])
__X__ The proposed project will involve the use of educational tests, survey procedures, interview procedures or observations of public behavior (unless information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects; and any disclosure of the human subjects' responses outside the research could reasonable place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation). (45.CFR.46.101.[b][2])
_____ Other exemption criterion (State: _____)

Although your study is exempt from IRB oversight, you are expected to follow the conventions of research ethics described in the Belmont Report and relevant professional guidelines. If aspects of your study change such that IRB oversight will become necessary, you must contact the IRB immediately.

If you have any questions, do not hesitate to contact the IRB. Best wishes with your scholarly inquiry!

Sincerely,

Marty Spies
Marty Spies, Co-Chair

Patricia Fedorka
Patricia Fedorka, Co-Chair

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