

A Pro Woman Approach: Screening for Chlamydia in an Outpatient Community Setting

By

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Abstract

Chlamydia trachomatis is the most common sexually transmitted bacterial infection worldwide (CDC, 2017, Newman et al., 2016) and can lead to a multiplicity of problems for patients, increased burden for clinics and emergency departments, and excessive costs to the healthcare system for treatment and hospital visits. This quality improvement project was developed to augment screening procedures in a nonprofit, community based outpatient clinic. This paper details a comprehensive plan for addressing patient knowledge deficits about chlamydia, examining antecedents to disease acquisition, providing evidence-based education, conveying care and compassion through provision of psychosocial support, and finally, restoring a sense of dignity and worth to patients. Disseminating evidence-based patient education regarding chlamydia and assessment via psychosocial counseling to those most at risk for chlamydia proved to be beneficial as evidenced by patient responses demonstrating advanced comprehension of risk factors. This innovative multidisciplinary approach augments delivery of care and proved invaluable in advancing patient knowledge.

FINAL DNP SCHOLARLY PROJECT**Title Page****Acknowledgements****DNP Project Team Approval Form****Abstract****Table of Contents (including appendices)**

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Chapter I: Introduction

Advanced Nurse Practitioners (APRNs) are at the forefront of a rapidly changing health-care field and are in a unique position to effect change in the lives of their patients and families. Envisioning better outcomes in the community health clinical setting commences at the practice level. Creating solutions to problems is a constant, evolving process that enables the APRN to transform healthcare. This paper will present a practice problem in a nonprofit and gynecologic outpatient community based clinic and outline a viable solution with scientific underpinnings and the application of core competencies for the APRN while utilizing an interprofessional approach (AACN, 2006).

In the community based health clinic, the question of how to address the high rate of patients presenting with sexually transmitted infections (STI's), but specifically, Chlamydia trachomatis (chlamydia), is a challenging one due to the volume of cases. Because chlamydia infection presents a detriment to patient health, the objective to diligently assist patients being screened for infection has great merit.

Conversations surrounding STI's and sexual health are challenging for patients due to the delicate nature of the topic. Patients experience shame, denial, self judgment, anger, and embarrassment with suspicion of, or diagnosis with, chlamydia. Further, patients must then have forthcoming dialogues with partners after diagnosis which places strain on relationships. Those who opt to conceal the diagnosis from partners experience guilt and more interpersonal conflict. The infectious process not only impacts the physical body but emotional and spiritual health as well. This project is designed to shed light on chlamydia, its transmission, risk factors, course, and sequelae in order to avert frustration, extremes, and imprudence in decision making for women.

Through the proposed quality improvement measures, it was hoped that modification of screening procedures with inclusion of enhanced patient education would naturally contribute to a reduction in adverse effects that infection has on patients overall. Another hoped upon outcome of the project was that, by contributing to patient welfare with the added elements of education and counseling to clinical practice, there would be an increase in patient uptake in screening and enhanced conversations with patients.

Female patients receiving the screening tool and counseling were provided with an opportunity for mindful reflection on their individual holistic health and sense of well being. It was hoped that the provider and patient interface could have more quality injected into the visit so that the patient could examine her safety, personal relationships, and emotional health more purposefully.

Through implementation of the interventions in this program, practitioners found many positive outcomes in working with patients being screened for STI's. Ultimately, the financial burden for patients and the healthcare system can be impacted as a result of a reduction in community chlamydial infection rates through a project such as this. In effect, downstream consequences will change as patient knowledge, patient behaviors, and patient decisions change. Furthermore, restoration of dignity is possible on an individual basis through the foundation this type of a program provides.

Background and Significance

Chlamydia is one of the most widespread of infections that are transmitted sexually in the United States (CDC, 2017). In its 2015 Surveillance Report, the Centers for Disease Control and Prevention (CDC) reported 1,526,658 cases of chlamydia infections in the United States and Dis-

district of Columbia. This figure represents an increase in infections of 5.5% from the previous reporting year. Globally, chlamydia has far reaching implications and is the most common sexually transmitted disease worldwide (Newman, et al., 2016).

Subjectively, women experience pelvic pain, vaginal discomfort, odor, discharge and symptoms of dysuria and pyuria. Complications of untreated chlamydia for women include pelvic inflammatory disease (PID), infertility, abdominal pain, chronic pelvic pain, ectopic pregnancy, and threatened and/or spontaneous abortion (Rekart et al., 2013). Additionally, other associated complications from chlamydia include cervicitis, urethral syndrome, urethritis, oophoritis, parametritis, peritonitis, salpingitis and other inflammatory disease of female pelvic organs and uterus; neonates can experience a deadly form of pneumonitis or conjunctivitis (Rekart, et al., 2013; Youngkin, Davis, Schadewald & Juve, 2013).

Social stigma is a concept linked to sexually transmitted infections further still; many women and young girls have difficulty being forthcoming during the clinical interview or being rigorously honest with health matters of such an intimate nature (Theunissen et al., 2015). Discussions relative to chlamydia testing and education might be avoided by patients or even by medical staff for these reasons. As well, some providers could find it difficult to broach the topic of sexually transmitted infections, especially when the patient is of the opposite sex. Lastly, a general knowledge deficit on the part of patients in relation to risk factors for chlamydia, transmission modes, and the disease itself plays a part in its being overlooked in settings outside of clinics dedicated to sexually transmitted disease testing and treatment (E. Rubio, personal communication, February 22, 2019).

Historically, the state of Arizona has higher than average high school dropout rates compared to the nation (NCES, 2018). Of the patients who come to the chosen setting and are immigrants from Mexico, which is close to 30%, there is an average education level below high school and at around sixth or ninth grade (E. Rubio, personal communication, February 22, 2019). It is imperative that providers are equipped to cater education to patients from diverse backgrounds and educational levels.

Rates of chlamydia cases in the state of Arizona and in Maricopa County for the Phoenix, Arizona area provide evidence which supports the significance of this disease. Of four aspects of chlamydia examined on the state level, Arizona rates continue to climb compared to other states, Arizona has higher rates than other states in the United States, and women in Arizona have persistently higher rates of chlamydia reported than men when compared to other states (AZDHS, 2018).

The total new cases of chlamydia for Maricopa County has risen dramatically by 104% since 2004 (Maricopa County AZ, 2018). Acquisition of chlamydia and HPV, the two more common STIs, gives way to other STIs and places the patient at risk for gonorrhea, HIV, syphilis and herpes infections as well. In 2016, cases of chlamydia, gonorrhea, and syphilis were all above the four year average for the time preceding the report (Maricopa County AZ, 2018). This represents a growing trend.

In summary, it is necessary to consider that the health of a population and community is defined by the health of individuals both physically, and certainly, emotionally. This project is an ideal way to facilitate introspection for individual patients in the healthcare setting and address both of these concerns.

Needs Assessment

Patients do not always experience symptoms of chlamydia (LeFevre, 2014) which leads to screening, diagnosis, treatment, and reporting challenges for patients, healthcare providers, and statisticians and lends more utility to this project. The United States Preventive Services Task Force recommends chlamydia screening for all pregnant women, for females aged 24 years or younger who are sexually active, and for older women who are at increased risk for infection (USPTF, 2018; LeFevre, 2014). Pregnant patients experience added strain when compared to non-pregnant patients due to the potential for improper or ectopic placement of pregnancy due to fibrous or scar tissue that replaces normal tissue after infection from chlamydia. There is also concern for the wellbeing of the unborn child. Screening efforts must be thorough and address the specific needs, questions, and knowledge deficit each individual patient might present. Empirical data which suggests that some patients have no symptoms in the presence of chlamydia infection, as mentioned, made this project more vital (O'Connell & Ferone, 2016).

A concept map tool (Moran, Burson & Conrad, 2017) was utilized to assess the need for this type of program in the organization selected (See Appendix A). The concept map assisted the doctoral student in organizing information and demonstrating the complexities needing to be considered when formulating a solution. Moran, Burson and Conrad posit that health is not just prevention or lack of disease (2017). This concept provided the impetus for the Pro-Woman Approach project. To illustrate this, one must be familiar with antecedents and other factors apart from practicing preventive measures only, taking vaccines, or undergoing screening tests, for example. Patient antecedents for chlamydia acquisition include poor/impulsive decision making with or without drug or alcohol abuse, an unhealthy or dysfunctional intimate partner relation-

ship or relationships, domestic violence, sex industry work in which there is disparity in power, lack of knowledge about partner and his history, lack of knowledge about partner STI status, and knowledge deficit related to chlamydia (See Appendix A).

There are three main categories of antecedents to the problem. First, impaired, uninformed, poor, or impulsive decision making plays an enormous role in the perpetuation of sexually transmitted diseases. Second, involvement in an unhealthy relationship that involves dishonesty, infidelity, or abuse plays a critical factor in disease transmission. Research demonstrates a link between unhealthy, intimate relationships or intimate partner violence and acquisition of sexually transmitted diseases (Guttmacher Institute, 2016). Patients who are unaware of a partner's positive disease status also play a role in the spread of disease. Lastly, little to no evidence based education on chlamydia impacts infection acquisition.

The critical attributes of the problem, as seen in Appendix A, include invasion by bacterial agent, characteristic symptoms and untoward sequelae as evidenced by genitourinary and gynecologic manifestations and social stigmatization (Theunissen et al., 2015). Consequences include long term chronic issues and potentially deadly ectopic pregnancy as mentioned, neonatal morbidity (Ditkowsky, Shah, Hammerschlag, Kohlhoff & Smith-Norowitz, 2017) and emotional repercussions. For the purposes of this project it was determined that health information should be mindfully relayed to patients in the form of education combined with counsel. The need was strong for a project that would address potential or present issues surrounding chlamydia and lost integrity and dignity for women.

The Strengths, Weaknesses, Opportunities and Threats (SWOT) Analysis (See Appendix B) was conducted to provide clarification for this quality improvement project (Moran, Burton &

Conrad, 2017). Internal and external forces influencing the project, both positively and negatively, were evaluated in order to formulate a strategy and plan of action.

One strength of this project was the particular site chosen, where patients who specifically seek STI testing are seen. The premise of this project strongly aligns with the mission statement at the site and the Medical Director, Executive Director, Board of Directors, and staff were open and eager for quality improvement for this patient population. There was great opportunity to see a large number of patients who would depart with a wealth of knowledge and psychosocial support in addition to routine medical testing and care for STIs. Moving forward, the project can be carried into the future with ease in implementation.

In terms of threats, the site is a small, non-profit setting with staffing and financial challenges (See Appendix B). On the other hand, it was important to consider that quality outcomes justified resources that were expended in this scenario. Another important cost consideration was that there were material resources within the facility that were readily on hand for utilization in this program. These materials had never been taken out of the boxes when they were purchased and were not being utilized. The utilization of these materials helped offset cost of the project. Another weakness of this project was that patients might not always be forthcoming with information due to the nature of the topic, but a built in mechanism to counteract this obstacle was formulated and will be explored further within the project itself and its methodology.

Problem Statement

Chlamydia is a problem because infection with this microorganism compromises sexual, reproductive, and emotional health for women. Individual patients are negatively impacted by strain the infection puts on physical and emotional health, as well as by its effects to the geni-

tourinary and reproductive systems. For the broader community, chlamydia negatively impacts communities in terms of the cost for treating infection and complications from infection that both individuals and taxpayers must bear.

Project Purpose

The Pro Woman Approach project was found to augment practice through actively integrating patients being seen for clinical visits into the counseling room for a brief psychosocial review via counseling services following the clinical visit. At that interface, the counselor screened for substance or alcohol use and abuse, other addictions, domestic violence, sex trafficking, work in the sex industry, or other psychosocial needs the patient may have had. A brief survey followed which helped patients assess personal knowledge of risk factors for, and information about, chlamydia. This post visit survey was compared to the pre visit survey at the end of the project. Project guidelines and processes were clearly articulated for ease of use for clinic staff, with focus and objectives clearly identified (Moran, Burson & Conrad, 2017).

There were two main objectives. The first objective was to expand patient knowledge about chlamydia via reception of tangible educational brochures and verbal instruction at the end of a scheduled or walk-in gynecologic related clinic visit at the urban community outpatient clinic. It was hoped that 90% of patient responses on the post visit survey would be reflective of an expansion of knowledge when compared to the pre visit survey.

The second objective was to provide opportunity for a brief psychosocial review and needs assessment with every gynecologic related visit as well. It was hoped that 90% of patient responses on the post survey would be reflective of a change after the psychosocial assessment.

This project was designed to restore dignity and worth to women affected by chlamydia infection, or suspicion of chlamydia infection. The overall purpose of this project was to improve quality of care in clinical practice via enhanced provision of patient education and an opportunity for individual mindful reflection involving decisions pertaining to sexual activity.

Clinical Question

The question that was to be answered was, "How do patient perceptions of risk of chlamydia trachomatis acquisition, before and after education and psychosocial assessment survey, differ for adult female patients in an outpatient community clinic?"

Congruence with Organizational Strategic Plan

This project demonstrated perfect alignment and congruence with the organizational strategic plan at the selected site. Specifically, and in its mission statement, Life Choices Women's Clinics (S. Gorslin, permission to use name, September 10, 2018) asserts,

Life Choices Women's Clinic is dedicated to improving the lives of women and their families by providing medical care, counseling and education that affirm the dignity of life of the mother and child. Our medical clinics offer a wide variety of medical services related to pregnancy and other areas of women's health delivered in an atmosphere of care and respect (Life Choices Women's Clinic, 2018).

To that end, this was an ideal place for the project proposed. An added bonus was that the project enhanced clinic staff capacity to follow through on the organizational mission deliverables that Life Choices Women's Clinic hopes to attain via medical care, counseling, and education mentioned. Too, clinic staff had the opportunity to address the ongoing public health crisis that chlamydia and STIs present.

In keeping with the clinic's singleness of purpose to elevate the lives of women and children (Life Choices Women's Clinic, 2018), the enhanced counseling and education permitted

also the active reach of introspection and reflection needed for one to achieve a healthy state and affirm the dignity of one's life. Thankfully, this particular clinic setting was optimal for the structural design and function of the Pro-Woman Approach.

Synthesis of Evidence

Literature review employed the use of CINAHL, PubMed, Google Scholar, the Cochrane Library and NCBI databases to scan for information pertaining to this topic. Manual searches were done as well by utilizing textbook material. The search was limited to research and material from within the past five years. Keywords such as chlamydia, sexually transmitted infections, PID, prevalence, incidence, risk factors, burden, and global incidence were utilized in the search. A total of 20 articles were retrieved. Articles were included that were pertinent to the specific focus of the study. Many articles were excluded as they related to men, were outdated, or had a heavy focus on evidence based polymerase chain reaction (PCR) DNA amplified testing versus other types of sampling and testing. Recommendations from respected authorities such as the Centers for Disease Control and Prevention and the United States Preventive Task Force were sought in order to provide a foundational base from which to work and familiarization with current guidelines for practice.

There is an abundance of articles with a plethora of information about the significance of chlamydia infection. A rapid critical appraisal (Mazurek Melnyk & Fineout-Overholt, 2015) was useful for identifying pertinent, supportive information. In addition, the literature review and rapid critical appraisal presented in the Evidence Evaluation Table (See Appendix C) provided the backdrop for the plan, affirmed the value of this project, and facilitated a synthesis of the evidence.

It is clear that the burden on lives from damage suffered and costs to individuals and taxpayers is large as it relates to outpatient visits, inpatient hospitalizations, reinfection, sexual health, PID, infertility, infant mortality, and treatment (Aghaizu et al., 2014; Ditekowsky et al., 2017; Low et al., 2016; Malhotra et al., 2014; O'Connell & Ferone, 2016; Price et al., 2013; Rekart et al., 2013). Long term sequelae and cost from chlamydia necessitating emergency department visit and hospitalizations is quite unfortunate and can be averted. Addressing individual health concerns on the front end of the problem and in the community clinic such as in the women's urban outpatient setting, is a solution.

Chronic, post infection pelvic pain and discomfort from untreated infection can be prevented with strong screening methods. Post infection diagnoses for complications for women listed by Rekart et al. (2017) are serious and affect various delicate organs composing the reproductive system and they are identified as salpingitis, oophoritis, parametritis, pelvic peritonitis, and other inflammatory diseases of female pelvic organs and uterus.

Undiagnosed chlamydial infection can lead to a host of issues for mother and child. Neonatal issues caused by the chlamydia trachomatis infectious agent pose diagnostic and treatment challenges for clinicians, especially if the mother is asymptomatic (CDC, 2019). Children born to a patient with untreated chlamydial infection may suffer from neonatal chlamydial conjunctivitis or a potentially fatal respiratory tract or nasopharyngeal infection, low birth weight, prematurity, or they can even be stillborn (Warr et al., 2019). Screening efforts and regular testing programs can help to identify and treat infections in patients before complications develop for them or their unborn children.

Numerous efforts have been made to document sequelae but also averted morbidity for women and their newborns after prompt diagnosis and treatment of chlamydia (Patel et al., 2010; Park et al., 2017; Ditkowsky et al., 2017; Thomas et al., 2017; Warr et al., 2018). Resultant potentially fatal ectopic pregnancy in post pelvic inflammatory disease states is a matter of grave concern and challenge for providers not just in diagnosis but treatment. To begin with, successfully diagnosing ectopic pregnancy itself presents a conundrum for many skilled obstetric and emergency room practitioners. Treatment is not just emergent but costly as it can also in many cases necessitate surgery and hospitalization. Alternatively, a patient might require hospitalization for management and observation of medication administration in ectopic pregnancy resolution. It is clear that undetected ectopic pregnancy leads to horrendous adverse outcomes (ACOG, 2018).

Early screening proves invaluable to averting problems for patients, but it is the quality of the program that is key. Dunville, Peterson, Liddon, Roach and Coleman (2018) delineate an effective program implemented in a school setting for screening at risk youth. More beneficial programs, such as the Dunville et al. (2018) study detailed, are needed. A successful screening approach that has utility but is engaging as well is an added benefit for patients (Denison et al., 2018; Martin-Smith et al., 2018; McKee et al., 2018; Ricketts et al., 2016; Woodall et al., 2016)). In many instances, researchers are looking to social media for dissemination of sexual health information to enhance screening capabilities (Gabarron & Wynn, 2016). Of note, it was demonstrated that well coordinated screening efforts in general practice do not increase burden for healthcare staff members in one particular study (Ricketts et al., 2016)

In an interesting compilation of data, Gravningen, Simonsen, Furberg and Wilsgaard (2013) annotate the gap between self-perceived risk on the part of patients, testing, and screening and chlamydia positivity. For this reason as well as others, the need was identified to commence the Pro-Woman Project. Erroneous self perceptions about risk were uncovered in this project and pre-clinic visit assessment was measured against post-clinic changes to assist the patient in uncovering these truths.

Kang et al. (2014) speak to risk for exposure to chlamydia as it relates to substance use and abuse. This is another important area in need of exploration for and by patients. Patients should be equipped with personal inventory taking skills regarding substance and alcohol abuse, which are especially useful for assessing risk for STIs. Those who deny a problem with illicit drug use and alcohol abuse will at least be provided an opportunity to examine how these activities might play a part in sexual decision making and engagement.

Ford, Barnes, Rompalo and Hook (2013) concluded that there is a need for more thorough appraisal of sexual health and more comfortable conversations for healthcare providers in an effort to assist patients in achieving sexual health. This project was designed to do just that. It was an excellent opportunity to open the dialogue between providers and patients.

Lastly, patients who have had past chlamydia and STI infections should be assessed for whether past infections have been treated completely (Geisler et al., 2015). To that end, history taking in the project implementation phase explored the incidence of past infection with chlamydia and treatment regimen prescribed and whether the patient was compliant. As well, clinic staff assessed patients for test of cure application for post treatment evaluation, which is recommend-

ed between 30 days and 3 months post treatment of infection (Mayo Clinic, 2019), when the patient had a history of sexually transmitted infection by chlamydia.

The findings mentioned directly related to the PICOT question for the Pro-Woman Approach project. In the proposed project, added education especially about what infection can cost the patient in terms of discomfort, infertility, or adverse effects to a newborn, was incorporated into the clinic patient visit. This was another element that added value and set the project apart from the screening methods employed prior to the project's implementation. In the end, patients gained an improved understanding of chlamydia's ill effects, and will hopefully be more equipped to mindfully approach sexual decisions in the future.

Theoretical Framework

The Interprofessional Education Collaborative's (IPEC) theoretical framework is that upon which the union of professionals from varying disciplines promotes health, and in this case, and also integrity for patients as proposed (IPEC, 2016). In addition to the Advanced Practice Nurse, the collaborating professions administrative services staff, lay counseling clinic staff, medical assistants, and registered nurses. Ancillary front office staff were critical to maintaining an even workflow of patients from the outset upon arrival to the clinic and during the clinical visit as patients transitioned from the exam room to the counseling room for the psychosocial intervention.

Combined interdisciplinary values, roles, competencies, communication, and teamwork were critical in guiding the process (IPEC, 2016; Joel, 2017). Improving patient experiences while honoring cultural sensitivity when discussing intimate matters with patients was a highlight of this project and the multidisciplinary approach was fantastically ideal. Reducing the bur-

den of disease became a truly engaging endeavor toward which to work for patients, families, and communities via application of the IPEC theoretical framework.

The IPEC standards facilitate interactive work between those in different professions (2016). There is a three part objective that involves improvement of the clinical experience of a medical visit for patients, improving patient health outcomes, and reduction of healthcare per capita cost. This is accomplished by following core competencies that encompass ethics, proper roles and responsibilities, communication between professionals, and teamwork.

Relative to values and ethics, having the sub-competencies guiding the project ensured that providers were able to work in a culturally diverse setting and honor differences which were seen in patients but also in others on the team. Teammates became more mindful of both staff and patient readiness, educational level, and preferences.

Relative to roles and responsibilities, one sub-competency that guided the project was respect for the part each team member played (IPEC, 2016; Joel, 2017; Mazurek Melnyk & Finneout-Overholt, 2015). The role of complementarity in the Pro Woman Approach set the stage for improving clinical practice but also perhaps for public health policy in the future should the program expand. Those involved in the team's work were able to work well in a concerted effort that was both illuminative and unitive for the patient and for team members.

The Essentials of Doctoral Education for Advanced Nursing Practice (AACN, 2016) call for increased interprofessional partnerships, communication and collaboration in delivery of patient centered care. There is a treasure that resides in the interface between a patient and the Advanced Nurse Practitioner and in the interface between the patient and her counselor. It is incum-

bent upon the Advanced Nurse Practitioner to utilize evidence based methodologies and to incorporate partnerships in order to advance and enhance each patient interaction.

Chapter II: Methodology

There were two key assumptions for this project. It was assumed that patients presenting for STI screening had some knowledge about chlamydia and knowledge of risk. It was assumed that patients also desired care that included education as part of their visit and treatment.

Project Design

This doctoral project is a quality improvement endeavour that was designed to augment practice protocols in the area of STI screening. Quality improvement translates to a high standard delivery of care process via an approach that encompasses key elements of patient safety and enhancement while utilizing innovative methods (Harris et al., 2016).

Team members. This project utilized an interprofessional team composed of Nurse Assistants, Registered Nurses, Counselors, and Advanced Practice Nurses. A protocol was developed for the project utilizing input from team members at the chosen project location. Oversight was demonstrated by the DNP Project Team Agreement, which provided evidence of coordination and efficiency by competent and prominent members of the medical community. The doctoral student collaborated with the Team Chairperson and two mentors to guide all phases of the project.

Methodology. The initial phase of the project utilized a concept map (See Appendix A) and collection of retrospective data via the literature search to support the problem. This preliminary information aided the compilation of surveys that were the major focus of the methodology and which were designed to enhance the patient-provider visit. By assessing differences in pre and post visit surveys it was possible to glean differences in patient knowledge of risk of infection.

Setting

The practice setting was two outpatient clinics situated in two inner city neighborhoods in Phoenix, Arizona. Specifically, the clinics are located in the North Phoenix Sunnyslope neighborhood and the West Phoenix 35th Avenue/McDowell area which offers access for patients living in north and east Phoenix and Glendale and south Phoenix. The clinics provide services for young girls and women with ages ranging from 12 to about 75. The average number of patients seen per clinic day, per clinic, is approximately 20-35, and approximately 7,000 patients visit the clinic every year.

Organizational assessment and evaluation revealed there was room for improvement. Clinical staff members reported a collective concern that testing and treatment only does not do enough. There was a large gap that existed between what patients receive from screening programs and disease, as evidenced by upward trends for chlamydia rates. For the clinic where the proposed plan was implemented, this project was an adjunct to the current process of screening, laboratory testing, and prescription writing which staff believed was not sufficient to provide all of what patients might have needed to effect personal change. Staff, management, and stakeholders at the chosen setting were in support of life affirming programs to support the care of women, and this project aligned nicely with objectives of the clinic's mission.

The clinic is a private, nonprofit organization largely funded by private donations. An average of 7,000 patients per year visit one of the three clinics which includes a mobile clinic that provides limited services at universities, health fairs, community events and other public domains. Patients present for testing for sexually transmitted infections, such as chlamydia, gonorrhea, trichomoniasis, HIV, syphilis, herpes simplex, hepatitis, and/or human papilloma virus,

which made the setting chosen an ideal location and one which demonstrated great need. About 50% of all STI related visits at the clinic result in either a diagnosis of, or treatment for an STI. Approximately one-third of patients for whom chlamydia and gonorrhea testing is performed receive positive results for chlamydia (E. Rubio, personal communication, February 22, 2019).

The organizational culture lent itself very well to the project implementation. Indeed, staff members in the past voiced repeated concerns that patients would receive what appeared to be mechanical diagnosis and treatment for STIs prior to implementation of this project. That reflection led them to conclude patients needed more and staff were therefore eager for change. This project was conceptualized to ameliorate those concerns. There was support from front office and ancillary staff including receptionists, medical assistants, nursing assistants, nursing, Advanced Nurse Practitioners and both the Medical and Executive Directors. As a result, key participants were readily in place. As an added benefit, there were not any anticipated staffing issues at the time of implementation.

A final note on the organizational culture is in relation to the gap analysis which included consequences to the particular antecedents which arose from concept mapping. The gap analysis was created at the project site and for the project site, ensuring its applicability to the organization and the organization's applicability to the project (See Appendix B).

Population

The focus population was that of the 12-60 year old female patient being seen at the community outpatient clinic for a gynecologic visit. Patients being seen for menopausal or breast health related visits were excluded. Those who fell in one of or all three categories of antecedents for disease and patients who were sexually active and under the age of 24 for whom screening

was most recommended (CDC, 2017) were included. This group of women benefitted greatly from the Pro-Woman Approach as chlamydia infection is the highest for those in the 15-24 age range (CDC, 2017).

During the clinic visit, staff did not know if patients were participants or not. When a patient decided to participate, there was no difference in care delivered to her. Neither was there a difference in care given to a patient who opted to not participate in the project.

The types of visits represented at this venue were more reflective of patient population needed for the project and easier to obtain as compared to that encountered in other outpatient clinics where the focus is not on women's health. Both the population and inclusion criteria were representative of studies in the literature (LeFevre, 2014).

The recruitment plan was straightforward. All patients meeting the specific criteria were given the optional pre-visit survey with the educational brochure at the beginning of the visit while waiting for the practitioner. At the end of the visit the patient was asked if she would like to answer one question for the post-visit survey, which was voluntary. It was explained that the answer would be anonymously recorded and entered into a locked box should the patient desire to participate.

Tools

Two tools were used to implement this DNP project. The first tool was a pre-visit survey which was administered upon patient's arrival, along with intake paperwork. The second tool, the post-visit survey, was collected along with the first tool and placed in a box maintaining anonymity after use. Both are simple tools developed by the author of this project for this project specifically. Each employ a Likert scale design. The difference between the two is that the first

survey assesses patient knowledge of chlamydia infection and risk for infection. The second survey assessed whether, and to what degree, patient knowledge changed after the visit.

The pre-visit tool was based on risk factors demonstrated in existing literature. There were five questions that assessed for 1) violence in the relationship, 2) work in the sex industry, having multiple or unfaithful partner(s), 3) suspicion of or knowledge of transmission of infection 4) prior infection, and 5) perception/understanding and knowledge of risk; all of which are predisposing factors for disease acquisition (Aghaizu et al., 2014; CDC, 2017; Guttmacher Institute, 2016; Kang et al., 2014; LeFevre, 2014; Malhotra et al, 2014; Price et al., 2013; USPSTF, 2018). Pre-visit tool questions were derived from the review of the literature; the questions were designed to promote personal reflection on specific risk factors for disease that were directly extrapolated from the most current evidence.

The last question in the pre-visit survey asked the patient how she rated herself in terms of being at risk, whether 1) not at all, 2) some, 3) medium, 4) high, or 5) very high risk. After her visit with education and brief psychosocial assessment, the post-visit evaluation assessed whether that rating changed as a result. The correlation between the post-visit question and the fifth question on the pre-visit survey were reflective of the patient having conducted a true re-assessment of risk. In other words, after her visit with education and brief psychosocial assessment, the post-visit evaluation determined that the patient's perception of her risk had changed as a result.

Project Plan

Selection of patients. A convenience-sampling technique was employed for recruitment of patients. The rationale for this was that the sensitive nature of the visits required the patients to give verbal consent to be participants. Those who were uncomfortable had the option to exclude themselves. The option for participation involved giving consent orally and anonymously. All patients who met criteria received the pre-visit survey for personal use along with the educational brochure whether or not they opted for participation.

Project steps. The step by step project algorithm with intervention implementation was delineated clearly in order to provide existing and new staff with education. The algorithm was provided at a general staff meeting, or individually for those who could not attend. The email communications of this plan were sent prior to the educational meeting along with a Save the Date Reminder (See Appendix D).

The in-service education meeting accommodated inclusion of all staff members and was incorporated into the regular clinic staff meeting, which was mandatory for all staff. Two weeks prior to that meeting, messaging was sent to all staff via inner office electronic messaging to remind staff to save the date. A reminder was sent to staff a week before the meeting. Two weeks and one week before the staff meeting there were copies of these emails in the two clinic common staff areas advertising the plan and a promise of a takeaway, chocolate, for those who attended the meeting (See Appendix D).

Staff received the Visit Algorithm handout (See Appendix E), the Pre-and Post-Visit Surveys (See Appendix F), and the evidence based educational brochure (See Appendix G) during

the staff meeting to prepare for the project. Questions were answered and teaching was completed with staff to ensure all understood the patient workflow.

The staff quality improvement project Staff Educational Meeting did not last more than 20 minutes, which was time usually set aside for special speakers or announcements. There was therefore no extra cost associated.

At the meeting, the explanation of the initial phase of the actual work with patients was given. First patients would go through routine completion of the intake form with patient health history upon arrival, as is customary in the office. They would also receive the first survey and after completion of both, the evidence-based STI educational brochure would be given to the patient. The waiting period prior to the actual clinic visit was ideal for the patient to peruse the educational brochure. It was explained to staff that the Pre-Visit Survey invited mindful, reflective time to evaluate psychosocial aspects impacting relationship and sexual activity related choices or demands from others. The brochure which provided evidence-based medical facts on chlamydia was reviewed with staff in or to allow them to familiarize themselves with it.

The explanation of the second phase of the project involved the patient's being seen for the medical visit as the visits usually transpired in the clinic. During the clinical interview and patient education time before and after the exam, the medical assistants, nurse assistants, nurses, and Advanced Nurse Practitioners engaged the patient in ongoing patient education relative to STI transmission, focusing on information in the brochure.

Following the routine clinic visit, the final phase transitioned the patient into the counseling room with a staff counselor for a brief psychosocial assessment and review of safety and/or other concerns. The psychosocial assessment was conducted per the counselor's usual protocol

and included assessment of safety, presence of violence, and/or involvement with human or sex trafficking.

It was then explained to staff that the counselor would be asking the patient whether she would like to submit her answers for the project to the clinic. This would occur at the end of the patient visit with the counselor. The Post-Visit Survey was to be given to the patient at that point. If the patient consented, her answers to the surveys would be marked anonymously and placed in a locked receptacle. The entire process was to take no longer than 20-30 minutes in actual implementation.

Rationale for interventions. These interventions were specifically chosen as staff had repeatedly expressed concern that not enough was being done to further educate patients and provide preventive health care for them (S. Gorslin, personal communication, August 8, 2018). These specific tools for the intervention were chosen, as they were, in order to promote facility of use and avoidance of high register language that might have been overwhelming for patients.

The proposed project information disseminated to patients by survey and educational brochure was meant to open a dialogue for the patient and staff during the medical visit. It was anticipated that this would invite questions from the patient and further exploration into variables or modifiable areas which the patient could reflect upon and change if necessary.

SMART Objectives. The hope was to impart new knowledge to patients and ensure well being and safety; the Post-Visit Survey assessed whether that had taken place and by how much in fulfillment of the SMART Objectives. The question for the patient on Post-Visit Survey was about whether knowledge surrounding transmission, risk factors, symptoms, and/or sequelae of *Chlamydia trachomatis* infection had changed and if so, how it had increased. In other words, if

the patient answered the question with a response of “1,” they have gained no new knowledge. If the patient answered with a “2,” “3,” “4,” or “5,” it was reflective of knowledge gained respectively from “none,” “some,” “medium,” “high,” to “very high.” Success was measured by evidence that patient responses were above a Level 1 on the Post-Visit Survey as Level 1 indicated no change. The outcome to be measured was how much the patient’s knowledge had increased or changed, and if it had changed at all. It was hoped that at least 90% of patients would rate above a Level 1 to indicate at least some change had been effected and the design of the surveys aligned nicely with the SMART objective assay.

Data collection procedure. The project administrators who were trained at the staff meeting included receptionists, medical assistants, nursing assistants and registered nurses who all perform front and back office duties. The front desk administrator of the day administered the Pre-Visit Survey at the time that the clinic Intake Form was completed. All staff were prepared to answer questions or elaborate on any information in the evidence-based brochure the patient might have had.

The Nurse Manager collected the forms from the locked box at the end of the day in the office conducting the surveys. The Nurse Manager was in charge of collection and she entered all data into an Excel spreadsheet manually. It was reiterated to staff and patients that only the number corresponding to the patient’s responses was entered into the Excel spreadsheet with no patient identifying information in order to assure patients of privacy.

This simple method of in-house data collection ensured ease of data acquisition and input. Clinic staff reported in the planning phases that this particular patient population is often lost to followup contact and it was uncertain as to whether they would be able to, or make the time

to, access an online survey following their visit. This was one consideration for the in-house post survey administration which made for ease in collection of surveys. All surveys that were submitted were shredded once data entry was complete.

The data collection and entry processes were very straightforward for those assisting in this phase of the project. To reduce risk that incorrect numbers were entered, surveys were sorted according to numbered response and counted and then tallied in the Excel spreadsheet to ensure all were entered accurately and that the quantity in each numbered response category was precise. Should the Nurse Manager not have been at work on a scheduled day, it was planned that the clinic Patient Care Director would set aside the survey materials for the Nurse Manager in a secure location, however, this was never necessary.

Evaluation. The plan to evaluate ongoing flow of the project necessitated the ongoing attendance of the Nurse Manager to assess problems or obstacles with implementation. The Nurse Manager was readily available to staff for concerns by phone as well. The doctoral student made arrangements to evaluate needs for extra surveys and brochures in both English and Spanish and ensure a sufficient supply of both. This alleviated pressure for staff.

The plan to evaluate the data involved the generation of a report after every clinic day following data entry at the clinic. This report reflected the total number of patients seen for qualifying visits, the total number of patients participating in the project, and responses on the pre-visit survey correlating to responses on the post-visit survey. The doctoral student collected data and ensured maintenance of data on a secure office laptop with data saved to secure backup disc daily. Data reports were reviewed daily as to completion of data entry, number of patients seen, number of participants, responses, and trends.

Sustainability. Ongoing measures to maintain success gained required initial Stakeholder recognition of the project's merit and ongoing oversight by the Nurse Manager. It also required that a designee be appointed to inventory and stock brochures and survey handouts. Since staff loyalty and ongoing use of surveys was positively impacted, the staff will now utilize the tools and have planned to collectively revisit the project and discuss impediments to ongoing implementation. In the future should it be discovered that the project is no longer effecting a change in patient perceptions over time, such as might be the case with patients with recurring visits, staff can decide to change the educational brochure as needed.

This type of a project is ideal for future application and utilization. The clinic is arranged to accommodate the project makeup and there is not much involved to continue the plan. Already, the clinic purchases a fair amount of educational brochures each year, many of which patients cannot access or of which are not used by providers for many reasons. There was also an abundance of other types of STI related educational brochures that are donated to the clinic using benevolent resources and they are not being utilized for these visit types. These extra brochures speak to other topics such as condom use or other specific STIs. At some point, the brochure given could be changed if staff opted for that in the future. Of course, there would need to be assurance that the information in the next brochure used is current and evidence-based if staff opts to change the brochure.

Prior to this project, there was a system in place to provide prepared educational packets to pregnant patients only. It was actually a welcomed gesture for staff to be able to have something to offer patients in the STI setting as well. In fact, one of the nursing assistants had already

spoken of designating a space in the front desk areas for educational brochures and surveys prior to commencement of the intervention.

The Nurse Manager orders brochures for the pregnancy information packets and she also orders other medical educational brochures when needed. As stated, the large stock in the offices is not being dispersed to patients and will be readily put to use to continue this project. Since a system has been in place for ordering brochures with pregnancy information already, this system can accommodate sustaining the Pro-Woman Approach effort.

There is a plan to prevent the new project information being overlooked or underutilized. The Nurse Manager and Medical Director requested that the Pro Woman Approach plan be enacted as clinic policy. The Medical Director and other stakeholders are excitedly anticipating this new change.

One unique aspect of the project is that the surveys can be retained by the patient for self-examination and reflection now that the initial quality improvement effort is complete and measurement of efficacy will no longer be necessary. Ensuring adequate copies of surveys and brochures is all that would be needed in the future. Staff might decide to revisit the project plan once a year to ensure the questions are changed for those patients who visit the clinics more often and to update with any new evidence. The goals for patients to verbalize a change in knowledge and understanding of personal, relational, and/or sexual health as a result of care delivered can continue easily.

New staff will be trained in the process by the Nurse Manager or other designee. The algorithm is designed for ease of use, as were the survey tools. Staff is eager to engage and have

been requesting a change in current delivery of care procedures for many years. This is an ideal atmosphere for staff and for patients. When one ceases to learn, one ceases to grow.

Data Analysis

The data collection undertaking and data entry process was unambiguous; there was no conflict with inter-rater agreement for data entry. There was no need for the use of an on site statistical consultant due to the lack of IRB institution. Data entry required one person and the procedure was quite straightforward.

Inferences made were drawn from quantitative data. The analysis of the quality improvement project outcomes was benevolently completed by Mr. Wilfred Drennen Whiteside, MS, and Ms. Mary Graettinger MBA, following both process and outcomes reviews. Missing information or problems with implementation and data collection were to be documented had there been any, but there were none. There was evidence of findings and calculations derived depicted via table and diagram format. These tables and diagrams included the number of patients seen, number of participants, responses, and trends.

Tool data analysis and data representation were arrived at using simple paired two tailed *t-tests*. Process improvement evaluation and information extrapolation gave insight into further investigation and implications for nursing, research, policy, and future practice.

Further support for sustainability was concluded after there was found to be a statistical significance between pre and post visit evaluations. It was projected that the project would influence policy in the clinics and that has already taken place. Since there was a statistical difference at the end of analysis, it is not necessary that the pilot project itself be modified.

Institutional Review Board and/or Ethical Issues

There were many ethical considerations for this project. First and foremost, a patient must be protected from harm. Protection from harm for patients involves respect, self-determination, and altruism (Grace, 2014). A diligent discussion and consideration of these aspects of care prefaced this project at the staff meeting prior to the project. At the time of that discussion, all staff were invited to review the proposed plan and identify any weaknesses or vulnerabilities especially in relation to working with patients.

Ethical Issues. All patients were free to either accept or decline participation through verbal informed consent. It was incumbent upon all administrators in this project that each patient receive informed consent for participation. No identifying information was collected. There was no designated space for or request for patient identifying information on the surveys. Confidentiality was maintained in the usual fashion. Surveys were deposited into locked boxes at the end of each visit.

The concept of social justice weighed heavily on the premise of this project (Grace, 2014). The delicate nature of the topic posed a risk for patients to potentially feel more vulnerable as they might be already at risk for sexually transmitted infection by involvement in the pornography industry, prostitution industry, and/or sex trafficking industry. Sexual health is an important aspect of overall health, and social justice calls for action to help patients but also restraint in action when patients exhibit reticence. To that end, patient welfare was safeguarded at all times.

Finally, there were no adverse reactions that could be foreseen, and neither that transpired, from this type of undertaking. Nevertheless and out of duty, measures were taken to en-

sure review by the appropriate Board that oversees such activity at the clinic sites. Clinic activities and services are overseen by the Board of Directors which consists of volunteer community members who serve as president, vice president, secretary, members at large, and treasurer. Both the Medical Director and Nurse Manager sit on this Board as well.

Institutional Review Board. This project is considered a quality improvement initiative and was not subject to the usual rigors by an Institutional Review Board (IRB) for proper research. Still, the approval process required necessary endorsement by the clinic Medical Director, Executive Director, and Board of Directors. The site is a small, private, nonprofit organization that does not have an official IRB; the Medical Director provided site authorization for the project. Formal approval for the DNP student to proceed was petitioned via application and approval (See Appendix H) to the Bradley University Committee of Use of Human Subjects in Research (CUSHR) which was granted July 15, 2019 after approval was received from the clinic Medical Director (See Appendix I).

Chapter III: Organizational Assessment and Cost Effective Analysis

Organizational Assessment

As previously mentioned, there was staff and stakeholder loyalty to patients, patient safety, and enhancing current practices at the project site. The display of readiness for change propelled the project. During a staff meeting, multiple staff provided feedback and verbal input and via written suggestions after the meeting. The Medical Director had expressed enthusiasm and a desire for improvement in care over some time and suggestions for ease of use of the tools had been made.

From the analysis of strengths, weaknesses, opportunities, and threats (Appendix B), two factors were identified as the biggest potential risks. It was possible patients would not feel comfortable sharing at the time of the visit. Having a counselor meet with patients following medical care was an ideal way to address this concern. A second threat was that funding is limited for most projects in the clinic. As it turns out the educational brochures were available and the cost of staff time was already incorporated into a regular clinic day. As part of the usual challenges with the nonprofit setting, staffing issues are always a concern but the clinic had hired new staff early in 2019 that enhanced and facilitated the project's design.

Another key element of threat in the SWOT analysis was the absence of information and resources regarding sustaining projects such as this in the nonprofit setting. There are few resources for private, nonprofit venues that do not utilize government funds for their STI related medical or educational programs. Fortunately, there was stakeholder buy-in and as the clinic already has an educational program in place for pregnant patients, the model was not too difficult to adhere to and follow.

Along with educational strengths of the clinic in another realm, the organizational plan promoted perfect alignment with the clinic Mission Statement that speaks to engendering healthy life choices for women. Fortunately, there was great stakeholder buy-in.

Cost Factors

Cost considerations were minimal. What was incorporated into standard medical visits were brochures that were already on hand but were not being utilized. Fortunately the brochures were up to date in evidence base. The time involved for patients was negligible because already patients have a wait time calculated into their visits. This time was perfect for them to peruse the information given and write any questions they may have. All staff were poised to fill the positions that were needed. Paper costs and printing costs for the survey tools were minimal and time for data entry were mostly in kind services that did not require further procurement of financial resources.

The budgetary needs table identified costs involved for technology, personnel, and paper products (See Appendix J). If anything, cost avoidance was assured, at least for patients who can avoid future visits for STI testing and treatment as a result of change effected after this program's implementation. One final benefit of this type of program was a sense of value and dignity that was imparted in the act of one human soul touching another in a caring and kind way. There is no price tag that can placed upon the lives affected by compassionate staff who equip patients with knowledge and give them back a sense of worth.

Chapter IV: Results

Analysis of Implementation Process

Initial steps and evolution. The implementation component for this project was fruitful and enlightening for both patients and staff as well. Prior to the initial steps of the intervention, staff meetings ensured staff were educated on the purpose of the project and on specifics of the implementation process. Staff were exceptionally receptive to the project's inception, formulation, and utilization. During implementation of the intervention, staff members viewed the project as a beneficial model for engaging patients on a deeper level during the brief office visit as the project evolved. At the end of project implementation, staff continued to view the intervention as necessary for future clinical practice.

The unfolding and organic progression of the project demonstrated a process that adhered closely to the timeline and algorithm as prepared in the planning stages (See Appendix A). Approval for the Quality Improvement project through the Committee on the Use of Human Subjects in Research (CUHSR) at Bradley University was expedient, likely due to the absence of risk to patients in contrast to proper research with human subjects. Too, the simplicity of the intervention being utilized lent itself to a very straightforward process with no encumbrances. Approval to commence implementation was granted July 15, 2019. There is no Institutional Review Board at the project site which was utilized for the project. As a result, permission to use the project site was requested and then secured from the Medical Director, an individual who as an aside, had high personal interest and investment in the project.

The intervention was smoothly incorporated into clinic visits and easily applied. Through a high volume of readily available patients presenting for patient visits, acquisition of subjects

was easily attained. Of the fifty patients who participated, 100% agreed to share their anonymous and confidential surveys. As planned, patients were given the pre-survey form at the time of patient registration and completion of the clinic intake form. Care was taken to ensure those to whom surveys were given fit the criteria previously outlined. During the individual patient visit, pamphlets and verbal education were disseminated along with a concurrent and brief psychosocial assessment. The post survey was administered while the patient was still in the counseling room, allowing for private and quiet time of reflection for the patient.

Modifications. Staff reported ease of application as a result of adequate training provided at staff meetings. All staff had the benefit of added individual prior experience working with the specific patient population which facilitated dialogue on this very sensitive topic. Although not all staff were available to meet on a group basis for training, individual staff education was given when necessary. It was necessary to have medical staff perform the psychosocial assessment from a medical standpoint as there was not a professional counselor on staff. The only other modification made was the addition of ongoing education to staff when questions arose or challenges were met with patients, such as an inability to have more than a brief dialogue with a patient. This was easily remedied with brief meetings, guidance, and discussions when necessary.

The two survey inventories given were authored specifically for this project. There was only one brief multiple choice question to answer on the pre-survey and the same question to answer on the post-survey which made the surveys very user friendly as planned. Data was collected daily and data entry was performed on a regular basis via manual entry into a computer laptop Microsoft Excel spreadsheet requiring a private password for access. One individual was responsible for data entry providing for standardization during this phase. As data was entered, surveys

were shredded. Fortunately, there were no issues of potential confidentiality breaches as none of the surveys contained private identifying patient information of any kind.

Lessons learned. The most important lesson learned was that this intervention needed to be incorporated into the patient visit after the point at which the patient had her questions and concerns about her visit addressed. In some cases, there seemed to be anxiety on the part of the patient regarding her reason for the visit and this precluded her being receptive or attentive to the information, according to staff delivering care. It was crucial for staff to be given iterations that although the intervention was a viable part of the patient visit, her reason for being in the clinic was different from staff reasons for presenting patient education and counsel. In other words, it was important to recognize patient preferences and/or address emergent issues as these were the priority. Staff plans were secondary to that.

Analysis of Project Outcome Data

Quantitative findings. Aggregate responses on both pre and post surveys were evaluated via comparative means analysis. Individual comparative analysis was meant to ascertain changes in perceptions of risk of acquiring chlamydia trachomatis infection after education and counseling on an individual basis as well. Descriptive statistics with paired sample *t*-test and trend analysis assimilation were employed.

Pre-implementation responses were compared to post-implementation scores for the entire group and on an individual basis ($n=50$). Then, responses in each category were compared to post implementation responses in their respective categories for differences in perceptions and whether greater change was related to lesser or greater rating prior to implementation.

There were 50 subjects ($n=50$). One hundred percent of subjects were between ages 17-24, identified as female, and characterized themselves as single. The first question, “On a scale of 1-5, how would I rate myself in terms of being at risk for chlamydia?” and the second statement, “My understanding of my risk of chlamydia has changed today” were both assessed with the same response selections. Participant choices were 1 = None, 2 = Some, 3 = Medium, 4 = High, or 5 = Very High. The information in Table 1 and the histogram in Diagram 1 demonstrate the findings. There is no missing data.

Pre and Postvisit Responses

Risk	Previsit	Postvisit
1.00	32	20
2.00	12	11
3.00	3	10
4.00	0	4
5.00	3	5

Table 1. Pre and postvisit responses for a Pro-Woman Approach: Screening for Chlamydia in an Outpatient Community Setting.

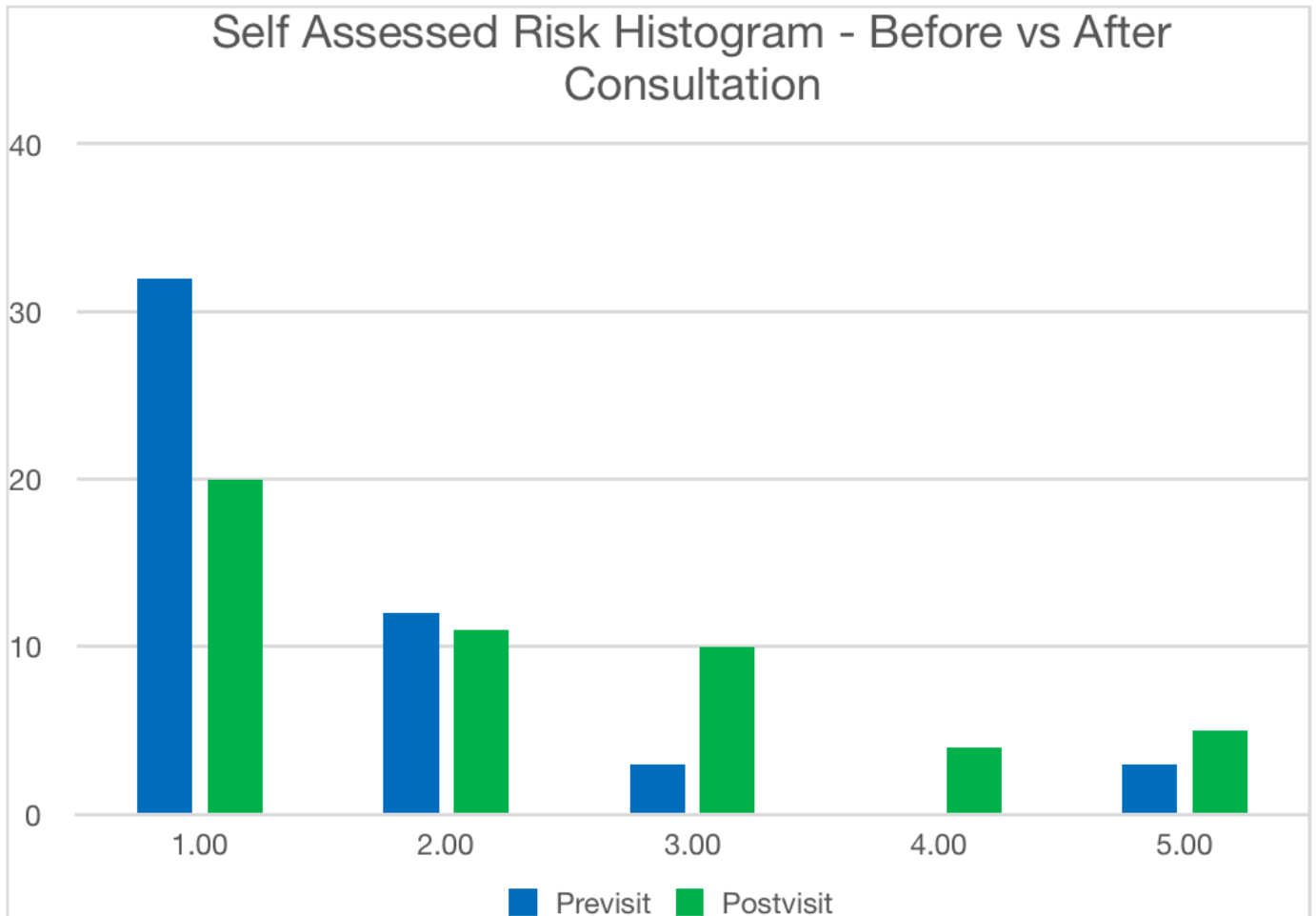


Diagram 1. Self assessed risk for a Pro-Woman Approach: Screening for Chlamydia in an Outpatient Community Setting.

The mean responses before and after survey were 1.6 and 2.3, respectively. The category demonstrating the biggest change in perception were the participants who ranked themselves as not having any risk at all initially. To begin, 64% of patients (n=32) rated themselves as having risk at all but that number was then reduced post survey to 46% of patients (n=20). In other words a smaller number of participants rated themselves having no risk at all after the survey. That change was an 18% difference.

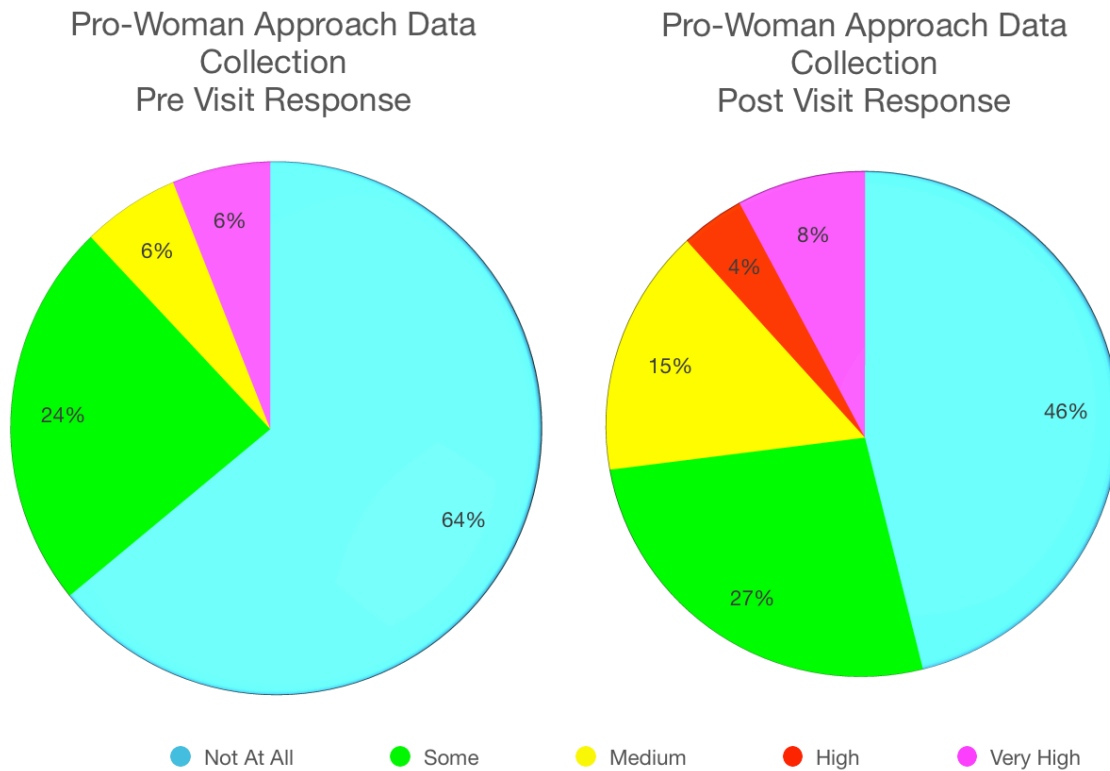


Diagram 2. Pre and post visit percentage of responses.

The other group to have the largest change was the high-risk category, which increased drastically from pre to post survey, 6% to 15%, respectively. The illustrations in Diagram 2 are representative of these observations.

The before and after calculations are meaningful. One aspect of this project not demonstrated pictorially is that not one participant lowered her score on post survey. The significance is that those who are at the highest risk for contracting chlamydia (CDC, 2018) were aware that in reality, their personal risk was actually higher than, or at least the same as originally thought prior to education and counseling. The scatterplots in Diagrams 3 and 4 allow for this representation.

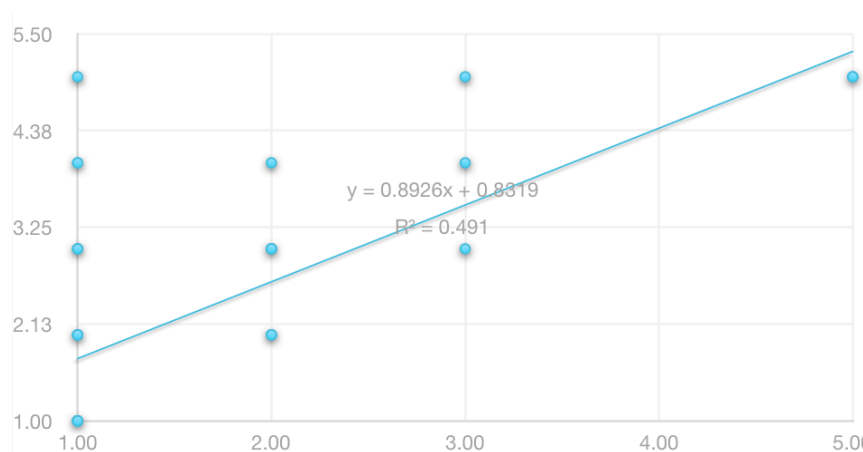


Diagram 3. Scattergram detailing pre and post responses.

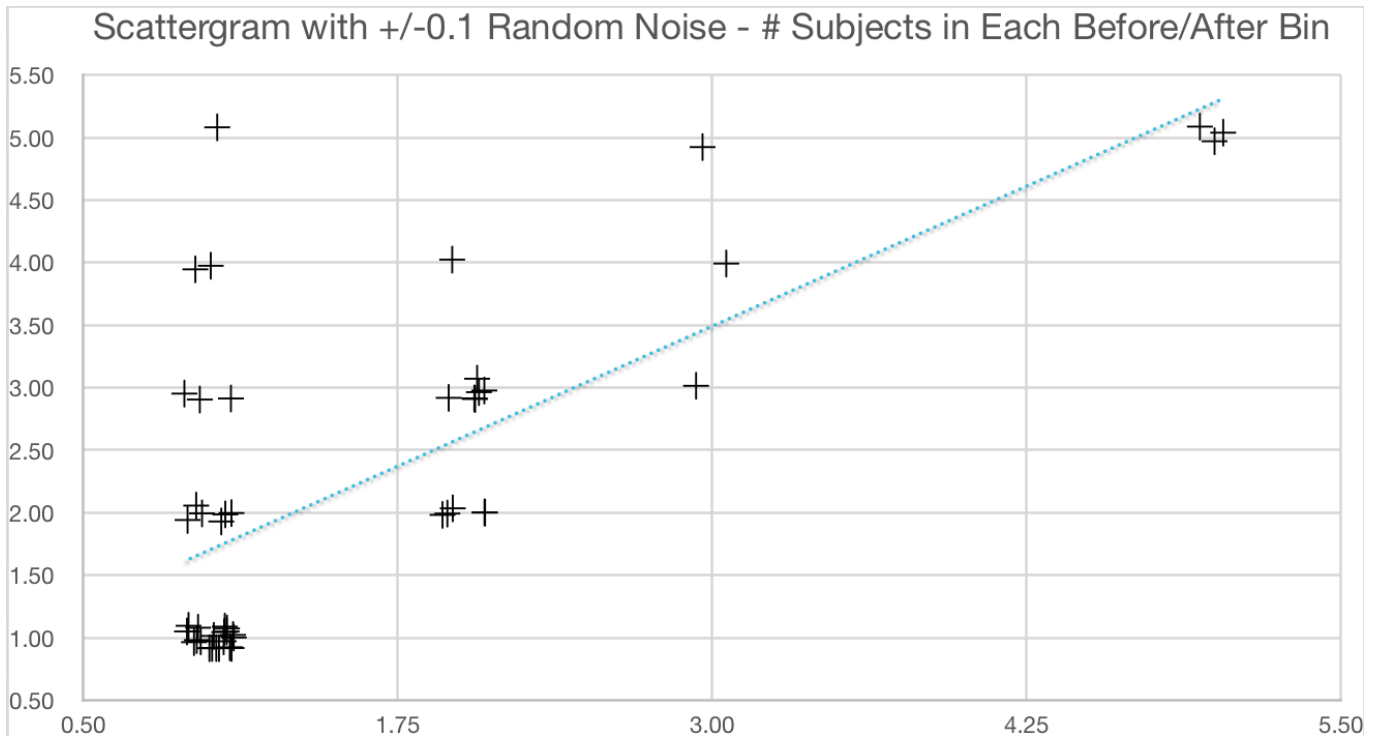


Diagram 4. Scattergram with random noise better detailing pre and post responses.

The benefit of this simple quality improvement intervention is illustrated nicely in Diagram 4 where the regression line is depicted. The *t-test* revealed that, assuming a Gaussian distribution, the average score change is very unlikely to be due to just random noise. The aggregated mean 0.66 difference in perception of risk is also indicative of intervention efficacy, as seen in Table 2.

Qualitative Findings

Mean Δ	0.66
Standard Deviation	0.96065
Standard Deviation of Score Change	0.14
t- value	4.86
Min t-value for 0.05 two tailed significance	2.05133
Prob of Avg Change <-0.66 or >0.66	0.00001256

Table 2. Summary of qualitative findings.

The null hypothesis is rejected and it was concluded with 95% confidence that changes were not a result of chance. The mean change between the two sets of pre-implementation perception of risk and post-implementation perception of risk was therefore significant. These findings were very positive.

Chapter V: Discussion

Summary of Findings

Link to SMART objectives. The project revealed statistically significant outcomes. The two objectives of this project were to expand patient knowledge regarding chlamydia and to provide psychosocial needs assessment for those with the highest risk criteria for acquisition of disease. These objectives were achieved. Staff reported patients had increased awareness and were open to dialogue in both areas more so than is usual.

Main changes observed in clinical outcomes. The project was designed with an overarching intention of helping women regain a sense of dignity and worth despite the often troublesome relationships they described. Although those are not objectively measurable variables, in general staff reported enhanced conversations with patients, what appeared to be more satisfied patients upon discharge from the clinic, and vivid gratitude. Patients also tended to have an increased awareness of themselves, be more pensive, and actively participate in experiential learning, according to staff. As opposed to what staff described as a sort of “robotic” delivery of care prior to intervention implementation, staff appreciated being involved on more of a humane level in patient care. These phenomena were accompanied by staff reports of a more personal investment of staff energetic compassion along with a greater sense of utility,

Successes and difficulties in implementation. It is important to remember that this was the first, and a one time, point of contact with patients. Many of the patients reported that they were listening to the education given to them for the first time and there was not a lot of time for patients to be given more than an overview of information. Though the population selected has been identified by the CDC (2018) as the highest risk category for acquisition of chlamydia, the

majority of the patients reported that they had no risk at all to acquire chlamydia upon commencement of the patient visit. Despite active engagement in sexual activity with often more than one partner within the past 12 months and/or more than one lifetime sexual partner believed their risk was nil upon presentation in the clinic. The difficulty presented was in how to properly educate patients in a meaningful way and still have sensitivity for the patient's circumstances and her readiness for learning. Once myths and barriers were broken, patients were able to have clarity and this is where the successes came into play for both patients and staff who had a great sense of satisfaction from being able to connect on a deeper level in an atmosphere of true compassion.

Effectiveness of the intervention. The interventions were influential in effecting a change in patient perceptions, interactions, and dialogue not normally seen on regular patient visits. It is difficult to discern the total influence and effectiveness that the intervention will have on future patient decisions and lifestyle changes, and whether that will impact future rates of chlamydia in the clinic. It is clear this is only a starting point.

Limitations or Deviation from Project Plan

There were quite a few limitations in the project plan. To begin, there was only one short point of contact for patients in the clinic. As stated before, a majority of patients reported having no risk at all for exposure to, and acquisition of, chlamydia. These patients did also report having multiple partners and/or having had children already, often disclosed to have been fathered by different men. As such, it would not be accurate to say that risk for an STI would be absolute zero and therefore, none at all. A solution would be to provide iterations of the didactic information and dissemination of educational pamphlets on subsequent visits. The exposure to educational posters in exam rooms and ladies' rooms over several visits are also needed in order for a

survey such as the one presented to effect more of a change for perception of risk (Zhan, Guo, Chen & Yang, 2018).

Another limitation is that those who presented as a first time patient to the clinic could have had added stressors making it difficult for them to fully focus on the education and survey portions of their visits. For example added stressors of finding the clinic, making the appointment time, not knowing what to expect, not knowing clinic staff, feeling nervous about what the clinical visit would reveal, or a host of other preoccupations could have been impediments for lower ratings on the surveys.

One limitation might have been the short space of time between the pre and post-surveys. Instead of having the post-survey to take home and complete for example even a week later online, the short period of time patients had to absorb and process information may not have been enough for more a significant change in responses to better have been revealed.

Learning style could have been a variable affecting the reason a greater difference was not encountered on post surveys. Although there is controversy in the literature regarding the correlation between learning style and academic performance (Paiboonsithiwong et al., 2016), one must consider the possibility that participants likely have varying learning modalities that work better for them. It was chosen no to use vivid pictures illustrating manifestations of STIs but that might have had a stronger effect and a different result had more of a visual learning interactive model been employed.

Given the nature of this highly sensitive topic, it is possible that many patients were not receptive to information or dialogue due to embarrassment, shame, guilt, religious or cultural constraints, for example. It is even possible patients were offended at an intervention aimed at

such an intimate part of their lives. These confounding factors when combined with short patient visits, readiness for learning, and receptivity to the information posed a conundrum for staff during project implementation.

Psychological, physical, and cognitive readiness (Joel, 2017) are three other possibly limiting factors in for this project. If a patient does not have motivation to learn something new, if the cognitive level is low or impaired by drugs or alcohol at the time of the visit, and/or if the patient is physically unable to learn such as those with chronic pain, these posed impediments to the effectiveness and productivity of the intervention. Often staff members voiced concern with these types of variables that seemed to impede the therapeutic process.

Finally, a last limitation is potentially that of trust between the participant and staff member providing care at the time of the visit. If the two were unknown to each other it is possible the patient providing the data was not entirely comfortable or forthcoming.

Implications for Practice Change

Practice. Staff at the clinical site are receptive to continuation of the project and support its sustainability. Although changes in perceptions were small after education and counseling for these high risk subjects, there are benefits and implications for future practice notwithstanding. The biggest implication for future practice at the organizational level is that delivery of care is of a higher quality. Also via evidence from this small project, the multidisciplinary approach was found to be warranted for future practice. Private practices, outpatient clinics, community clinics, and urgent care practitioners might consider the creation of an educational template or specific algorithm for use with at risk populations. Where possible the multidisciplinary approach could be employed and psychosocial support given as well.

Research. Unfortunately, there is a paucity of data on the advantages or specific types of educational and/or psychosocial approaches to working with this patient population. The multidisciplinary platform is ideal and should be explored further in future research. The addition of a psychosocial component appeared to work well with education to avert ignorance, counteract barriers, and assist patients in confronting realities of risk. Future research could explore strategic means of expanding patient information and support. For example, Solution Focused Brief Therapy is only one treatment modality of many that merits exploration in future research.

Nursing. This project has implications for the fields of nursing and advanced practice nursing. One of the lessons learned was a revelation that there is a certain acquired charism that must be learned and incorporated into practice when approaching individuals with information regarding such a sensitive topic as human sexuality. In order for this to transpire, perhaps training could be incorporated into nursing educational programs, staff meetings, or coursework which would speak to ways to develop oneself professionally in this regard. Registered Nurses and Advanced Practice Nurses would have more tools needed to initiate and continue conversations. There would not need to be any changes in the plan, unless the counseling component of the multidisciplinary approach was not available.

Health policy. Organizations such as the State Nursing Board, the Centers for Disease Control (CDC), and/or the eAmerican College of Obstetrics and Gynecology (ACOG) might consider the implications of a project such as this in developing Practice Acts, protocols, and guidelines for care of at risk patients. There would be no policy or regulatory issues impeding employment of the project the way it is. It is certainly change at the individual level that changes

the culture of an organization and then has the capacity to impact communities towards a positive end. This project was a great beginning.

Chapter VI: Conclusion

Value of the Project

It was not difficult to ascertain the value of this project, albeit changes however small. That there were changes in perceptions in this high risk population has merit. It would be interesting to measure changes in perceptions of risk and then rates of chlamydia for those who have participated in this type of a project versus those who have not.

What cannot be measured is the investment in patients and the connections made with their minds, hearts, and souls. The satisfaction staff received from knowing patients were assisted on a deeper level was palpable; indeed this project was conceptualized after expressions from staff about a robotic delivery of care that focused on test results rather than the individual human being. There is also no way to measure the transformations that took place in patients who shared candidly, their insecurities about personal risk for STIs, struggles in their lives, and also their deep seated concerns relative to their intimate relationships, or lack thereof.

DNP Essentials

The relationship between this Doctoral Scholarly Project and the DNP Essentials (AACN, 2006) cannot be articulated well enough. All eight of the guidelines provided structure for the project and it was exciting to be able to reflect along the way at evolution of new skills as they were manifested. At the same time, the project provided opportunities for the DNP student to develop the competencies and skill sets within the DNP Essentials (2006).

DNP Essential I: Scientific Underpinnings for Practice. This quality improvement project was preceded by a set of scientific guidelines from the Literature Search; the construction of an evidence table from the Literature Review; the analysis of Strengths, Weaknesses, Opportunities, and Threats; the application of a Theoretical Framework; and the utilization of comparative means analysis to review data. The scientific method was used to develop survey tools and counseling with patients and to evaluate data. The scientific method was also utilized in construction of the brochure used for this project. The scientific composition of the “Your Sexual Exposure” pamphlet is evidenced by references utilized and cited in its compilation.

DNP Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking. The application of DNP Essentials II which speaks to leadership and DNP V, which speaks to health care policy and advocacy, merged into one during the active implementation portion of the project. Joel (2017) discusses the genesis of patient advocacy through the pioneering work of Florence Nightingale and Sojourner Truth. This charisma, when combined with strong leadership, propels nurses into advanced nursing roles during the transition from a registered nurse position to that of the Advanced Practice Nurse. DNP Essentials II and V were better developed by way of this project. Leaders recognize how shifting staff and patients from their original points of reference requires a delicate balance. Motivational, influential, and inspirational aspects of leadership evolved slowly through the inner workings of this project. A referent leadership style emerged through working with staff on the multidisciplinary team and in working with patients (Sherman & Cohn, 2019). Future dissemination of this project will continue to add to the strength of DNP Essentials III and V as the penchant for leadership and advocacy grow.

DNP Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice. In essence, this project was the culmination of experiential knowledge, advanced education, personal approach to nursing practice, and clinical judgment. The DNP student acquired stronger analytical methods and clinical judgment by way of this project (Joel, 2017) as the scientific method was used to inform decisions.

Clinical responses had to be tempered with both progress, but also obstacles, encountered. For example, when staff appeared to reach an impasse with their roles in the project, it was necessary to generate additional or alternative delivery approaches and continue to systematically assess for areas of opportunity for improvement for all involved, both patients and staff.

Several types of clinical judgment emerged for the doctoral student. The one type of judgement that was the most useful, and that became stronger, was one in which active, reflective thinking provided opportunity to constructive review and revision (Joel, 2017).

DNP Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care. One of the more fascinating DNP Essentials is DNP Essential IV, which speaks to incorporating background science together with technological interfaces. Metrics used in this project directly contributed to impacted change (Mazurek Melnyk & Fineout-Overholt, 2015). Developing a robust strength in the areas of information systems and technology assisted the student in manufacturing the DNP Scholarly Project which became evidence of transformation for patients. The lives of patients and staff were touched during the implementation phase of this project by way of DNP Essential IV as well as the others. A project of this scope is not possible without a grasp on technological systems, databases, and data sets.

DNP Essential V: Health Care Policy for Advocacy in Health Care. Critical surveillance and methodical review of the project at varying stages helped to ensure utility of the project for individual patients. As a result, this project has the capability of being applied to larger populations, hopefully impacting larger groups in the public arena. Integrating advocacy skills with policy making paves the way for change.

DNP Essential VI: Interprofessional Collaboration for Improving Patient and Populations Health Outcomes. It was necessary to have varying members of different healthcare disciplines for this effort to work. Staff members appreciated being engaged in a new way as they approached patients. The project provided the opportunity for staff to also function at a high level of skill and cohesive ability (Moran, Burson & Conrad, 2017). In addition to enhancing productivity the project laid groundwork for future projects.

In the end, the public concern of chlamydia can be better addressed when patients have more healthcare team members advocating for them. Preceding this step, of course, is the element of advocacy that must be developed prior to embarking on this type of a collaborative approach to address the health concern. It is impossible to quantify all that the collaborative effort contributed to this project.

DNP Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health. Competencies for understanding prevention and ultimately, how to impact communities and the nation, begin at the individual level. As the understanding grows, upstream thinking evolves.

Through diligence with time spent during practicum hours, the doctoral student was able to gather organizational leadership skills, emotional intelligence, and a better internal locus of control (Moran, Burson & Conrad, 2017). Attending public meetings of the Arizona State Board of Nursing was also helpful in the development of this DNP Essential.

DNP Essential VIII: Advanced Nursing Practice. This project contributed to evidence based practice. The opportunities for professional and personal growth that presented themselves through each stage of the Doctoral Scholarly Project were invaluable for the doctoral student's growth, development, and advancement. As that took place, the DNP Essentials materialized in a rather insidious and delightfully organic way, guiding every aspect of clinical reasoning and decision making both within the project and in clinical practice outside the scope of the Scholarly Project.

Plan for Dissemination

The final part of the project involves a Powerpoint Presentation of the Doctoral Scholarly Project to staff and students at Bradley University which is anticipated to take place late November, 2019. Following that, the Doctoral Scholarly Project document will be uploaded to the Doctors of Nursing Practice Project Repository online.

The continued plan for dissemination, sustainability, and application at the clinical site will be scheduled for December, 2019. Findings and a newly designed clinic protocol will be presented to the Board of Directors at Life Choices Women's Clinic and followed by presentation to staff in January, 2020. It is hoped that there would not be much of a delay in application of these interventions for the practitioner and patient interface.

There is also opportunity to share this project with the seven other, similar urban, non-profit women's centers in Phoenix. As these organizations operate with similar business models and Mission Statements, it would be ideal to expand into those settings with local presentations.

Attainment of Personal and Professional Goals

In a personal statement drafted in 2016, personal goals and intentions were set prior to commencing this graduate program. The threefold personal mission was to continue to minister to others in the non-profit setting, work to increase the quality of services to those who are marginalized, and deepen the level of service to patients and families through a higher level of care. Suddenly, these appear to have been achieved!

From a professional standpoint, building confidence and competence have been two strongly sought after skills over the past thirty years of practice as a registered nurse. This graduate program at Bradley University and the completion of the Doctoral Scholarly Project have finally made that possible.

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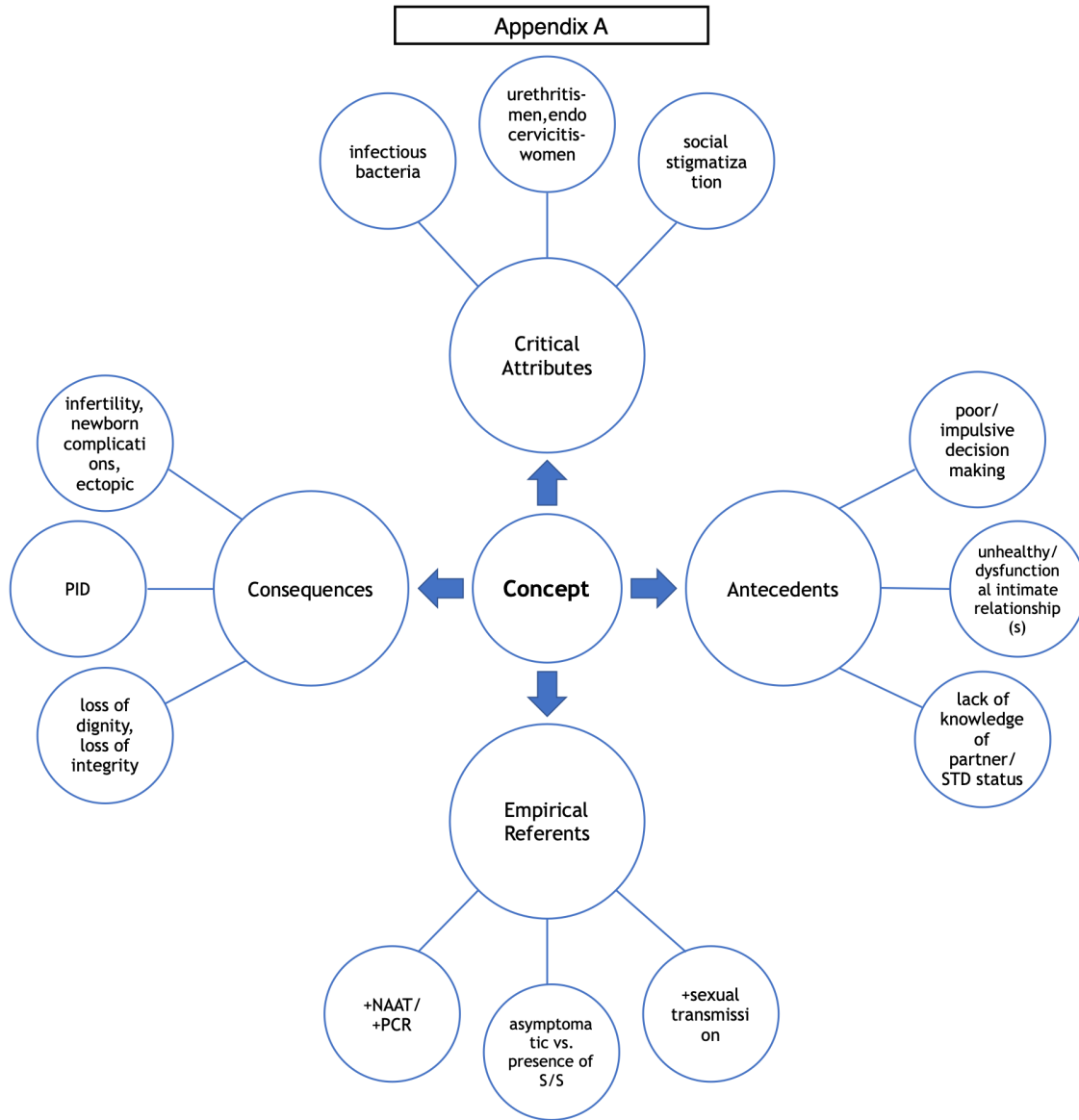
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APPENDICES



Appendix B

Objective:
<p>How do patient perceptions of risk of chlamydia trachomatis acquisition before and after education and psychosocial assessment survey differ for adult female patients in an outpatient community clinic?</p>

Internal Factors	
Strengths (+)	Weaknesses (-)
<ol style="list-style-type: none"> 1) The setting is a community based clinic that has sees patients for STI screening. 2) Stakeholders on staff, Board of Directors, and management strongly support this research paradigm. 3) The organization will directly aid the objective as its Mission Statement pertains to engendering healthy life choices for women. 	<ol style="list-style-type: none"> 1) This is a non-profit organization with staffing challenges. 2) Patients participating and meeting with the counselor for the psychosocial survey and assessment will need to be forthcoming in sharing their stories, and amenable to assistance. 3) Patients are at times not willing or able to engage with the clinic personnel which could inhibit interactions.

Appendix B (cont)

External Factors	
Opportunities (+)	Threats (-)
<p>1) This clinic receives numerous referrals from outside community agencies.</p> <p>2) Patients will emerge with better understanding of risk factors for acquisition of CT, and a new tool for personal inventory taking.</p> <p>3) Community based programs can utilize this research tool for effecting change on CT rates outside of this agency.</p>	<p>1) Funding is limited for this agency as it is a private, non-profit organization.</p> <p>2) There is a dearth of information regarding this type of a project and its implementation in the nonprofit setting and lack of resources.</p> <p>3) This project requires efficient and engaging skills in order to better serve patients in a novel and unique manner.</p>

Evaluation of Objective:
<p>Positive internal and external factors will help drive acquisition of data as balance is kept to minimize communication problems and followup with patients so as to keep the project in forward motion.</p>

APPENDIX C

Evidence Evaluation Table											
Clinical Research Question (PICOT or PICO): How do patient perceptions of risk of chlamydia trachomatis acquisition before and after education and psychosocial assessment survey differ for adult female patients in an outpatient community clinic?											
Headings	Study, Source, and Search Terms	Purpose of Study	Design/Method	Sample/Setting	Major Variables	Measurement Tools	Data Analysis	Findings	Concepts/Themes	Applicability to Own Research	Appraisal: Level of Evidence Impact on Practice Conclusion(s)
Explanation of Headings	(APA Citation, Database, Key Words)	(Why study was done as stated by authors)	(How was study carried out?)	(Number & characteristics of participants; attrition rate & why) (How are subjects' rights protected; risks vs benefits; informed consent, etc.)	(List & define independent & dependent variables)	(Name & author of scales) used to measure outcome variables; include reliability & validity data)	(Statistics used to answer clinical question)	(Statistical or qualitative findings)	(Identify main concepts/themes & provide a descriptor or definition. These will help organize the literature review)	(Describe how/why it relates to your research)	Study's level of evidence? Refer to pyramid in week 1 Strengths, weaknesses, limitations; feasibility of use in practice. Level of evidence + quality of evidence = strength of evidence & confidence to act
	Aghajoo, A., Reid, E., Kerry, S., Hay, P. C., Neilson, H., James, J. S., Kerry, S., Kerry, S. & Okonofua, P. (2014). Frequency and risk factors for incident and re-detected Chlamydia trachomatis infection in...	This study was done to examine the characteristics of those at risk for chlamydia infection and reinfection.	The study was performed utilizing questionnaires and samples taken for correlation.	954 women from universities and colleges received informed consent to participate.	This is a cohort study.	Prevention of Pelvic Infection screening protocols were used to gather data.	Analysis was made by binomial regression.	Factors such as being <20 yrs old, a smoker, of black ethnicity, having a partner of <12 months, having BV and/or HPV were predictors of infection.	risk factors reinfection new partner	This is powerful evidence for characteristics of patients who would benefit from screening and education efforts and has relevance for the research question.	This is a Level I study. A strength is that it has high level quality and quantity of evidence pertaining to clinical practice. This information will definitely be utilized for current study.
	Centers for Disease Control and Prevention. (2013). 2013 Sexually Transmitted Disease Surveillance - Atlanta, GA. Department of Health and Human Services.	This study was done to demonstrate the breakdown of disease by region, sex, age, and race and to demonstrate its prevalence, especially among women.	This study was carried out based on a collection of data from mandatory reporting reports across the United States.	Data was collected from mandated reports only; there were 1,526,458 patients who tested positive in 2013.	Only those patients with positive chlamydia results were included.	Centers for Disease Control and Prevention collected and recorded data from all reports submitted.	Direct reports resulted in accumulation of final numbers of cases.	1,526,458 cases reported	chlamydia cases chlamydia surveillance prevalence	This relates entirely to the research question as it demonstrates a need for more research such as the project being proposed.	This is a Level II study. Its strength is that it reflects high quality data and evidence of the problem. It has the actual, direct evidence needed to illustrate the scope of the problem of chlamydia. This, it speaks to the utility of this project.
	Chikwale, J., Shah, K. H., Hammarling, M. W., Kothari, S., S. Smith-Horowitz, Y. A. (2017). Cost benefit analysis of Chlamydia...	This study was done to estimate the value of screening versus burden of disease.	A cohort of 6,444,686 pregnant women were followed for a year and estimates made for treatment and mortality for both...	Data was collected from 6,444,686 pregnant women and analyzed by a decision analysis model. This was done by using national data to protect subjects.	DI-screening, DI-chlamydia	Therapy Prostate 2014 decision analysis model used with good reliability.	A Monte Carlo multivariable probabilistic sensitivity analysis was employed.	Screening decreased mortality related sequelae with less cost.	screening cost-benefit mortality	This directly relates to the proposed project in that it validates the need for more in depth screening process and availability.	This is a Level I study. This is a strong study that utilizes and produces high quality data, investigation and data for concrete evidence of a need to pursue the research project. This article lends even more purpose to the project.
	Shaw, R., Peterson, A., Liddell, H., Roach, M. & Coleman, K. (2018). Sustained reduction in Chlamydia infections following a...	This is a determination of the merit of early screening and treatment in reduction of PID incidence from Chlamydia infection.	The study was performed utilizing a school based screening program to effect a decrease in CT rates.	3,388 valid samples were evaluated and patients were protected during the process.	DI-screening, DI-chlamydia	Detrol Screening Tool was utilized to facilitate early screening for those with positive chlamydia tests.	A parametric statistical test was employed.	A decrease in the prevalence of C. trachomatis was demonstrated, (p < .01) from 10.24% to 6.27%.	early detection early screening	This study has direct correlation to the subject being studied and indeed has valuable application.	This is a Level I study. The strength of this study is that it produces precisely the specific type of data and evidence needed to support the clinical question, the investigation, and future practice.
	Fink, J. V., Barlow, R., Remonts, A. & Hoak, E. W. (2013). Sexual health training and education in the U.S. Public Health Reports. DOI:10.1093/aphip/101. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/...	This study examined approaches to working toward sexual health, stigma associated with it, and ways and types of assessing problems and providing support.	This article reviewed various concepts in the United States meant to support patients toward sexual health.	n/a	n/a	n/a	n/a	n/a	sexual health screening sexual orientation contraception assistance STI screening	This study has a major impact on the clinical question as it speaks to the merit of and opens the doorway for the type of research proposed.	This is a Level V review. The strength of this study is that it is a compilation of current practices and efforts to redirect providers toward enhancing patient conversations and care in support of patient sexual health.
	GeneticsGenes, W. B., Singh, A., Lee, J. Y., Lemay, S. T., Johnson, S., Perry, R. C., Kadliska, C. B. & Morris, R. B. (2015). Antichlamydia...	This study was done to examine the utilization of azithromycin versus doxycycline for treatment of chlamydia trachomatis.	This was a randomized control trial with assignment of each medication to two different groups.	Patients were examined by test of cure for efficacy of medication in treatment of chlamydia.	DI-ship, DI-chlamydia	SAS software was used for analysis.	Fisher's exact test or a Wilcoxon rank-sum test were used to evaluate the data.	There was 100% efficacy with use of Doxycycline, versus 97% for Azithromycin (95% confidence interval [CI], 0.8 to 2.4).	treatment Doxycycline Azithromycin	This has direct relevance as those patients who do not report past treatment adherence with prescribed regimen will skew data.	This is a Level I study. The strength in this study is it has direct relevance by providing both the high caliber level and quality of evidence for direct application with patients in the proposed study. Another strength is in its presentation of posing risk of reinfection when not treated adequately.
	Carvillan, K., Simonsen, L. S., Furlong, A. S. & Weisbart, T. (2013). Factors associated with Chlamydia trachomatis testing in a high school...	This study was done to determine how self-perception of risk of infection compares to actual risk of infection.	This was a non-experimental, systematic review.	Data was evaluated from surveys completed by participants and assigned against actual disease acquisition.	DI-screening risk, DI-chlamydia testing	Web based questionnaires and PCR analysis of urine samples were correlated.	Implementation of binary and ordinal logistic regression analyzed data.	High unmet/underestimated risk: girls underestimated risk (52% vs 30%), respectively, and 15% vs 21% (p<0.001).	self perceived risk actual risk perceptions of risk	This study has merit for the clinical project as it is vital to consider self perceived risk vs. actual risk relative to readiness for learners.	This is a Level III study. The strength in this study is with correlation to the clinical question as readiness for intervention and learning will be great for those providers who tend to underestimate their risk for infection. They would greatly benefit from education and incorporation of these concepts into the plan.

APPENDIX C (cont)

Kang, M., Rochford, A., Skonec, S. M., Woodhouse, A., Webb, M., Peat, J. B. (2014). Sexual behaviour, sexually transmitted infections and	This study examined attitudes and substance use to positive chlamydia infection.	This study was a randomized control study.	Participant information statement and ethical approval obtained from The University of Sydney Human Research Ethics Committee guaranteed confidentiality.	W= substance use, D=chlamydia	Data were analyzed using SPSS v19.0 (IBM, USA)	Logistic regression analyses made possible correlative conclusion of substance abuse with infection.	Subjects engaging in substance use tended to have higher rates and risk of chlamydia.	sexual activity substance use testing risk	This study is pertinent as it will be a factor in the proposed project for those who participate.	This is a Level I study. There is great strength with this study with the incredible applicability to the research question in helping to define criteria that will be used in the survey instrument.
LeFevre, M. (2014). Screening for Chlamydia and gonorrhoea: U.S. Preventive Services Task Force recommendation statement. <i>Annals of Internal Medicine</i> .	This is a review of the USPSTF guidelines for testing and screening.	The purpose of this article is to summarize evidence and review data.	A review of current guidelines for screening was made.	n/a	n/a	n/a	n/a	risk testing screening detection	The recommendations will need to be followed and observed during conduction of this clinical piece.	This is a Level III study. Its strength is that it reviews high quality data and provides further evidence of the problem. It has the actual, direct strength of evidence of the scope of the problem of chlamydia. Another strength is that it reviews guidelines and recommendations for care.
Low, H., Redmond, S., Luukkainen, A., Van Bergen, J., Ward, H., Anderson, B., Gola, H. (2014). Screening for genital chlamydia infection. <i>Canadian Medical Association Journal</i> .	This is a systematic review which looked at screening versus no screening for pregnant and non-pregnant females.	The purpose of the review was to extrapolate need for screening in various clusters of controlled and randomized trials.	A total of 359,078 men and women were included in the review from six clusters of controlled and randomized trials.	n/a	n/a	Meta-analysis guided data review.	A fixed-effect model was utilized to estimate risk ratios (RR) with 95% confidence intervals, CI).	screening pregnant non-pregnant detection	The recommendations are pertinent to the study proposed and will be incorporated accordingly.	This is a Level III study. The strength is in its examination of the merit of early screening and detection for pregnant and non-pregnant females, which has clinical correlation to the proposed study. The weakness is that the discussion concerning males is not pertinent.
Mahlorra, Mahlorra, H., Toed, S., Mahlorra, A., Muralidhar, S. B. Baba, M. (2014). Genital chlamydia trachomatis: An update. <i>Indian Journal of Medical Research</i> , 138(3), 303-316. Retrieved from http://	This study was done to delineate specifics of the chlamydia trachomatis pathogen, infectious process, and interactions with host.	The study was performed by examining elements of the chlamydia microorganism through review of studies.	This was a review of the literature.	n/a	n/a	n/a	n/a	bacteriology epidemiology treatment	The practical informative tools are useful clinically in leading evidence for the gravity and complexity of pathogenesis and need for the research question.	This is a Level III study. The strength is that it is a compilation of high quality evidence regarding epidemiology and bacteriology of the infectious agent, chlamydia trachomatis. The weakness is that the in-depth analysis goes beyond the scope for the project.
Nickles, M. D., Alderman, E., York D. V., Blank, A. E., Briggs, R. D., Hodal, K. E., Nae, C., Lachuga, C., Mann, M., Mendenhall, P., Patel, H., & Racine, A. D. (2018). A learning collaborative approach to improve primary care STI	This study was done to improve the quality of assessments for purposes of improving screening and diagnosis and treatment outcomes.	The study was performed with the review of records to reflect and improve efforts at screening.	This study had 373 participants from 21 sites. It was considered to be quality improvement by the IRB and had exempt status.	W=screening tool D=chlamydia testing	n/a	n/a	Sites with higher risk subjects reported greater screening incidence @ DR9 vs 0.014 + 0.004, P = .027).	sexually transmitted screening STI morbidity	The information demonstrates relevance to the research questions as it heightens knowledge of the utility of early screening that is precise and thorough.	This is a Level III study, its strength is that it provides a systematic review of the utility of early screening.
Reemtsma, L., Barend, J., Vander Hoorn, S., Wijesooriya, H. S., Ikeno, M., Lee, H., Stevens, G., Gottlieb, S., Marit, J., & Temmerman, M. (2016). Global estimates of the prevalence and incidence	The purpose of this study was to state global prevalence of STIs and to seek to improvement of reporting and estimate measures.	The study was performed as a review of international data from 2005-2012.	The study reviewed international data from 2005-2012.	n/a	n/a	Bayesian meta-analytic approach was used to analyze information.	Global incidence of chlamydia was cited. Regional differences globally were delineated as well.	epidemiology global prevalence global incidence	The study is clinically applicable as it stresses the inherent dilemma posed globally, to communicate and ultimately to individual patients.	This is a Level III study. It has many strengths in that it is a treasure trove of a wealth of information regarding impact and burden of chlamydia on the global stage, in communities and upon individual lives.
O'Connell, C. M. B., Ferretti, M. E. (2016). Chlamydia trachomatis genital infection. <i>Microbial Cell</i> , 3(9), 392-403. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/	The purpose of this article is to review disease acquisition, risks, pathogenesis, bacteriology and treatment.	This article is a review of the literature.	n/a	n/a	n/a	n/a	Women at risk are those >30 years old who have cervicitis, >1 partner in the past 12 months.	bacteriology bacteriology risk factors treatment	This study provides an overview of various clinical aspects of chlamydia and is use for the research question in background information.	This is a Level V article. A huge strength lies in its presentation of background information that provides specifics about chlamydia including pathogenesis, bacteriology, sequelae, treatment and a general overview of the clinical course. It has direct clinical evidence to support the assertions made.
Park, S. Y., Lee, S. H., Kim, M. J., Kang, Y. M., Moon, H. M. & Chun, C. (2017). Clinical characteristics of genital chlamydia infection in pelvic inflammatory disease. <i>Sex Women's Health</i> , 17, 5. Retrieved	This review examined clinical characteristics of patients with chlamydia associated PID along with its sequelae.	This was a review of relevant records of patients with positive PID associated chlamydia infections.	There were 497 subjects of whose records were examined post facts.	n/a	The utilization of the two-tailed Student's t-test and a Z test were applied.	Logistic regression analysis was used to compare PID patients with those with chlamydia.	Acute PID infection associated with chlamydia leads to higher surgery risk higher levels of inflammatory markers of CRP, CBR and CA-125.	inflammatory significance PID sequelae	This overview lends correlative support for the burden and sequelae subsequent to untreated chlamydia infection.	This is a Level V article. The strength with this article lies within its support from the literature surrounding inflammatory markers and consequence to chlamydia associated PID. The information is relevant for substantiating a need for the proposed project's application in clinical practice.
Patel, A. L., Sachdev, D., Nagai, P., Chaudhry, S., Sonkar, S. C., Suman, S., Mendiratta, L. & Saluja, D. (2016). Prevalence of Chlamydia infection among women visiting a gynecology outpatient department: evaluation of	This study reviewed cost effective screening methodology for chlamydia infection.	The study was performed by examining diagnostic tools and comparing costs, sensitivity, and specificity.	593 patients seen in an outpatient clinic were part of this study in which informed consent was given for test sampling and interview.	W= in-house PCR method versus DFA D=chlamydia	In house PCR versus DFA testing results used for comparisons.	GraphPad Prism version 5.03 software used for data analysis.	NAAT testing revealed true positives more frequently.	testing diagnostics NAAT PCR DFA	This article lends itself for inclusion in the research project as it verifies type of testing that is superior for chlamydia detection.	This is a Level I study. One strength of the study is that it subjected all samples to repeat testing when necessary despite and after testing by two methods. Its rigorous methods and discussion has direct clinical relevance and application for clinicians and this project. Another strength is that the study also declares high quality testing that is at the same time cost effective.

APPENDIX C (cont)

<p>Kim, S. T., Lee, S. W., Kim, H. J., Kang, Y. M., Moon, H. A., & Chun, C. (2017). Clinical characteristics of genital chlamydia infection in pelvic inflammatory disease. <i>BMC Women's Health</i>, 17, 5. Retrieved</p>	<p>This review examined clinical characteristics of patients with chlamydia associated PID along with its sequelae.</p>	<p>This was a review of relevant records of patients with positive PID associated chlamydia infections.</p>	<p>There were 497 subjects of whose records were examined post fact.</p>	<p>n/a</p>	<p>The utilization of the two-tailed Student's t-test and χ^2 test were applied.</p>	<p>Logistic regression analysis was used to compare PID patients with those with chlamydia.</p>	<p>Acute PID infection associated with chlamydia had to higher surgery risk, higher levels of inflammatory markers of ESR, CRP and CA-125.</p>	<p>Inflammatory significance PID sequelae</p>	<p>This overview lends correlative support for the burden and sequelae subsequent to untreated chlamydia infection.</p>	<p>This is a Level V article. The strength with this article lies within its support from the literature surrounding inflammatory markers and consequence to chlamydia associated PID. The information is relevant for substantiating a need for the proposed project's application in clinical practice.</p>
<p>Patel, A. L., Sachdev, D., Nagai, P., Chaudhry, S., Sankar, S., C. Saman, S., Wondratschke, L., & Saluja, D. (2010). Prevalence of Chlamydia infection among women visiting a gynaecology outpatient department: evaluation of</p>	<p>This study reviewed cost effective screening methodology for chlamydia infection.</p>	<p>The study was performed by examining diagnostic tools and comparing costs, sensitivity and specificity.</p>	<p>593 patients seen in an outpatient clinic were part of this study in which informed consent was given for test sampling and interview.</p>	<p>In-house PCR method versus DFA assay</p>	<p>In house PCR versus DFA testing results used for comparisons.</p>	<p>GraphPad Prism version 5.03 software used for data analysis.</p>	<p>NAAT testing revealed true positives more frequently</p>	<p>testing diagnostics NAAT PCR DFA</p>	<p>This article lends itself for inclusion in the research project as it verifies type of testing that is superior for chlamydia detection.</p>	<p>This is a Level I study. One strength of the study is that it despite and after testing by two methods. Its rigorous methods and discussion has direct clinical relevance and application for clinicians and this project. Another strength is that the study also declares high quality testing that is at the same time cost effective.</p>
<p>Price, M. J., Aoki, R. E., DeAngelis, D., Weston, N. J., Macleod, J., Siddan, R., Simms, L., Turner, K. B., Horner, P. J. (2013). Risk of pelvic inflammatory disease following chlamydia trachomatis infection: Analysis</p>	<p>This study examined PID sequelae of chlamydia infections and estimated those cases that would progress.</p>	<p>This study appraised randomized and nonrandomized trials to derive at conclusions about PID prediction and screening to prevent.</p>	<p>8 studies were reviewed that were derived in both sexually transmitted clinical and general community settings.</p>	<p>n/a</p>	<p>n/a</p>	<p>Bayesian meta analysis provided interpretation for the study.</p>	<p>Although those presenting in an STD clinic are more likely to have chlamydia the value of screening to prevent PID is verified.</p>	<p>PID infertility mass screening</p>	<p>This is pertinent to the research question as it supports the value of developing strong screening techniques to capture chlamydia diagnosis in any at risk population.</p>	<p>This is a Level V study. The strength of this study is in its providing strong quantitative evidence for the value of screening to prevent PID related complications such as tubal pregnancy and infertility. Another strength is its in depth review of PID.</p>
<p>Thomas, P., Spangenberg, J., Kahl, A., Lammence, R., Davel, A., Lal, J. A. B., Horner, S. A. (2017). Burden of Chlamydia trachomatis in India: a systematic literature review. <i>Pathogens and Disease</i>, 75(1).</p>	<p>This review was conducted to examine the prevalence, diagnostic measures, and evidence based treatment and therefore burden of chlamydia infection in one country.</p>	<p>This article is a review of the literature.</p>	<p>n/a</p>	<p>n/a</p>	<p>n/a</p>	<p>n/a</p>	<p>PCR endocervical sampling and testing versus ELISA testing yielded higher rates of CT and therefore more burden and cost in terms of infertility, infant mortality, etc</p>	<p>epidemiology burden infertility ectopic pregnancy</p>	<p>This review relates to the research question as it lends further credibility to the notion that adequate screening, proper testing and treatment decreases the burden for individuals.</p>	<p>This is a Level V study. The huge strength of this study is that it is pertinent to clinical practice and this project as it reviews the strong evidence for burden of disease presented by chlamydia infections in one country.</p>
<p>Wright, M. L., Gilbert, M., Neill, R., Kim, P. H., Chang, M., Hone, D. M., & Bruchman, R. C. (2013). Chlamydia public health programs and the epidemiology of pelvic inflammatory disease and ectopic pregnancy. The</p>	<p>This review examined rates of outpatient visits, hospitalizations, ectopic pregnancy and PID related chlamydia infections.</p>	<p>This study appraised and tracked trends and epidemiology for PID and other chlamydia related sequelae.</p>	<p>Two large databases were reviewed; innovation was used from databases that had deidentified data.</p>	<p>n/a</p>	<p>Comparisons were made using cross-correlation function method and Granger causality testing to evaluate data.</p>	<p>This study used time-series analysis was used to answer research question.</p>	<p>There is a downward trend of long lasting effects of chlamydia involving infertility however the rate of ectopic pregnancy is on an upward trend.</p>	<p>epidemiology infertility ectopic pregnancy public health programs</p>	<p>This study is valuable for patient education that involve real life consequences for at risk behavior and for prevention of infection and reinfection.</p>	<p>This is a Level V study. The three strengths of this study lies in the fact that it also lends strong credence to the merit of furthering efforts to educate patients on disease progression, transmission and prevention.</p>
<p>U. S. Preventive Services Task Force. (2016). Final recommendation statement chlamydia and gonorrhea screening. Retrieved from http://www.uspreventiveservices.talkforce.org/pager</p>	<p>This article provides current guidelines for diagnosis, treatment, and management of chlamydia infections.</p>	<p>This is a summary provided by a national recognized expert panel in the field that represents clinical practice guidelines.</p>	<p>These guidelines were made from a review of the literature to provide a consensus.</p>	<p>n/a</p>	<p>n/a</p>	<p>n/a</p>	<p>Standardized methods for identifying and treating patients at risk are presented.</p>	<p>early detection testing screening at risk</p>	<p>These statements have clinical applicability as they represent the standard of care for an approach to patients at risk that can be utilized for the research question.</p>	<p>This is a Level IV statement from a nationally recognized committee. It is highly valuable and its strength is that it is entirely evidence based. Another strength is its provision of the strongest level of confidence for utilization in practice as well as in guiding best practices for clinicians.</p>
<p>Warr, A. J., Payne, J., Hewitt, J., Drake, A. L., Unger, J. A., McClelland, R. S., Malone, D., Osborn, L. B., Johnson, G. (2016). Sexually transmitted infections during pregnancy and subsequent</p>	<p>This study presented an overview of complications for pregnant women, and their unborn babies, with prenatal chlamydia infection.</p>	<p>A nested longitudinal analysis; this study was carried out utilizing data from a cohort study.</p>	<p>592 women positive for STIs were followed using data from a previous perinatal study.</p>	<p>In-chlamydia Divulgent mortality</p>	<p>n/a</p>	<p>Logistics regression and Cox proportional hazards models were applied for data analysis.</p>	<p>There is evidence that perinatal STI infections contribute to infant mortality.</p>	<p>STIs infant mortality infant outcomes chlamydia and pregnancy</p>	<p>This article supports the proposed research as it lays a foundation for enhanced screening and treatment protocols for those at risk and also for pregnant women.</p>	<p>This is a Level III report. The strengths lie in the fact that it all reviews pertinent cases that provide a high level of information and confidence for practitioners and it guides practitioners to practice diligence in screening and testing for at risk and pregnant patients.</p>

Appendix D

LIFE CHOICES WOMEN'S CLINIC
EMAIL COMMUNICATION

602.305.5100
info@lcwcaz.org

9303 N. 7th St.
Phoenix, AZ
85020

SAVE THE DATE

Date

Dear Team,

There will be a planning meeting in two weeks, April XX, XXXX, during the time of the next staff meeting. This is planned in preparation for implementation of the quality improvement project. The Pro-Woman Approach to Screening for Chlamydia Trachomatis in An Outpatient Setting is a valuable program for improving delivery of care for our patients and we look forward to seeing you there. (It is possible that there *might be chocolate, too!)

Please call if you have any questions. I am available by phone at 602.565.1073.
Thanks very much and I look forward to working with you!

Laurie Luciani

Appendix D (cont)

LIFE CHOICES WOMEN'S CLINIC
EMAIL COMMUNICATION

602.305.5100
info@lcwcaz.org

9303 N. 7th St.
Phoenix, AZ
85020

REMINDER OF MEETING

Date

Dear Team,

There will be a planning meeting in two weeks, April XX, XXXX, during the time of the next staff meeting. This is planned in preparation for implementation of the quality improvement project, The Pro-Woman Approach to Screening for Chlamydia Trachomatis in An Outpatient Setting. This is a valuable meeting that will help understand the method of improving delivery of care for our patients and we look forward to seeing you there. (I heard there will be chocolate, too!)

Please call if you have any questions. I am available by phone at 602.565.1073.
Thanks very much and I look forward to working with you!

Laurie Luciani

Appendix E

A Pro Woman Approach: Screening for Chlamydia in the Outpatient Community Setting

Project Overview

- Patients do not always experience symptoms of chlamydia (LeFevre, 2014)
- The United States Preventive Services Task Force recommends chlamydia screening for all pregnant women, for females aged 24 years or younger who are sexually active, and for older women who are at increased risk for infection (USPTF, 2018; LeFevre, 2014)

Research Question

How do patient perceptions of risk and knowledge about chlamydia trachomatis acquisition before and after education and psychosocial assessment differ for adult female patients in an outpatient community clinic?

Chlamydia Screening Visit Workflow/Clinical Tool

Clinic Personnel Involvement

Appendix E (cont)

Date TBD
Staff Educational Meeting Topics
Pro-Woman Approach
Intake Form, Pre-Visit Survey
Educational Brochure
Vital signs, Triage
Clinical Interview, Chief Complaint, History of Present Illness
Visit & Exam with Nurse Practitioner
Post Exam Discussion and Education by NP
Psychosocial Assessment/Visit with Counselor
Patient receives Post-Visit Survey and Participation Option
Surveys Submitted
Patient proceeds to checkout

Appendix F

**Life Choices Women's Clinic****Pre-Visit Survey**

Welcome to Life Choices. We are glad you are here. In order to get the most out of your visit today, please write your questions down to make sure they all get answered today.

Your visit and this questionnaire allow you space to express your concerns and reflect. Our hope is for you to achieve optimal health and relationships. Please know we are here to serve you and to help. We have several questions for self-reflection that do not need to be shared unless you would like.

- Am I in a safe environment and free from any type of mistreatment at home?*
- Am I in the type of committed relationship that I would like to be in?
- Has someone told me that they have a sexually transmitted infection (STI) that I was to exposed to?
- Have I ever had an STI in the past?

- **On a scale of 1-5, how would I rate myself in terms of my understanding of risk of chlamydia:**
 1. None at all
 2. Some
 3. Medium
 4. High
 5. Very high

*Clinic personnel will be available to talk after your visit and/or provide referrals for you if needed.

Appendix F (continued)



Life Choices Women's Clinic



Post-Visit Survey

My understanding of my risk of chlamydia has changed today:

1. None at all
2. Some
3. Medium
4. High
5. Very high

Appendix G

Won't Condoms Protect Me?

Here's what the Centers for Disease Control says:

Condoms, when used consistently and correctly, can **reduce** the risk of transmission of **chlamydia**.^{1,17}

Condoms, when used consistently and correctly, can **reduce** the risk of transmission of **gonorrhea**.^{2,17}

Genital ulcer diseases **can occur** in both male and female genital areas that are covered or protected by a latex condom, as well as in areas that are not covered. Correct and consistent use of latex condoms can **reduce** the risk of **syphilis**, as well as **genital herpes** and **chancroid**, **only** when the infected area or site of potential exposure is protected.^{14,13,19}

Condoms **may lower** the risk of **HPV**, if used all the time and the right way.^{13,9}

Condoms, when used consistently and correctly, can **reduce** the risk of transmission of **trichomoniasis**.⁸

Condoms were found to **reduce** the risk of **HIV** transmission during vaginal sex by 85% when used consistently and correctly following the directions exactly and using them at every occurrence of sex, without exception.^{1,8,10}

Using condoms 100% of the time still leaves a 15% risk of HIV infection compared to not using condoms at all. HIV is the virus that without treatment causes AIDS.

You can be infected with any STD even when using condoms 100% of the time.

Are you looking for complete protection from STDs and Pregnancy, guaranteed 100% of the time?

The only guaranteed way to avoid pregnancy or infection with a sexually transmitted disease is to practice sexual abstinence (abstain from any sexual contact) while single. If you marry, select a partner who is not infected with an STD and remain sexually faithful during marriage.

All other methods leave you at risk.

It is your personal choice. Make it a good one.

Sources and Resources

1. http://www.cdc.gov/std/chlamydia/Chlamydia_Treatment.cfm
2. http://www.cdc.gov/std/gonorrhea/Gonorrhea_Treatment.cfm
3. http://www.cdc.gov/std/syphilis/Syphilis_Treatment.cfm
4. http://www.cdc.gov/std/genital-ulcers/Genital-Ulcers_Treatment.cfm
5. http://www.cdc.gov/std/hiv/HIV_Treatment.cfm
6. http://www.cdc.gov/std/hiv/HIV_Treatment.cfm
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18. http://www.cdc.gov/std/hiv/HIV_Treatment.cfm
19. http://www.cdc.gov/std/hiv/HIV_Treatment.cfm

This has been verified as used in the brochure, when to make these condoms, and does not refer to these condoms, and is not intended to be used in any other way, and is not intended to be used in any other way.

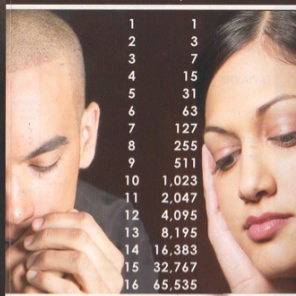
The table on the cover assumes each person involved has had only one partner as you have. Each individual, regardless of gender, is considered to have several partners. The table is given by P=1 x 2 = 1 where 1 is the number of partners you have had.

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Your Sexual Exposure

Each time you choose another partner, your chance of contracting a sexually transmitted disease goes up dramatically. Look at the numbers below.

Your partners	Your exposure
1	1
2	3
3	7
4	15
5	31
6	63
7	127
8	255
9	511
10	1,023
11	2,047
12	4,095
13	8,195
14	16,383
15	32,767
16	65,535



"When you have sex with someone, you are having sex with everyone they have had sex with for the last ten years, and everyone they and their partners have had sex with for the last ten years."

C. Everett Koop, M.D., Former U.S. Surgeon General

Appendix G (cont)

The Most Common STDs			
STD	Symptoms	Damage	Numbers
Chlamydia ¹	Men - Usually none. Some experience discharge from the penis and burning with urination.	Men - Infertility	1) Estimated 2.86 million new cases annually. ¹¹ 2) Most are unaware of infection. 3) Repeat infection with chlamydia is common.
	Women - Called the "silent disease". Usually no symptoms. Some experience pain and/or vaginal discharge.	Women - Considered to be the most common cause of infertility. Advanced stage may require removal of uterus, tubes, and ovaries. Can cause PID (below).	
Gonorrhea ²	Men - Pus from urethra. Burning upon urination.	Men - Infertility. Scarring of the urethra and urinary tract problems.	1) Estimated 820,000 new cases annually. ¹¹ 2) Most are not aware they are infected in the early stages.
	Women - If symptoms occur at all, they include pelvic pain, painful urination and pus-like discharge.	Women - Infertility. Surgery in severe cases. Common cause of PID (below). Both - Can increase risk of HIV infection two to five times.	
Syphilis ³	Men - 1st stage: swollen non-painful ulcers on external genitalia. 2nd stage: changes of skin: fever, enlarged lymph nodes.	Men - Brain disorders, heart disease, blindness, dementia and death.	1) 63,450 new cases reported annually in the U.S. ⁷ 2) Many people have no symptoms for years until late stages.
	Women - 1st stage: often unnoticed. 2nd stage: same as men.	Women - Same as men. Can cause birth defects or death in newborns if mother is infected. Both - Can increase risk of HIV infection.	
HIV/AIDS ⁴	Men - Fever, sore throat, fatigue, swollen lymph glands. Must be tested, as symptoms mimic many other diseases.	Men - Immune system breakdown, death.	1) 1,194,039 ⁵ current, AIDS cases in U.S.; 12 million ⁶ living with HIV 2) Worldwide 34 million have died and 36.9 million are living with HIV. ⁷
	Women - Same as men.	Women - Same as men.	
Genital Herpes ⁴	Men - Lesions appear at the site of infection - periodic eruptions of painful blister and ulcers anywhere on the body.	Men - Continuous outbreaks. Eventually may lead to hospitalization. Lifetime medication required.	1) 16% of U.S. infected. 2) 796,000 new cases annually 3) 87% unaware of infection. 4) About 1 in 6 have this disease, over 24 million cases. ¹²
	Women - Same as men.	Women - Same as men. HSV infection during pregnancy and delivery can have very serious effects on newborns.	
HPV ⁵ Human Papilloma Virus	Men - Wart like genital growths.	Men - Cancer of the penis and anus.	1) 79 million people are currently infected. 2) 14 million cases/yr. 40+ types infect genitals. 3) Can cause cervical and other cancers.
	Women - Often no visible symptoms. Some experience vaginal itching and pain. Abnormal pap smears.	Women - Initially premalignant changes. Difficult to eradicate - May develop into cervical cancer if not treated. Vaccine for 4 types of HPV. ¹³	
Trichomoniasis ⁶	Men - Most men have no symptoms. May have irritation, discharge, burning with urination.	Men - Bladder and prostate damage.	1) Estimated 3.7 million cases in the U.S. 2) Most common curable STD in young, sexually active women.
	Women - Frothy, yellow-green vaginal discharge with a strong odor.	Women - Genital inflammation can increase a woman's susceptibility to HIV infection if she is exposed to the virus. May increase the chance that an HIV-infected woman passes HIV to her sex partner.	
PID ⁷ Pelvic Inflammatory Disease	Men - This disease affects only women.	Men - This disease affects only women.	1) Untreated STDs can cause PID. 2) 1 in 8 women with a history of PID experience difficulties getting pregnant.
	Women - See chlamydia & gonorrhea. Often symptoms are minor and mistaken for menstrual cramps. Chlamydia and gonorrhea may lead to PID.	Women - Scarring from infection increases risk of ectopic pregnancy (by 6 times), risk of infertility (ranging from 8% after first episode to 40% after 3 episodes), and chronic pelvic pain (18% after 1 episode).	

It's Your Choice

You are the person who decides whether to expose yourself to STDs. The number of infected people is constantly increasing. And most of these people don't even know that they are carriers of disease.

An estimated 110,000,000 people in the United States currently have an STD.¹¹

Some of these diseases can be treated with antibiotics, others cannot and will remain with you the rest of your life. And some are quite deadly. All have consequences that no one wants.

There are about 20 million new sexually transmitted infections in the United States each year.⁷ Half of these infections occur in people under the age of 25.¹¹ Being sexually active has always carried the risk of disease, but today the risk has increased many times.

If you do become infected, you probably will not know it, at least at first. Some STDs take weeks, months or possibly even years to show symptoms. Being sexually active during this time can infect your sexual partners.

If you become infected with certain common STDs, it can increase your chance of contracting HIV/AIDS by up to 5 times.¹² That is a frightening thought, considering that HIV can quickly cause damage to the immune system and can lead to AIDS.

For women who are infected with chlamydia or gonorrhea there is also a greater chance of developing Pelvic Inflammatory Disease, or PID. Undiagnosed STDs cause 24,000 women to become infertile each year.⁷

The epidemic of STDs has increased the danger of sexual activity dramatically. However, you also live at a time when more is known about these diseases than ever before. You can avoid the consequences, but it is a choice only you can make.

What about condoms?...(over)

Appendix H



DATE: 15 July 2019

TO: Laurie Luciani, Sarah Silvest-Guerrero
FROM: Bradley University Committee on the Use of Human Subjects in Research

STUDY TITLE: A pro women approach: Screening for chlamydia in an outpatient community setting
CUHSR #: 42-19
SUBMISSION TYPE: Initial Review

ACTION: Approved
APPROVAL DATE: 15 July 2019
REVIEW TYPE: Quality Assurance

Thank you for the opportunity to review the above referenced proposal. The Bradley University Committee on the Use of Human Subject in Research has determined the proposal to be NOT HUMAN SUBJECTS RESEARCH thus exempt from IRB review according to federal regulations.

The study has been found to be not human subject research pursuant to 45 CFR 46.102(i), not meeting the federal definition of research (not contributing to generalizable knowledge). Please note that it is unlawful to refer to your study as research.

Your study does meet general ethical requirements for human subject studies as follows:

1. Ethics training of research personnel is documented.
2. The study involves no more than minimal risk and does not involve vulnerable population.
3. Subject selection is equitable.
4. There is a consent process that:
 - a. Discloses the procedures
 - b. Discloses that participation is voluntary
 - c. Allows participants to withdraw
 - d. Discloses the name and contact information of the investigator
 - e. Provides a statement of agreement
5. Adequate provisions are made for the maintenance of privacy and protection of data.
6. Your study is exempt for HIPAA regulations in that no protected health information is used or personal identifiers are used.

Please submit a final status report when the study is completed. A form can be found on our website at <https://www.bradley.edu/academic/cio/osp/studies/cuhsr/forms/>. Please retain study records for three years from the conclusion of your study. Be aware that some professional standards may require the retention of records for longer than three years. If this study is regulated by the HIPAA privacy rule, retain the research records for at least 6 years.

Be aware that any future changes to the protocol must first be approved by the Committee on the Use of Human Subjects in Research (CUHSR) prior to implementation and that substantial changes may result in the need for further review. These changes include the addition of study personnel. Please submit a Request for Minor Modification of a Current Protocol form found at the CUHSR website at <https://www.bradley.edu/academic/cio/osp/studies/cuhsr/forms/> should a need for a change arise. A list of the types of modifications can be found on this form.

While no untoward effects are anticipated, should they arise, please report any untoward effects to CUHSR immediately.

This email will serve as your written notice that the study is approved unless a more formal letter is needed. You can request a formal letter from the CUHSR secretary in the Office of Sponsored Programs.

Appendix I

Budget Item	Type of Cost	Cost Per Item/Pt	Total Cost
Brochures (Supplies)	In-Kind	0.10/each	free
1 Ream of Paper (Supplies)	Direct	\$10.79	\$10.79
1 Canon Ink Cartridge for Canon MF420 Series (Supplies)	Direct	\$98.40	\$98.40
Counselor Time (Salary)	Direct	\$24/hr--\$3.00/pt	TBD
NP Extra Education Time (Salary)	Direct	\$50/hr--\$2.50/pt	TBD
NA/MA Extra Time (Salary)	Direct	NA/MA \$15/hr \$1.25 for 5 mins	Negligible
Laptop Usage	Indirect	Included in Visit	\$0
RN Time Data Collection, Entry (Salary)	In-Kind	\$32/hr	free
NA/MA Time Data Entry (Salary)	In-Kind	NA/MA \$15/hr \$1.25 for 5 mins	TBD
Total	---	---	\$109.19+

Appendix K

Timeline for Implementation
for Pro-Woman Approach

Timeline Task	6/19	7/19	8/19	9/19	10/19	11/19	12/19
Meetings with Site Staff	x	x	x	x	x		x
Submit CUHSR Application	x	*x					
Commence Implementation		x	x	x			
Data Collection and Entry		x	x	x			
Analysis, Discussion, Conclusion				x	x	x	
Deliverable to Bradley						x	
Deliverable to Clinical Site							x

*CUHSR application resubmitted