

Risk Factors Contributing to Transmission Rates of
Chlamydia trachomatis and *Neisseria gonorrhoeae* Among Women in
Veron, Dominican Republic

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Camille J. Henson

Abstract

Background

Selected factors place Dominican female adolescent and adults at risk for sexually transmitted infections (STIs) such as Chlamydia, causative organism *Chlamydia trachomatis*, and Gonorrhea, causative organism *Neisseria gonorrhoeae*. The purpose of this study was to determine the prevalence of Chlamydia and Gonorrhea among adolescent and adult females that utilize the clinic in Veron, Dominican Republic. Clinical standards of care for these STIs and educational programs for prevention were developed from the data gathered from this study. Significance at 0.05 α of the relationship of educational level, management of risk factors and other selected independent variables on prevalence rate of Chlamydia and Gonorrhea in the clinic population of Veron, Dominican Republic were determined. The objectives of the study were to 1) determine the prevalence of adolescent and young adult females diagnosed with Gonorrhea and Chlamydia who visit the clinic for prenatal visits, annual pap smear exams and gynecological complaints; 2) determine the extent to which educational level is a predictor of positive diagnosis or risk for infection of Chlamydia and Gonorrhea and; 3) determine which selected demographic and risk factors are associated with positive test results for Gonorrhea and Chlamydia.

Methods

All adolescent and adult females ages 15 years and older visiting the clinic in Veron for prenatal exams, pap smear exams and gynecological complaints between January 28, 2008 –March 3, 2008 were invited to participate in this prevalence study. Of the 90 invited, the accepting sample was 90 who signed an informed consent form. Prior to STI testing each patient completed a verbal interview and questionnaire on sociodemographic characteristics as well as knowledge, attitudes, and beliefs related to Chlamydia and gonorrhea, sexual experiences and behaviors and illicit drugs use. Specimens collected from the endocervical canal of each female were tested and results provided within two hours, followed by immediate treatment by a licensed Dominican physician and follow-up care based on the guidelines and standards of care. The data were analyzed using descriptive statistics, chi square, t-test and logistic regression.

Results

A total of ninety women participated in the study. Chlamydia was detected in 6.7% of the patient population and Gonorrhea was detected in 22.2% of the patient population. Co-infection of both Chlamydia and Gonorrhea was present in 2 cases. Among the positive Chlamydia tests results, 50% had less than a six-year education and 50% had more than six years of education. In addition, 83.3% of the patients with positive Chlamydia results answered “yes”, they could read and 16.6% stated they could not read, while 83.3% of the patients with positive Chlamydia results stated they could write and 16.6% stated they could not write ($P>0.05$). Among the patients that tested positive for Gonorrhea, 55% stated they had less than six years of formal education and 45% had more than six years

of formal education ($P>0.05$). There were 75% of the patients that tested positive for Gonorrhea that stated they could read and 25% who stated they could not read ($P>0.05$); while 85% of the patients with positive Gonorrhea results stated they could write and 15% stated they could not write ($P> 0.05$).

Conclusion

Educational level and other selected demographic characteristics and risk factors in this study are not a significant predictor of positive diagnosis or risk of infection for Chlamydia or Gonorrhea. We cannot conclude that specific risk factors are associated with positive test results for Gonorrhea and Chlamydia. For the physicians involved in the clinical decision-making regarding the female patients at the Veron clinic, more data are needed to determine appropriate populations for screening of Gonorrhea and Chlamydia as well as appropriate educational tools on sexually transmitted infections.

Dedicated to the Henson and Anderson Family

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Chapter One

Introduction

The Dominican Republic Ministry of Health exhibits a number of internal problems, typical of many countries in Latin America. Historically, the health sector has been in crisis with inadequate preventive and curative services, low and irregular quality, disparity of services concentrated in the capital and in tertiary care facilities and highly inefficient systems (Glassman, Reich, Laserson, & Rojas, 1999). There is a need for health care changes in developing countries, particularly in areas that are more rural and where poverty is prevalent. According to The World Fact Book (2008), the estimated population in the state of the Dominican Republic was 9, 507, 133 persons in 2008 and it is estimated that about half of the Dominicans live in rural areas and many are small landowners (CIA, personal communication, May 15, 2008). The World Health Organization estimate that there are 38 million cases of curable sexually transmitted infections (STIs) each year in the Latin American and Caribbean regions (Garcia, Yam & Firestone, 2006). The Dominican Republic has a high number of people in the sex trade per capita, with some 50,000 female sex workers in Santo Domingo alone (Garcia, Yam & Firestone, 2006).

The Veron clinic, “Clinica Rural El Veron”, is located in a rural, impoverished community in the Dominican Republic. It provides services to sixty to seventy patients a day with complaints varying from ambulatory to acute care for infants, children and adults. Although there have been advances in many clinical areas in the past two years,

standards of care for gynecological services need improvement. This clinic provides family planning, supports women's health and serves the primary care needs of the community and schools.

One of the major health problems in the United States is STIs, particularly in adolescent and young adults aged 15-25 (Campos-Outcalt, 2003). Sexually transmitted infections are a major health issue worldwide, exacerbated by poverty and lack of education in developing countries. Some of the most common sexually transmitted infections include Chlamydia and Gonorrhea. It is important to understand the culture habits and contributing factors of high-risk populations in different clinical settings, in this case Veron, Dominican Republic. A lack of evidence-based criteria to address the variation in prevalence across populations and background serves as a limiting factor in detection and treatment. Many STIs persist asymptotically. Screening for asymptomatic infections has been a cornerstone of public efforts to control bacterial sexually transmitted infections (Manhart, Marrazzo, Fine, Kerani, & Golden, 2007). New standards of care and knowledge of the at-risk populations are needed for the prevention of STIs in Veron, Dominican Republic.

Most people with Chlamydia are unaware of their infection making Chlamydia one of the most under-reported diseases (Center for Disease Control [CDC], 2007). Chlamydia is a common cause of urethritis, cervicitis, and serious sequelae that include pelvic inflammatory disease (PID), infertility, ectopic pregnancy and arthritis (CDC, 2007). Conjunctivitis and pneumonitis can develop in infants exposed during passage through a Chlamydia-infected birth canal (CDC, 2007). Chlamydia is reported more often in women than in men thus, better screening of women is required for family planning

programs and during prenatal care (Campos-Outcalt, 2003). Testing in family planning clinics has yielded Chlamydia infection rates of 5.6% among women in the United States (Campos-Outcalt, 2003). Re-infection rates are often high secondary to partners not being treated (Cross, DeAugustine, Douglas, et al, 2006).

Gonorrhea infections are frequently asymptomatic, particularly in women (Barry & Klausner, 2006). Even when women do present with symptoms they are often non-specific and mistaken for urinary tract infections or vaginal infections (CDC, 2007). The initial symptoms and signs include a painful or burning sensation when urinating, increased vaginal discharge or vaginal bleeding between periods (CDC, 2007). Untreated gonorrhea can cause serious health problems. Gonorrhea is a common cause of pelvic inflammatory disease or PID (Cross, 2006).

Statement of the Problem

There is limited data to develop preventive education and to design effective health care programs to address the incidences of Chlamydia and Gonorrhea among adolescents and young adult females presenting at the Veron Clinic in the Dominican Republic. Low levels of education among these patients may present obstacles for programs designed to address STIs and educational level is thus used in this study as a surrogate marker for social economic status, access to healthcare and predictability of the practice of preventive healthcare.

Purpose of the Study

The specific purpose of this study was to determine risk factors that contribute to the prevalence of Chlamydia and Gonorrhea among adolescents and young adult females

who utilize the Veron clinic, in order to develop an educational program for prevention and clinical standards of care for these STIs.

Objectives

1. Determine the extent to which selected demographic and risk factors are associated with Gonorrhea and Chlamydia.
2. Determine the prevalence of Gonorrhea and Chlamydia diagnosis among adolescent and adult females presenting at the clinic for prenatal visits, annual Pap smear exams and gynecological complaints.
3. Determine the extent to which educational level is a predictor of positive diagnosis or risk for infection of Chlamydia and Gonorrhea.

Significance of the Study

The study was used to determine the significance of behavioral predictors for Chlamydia and Gonorrhea infection in the rural community of Veron, Dominican Republic. Failure to surpass primary school was used as an indication for screening and used in a systematic approach to define high-risk groups for positive diagnosis of Gonorrhea and Chlamydia in this patient population. The Du study found that some college-educated populations were associated with decreased Gonorrhea rates (Du, McNutt, O'Campo & Coles, 2009). This information can be used to help design patient services such as screening protocols and educational interventions. Findings from the study have implications for advancing the clinical protocol for sexually transmitted infections at the Veron Clinic and for other similar clinics in the Dominican Republic. In addition, there are implications for other countries with similar standards of socioeconomic status and development. Health educators in the public schools and health

promoters may benefit from the findings in this study to adapt curriculum and gain insights about those in the population who are most at risk.

Limitations and Delimitations

Male patients are excluded from the data set because they are beyond the parameters selected for the investigation. Although there are many sexually transmitted infections that have devastating outcomes, this study was limited to only Chlamydia and Gonorrhea. It is not feasible for a single study to address the wide range of populations dynamics and situations associated with STIs. By focusing on adolescents and adult females 15 years old or older, the study has potential to delineate information within the time frame and resource base to make positive contributions to the literature and related practice. The study was restricted to the female populations within the geographical service area of the Veron clinic who present for pap smear exams, prenatal visits and gynecological clinic visits. In addition, self-reporting bias could be a limitation depending on accurate answers to survey questions and interviews. Bias was controlled in part by the medical examination and related tests.

Limiting sampling parameters to persons seeking care at the clinic may not provide a random sample generalizable to the entire community. For example, a segment of the Haitian population without proper authorization to be in the country may not come to the clinic. Even so, the sampling technique should represent the accessible population for education and treatment at the clinic. The researcher gained important information on certain segments of the population as a result of the study. While the findings are specific to Veron, there are potential implications to similar populations and settings. For example, CDC, Division of STD and Prevention (2007) indicated that data cannot be

generalized to the population as a whole. Yet, there may be important insights that can be tested with other similar populations. Sample size limitations were within the parameters of this study given the length of time available and resources. While large sample size is not realistic for this particular study, future studies will benefit from larger sample sizes and also replication in other settings and with different populations.

Definition of Terms

Sexually transmitted infections: infections that are spread primarily through person-to-person contact; there are more than 30 different sexually transmissible bacteria, viruses and parasites.

Chlamydia trachomatis: an obligate intracellular bacterium that can infect the genital tract primarily during sexual intercourse and causes mucopurulent cervicitis, urethritis, Bartholinitis, acute salpingitis and perihepatitis in women; can be asymptomatic; and has at least 18 distinct serotypes.

Neisseria gonorrhoeae: sexually transmitted infection of the epithelium which commonly manifests as cervicitis, urethritis, proctitis, and conjunctivitis; if untreated, infection at these sites can lead to local complications such as endometritis, salpingitis, tuboovarian abscess, Bartholinitis, peritonitis and perihepatitis.

Risk factors: the characteristics that contribute to positive diagnosis for sexually transmitted infections and include socioeconomic status, age of first intercourse, low educational achievement, multiple partners, poverty and low access to health care.

Summary

The Dominican Republic health care system exhibits areas of weakness when reaching out to its citizens in rural and impoverished communities. As populations

increase in these underserved areas without improvements in the health sector, an epidemic of sexually transmitted infections may progress. These factors include characteristics of the pathogen, sexual behaviors in a population, and knowledge about control and prevention. Prevention and control strategies need to be more aggressively incorporated into the health system to effectively control the spread of STIs. Two commonly encountered STIs in a primary care setting worldwide include Gonorrhea and Chlamydia. This study focused on educational achievement as a surrogate marker for predictability for a positive diagnosis of Gonorrhea and/or Chlamydia. In addition, this study was designed to assess other risk factors that contribute to positive diagnosis in the female population that visit the clinic in Veron, Dominican Republic. A desired outcome of this study was to utilize the information gathered about the population to design and implement preventive educational programs and procedures to control and bring awareness about Chlamydia and Gonorrhea in this community. These two STIs can lead to devastating morbidity in females.

Chapter Two

Review of the Literature

Introduction

Most clinicians and researchers now recognize that sexually transmitted infections (STIs) still remain a major health burden in America, developing countries and worldwide, despite efforts to raise awareness of HIV and other STIs. Because of the potential impact of infections on women's reproductive health, it is important to determine whether different factors are predictors of infection in women in various cultures. STIs not only impact women's health; they are also expensive: direct cost of curable and reported STIs are estimated at \$329 million among American adolescents and young adults, and stem largely from the treatment of complications in women (Pultorak, Wong, Rabins & Mehta, 2009). The prevalence and predictors of gonorrhea and chlamydia infection differ significantly between races, cultures and persons from various social demographics in America (Einwalter, Ritchie, Ault, and Smith, 2005). Similar differences may exist between the female populations in Veron, Dominican Republic. The Dominican ethnicity is predominately mixed (73%) with 16% white and 11% black (The World Fact Book, 2008). The Veron Clinic community is comprised of Dominican, Haitian and other ethnicities. Haiti is one of the poorest and one of the most densely populated countries in the western hemisphere (Dorjochoo & Noel, et al, 2009). This, along with other reasons, is why there is often an influx of Haitian immigrants into communities like Veron. Until these disparities are better understood, it will be difficult to establish screening criteria for Gonorrhea and Chlamydia in the public health clinic in Veron, Dominican Republic. Examples of these disparities may include access to health care, safe sex practices and knowledge and understanding about STIs.

The need for a new breed of committed, flexible, and effective team players, capable of addressing the challenges of rapid change and effectively directing the coordination of interventions by multiple actors involved in STI prevention and control is being addressed and evaluated on a regional scale in Latin America (Betts, Bracho, & Carrington, et al., 1996). Educational level may impact how successfully a behavioral model is incorporated into underserved communities like Veron, Dominican Republic. A study by Betts, Bracho and Carrington et al. (1996) found that the needs of modern program management require more than is offered in courses that use the “banking” model of delivering information and assuming the participants will “buy in” and translate the information into concrete actions. Paulo Freire was a Brazilian educator and is an influential theorist of education. Paulo Freire developed a model focusing on training of illiterate adult Brazilian peasants, which is being used successfully in other contexts (Betts, Bracho, and Carrington, et al., 1996). Educational intervention models should be influenced by the cultural, economic and educational levels of the target population.

Chlamydia trachomatis (Chlamydia) and *Neisseria gonorrhoeae* (gonorrhea) are the most common bacterial sexually transmitted infections in the United States and are two of the most common worldwide (Center for Disease Control [CDC], 2007). Chlamydia is the most frequently occurring bacterial sexually transmitted infection in the United States with Gonorrhea as the second most frequent (Gershman, & Barrow, 1996). Both infections can cause the following symptoms discharge from the vagina or penis; pain with urination; and/or abdominal pain (CDC, 2007). For women, the complications can be severe and can cause infertility, pelvic inflammatory disease (PID), ectopic pregnancies, and pelvic pain (Goldie, Hook, and Hu, 2004). These infections in pregnant

women can lead to prematurity, low birth weight and serious infections in the newborn (CDC, 2007). Several studies (Barry & Klausner, 2006; Goldie, et al. 2004; Einwalter, Ritchie, Ault, & Smith, 2005; Domeika, Butylkina, & Hallen, 2001) state that both Chlamydia and Gonorrhea are major health burdens for women. The United States Preventive Services Task Force (USPSTF) (2006) weighed the benefits of screening sexually active adolescents and adults for Chlamydia and Gonorrhea and concluded this would improve fertility, pregnancy outcomes, infection transmission rates, anxiety, relationship problems, and unnecessary treatment of false-positive results.

According to Barry and Klausner (2006) sexually transmitted infections remain an important cause of morbidity in the United States and throughout the world. Chlamydia and Gonorrhea are the key causes of preventable infertility among women (CDC, 2007). Chlamydia, Gonorrhea and other sexually transmitted infections such as genital herpes and syphilis increase the acquisition and transmission of human immunodeficiency virus (HIV) infection by three to five times (Barry & Klausner, 2006). Recent developments in diagnosing and treating STIs continue to make this field interesting and worthy research.

Chlamydia

Disease Characteristics

Chlamydia trachomatis is an obligate, intracellular bacterium and is always a pathogen; it is not a part of the normal flora of the urogenital track, despite the fact that infection is often asymptomatic (Adderley-Kelly & Stephens, 2005). As many as 85% to 90% of *C. trachomatis* infections in men and women are asymptomatic (Peipert, 2003). Asymptomatic infections can persist for several months. There are numerous different serovars of *Chlamydia trachomatis* (Lampe, Suchland, and Stamm, 1993). Some cause

urogenital infection, some ocular trachoma, and others lympho-granuloma venereum (CDC, 2007). *C. trachomatis* has been the most extensively studied species because of its association with ocular trachoma and its importance as a sexually transmitted pathogen (Mandell, Bennett, and Dolin, 2005). *C. trachomatis* serovars L1, L2, and L3 are more invasive than the other serovars; they spread to lymphatic tissue, and grow readily in macrophages; they produce the clinical syndromes of lymphogranuloma venereum and hemorrhagic proctocolitis (Jones, 2004). In addition to these more commonly reported syndromes, *C. trachomatis* has been reported as an infrequent cause of other infections, including endocarditis, peritonitis, pleuritis, and periappendicitis (Jones, 2004). The incubation period from the time of exposure to the exhibit of symptoms is from one to three weeks, but the pathogen may be present in the genital tract for months or years without producing symptoms (CDC, 2007).

The disease process and clinical manifestations of infection are probably caused by both pathogen-mediated tissue damage and the inflammatory response (CDC, 2007). *Chlamydia trachomatis* invades the columnar epithelial tissue in the reproductive tract and causes clinical manifestation similar to that of gonorrheal infection (CDC, 2007). The bacteria are intracellular and the infected woman experiences tissue damage from an inflammatory cellular immune response (Jones, 2004). Chlamydia can infect the vagina, the anus and the oral cavity of adults (CDC, 2007). The bacteria can infect the cervix, fallopian tubes and urinary canal and lead to pelvic inflammatory disease or PID, which is among the most serious threats to female reproductive capability (Miller, Cain, & Rogers, 1999). PID is caused most frequently by Chlamydia infection and Gonorrhea that

ascend past the cervix into the upper reproductive tract and results in scarring and either complete or partial blockage of the fallopian tubes (Miller, et al. 1999).

A pregnant woman infected with Chlamydia can transmit the organism to her newborn as the baby passes through the birth canal, resulting in eye infection and pneumonia in the infant (CDC, 2007).

According to Barry and Klausner (2006), it is estimated that 2.8 million new infections of Chlamydia occur in women and men each year in the United States. Most cases are among persons between 15 and 25 years of age (Barry & Klausner, 2006). The CDC (2007) recommends that sexually active women ages <25 years be screened for Chlamydia every year. The number of identified cases of Chlamydia has continued to increase, probably, in part, as a result of increased testing. There may also be other contributing factors. Developing countries such as the Dominican Republic have yet to incorporate sophisticated screening protocols into their public health clinics. It is important to understand risk factors for a population in order to design effective screening protocols. Currently, in the clinic in Veron, Dominican Republic screening for Chlamydia is not part of the STI protocol.

Pathophysiology: Chlamydia trachomatis

In an original study by Schachter and Stamm entitled *Chlamydia* (1999) from the Manual of Clinical Microbiology it has been determined:

The chlamydiae are obligate intracellular bacteria that produce a wide variety of infection in many mammalian and avian species. All chlamydiae share a unique life cycle characteristic of the genus. The organism is transmitted in an extracellular non-replicating form known as the elementary body. The elementary body adheres to and is phagocytosed into a host epithelial cell. Once inside the cell, the elementary body transforms into the intracellular replicative form of the organism, the reticulate body. The reticulate bodies divide by binary fission within membrane-bound vacuoles called inclusions. After approximately 36

hours, reticulate bodies condense into elementary bodies, inclusion ruptures, and the elementary bodies disperse to infect adjacent epithelial cells or be transmitted to other hosts. A unique feature of the chlamydial inclusion is its ability to resist lysosomal fusion; the mechanism of resistance is yet unknown. The intracellular milieu also provides the organism with nutrients and serves as a refuge from host immune defense mechanism. Although Chlamydia was initially thought to be a large virus, they in fact possess both DNA and RNA, have a cell wall and ribosome's similar to those of gram-negative bacteria. *Chlamydia trachomatis* has at least 18 distinct serotypes (serovars). These serotypes confer tissue tropism and disease specificity; serovars A, B, Ba and C are associated with trachoma, whereas serovars D and K are associated with sexually transmitted and perinatally acquired infections.

Gonorrhoea

Disease Characteristics

According to Barry and Klausner (2006) gonorrhoea was recognized by ancient Greek practitioners who named it for its milky urethral discharge (*gono*-meaning seed or sperm, and *rhea*-meaning flow). Gonorrhoea is an STI caused by a bacterium that can grow and multiply easily in the warm, moist areas of the reproductive tract, including the cervix, uterus, the fallopian tubes, and the urethra in women and men (CDC, 2007). The bacterium can also grow in the mouth, throat, eyes, and anus (CDC, 2007). Often signs are asymptomatic or mild in women. Some 30-60% of Gonorrhoea-infected women have been reported to be asymptomatic (Einwalter, et al. 2005). Transmission from asymptomatic persons may be responsible for most new infections in a community. Untreated infections can progress to pelvic inflammatory disease, and approximately 20% of women with PID later have fertility problems (CDC, 2007). Ophthalmia neonatorum is a complication that may occur in an infant when a baby passes through an infected birth canal (Platt, Rice, & McCormack, 1983).

Gonorrhoea is increasing in some countries and has rapidly developed resistance to multiple classes of antibiotics (Jones, 2004). Ceftriaxone injection is the only available

universally recommended treatment in the United States, because fluoroquinolone-resistant gonorrhea seems to be rapidly spreading from West to East (CDC, 2007). There has been an increasing prevalence of drug-resistant isolates to fluoroquinolones. The Gonococcal Isolate Surveillance Project found 6.8% of isolates to be resistant in 2004, up from 4.1% in 2003 (Kirkland, 2006). Drug resistance is another reason for the importance of determining risk factors for Gonorrhea to assure clinicians are diagnosing and treating patients effectively (CDC, 2007).

Screening programs for Gonorrhea were initiated in the 1970s in the United States (Manhart, Marrazzo, Fine, Kerani, and Golden, 2007). Screening for asymptomatic infections is the cornerstone of public health efforts to control bacterial sexually transmitted infections like Gonorrhea. In the public health clinic in Veron, Dominican Republic screening is not a part of the STI protocol for Gonorrhea.

Pathophysiology: Neisseria gonorrhoeae

In an original study by Cohen and Cannon entitled *Human experimentation with Neisseria gonorrhoeae: progress and goals* (1999) it was determined:

Neisseria gonorrhoeae is a gram negative, non-motile, non-spore-forming organism that grows single and in pairs. Exclusively a human pathogen, the gonococcus contains on average, three genome copies per coccal unit; this polyploidy permits a high level of antigenic variation and the survival of the organism in its host. Gonococci, like all other *Neisseria* species are oxidase positive. They are distinguished from other neisseriae by their ability to grow on selective media and to utilize glucose but not maltose, sucrose, or lactose. *N. gonorrhoeae* has a complex set of molecular mechanisms for invasion and survival in humans. The activation of this complex armamentarium of cellular machinery begins when the pathogen arrives on a mucosal surface. The basic sequence of steps includes (a) long-range attachment by means of pili, (b) close attachment, (c) invasion of mucosal columnar cells, perhaps mediated by porin proteins, (d) transportation through the cell in phagosomes and (e) occasional “transcytosis” into the submucosa and then, rarely, invasion into the blood stream. Once established in the host, *N. gonorrhoeae* is antigenically heterogenous, changing its surface structures to avoid host defenses. Several important antigenic

structures include pili, porin proteins, opacity (Opa) proteins, reduction-modifiable protein, and lipooligosaccharide (LOS). Pili are the hair like structures that extend several micrometers from the cell surface and enhance attachment to host cells, as well as help resist phagocytosis. There is great variability in their antigenic structure, through expression of different pilin structural subunit types, as well as variability in expression of different Opa proteins. Gonococci can express several LOS chains simultaneously, but, unlike lipopolysaccharide from other gram-negative bacteria, the gonococcal LOS does not have long O-antigen side chains. The endotoxic effects of LOS are responsible for the systemic toxicity observed in patients with disseminate disease.

Pelvic Inflammatory Disease

Pelvic inflammatory disease or PID is an infection of the female upper genital tract, which can consist of a range of inflammatory disorders, including endometritis, salpingitis, tubo-ovarian abscess and pelvic peritonitis (Akhter, Beckmann & Gorelick, 2008). Infection with *N. gonorrhoeae* and *C. trachomatis* is often implicated in cases of PID. Treatment of PID should be initiated promptly after a presumptive clinical diagnosis has been made in order to prevent long-term sequelae, such as infertility (Akhter, Beckmann & Gorelick, 2008).

Risk Factors

Researchers continue to bring together the biological, sociological and behavioral information on sexual risk factors among adolescents and adults. Sexually transmitted infections constitute a major health burden on any society. There are approximately 14 million cases of STIs occurring in the United States each year (Ghanem, 2007). The current epidemic is complicated by the high asymptomatic carrier state associated with most STIs (Adderley-Kelly & Stephens, 2005).

According to the CDC (2007) 2 of the top 10 infections reported in the U.S. are Chlamydia and Gonorrhea. The highest incidence of Chlamydia and Gonorrhea is in teens and young adults from ages 15 to 25 (Ghanem, 2007). The CDC (2007) estimates

that about 4 million acute cases of Chlamydia infections occur each year in the United States. More than 50 million cases of Chlamydia urogenital infections occur worldwide (Gaydo, Gaydos, Howell, McKee, and Quinn, 1998). It is estimated that annually there are 62 million incidents of Gonorrhea cases worldwide, of which 800000 occur in the United States (Gaydos, Hartman, Kacena, Quinn, and Quinn, 1998). One study by Ghanem (2007) estimates 340 million cases of curable sexually transmitted infections per year worldwide with about 38 million occurring in Latin America and the Caribbean. Currently, there is limited data collected on the prevalence of sexually transmitted infections in Veron, Dominican Republic.

Nearly half of the world's population is under the age of 25 years; 87% of those under age 25 live in developing nations (Koyama, Corliss & Santelli, 2009). In 2007, young people aged 15-24 years made up 1.2 billion of the three billion children and youth (0-24 year) in the world (Koyama, Corliss & Santelli, 2009). Many young people begin their sexual lives successfully avoiding pregnancy and sexually transmitted infections and develop mutually respectful, committed and healthy relationships (Koyama, Corliss & Santelli, 2009). Other young people engage in risky behaviors and lack adequate knowledge about pregnancy and STI prevention, communication and negotiation skills and social support. STIs disproportionately affect adolescents and young adults for a variety of behavioral, social and biological reasons. Among the 14 million cases occurring in the United States in 2007, four million occurred in adolescents and six million in young adults (Ghanem, 2007). In 1997, it was reported that females ages 15 to 19 had the highest reported cases of Chlamydia and Gonorrhea among women (Manhart, et al. 2007). One of the reasons that adolescents and young adults are at higher risk is

because they are more likely to have multiple partners than a single long-term relationship (Han, Coles, & Hipp, 1997). An additional contributing factor may be that adolescent women may have a physiologically increased susceptibility to infection due to increased cervical ectopy (Adderley-Kelly & Stephens, 2005). Studies have shown that when testing asymptomatic women for Chlamydia or Gonorrhea, clinicians should place a higher priority on adolescents with previous STIs (Anschuetz, Beck, Asbel, Goldberg, Salmon & Spain, 2009). The Lazarus study found that condom use among adolescents in European Union countries and schools was low and was correlated with alcohol use, a history of bullying behavior and gender (Lazarus, Moghaddassi, Godeau, Ross, Vignes, Ostergen & Liljestrang, 2009).

Disparities in the prevalence of STIs exist among different populations. STIs do affect all racial, cultural, economic and religious groups. Some groups are disproportionately more affected by STIs and their complications. In the United States race and ethnicity contribute to fundamental determinants of health status (CDC, 2007). Data have shown that African American and Hispanic groups have a higher risk factor for STIs as compared with the infections rates of Caucasians in America (Einwalter, et al. 2005). Because racial and ethnic groups are more likely to receive services for STIs from public sector clinics, where timely and complete illness reporting is the rule, National Surveillance data may over-represent STIs in these groups. Similar disparities may exist in the Dominican Republic among races due to sociodemographic factors. The Veron, community consists of Dominicans, Haitians and Americans and may show disproportionate distributions of infection in various ethnicities due to utilization of the public health clinic, language barriers and attitudes toward health services.

Both gender and age influence the likelihood of acquisition of STIs through effects on biologic susceptibility, sexual behavior, and partner choice (Paul, van Roode, Herbison & Dickson, 2009). Gender inequality also plays a role in the transmission of STIs. Women are experiencing a growing burden of HIV infections in many regions, for which the gender imbalance is partly responsible (Ehrhardt, Sawires, McGovern, Peacock & Weston, 2009). This can likely apply to many other sexually transmitted diseases. Women's subordination to men both increases their risk of HIV infection and decreases their chances of survival once infected (Ehrhardt, Sawires, McGovern, Peacock, Weston, 2009). Women are twice as likely as men to contract diseases such as HIV from an episode of unprotected sex; this renders them disproportionately vulnerable to infections. In many places, infected women risk rejection by their families and communities, and because their access to health care is weaker than that of men, they suffer more complications. (Ehrhardt, Sawires, McGovern, Peacock & Weston, 2009).

Other risk factors identified include but are not limited to poverty, limited or no access to quality health care and fewer attempts to get medical care (CDC, 2007). The Du study reported that cross-sectional results reflected clear socioeconomic gradients for gonorrhea rates, demonstrating that inner-city urban census tracts with low socioeconomics had the highest Gonorrhea rates and that rates were lower among communities with better socioeconomics (Du, McNutt, Campo & Coles, 2009).

An additional risk factor may include the number of terminated pregnancies a woman may have undergone. A study by Patel demonstrated that there was a comparatively high prevalence rate of Chlamydia-positive patients in a termination clinic. The study went on to suggest that secondary to poor follow-up, this population of patients

should undergo screening as part of this particular procedure (Patel, Rashida, Godfey & Panchal, 2008). Women are at higher risk than men for most STIs, and young women are more susceptible to some STIs than older women (Adderley-Kelly & Stephens, 2005).

Sexual abuse is reported in both developed and underdeveloped countries. In spite of the high prevalence of sexual abuse, estimated to be 12-25% of girls in the US most abused children will not have any physical examination findings nor any sexually transmitted infections (Shapiro & Makoroff, 2006). Screening is not commonly done in prepubertal children populations.

Additional risk factors include illicit drug use, living in communities with a high number of cases of STIs, having unprotected sex with multiple partners, and lower socioeconomic status (CDC, 2007). Women who are unmarried, have new or multiple sexual partners, have cervical ectopy and use barrier contraceptives inconsistently may also see increased rates (Einwalter, et al. 2005).

When discussing risk factors one must also review factors that contribute to re-infection rates. An STI re-infection signals continued poor sexual health, which is inextricably entwined with the effectiveness of risk-reduction counseling and partner management. Some studies show that age, gender and socioeconomic status contribute to re-infection rates of STIs (De, Singh, Wong, Kaida, 2007.)

Screening for STIs on the basis of age, behavioral characteristics, and clinical characteristics, or in some instances universally, has been shown to be cost-effective for women by preventing costly complications (Metha, Rompalo, Rothman, Londner, Zenilman, 2003).

Clinical Diagnostic Testing

The major different types of diagnostic test for chlamydial infections are direct fluorescent antibody, EIA, DNA probe assay and DNA amplification (Cook, St. George, Lassak, Tran, Anhalt, and Rinaldo, 1999). Each of these diagnostic modalities varies in sensitivity and specificity. Both polymerase and ligase chain reaction (PCR, LCR) assays have been used to detect Chlamydia in urine and endocervical specimens in female adult populations (Beck-Sague, Farshy, Jackson, et al., 1998).

The method for the diagnosis of Gonococcal infection is a Gram stain or a number of commercially available genetic techniques. These include nonamplified DNA probe and a Nucleic Acid Amplification Test (NAAT). The increased sensitivities and specificities of nucleic acid amplification techniques have led to the evaluation of less invasive specimen collection procedures for screening Gonococcal and Chlamydial urogenital infections (Fang, Husman, DeSilva, Chang & Peralta, 2008). For urethral and cervical infections, assays based on nucleic acid probes can detect Gonococcal infection rapidly and reliably. Nucleic acid probe tests are sometimes substituted for culture for the direct detection of Gonorrhoea in urogenital specimens (Ison, 1990). The NAAT became available in the last decade for use in clinical microbiology laboratories and has been considered the most sensitive and promising test in identifying CT and NG organism. The ability to detect CT and NG using urine and vaginal specimens without a pelvic examination is a key advantage of nucleic acid amplification test, and the ability facilitates screening females in situations other than traditional venues (Fang, Husman, DeSilva, Chang & Peralta, 2008).

NAAT have become the most commonly used assays for screening and diagnosis of Chlamydia and Gonorrhea with a urine sample (Manhart, et al. 2007). Some products test for both Gonorrhea and Chlamydia in a single specimen. NAAT can be used on urethral and endocervical swabs as well as urine samples. This offers the ease of urine collection in both men and women, with the added benefit of sensitivities and specificities equal to those obtained from urethral or endocervical samples (Ison, 1990). NAATs make possible screening in settings where urethral and cervical samples may not be possible because of logistics or patient non-acceptance (Geisler, & James, 2008). In addition, using urine as a clinical specimen would be an ideal method of screening when adolescents are the population being tested, particularly in settings where pelvic examinations are not easily performed.

NAAT does not require the presence of live organisms, and only a small number of organisms are needed for accurate test results (Ison, 1990). The CDC (2007) believes that NAAT's on urine samples are acceptable methods of screening for genital Gonorrhea and Chlamydia in both men and women, although for gonorrhea, cultures of urethral and endocervical swabs are preferred so that sensitivity can be obtained. Gonorrhea and Chlamydia cultures are recommended for diagnosing oropharyngeal or anal infections (Campos-Outcalt, 2003). One disadvantage of these tests is an inability to determine antibiotic sensitivities. Another is occasional false-positive results from dead organisms, which can occur if test of cures are performed too soon after treatment (less than 3 weeks) (Manhart, et al. 2007).

Point-of-care tests for Chlamydia and Gonorrhea screening are less sensitive than laboratory-based tests and are utilized in situations where screening-test-positive persons

might fail to return for treatment or return after a substantial number of days. Products such as Clearview Chlamydia (point-of-care product) provides a simple direct detection assay for chlamydia antigens in endocervical swab specimens, which is sensitive, specific and rapid, making the test suitable for either single testing or batch use. According to Inverness Medical Professional Diagnostic Group, Clearview Chlamydia is an immunoassay for the direct qualitative detection of chlamydia antigen in female endocervical swab specimens. The Clearview Chlamydia sensitivity was determined to be 87.0%, the specificity 98.8% and overall agreement with culture 97.3%.

According to the Inverness Medical Professional Diagnostic Group, BioStar OIA/GC assay is an optical immunoassay (OIA) test for the rapid, qualitative detection of gonococcal antigen in female endocervical swab and male urine specimens. Urine specimens must be prepared using an accessory Urine Filtration Device for concentration and extraction. The test is intended for in vitro diagnostic use as an aid in identifying the presence of *Neisseria gonorrhoeae* antigen. The assay is intended for use with symptomatic females and males in populations at risk for STIs. The OIA test detects a unique target antigen on the ribosomal protein, L7/L12, which is common to all strains of GC. L7/L12 proteins are part of the 50S ribosomal protein complex with subunit molecular weights of approximately 12-14 kDa. Use of the GC L7/L12 protein as the OIA GC assay target permits the use of a single pair of complementary monoclonal antibodies that react with all strains of *N. gonorrhoeae*. Rapid antigen detection may facilitate timely presumptive laboratory evidence.

In the last 10 years, researchers have assembled an impressive collection of evidence that screening for Chlamydia, Gonorrhoea and Trichomonas can be conducted

effectively outside of the clinic environment. One study reviewed demonstrated that home-based self-collection and self-testing are acceptable, feasible, and result in a slightly high response rate to testing for STIs. (Lippman, Jones, Luppi, Pinho, Veras & De Wiggert, 2007). The Lippman trial studied self-testing for trichomonas using the Xenotope Diagnostic Inc. Trichomonas Test, an immunochromatographic test that detects antigens directly from self obtained vaginal swabs and provides results within 10 minutes. Dry self-obtained vaginal swab specimens were delivered to the laboratory where they were tested for presence of Chlamydia and Gonorrhea using COBAS AMPLICOR CT/NG PCR (Lippman, Jones, Luppi, Pinho, Veras & De Wiggert, 2007). This may serve as a promising alternative to clinic-based STI screening across diverse contexts and thus aid in decreasing transmission rates.

Clinical Treatment

Treatment of Chlamydia infection depends on the site of the infection, the age of the patient, and whether the infection is complicated or uncomplicated. Treatment differs during pregnancy.

For uncomplicated Chlamydia the CDC (2007) recommends a single dose of Zithromax (1g azithromycin) or 100mg Doxycycline (Vibramycin) orally twice per day for seven days. These regimens have similar cure rates and adverse effect profiles, although a benefit of azithromycin is that physicians can administer the dose in the office. If the patient vomits the dose of azithromycin within one to two hours of taking the medication, an alternative treatment is considered. Doxycycline is the treatment of choice in the clinic in Veron, mainly because it is effective and inexpensive.

According to the CDC (2007) alternative regimens are Erythromycin base 500 mg orally four times per day, or Erythromycin Ethylsuccinate 800 mg orally four times per day, or Ofloxacin (Floxin) 300 mg twice per day, or Levofloxacin (Levaquin) 500 mg once per day. Each alternative medication should be taken for seven days. Patients with urethritis should have follow-up only if symptoms persist or recur after completion of the antibiotic course.

Recommended treatment according to the CDC (2007) for gonorrhea is ceftriaxone 125 mg intramuscularly in a single dose or cefixime (Suprax) 400 mg orally in a single dose, or ciprofloxacin 500 mg orally in a single dose, or ofloxacin 400 mg orally in a single dose or levofloxacin 250 mg orally in a single dose plus recommended regimen for Chlamydia if infection is not ruled out. Ceftriaxone and spectinomycin are safe and effective treatments of Gonorrhea during pregnancy. Ceftriaxone is the treatment of choice in the Veron Clinic. Patients should be advised to abstain from sexual intercourse for seven days after treatment initiation. Partner notification is an important component of the management of both curable and incurable as well as chronic STIs (Hogben, Burstein, Golden, 2009). Some studies have shown that expedited treatment of partners without clinically evaluating them was an effective form of reducing persistent or recurrent Chlamydia and Gonorrhea infections (Golden, Whittington, Handsfield, James, Hughe, Stamm, Hogben, Clark, Malinski, Helmers, Thomas & Holmes, 2005). However, benefit must be weighed against potential risk.

STIs in Developing Countries

It may be speculated that the prevalence of sexually transmitted infections is highest in developing countries due to the lack of diagnosis and treatment, low condom

use and early age of first intercourse. Because of certain risk-taking behaviors among women in developing countries a closer look needs to be taken at the prevalence of sexually transmitted infections.

In 1988, Dominican Republic had the third lowest Gross Domestic Product per capita in the Americas, after Haiti and Bolivia (Glassman, Reich, Laserson, & Rojas, 1999). In June, 1995, it was one of the poorest countries in Latin America (Glassman, et al. 1999). Although there have been many advances in the past decade many rural areas are still disproportionately impoverished from the major cities. In these areas health care facilities are often underserved and people live with chronic illnesses. The transmission of STIs is one of many health concerns. Little is known about the sexual risk behaviors among young women in the Dominican Republic (Glassman, et al. 1999).

Public Health Recommendations

Secretariat of Health (SESPAS)

Programs offered through the Secretariat of State for Public Health and Social Welfare in the Dominican Republic covered 70 to 80 percent of the population in the late 1980s (Haggerty, 1989). Both personnel and public facilities were concentrated in the two largest cities. For example, there were roughly 3,700 inhabitants per physician nationally but this figure ranged from about 1,650 in the National District to roughly 5,000 in some southeast provinces and in the south central provinces of the Dominican (Haggerty, 1989). Similarly, more than half of all hospital beds were in the National District and the central Cibao (Glassman, et al. 1999). Secretariat of Health (SESPAS) and Social Security Institute Dominican Republic (IDSS), the largest institutional actors

in the public sector, have shown little capacity to respond to the major problems in the health sector (Glassman, et al. 1999).

SESPAS began a major effort to improve rural health care in the mid-1970s (Glassman, et al.1999). By the early 1980s, the government had set up more than 5,000 rural health clinics, health subcenters and satellite clinics (Haggerty, 1989). Doctors performing their required year of social services, as well as a variety of locally hired and trained auxiliary personnel, staffed the facilities. Critics charged that lack of coordination and inadequate management hampered the program's effectiveness (Haggerty, 1989). In 1985, 8.8 percent of the national budget supported health services (Haggerty, 1989).

Educational Infrastructure in the Dominican Republic

Formal education in the Dominican Republic includes the primary, secondary, and higher education levels (Haggerty, 1989). The six-year primary cycle for children is compulsory. Three years of preschool is offered in some areas, but not on a compulsory basis. There are several types of secondary schools; about 90% of students attend the six year *liceo*, which awards the *bachillerato* certificate upon completion and is geared toward University admissions (Haggerty, 1989). Other secondary programs include teacher training schools, polytechnics, and vocational schools. All primary and secondary schools are under the formal jurisdiction of the Secretariat of State for Education and Culture (Haggerty, 1989).

Only 17 percent of rural schools offered all six grades despite the compulsory nature of primary education and there is low enrollment at the secondary level (Haggerty, 1989). For those who go to the secondary level, academic standards were low and drop-out rate reportedly was high, and all but the poorest students had to buy their textbooks

(Haggerty, 1989). This would be another disincentive to enrollment for many families in poor rural communities.

Sexuality education has been studied in great detail, yet its impact on reproductive health outcomes is still largely unknown. A review study reported that school-based sexuality education improves awareness of risk and knowledge of risk reduction strategies, and increases self-effectiveness and intention to practice safer sex (Wellings, Collumbien, Slaymaker, Singh, Hodges, Patel, & Bajos, 2006). For these reasons, sexual education should be understood as a public good, despite the difficulty of measuring its impact on sexually transmitted infections. However, there is substantial debate and disagreement surrounding the details of sex education, such as who should teach it, how it should be taught, what should or should not be included and the developmentally appropriate ages for when it should be taught.

Educational Health Promotion Models for Prevention and Intervention

Investigations about sexual behavior have been on the increase for a few decades. Things such as the outbreak of AIDS have made sexual and reproductive health policies more difficult. (Bozon, Gayet & Barrientos, 2009). In an overview of the demographics of Latin America and the Caribbean since 1950, the authors stressed common trends in the region: abrupt decline of fertility in majority of countries, little change in nuptiality and celibacy levels, and unprecedented progress in educational levels together with worsening social inequality and high poverty levels (Bozon, Gayet & Barrientos, 2009). These factors help support the necessity of carrying out more sexual behavior surveys of this population to understand the social differences and appropriate interventions.

In low income countries, the management of STI cases is usually inadequate and STI control programs often fail, mainly due to failure to recognize the magnitude of the problem in the population, failure to associate the diseases with serious complications and sequelae, failure to provide adequate coverage of care and failure to identify asymptomatic individuals until complications develop (Lan, Mogren, Phuc & Lundborg, 2009). Individual practice of risk reduction is the primary avenue for prevention of sexually transmitted infections. The development of effective educational programs that will achieve this expected outcome is vital in societal efforts to control these diseases. Knowledge alone does not necessarily lead to change in behavior; preventive strategies that focus on providing information have had minimal success (Shain, Piper, Newton, Perdue, Ramos, Champion & Guerra, 1999). More successful interventions, tested in randomized controlled trials, have had a theoretical basis and have promoted self-efficacy and communication skills. (Shain, Piper, Newton, Perdue, Ramos, Champion & Guerra, 1999). One study that was reviewed showed that participation in a program of counseling and testing that specifically targets both members of HIV serodiscordant couples may have resulted in a considerable proportion of couples ceasing sexual risk practices and a decline by half in the overall frequency of unprotected coital relation (Hernando, Romero, Garcia, Rodriguez, Amo and Castillo, 2009). The focus of this article was on reducing sexual risk behavior as it pertained to the risk factors for HIV, but it could be applied to many other sexually transmitted diseases.

The Dominican Republic (DR) has a long history of innovative HIV prevention programs in the female commercial sex industry (Barrington, Ellen, Kerrigan, Latkin, Moreno & Sweat, 2009). An environmental-structural intervention integrating

community solidarity and government policy strategies demonstrated significant reduction in sexually transmitted infections and increases in condom use among female sex workers in the DR (Barrington, Ellen, Kerrigan, Latkin, Moreno & Sweat, 2009). In Santo Domingo, the Centro de Orientacion e Investigacion Integral (COIN), a non-governmental organization (NGO), has worked with local sex workers to establish a network of peer health educators, to develop and distribute educational materials and to implement HIV prevention activities since the 1980s. Their educational materials featuring a Dominican sex worker called *Martiza* have been particularly successful as a peer education tool in addressing strategies such as negotiating and erotizing condom use with clients, refusing drunk, high violent clients and keeping the client interaction as safe as possible for the sex worker (Garcia, Yam & Firestone, 2006). This has been poorly evaluated in non-sex workers.

Another study revealed several barriers for prevention of the transmission of HIV with heterosexual Latino couples. One of the most salient cultural imbalances in Latino heterosexual couples is the strong influence of conservative beliefs about sexuality and sexual behavior, often attributed to teachings of the Catholic Church. Participants reported that safer sex behavior was often inhibited in heterosexual couples because of compliance with church doctrines against condom use and other forms of sexual risk reduction (Perez-Jimenez, Serrano-Garcia & Seal, 2009). Some among this study group thought involving the Catholic Church in prevention activities could strengthen their influence.

Many of the behavioral models for STI prevention are concentrated around the spread of HIV. We can use what is known regarding HIV models of prevention for other

STIs. Throughout the 1980s and 1990s, prevention was strongly influenced by cognitive theories of behavior change that emphasized knowledge, attitudes, beliefs and skills related to HIV/AIDS (Kerrigan, Ellen, Moreno, Rosario, Katz, Celanto & Sweat, 2003). In recent years attention has increasingly been focused on the role of environmental-structural factors and the transmission and prevention of HIV. Much of the conceptual shift can be attributed to several key papers published in the mid to late 1990s which questioned the long-term effectiveness of prevention models based solely on individual-cognitive theories of behavior change, and highlighted the importance of integrating environmental-structural factors into the conceptual frameworks utilized to explain and address HIV-related vulnerability (Kerrigan, Ellen, Moreno, Rosario, Katz, Celanto & Sweat, 2003).

For individuals in high risk populations for contracting and transmitting sexually transmitted infections, it is important to utilize a multifaceted approach regarding educational intervention. The use of a single method of information delivery is less effective than a combination of methods that motivate, facilitate and reinforce positive behavioral change among individuals (Rosenstock, Strecher, and Beacker, 1988). A successful educational intervention should demonstrate its clinical relevance.

A variety of training models have been developed and show promising results (Rosenstock, et al. 1988). The alternative behavior change models, including health belief model, social cognitive theory model, theory of reasoned action model, theory of planned behavior model, theory of personal investment model, multi-component stage model, risk reduction model, and information-motivation-behavioral skills model are often used (Martich, St. Lawrence, Hall, Hartsfield, 2001). Choosing the best model is critical.

Individual-level interventions that have proven effective in HIV/AIDS research with other populations are usually interactive and labor intensive (Ortiz-Torres, Serrano-Garcia, Torres-Burgos, 2000). They focus on strategies such as workshops, small group interactions and counseling. These strategies can be used with Dominican women if the content of the intervention places strong emphasis on examining and questioning cultural norms and beliefs. As mentioned above COIN has been engaged in HIV prevention in the female sex industry of the Dominican by developing a network of sex worker peer-educators in Santo Domingo and several other regions of the country (Kerrigan, Ellen, Moreno, Rosario, Katz, Celanto & Sweat, 2003). These peer educators have conducted both individual and small group information, education and communication sessions using specialized educational materials and community mobilization designed to increase HIV-related protective behavior (Kerrigan, Ellen, Moreno, Rosario, Katz, Celanto & Sweat, 2003).

Some studies have demonstrated that prioritizing systems are effective in differentiating between patients at high and low risk for STIs, contributing to provision of tailored STI services and increasing efficiency and client access to STI services (Heijman, Van der Bij, de Viries, van Leent, Thiesbrummel & Fennema, 2007). The Heijman study implanted a prioritizing system that classified visitors to an outpatient clinic as high or low risk depending on reported sexual behavior and previous STI events. The high and low risk groups were assigned to standard and short screening protocols, respectively. Both protocols included diagnostic testing for STIs. The prioritization system was feasible, easy to use and effective in differentiating between high and low risk visitors. The prevalence of STI/HIV was significantly lower for visitors in the short

screening protocol (low risk) than for those in the standard protocol (high risk) (Hiejman, Van der Bij, de Viries, van Leent, Thiesbrummel & Fennema, 2007).

Sociodemographics of Veron, Dominican Republic and regional cultural practices, along with health, educational level and environmental risk factors are important considerations for successful programs. Models for health prevention and intervention are useful in designing successful screening protocols and educational material about Chlamydia and Gonorrhea for the female population that utilizes the clinic in Veron, Dominican Republic.

Summary

Despite the development of proficient diagnostic equipment and drug treatment for sexually transmitted bacterial infections such as Chlamydia and Gonorrhea these infections continue to burden society. Research proposed in this study could provide important data to consider modification to the standards of care in the Veron, Dominican Republic clinic to ensure effective protocols for treatment. It is important for clinicians to understand the risk factors that contribute to the transmission of these diseases. Both Gonorrhea and Chlamydia are primarily transmitted through sexual contact and lead to devastating morbidities in the female population. Global estimates for these diseases are 340 million cases per year with about 38 million in Latin America. Risk factors range from biological, sociological and behavioral causes. Females between the age of 15 and 25 are at highest risk for contracting both Chlamydia and Gonorrhea in the United States. Other risk factors include poverty, limited or no access to quality health care and fewer attempts to get medical care. Women are at higher risk than men. The ability to diagnosis Chlamydia and Gonorrhea can be accomplished with a variety of diagnostic modalities;

however, point-of-care tests provide quick, accurate results in high-risk populations. Clearview Chlamydia and OIA Biostar are two test kits that can be used to diagnose Chlamydia and Gonorrhea respectively. Drug treatment as recommended by the CDC (2007) includes a single dose of 1g azithromycin for Chlamydia and ceftriaxone 125 mg intramuscularly in a single dose for Gonorrhea. Alternative treatments are also available in the case of pregnancy and for drug-resistant areas. The Veron clinic is sponsored by SESPAS, the government branch that is responsible for overseeing public health initiatives. Often times the SESPAS-sponsored clinics are underserved and underfunded. Socioeconomic status may impact the risk for these STIs and educational level may be a direct contributor to socioeconomic status. Formal education in the Dominican Republic includes primary, secondary, and higher education levels. Dropout rates are high in the first six years and even higher in secondary level. Despite the educational challenges in many rural communities like Veron, educational health promotion models for prevention should be developed to control the spread of these diseases.

Chapter Three

Methodology

Purpose

The purpose of the this study was to determine risk factors that contribute to the prevalence of positive Chlamydia and Gonorrhea among adolescent and young adult females who utilize the Veron clinic in order to develop educational programs for prevention and clinical standards of care for these STIs.

Procedure

The methodology was a cross-sectional study involving Chlamydia and Gonorrhea and related risk factors among adolescent and young adult women presenting at a public health clinic in Veron, Dominican Republic. Prior to the study, IRB approval was acquired through the VCOM Institutional Review Board January 7, 2008 (Appendix H). The study was conducted during January 28, 2008 through March 3, 2008 for a total of 5 weeks. Only the accepting sample of those who visited the clinic in Veron, Dominican Republic for prenatal visits, pap smears and gynecological complaints were included.

The survey instrument was developed on the basis of both preliminary research and a review of the existing literature to include an appropriate sample and factors that were likely to contribute to the outcomes of the study. The patient history form gathered information about age (self-reported), marital status, occupation, educational level, living environment, chief complaint, illicit drug use, sexual history (self-reported), sexual knowledge and gestational history to determine risk factors for positive test results for Chlamydia and gonorrhea (see Appendix D, E, F). Those eligible for enrollment and

invited to participate in the study included patients aged 15 years old and older being examined at “Clinica Rural El Veron” for prenatal, annual pap smear and gynecological visits presenting with symptoms or asymptomatic. Patients excluded were those who declined participation and those patients who had received antimicrobials within 2 weeks prior to the visit.

Patients were asked to sign an informed consent form translated into the respective language of comprehension (see Appendix A, B, C) that included English, Spanish and Creole. Consent forms and related protection of human subjects along with a comprehensive plan were submitted and approved by IRB at the Virginia College of Osteopathic Medicine (VCOM) November 2007. See Appendix H for the IRB documentation. Due to the variety of demographics and languages in the Veron, Dominican Republic community the documents were provided in Spanish, English and Creole. The patients were informed that their participation was strictly voluntary. The patients who agreed to participate were escorted to a private exam room for a face-to-face structured interview.

Each patient’s past medical history was obtained during patient interview and at the time of enrollment. Each patient was interviewed and completed a socio-demographic questionnaire on their general and sexual history. The researcher completed the patient history and assessment form based on questions answered verbally by the participants. Each form was coded, collected and locked in a secure cabinet.

Following the survey and consultation each patient was asked to undergo a vaginal exam for specimen collection to be sent for laboratory diagnosis. When testing for Gonorrhea, laboratory techniques included BioStar OIA GC tests to detect the

ribosomal protein L7/L12, found in *Neisseria gonorrhoeae*. The OIA GC test detects a unique target antigen on the ribosomal protein, L7/L12, which is common to all strains of GC. Clearview Chlamydia tests were used for the detection of *Chlamydia trachomatis*. This is a rapid immunoassay for the direct qualitative detection of *Chlamydia trachomatis* antigen in female endocervical swab specimens.

Specimens were sent to the clinic laboratory for analysis. Patients were informed about their results upon completion of the test (see Appendix G). Treatment was conducted based on the standard of care of the clinic and is not a function of this study. Patients were referred to the licensed Dominican doctor on staff for treatment and follow-up care. In addition, each participant received educational materials in brochure/pamphlet form to aid in preventive knowledge for the future.

Design

This is a descriptive correlational study to address the research objectives. Appropriate methodology was used to control for internal and external validity within the context of the case study design.

Site Selection, Population and Sample

The site selection was Veron, Dominican Republic, which included a patient population from the surrounding geographical communities (Figure 1). The surrounding communities include barrios such as Barrio Nuevo, Villa Playwood, Kosovo, Punta Cana, Cruce de Domingo Maiz, Sabana Grande de Boya, San Pedro de Marcoris, Villa la Fa, La Jarda, Friusa, Elias Pina, Maria Cristina, Santiago and Navarrette. Moreover, this is a region of the Dominican with poverty and underserved medical care. The community has health care assistance through the outreach mission of the Edward Via Virginia College

of Osteopathic Medicine, where the medical school has a full time clinic and necessary support for a study of this scope.

The accepting sample was females from the population presenting at the Veron Clinic from January 28, 2008-March 3, 2008. Unfortunately, the population of Veron is highly dynamic with people coming to and leaving the region daily. There is not a phone book, census or any other way to verify every member of the population at any point in time. Therefore, the population for this study was vested in the clinic setting to include females aged 15 years old and older as of January 1, 2008 who presented during the time frame. The power and sample size calculator from the Department of Biostatistics at Vanderbilt University was used to test the hypothesis. It was determined that for a significance of 0.05 ($p=0.05$) and 80% power the study would need a total group size of 84 patients. The sample size was increased by 10% to compensate for patients with missing cultures, lab errors, or who otherwise could not be counted in the data analyses. Therefore, 90 patients were selected for the study for participation during the 5 week time period.

Inclusion Criteria

Inclusion criteria describes the characteristics that defined who was asked to participate in the study. Inclusion criteria for this study are females aged 15 and older who are presenting to the clinic for prenatal exams, pap smear exams or gynecological complaints.

Exclusion Criteria

Exclusion criteria describe the characteristics of persons who were not invited to

participate in the study. Exclusion criteria for this study are male patients visiting the clinic for well-visits and all patients presenting chief complaints inconsistent with the study objectives.

Instrumentation

The study utilized a socio-epidemiological questionnaire to gather information on risk factors and related health history. The questionnaire was administered via verbal interviews by the researcher at the clinic. Information was gathered on age (self-reported), marital status, occupation, educational level, living environment, chief complaint (reason for clinic visit), illicit drug use, sexual history, sexual knowledge and gestational history (see Appendix D, E, F). The chief complaint or reason for the clinic visit was further divided into abdominal pain, gynecological complaints, prenatal visits, pap smear exams (papanicolaou exam) or other complaints. A papanicolaou exam is performed by taking a sample secretion from the endocervical canal and scraping the transitional zone for the purpose of screening for cervical carcinoma (Droegemueller, Herbst, Mishell & Stenchever, 2001). The sexual risk behaviors (self reported), were determined by the results of the questions that pertain to age of first gestation, number of sex partners in the past 6 and 12 month period, usage of condoms, sexual partners 3 years older, history of sexually transmitted infections and history of sexual abuse. The sexual knowledge was determined by a series of questions that tested knowledge about sexually transmitted infections, specifically Gonorrhea and Chlamydia.

Each questionnaire was coded so that at no time was the patient's name appearing with the data. Instead a code book was maintained in a secure location for tracking

purposes. All data will be destroyed within two years after the study is completed to ensure protection of anonymity of all participants, according to IRB approval.

Each laboratory technician was trained to utilize the BioStar and Clearview equipment needed in this study. Upon completion of training each technician had to successfully pass an exam in order to utilize the equipment. The BioStar OIA GC assay is an Optical ImmunoAssay (OIA) test for rapid detection of the gonococcal antigen (L7/L12) ribosomal protein in female endocervical swabs. The OIA GC test has a specificity of 87.8% and sensitivity of 98.5%. Clearview Chlamydia is a rapid immunoassay for the direct qualitative detection of *Chlamydia trachomatis* antigen in female endocervical swab specimen. The CLIA has a specificity of 99% and sensitivity 87% for *C. trachomatis*.

Data Collection

Each patient received a socio-epidemiological questionnaire at the time of enrollment in the study. Questionnaires were developed based on past research that has highlighted potential risk factors in a similar demographic population. The forms included information about age (self-reported), marital status, occupation, educational level, living environment, chief complaint, illicit drug use, sexual history (self-reported), sexual knowledge and gestational history (see Appendix D, E, F). Patients were given an anonymous identifier coded by their geographical dwelling. Data were collected by the researcher under the supervision of a licensed Dominican doctor. Treatment was exclusively a function of the clinical practice. The research files were secured at all times.

Each patient received a clinical examination by a licensed physician or an investigator with a minimum of four years of medical school training deemed sufficient

to conduct exam by the licensed physician and under his supervision. Cervical swabs were obtained during the patient exam. All specimens were immediately taken to the Government Ministry of Health laboratory located in the clinic. The laboratory data were obtained using BioStar OIA for Gonorrhea and Clearview Chlamydia rapid immunoassay detection. Both are point-of-care diagnostic techniques. Results were recorded on a form shown in Appendix G.

Table 1.1 shows the type of data and data analyses associated with each objective of this research. It provides a ready access guide and framework pertaining to the use of data.

Table 1.1 Data Collection Methods and Analysis of Objectives

<i>Objectives</i>	<i>Data Collection Method</i>	<i>Data Analysis Strategy</i>
1. Determine the extent to which selected demographics and risk factors are associated with Gonorrhea and Chlamydia.	The data were collected by interviewing the participants using a sociodemographic questionnaire to gather information about dependent and independent variables that may affect risk for infection.	The data were analyzed using Fisher's exact test to determine the relationship between race, marital status, ability to read and write occupation, distance from clinic, alcohol, illicit drug use, condom use, history of sexual abuse, age of first pregnancy and test results for Chlamydia and Gonorrhea.
2. Determine the prevalence of adolescent and adult females diagnosed with Gonorrhea and Chlamydia who visit the clinic for prenatal visits, annual Pap smear exams and gynecological complaints.	These data were determined by positive or negative test results from endocervical specimens for Gonorrhea and Chlamydia	The data were analyzed using frequency tables to determine prevalence.
3. Determine the extent to which educational level is a predictor of positive diagnosis or predictor of risk of infection for	The data pertaining to the educational level were determined during the patient interview and during the specimen collection,	The data were analyzed using a t-test analysis to determine the relationship between educational level and sexual history score and

Chlamydia and Gonorrhea	which was tested for Chlamydia and Gonorrhea.	Chlamydia and Gonorrhea test results.
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Validity and Reliability

Content validity was established by a panel of experts who received the purpose and objectives for the study along with the instruments for their review and assessment to ensure the questionnaire and study procedures were appropriate. Standard of care and appropriately referenced medical recommendations such as the CDC guidelines were used to establish valid and reliable results for the clinical procedures. Data were at the nominal and ordinal levels; not including Likert type scales. Reliability coefficients could not be established.

Data Analysis

Analyses were conducted with the Statistical Analysis System version 9.1.3 (2009 SAS System Inc, NC.).The data were analyzed using fisher exact test, t-test analysis and logistic regression. The data collected were further analyzed to meet the study objectives. Demographic information, reason for visit to the clinic, behavioral risk factors, and physical examination findings were independent variables used as predictors for positive diagnosis of Chlamydia and gonorrhoea. These variables were analyzed using descriptive statistics.

Ethical Considerations

Ethical considerations were of supreme importance to the principal investigator and required for IRB clearance. All data collected are property of the principal investigator. Interviews were conducted in a private room with only participants and principal investigator. No data from interviews were produced that would connect the

participants to their questionnaire. Special consideration was taken to keep data results about the patients tested for Gonorrhea and Chlamydia anonymous, to prevent physical or emotional harm to the participants. Pregnant women were invited into the study. At no point in time did the principal investigator put the women or fetuses in danger. The principal investigator also received permission from the Virginia College of Osteopathic Medicine Institutional Review Board for Research to conduct research on human subjects (Appendix H).

Chapter Four

Results

Introduction

This study was designed to provide important data to help formulate modifications to the standards of care in the Veron, Dominican Republic clinic to ensure effective protocols for treatment of STIs such as Gonorrhea and Chlamydia. It is important for clinicians to understand the risk factors that contribute to the transmission of these diseases. Both Gonorrhea and Chlamydia are primarily transmitted through sexual contact and when untreated lead to devastating morbidities in the female population. The specific purpose of this study was to determine risk factors that contribute to the prevalence of Chlamydia and Gonorrhea among adolescent and young adult females who utilize the Veron clinic, in order to develop an educational program for prevention and clinical standards of care for these STIs.

Objectives

1. Determine the extent to which selected demographic and risk factors are associated with Gonorrhea and Chlamydia.
2. Determine the prevalence of Gonorrhea and Chlamydia diagnosis among adolescent and adult females presenting at the clinic for prenatal visits, annual Pap smear exams and gynecological complaints.
3. Determine the extent to which educational level is a predictor of positive diagnosis or risk for infection of Chlamydia and Gonorrhea.

Of the 90 females who were approached to participate in this descriptive study, 100% provided informed consent. Of those, two had insufficient data on the Gonorrhea test results to be included in the study.

Demographics

The mean age of the 90 participants was 28.7, ranging from 16 to 65 years of age. The race distribution consisted of 69 Dominican (76.7%) and 21 Haitian (23.3%). Nearly half of the subjects (52.2%) in the study resided in the community of Veron while (47.7%) were from neighboring communities such Maria Cristina, Barrio Nuevo, Villa Playwood, Kosovo, Punta Cana, La Jarda, Cruce de Domingo Maiz, Navarette, Elias Pina, Villa la Fa, Santiago and Friusa (See Figure 1). Of those from neighboring communities, 75.5% of the subjects lived 0-8 km from the Clinica Rural El Veron, 22.2% lived 8-15 km while 2.2% subjects did not know.

Marital status included cohabitating (55.5%), married (27.7%), never married (7.7%), separated (4.4%) divorced (4.4%). The occupation among the subjects was divided into three categories that included “work in the home”, “outside of the home” or “other”. The majority of the participants worked in the home (64%), outside of the home (12%) and (14%) stated other (not specified) (see Figure 2).

Education History

Subjects were also asked to categorize whether they completed primary (less than six years of formal school) and/or secondary educations greater than six years of formal school). However, it was not determined if these individuals completed high school, only that they had greater than six years. Formal school was defined as government funded (public) or private funded schooling. It was determined that 49% had greater than six

years of formal school while 39% of the participants had less than six years of formal school (See Figure 3). Responses to literacy questions of “can you read?” or “can you write?” indicated that approximately (81.1%) stated they could write and (77.7%) of the women interviewed could read. There was not an attempt to quantify the level of proficiency of those responding only their self-reported perception.

Presenting Chief Complaint

The chief complaints, or reason for clinic visit, were divided into five categories that included abdominal pain, gynecological complaints, prenatal visits, pap smear exams (papanicolaou exam) or other complaints. Of those five categories the frequency of chief complaints were as follows: gynecological complaints 34.4%, pap smear exam with no symptoms 33.3%, abdominal/pelvic pain 14.4%, prenatal 11.1%, and complaints categorized as other (not specified) included 6.7% of the subject population.

Substance Use

The data obtained on alcohol and illicit drug use showed that an overwhelming majority of the subjects denied ever using illicit drugs (97.7%). Approximately (68.8%) of subjects admitted to social or regular alcohol use.

Sexual Experience

Information regarding condom use during sexual intercourse, sexual partners and history, pregnancy and history of sexual abuse was obtained in the sociodemographic questionnaire. Results showed that 65.1% of the participants indicated to never using condoms, while 34.8% reported to sometimes or always using condoms during sexual intercourse (see Figure 4). All participants were sexually active. Ninety-seven percent

stated they had less than five partners in the past year. This is relevant because studies have shown that an increase in sexual partners increases risk of infection with STIs.

Questions on whether participants had a history of sexual abuse revealed that 19.3% or 17 of the 90 subjects in the study had been sexually abused at one point or more by a friend or family member (see Figure 5). All others reported no sexual abuse. When asked whether they had ever been diagnosed with a sexually transmitted infection (STI) before, 81.8% stated they had never been diagnosed with a STI. All others reported a history of being diagnosed with a STI in the past that they did not specify. This study did not take into account whether the participants were appropriately treated at that time.

The sociodemographic questionnaire divided time of first pregnancy by age. The results indicated that 43.5% were older than 19 at the time of their first pregnancy, 41.1% between the ages of 16-18 and 15.2% of the women had their first pregnancy between the ages of 10-15 (see Figure 6).

Chlamydia and Gonorrhea Testing

Gonorrhea tests found 68 (75.6%) subjects negative and 20 subjects (22.2%) positive.

Chlamydia tests detected 84 subjects (93.3%) negative for infection and 6 subjects (6.7%) positive. Co-infection of both Chlamydia and Gonorrhea was present in two cases only.

There were two invalid Gonorrhea specimens that yielded no results.

Analyses of Participants with Positive Chlamydia by Selected Factors

Positive Chlamydia test results were first compared by race. The predominant ethnicities that utilize the clinic are Dominican and Haitian females. One hundred percent of those with positive Chlamydia results occurred in Dominican females including 6 subjects (100%) and 0% in Haitian females. A prior significance test for p values was

established at 0.05. When analyzed for significance with fisher's exact test (N= 90) the $p = 0.32$ found no significance by race.

When the positive Chlamydia test results were compared with marital status 16.6% were married, 0% never married, 16.6% separated, 16.6% divorced and 50% were cohabitating. The test for significance with fisher's exact test found $p = 0.18$ which was not significant for marital status.

When positive Chlamydia test results were compared with literacy, 83.3% of those with positive Chlamydia tests results stated "yes" they could read and 16.6% stated "no" they could not read. The cell count was too low for significance testing.

For those testing positive for Chlamydia 83.3% indicated the ability to write and 16.6% stated "no" they could not write. The cell count was also too low for significance testing.

Those with positive test results for Chlamydia were also compared on their completion of formal education. Results indicated that 50% of the subjects had less than six years of formal education and 50% had greater than six years of formal education. Due to the low cell count, significance could not be tested.

Positive Chlamydia test participants were analyzed by occupation which found 66.6% worked in the home, 16.6% worked out of the home and 16.6% answered other (not specified). The cell count was too low for significance testing.

When comparing positive Chlamydia test results with distance each participant resided from the clinic, 83.3% of the participants lived 0-8 km from the clinic and 16.6% lived 8-15 km. Significance testing was not done due to low cell count.

Among those who tested positive for Chlamydia, 33.3% stated they used alcohol and 66.6% stated they never consume alcohol. The cell count was too low for significance testing.

When Chlamydia results were compared with illicit drug use, zero percent indicated drug use and 100% had never tried illicit drugs. Due to low cell count, significance was not tested.

When positive Chlamydia test results were compared for condom use, 66.2% of the participants stated they never used condoms and 33.7% participated stated they used condoms sometimes. $P = 0.41$ indicates no significant difference.

One hundred percent of the women who tested positive for Chlamydia indicated no history of sexual abuse. Thus, significance was irrelevant.

Positive Chlamydia results were compared with participants who had previously been diagnosed with a sexually transmitted infection. Among the positive Chlamydia test results, 83.3% stated no history of a STI and 16.6% stated they had a previous diagnosis of a sexually transmitted infection. Significance testing was not done due to low cell count.

Positive Chlamydia test results were compared with participant's age of first pregnancy. Fifty percent stated that their first pregnancy was between ages 16-18, 33.3% 19 years old or older and 16.6% between 10-15 years old. When positive test results were compared to age of first pregnancy, $p = 0.86$ and was not significant.

Analysis of Participants with Positive Gonorrhea by Selected Factors

Of the ninety participants in the study, 20 participants tested positive for Gonorrhea; 68 tested negative for Gonorrhea and 2 results were inconclusive.

When positive test results were compared by race, 90% classified themselves as Dominican women and 10% classified themselves as Haitian. When analyzed for significance; $p = 0.21$ was not significant.

When positive Gonorrhoea test results were compared by marital status 65% were cohabitating, 25% were married, 5% never married, 5% divorced and 0% separated. The test for significance with Fisher's exact test found a $p = 0.89$ which was not significant.

Positive Gonorrhoea results were compared by literacy level. Of the positive gonorrhoea results, 75% answered "yes" they could read and 25% answered "no" they could not read. Fisher's exact test of $p = 0.86$ found no significant difference.

Among the positive Gonorrhoea results, 85% of the participants answered "yes" they could write and 15% answered they could not write among the total participants. When this was analyzed with Fisher's exact test ($p = 0.83$), it was found not significant.

Those testing positive for Gonorrhoea were compared according to formal education. It was determined that 55% had completed fewer than 6 years of formal education and 45% had more than 6 years of formal education. Fisher's exact test found $p = 0.53$ which was not significant at 0.05 Alpha.

When positive test results for Gonorrhoea were compared by occupation, 65% worked in the home, 20% worked outside of the home and 15% classified their occupation as other (not specified). Fisher's exact test of $p = 0.37$ found no significant difference at 0.05 Alpha.

When positive Gonorrhoea results were compared with living distance from the clinic, 75% of the participants lived 0-8 km from the clinic, 20% of the participants lived

8-15 km and 5% of the participants stated they didn't know. A $p = 0.48$ was found to not be significant.

Positive test results were compared with alcohol consumption, 60% stated to have never drank alcohol and 40% stated "yes" they consumed alcohol. When analyzed with fisher's exact test the $p = 0.46$ was found to not be significant.

When positive test results were compared with illicit drug use 95% stated they had never used drugs and 5% stated they used illicit drugs. This was analyzed using fisher exact test $p = 0.43$ was found to not be significant.

Positive test results for Gonorrhea were compared with condom use during sexual relations. Among the positive Gonorrhea results, 65% stated never using condoms and 35% admitted to using condoms always or sometimes. The cell count was too low for significance testing.

Positive Gonorrhea results were compared to history of sexual abuse. Among the positive gonorrhea results, 70% denied a history of sexual abuse and 30% of the participants admitted being victims of sexual abuse. A $p = 0.33$ and was found to not be significant.

Positive Gonorrhea patients' results were compared with the participants who had a history of a previous diagnosis of a sexually transmitted infection. There were zero positive Gonorrhea participants who stated a previous history, that accounts for 9% of the entire participant population. When analyzed using fisher exact test the $p = 0.03$ indicates a significant relationship at 0.05 alpha between no previous history of STI and their first case of Gonorrhea.

The age of first pregnancy was compared with positive test results for Gonorrhea. Among the positive test results, 46.1% were older than 19 years old at the time of their first pregnancy; 40% of the participants stated their first pregnancy occurred between 16-18 years old, 13.8% of the participants states their first pregnancy was between the ages 10-15. When analyzed using fisher exact test the $p = 0.66$ was found not to be significant.

Logistic Regression

The data were also analyzed using logistic regression to determine if there could be a prediction model between positive Chlamydia test results or positive Gonorrhea test results with specific demographic data. Logistic regression was used to predict, upon admission to the clinic, whether the patients of certain ages, number of past sex partners, number of pregnancies and number of miscarriages would test positive or negative for Chlamydia, likewise for Gonorrhea.

Positive Chlamydia

When age was used as a predictor for positive Chlamydia results $p = 0.62$ with a coefficient of 0.02 and found not to be significant. When the number of sex partners was used as a predictor for positive Chlamydia test results $p = 0.1526$ and the coefficient was 0.4224 was not significant. The number of pregnancies was also used as a predictor for positive Chlamydia however, the $p = 0.23$ with a coefficient of 0.20 and was not significant. The number of miscarriages was compared to positive Chlamydia and the $p = 0.79$ with a coefficient -0.11 and was not significant.

Positive Gonorrhea

When age was used as a predictor for positive Gonorrhea results $p = 0.08$ with a coefficient of 1.050 and was found to not be significant. When the number of sex partners

was used as a predictor for positive Gonorrhea test results, $p = 0.45$ with a coefficient of 0.1613 was not significant. The number of pregnancies was also used as a predictor for positive Gonorrhea however, the $p = 0.07$ with a coefficient of 0.1613 was not significant. The number of miscarriages was compared to positive Gonorrhea and the $p = 0.68$ with a coefficient of -0.1124 was not significant.

Knowledge & Perceptions About Chlamydia and Gonorrhea T-test Analysis

The sociodemographic questionnaires section on sexual knowledge required each participant to answer four multiple-choice questions about Chlamydia, Gonorrhea and disease transmission to assess their sexual knowledge. The test was given at the beginning of each verbal interview prior to any literature provided on STI or vaginal exams. The questions were as follows:

Table 1.2 Test Questions on STI Knowledge

You can contract a sexually transmitted disease by	<ul style="list-style-type: none"> a. shaking hands b. sex c. bathing d. don't know
Symptoms from Gonorrhea may cause	<ul style="list-style-type: none"> a. coughing b. vaginal/penile discharge c. runny nose d. don't know
Treatment for Chlamydia may include	<ul style="list-style-type: none"> a. medication b. bathing c. resting d. don't know
You learned about sexually transmitted diseases?	<ul style="list-style-type: none"> a. family b. at school c. friends d. independently e. doctor or healthcare provider

The first three questions were scored and analyzed with a t-test for significance with positive and negative Gonorrhea and Chlamydia test results. The total score any one person could receive was 4 indicating 100% correct. Among the 68 negative gonorrhea test results, the mean of correct scores was 2.0 and among the 20 positive test results for gonorrhea the mean score was 2.3. The t-test analysis showed the $p = 0.37$ was not significant. Among the 84 negative test results for Chlamydia the mean score for the sexual knowledge test was 2.0 and among the positive test results the mean score was 2.6. The t-test analysis $p = 0.17$ was not significant.

Summary

A total of 90 participants completed the core study. The results of this study indicate the mean age of the participants was 28.7. The race distribution consisted of 69 Dominican (76.7%) and 21 Haitian (23.3%) females. Gonorrhea tested negative in 68 participants (75.6%) and 20 participants tested positive (22.2%) for gonorrhea. Chlamydia test revealed 84 participants were negative for infection (93.3%) and 6 participants (6.7%) were positive for infection. Co-infection of both Chlamydia and Gonorrhea was present in two cases only. There were two invalid gonorrhea specimens that yielded no results. This study attempted to determine the extent to which educational level is a predictor of positive diagnosis or risk for infection of Chlamydia and gonorrhea. It was determined that 49% of the participants had greater than six years of formal school while 39% of the participants had less than six years of formal school. Responses to literacy questions of “can you read?” or “can you write?” indicated that approximately (81.1%) stated they could write and (77.7%) of the women interviewed could read.

The researcher first analyzed the data from the positive Chlamydia test results. Chlamydia test results were compared with literacy, 83.3% of those with positive Chlamydia tests results stated “yes” they could read and 16.6% stated “no” they could not read. Fisher exact test found, $p = 1.0$, not significant. For those testing positive for Chlamydia 83.3% indicated the ability to write and 16.6% stated “no” they could not write. Fisher’s exact test $p = 1.0$ which was not significant at 0.05 alpha. Those with positive test results for Chlamydia were also compared on their completion of formal education. Results indicated that 50% of the subjects had less than six years of formal education and 50% had greater than six years of formal education. The analysis by fisher’s exact test found $p > 0.05$.

The researcher then reviewed the data from the positive gonorrhea test results. Of the positive gonorrhea results, 75% answered “yes” they could read and 25% answered “no” they could not read. Fisher’s exact test the $p = 0.86$ found no significant difference.

Among the positive gonorrhea results, 85% of the participants answered “yes” they could write and 15% answered they could not write. When this was analyzed with fisher’s exact test $p = 0.83$ it was found to be not significant. Those testing positive for gonorrhea were compared according to formal education. It was determined that 55% had completed fewer than 6 years of formal education and 45% had more than 6 years of formal education. Fisher’s exact test found $p = 0.53$ which was not significant at 0.05 Alpha. The following chapter summarizes what can and cannot be concluded from the data gathered in the study on the risk factors that contribute to infection rates of Chlamydia and Gonorrhea in this study’s participants.

Chapter Five

Summary, Discussion, Conclusion and Recommendations

Summary

The purpose of this study was to examine factors that may place female Dominican and Haitian adolescents and young adults at risk for Chlamydia and Gonorrhea. The three objectives were addressed:

1. To determine the extent to which selected demographics and risk factors are associated with Gonorrhea and Chlamydia.
2. To determine the prevalence of adolescent and adult females diagnosed with Gonorrhea and Chlamydia who visit the clinic for prenatal visits, annual Pap smear exams and gynecological complaints and how it correlates with educational level.
3. To determine the extent to which educational level is a predictor of positive diagnosis or predictor of risk of infection for Chlamydia and Gonorrhea.

Chapter 4 provided the results from data analyses of the sociodemographic questionnaire and the Gonorrhea and Chlamydia test results. The conclusions are summarized in Chapter 5.

Discussion

This study brings together biological, sociological and behavior information on sexual health risk among women who visited the Veron clinic for primary care, a population for which there is no known published or documented research. However, research has been conducted in rural communities that are similar to Veron, Dominican Republic. The population of young Dominican and Haitian women are subject to a

variety of risk-taking behaviors that may expose them to sexually transmitted infections (Allen, Carey, Griensven Jenkins, Kilmarx, Manopaiboon & Uthaivoravit, 2003). The risk factors include unprotected intercourse, sexual coercion, drugs and alcohol and access to health care. Apparently, the women in this study were aware of the need for STI testing because 100% of the females presenting at the Veron Clinic for routine exams, accepted the offer to undergo diagnostic testing for Gonorrhea and Chlamydia. Point of care Clearview Chlamydia and BioStar OIA GC technique provided valid results while women were still in the clinic, thus avoiding the chance that women might not return to the clinic.

Although a substantial proportion of the female respondents admitted to a sexual history, there was a lack of consistent use or lack of condom use at all. It is unknown why the participants share this vulnerability to sexually transmitted infections. Perhaps, there is a lack of funds to purchase condoms, lack of access, inconvenience associated with use or personal preferences. Further in-depth inquiries are needed to substantiate contributing factors to low condom use. The overall rate of unsatisfactory specimens was low with only two of the ninety gonorrhea specimens not yielding results. It was likely secondary to blood contamination during specimen retrieval. One hundred percent of Chlamydia test results yielded a result of either positive or negative. These outcomes suggest value of rapid PCR testing for Chlamydia and Gonorrhea at clinics such as Veron.

This study has several limitations. First, the sample size for individual strata was small and limited. This limited the power to detect significant differences between marital status, occupation, ability to read and write, level of education, usage of condoms, location of residence and distance, illicit drug use, history of sexual abuse, history of

previous diagnosis of STIs age of first pregnancy and positive gonorrhea and/or Chlamydia test results.

The second limitation was generalizability. This study was conducted in a small public clinic in Veron, Dominican Republic. Caution should be exercised when extrapolating the results to the entire Dominican Republic population.

The third limitation was language barrier. Although all documents were translated in every patient's respective language during the interview there may have been some components of language barriers in communicating. The researcher is neither a native Spanish speaker nor a native Creole speaker. Actions were taken to decrease this limitation through the presence of a native Spanish and Creole interpreter when needed, but this was not a guarantee of complete communication equal to native speakers.

This study has several strengths. The material used to test for gonorrhea and Chlamydia were commercial products with high specificities and sensitivity. Therefore, it is assumed that the number of false positives and negatives was low when testing for Gonorrhea and Chlamydia.

Veron is a multi-culture community. This study utilized instruments translated in the respective languages of the patient populations for the clinic to decrease inaccurate data collection due to language barriers.

This study chose to include multiple sociodemographic variables in the analysis for the most complete assessment possible of risk factors that may contribute to the spread of Gonorrhea and Chlamydia.

Conclusion

The mean age for the participants was 28.7 years old. A majority of the participants categorized themselves as Dominican (76.7%) and the remainder Haitian (23.3%). Over half (52.2%) of the participants resided in Veron. Patients without a previous history of STI were more likely to have a positive test than those with previous STI history. Since history of STI is a well-established risk factor for infection based on the literature review in Chapter Two as cited in the De, Singh, Wong and Kaida study, this study should be replicated.

Positive test results for Chlamydia and Gonorrhea were not related to race, marital status, ability to read and write, occupation, educational history, living distance from the clinic, alcohol use, illicit drug use, condom use, history of sexually transmitted infections and age of first pregnancy. History of sexual abuse was not related to positive Chlamydia and Gonorrhea test results. These conclusions are supported by the current medical literature cited in Chapter Two from the Shapiro and Makoroff study (Shapiro & Makoroff, 2006). This study in the literature review showed in the US most abused children will not have any physical examination findings nor any sexually transmitted infections. When analyzing positive Chlamydia test results to occupation, literacy, educational history, living distance from clinic, alcohol and illicit drug use and history of SITs, the cell counts for this study were too low for significant testing. This was also the case when analysis was done between positive Gonorrhea results and condom use. These demographic variables and risk factors were no more prevalent nor distributed any differently between those with Chlamydia and Gonorrhea and those without. Educational level cannot be used as a risk factor of infection for Chlamydia or Gonorrhea.

Demographic data such as ages, number of sex partners, number of pregnancies and number of miscarriages were not predictive of positive or negative Chlamydia and/or Gonorrhea test results. Thus, prediction models were not possible using the variables selected for this study. The level of sexual knowledge was not related to Chlamydia and Gonorrhea. Rapid PCR application test for Chlamydia and Gonorrhea was highly successful in this study and should be considered for implementation in the clinic if financially feasible for STI testing. The 100% participation of women invited to participate in the STI study suggest very high interest if given the opportunity. Receptivity to diagnosis, STI prevention education and treatment among women in this study suggest high potential to reduce STIs through effective intervention programs. Further studies need to include a large number of participants in order to ensure an adequate number of positive tests for both parameters and non-parameter analyses. Replication of this study with increased sample size is needed to further verify analyses of relation variables. Health promotion and health education on STI prevention should be implemented. There should be collaboration with the Dominican Ministry of Health and partner organizations to address STIs and related health care needs. While results from this study are specific to Veron and in need of replication and further study, implications from this study design and results should be considered in similar settings. Since prevalence of STIs among men was not addressed in this study future studies and clinical support should be considered which would also hold promise for reducing prevalence between both genders.

Recommendation for Future Research

The researcher conducted both a qualitative and quantitative analysis of risk factors that contribute to the transmission rates of two sexually transmitted diseases, *Chlamydia trachomatis* and *Neisseria gonorrhoea*. These risk factors were defined from previous studies in various patient populations.

There are many opportunities for future research and development. For example, there is a pressing need to develop core educational materials in STIs for the clinic. There are researchable questions applicable to use of educational material. For example, does each social population require unique composites of educational material to decrease disease prevalence among their population? Further studies need larger sample sizes and a longer time period to validate specific risk factors for the Veron community of women.

Several participants mentioned that knowledge about sex was obtained from home or school. This suggests the need to address researchable questions such as to what extent do sex educational courses taught in school have an impact on reducing sexually transmitted infections among a similar population? To what extent do sex educational materials available at the clinic impact reducing STI rates in the community?

Recommendation for Practice

High-quality medical education is crucial to the delivery of high quality medical care. According to the International Medical Education Directory, there are ten medical schools listed in Dominican Republic (van Zanten, Parkins, Karle & Hallock, 2009). In the effort to reduce sexually transmitted infection rates, it is important to create and evaluate behavioral interventions that are specific to the target population. This should be taught during medical school and in training. In many rural sociodemographic

populations, healthcare is obtained only when disease states are chronic or at an advanced stage. Untreated diseases such as Chlamydia and Gonorrhea lead to potential ramifications such as infertility or tubal pregnancies both of which can have devastating physical and psychological effects.

The researcher recommends that the Clinica de Veron adopt the guidelines as outlined by the U.S American College of Obstetricians and Gynecologists. These guidelines suggest screening all young sexually active women and other women at high risk for infection. This may prove to be expensive for a government-sponsored clinic. An alternative is guidelines from the U.S. Preventative Services Task Force for Chlamydia and Gonorrhea screening if more cost effective. These guidelines include screening all sexually active women less than or equal to twenty-five years of age and other asymptomatic women at increased risk for infection. In addition, the guidelines recommend screening all asymptomatic pregnant women less than or greater than twenty-five years of age and others at increased risk for infection. In 1987, the Dominican government launched a National AIDS Program, and since then various nongovernmental organizations (NGO) have implemented HIV prevention activities in the country (Halperin, de Moya, Perez-Then, Pappas & Calleja, 2009). This same initiative could apply to other sexually transmitted infections. Interventions that reduce the risk of contracting a sexually transmitted disease such as Gonorrhea or Chlamydia may also help prevent HIV infection.

The nature of the topic of sexually transmitted infections is sometimes sensitive and uncomfortable. However, culturally appropriate interventions that increase awareness of and ability to respond to these sexual health risks are needed for the Clinica Rural de

Veron. Health care providers should use culture-specific prevention strategies and should address cultural roles and values of the Dominican community to empower Hispanics to reduce high-risk behavior. As cited in one study, skill-building, group participatory tools that engage the individual to examine high risk behaviors and provide methods to make behavior changes, and health care counseling, which focuses on an individual's specific risk behaviors, are more effective modes of reducing high risk behaviors in women than an information-only intervention (Alexander, Corbo and Russell, 2000).

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Figure 1: Location of Barrios near Veron, Dominican Republic



Figure 1. The surrounding barrios that are home to the patients that utilize the Veron Clinic.

From www.earth.google.com.

Figure 2: Negative Chlamydia & Gonorrhea Results & Occupation of Participants

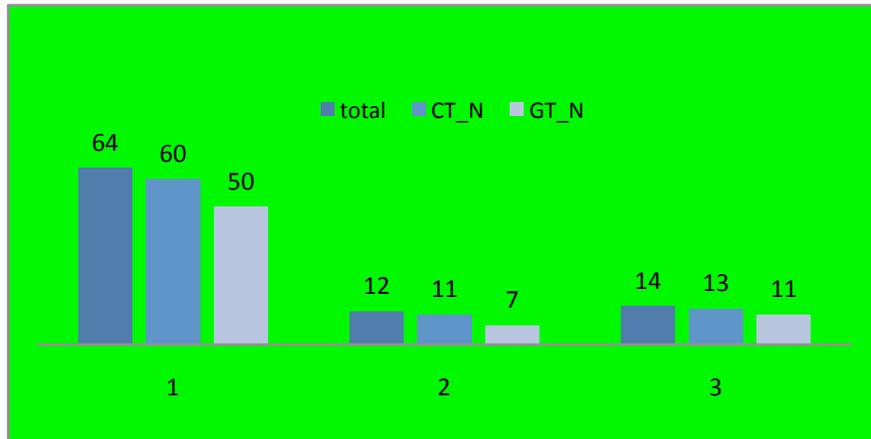


Figure 2. The participants (N=90) with negative test result for Chlamydia (CT)_N and Gonorrhea (GT)_N by occupation. The (1) defines the participants that worked in the home, (2) the participants that worked outside of the home and (3).

Figure 3: Negative Chlamydia & Gonorrhea Results & Education of Participants

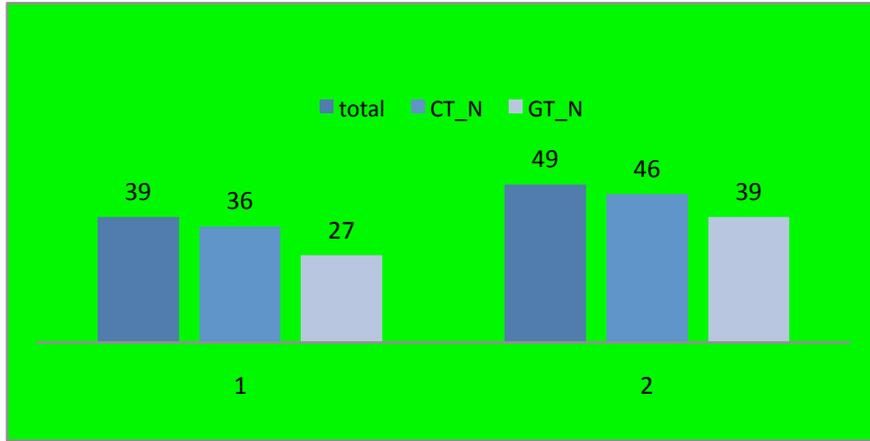


Figure 3. The percentages (N= 90) of participants that stated that they completed primary education or less than six years (1) and greater than six years (2) and the negative test results for Chlamydia test (CT)_N and Gonorrhea (GC)_N test and their level of education.

Figure 4: Negative Chlamydia & Gonorrhea Results & Condom Use

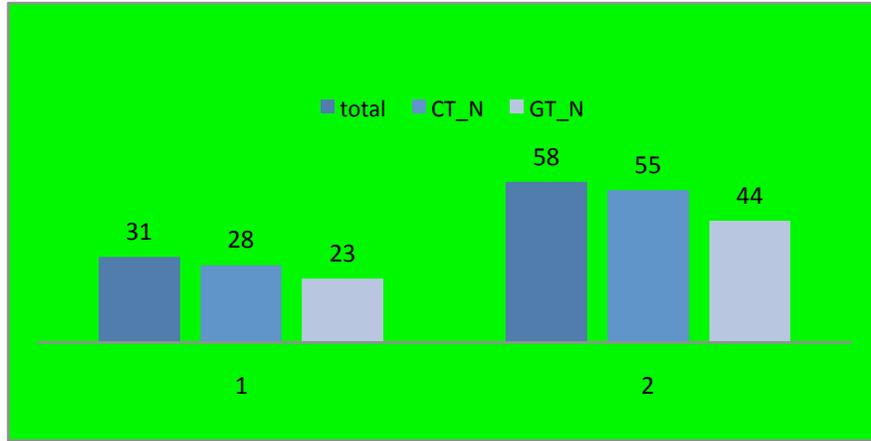


Figure 4. The percentages of negative test results for Gonorrhea and Chlamydia and patients that did or did not use condoms. The (1) represents always/sometimes used condoms and (2) represents never uses condoms.

Figure 5: Negative Chlamydia and Gonorrhea Results & Sexual Abuse

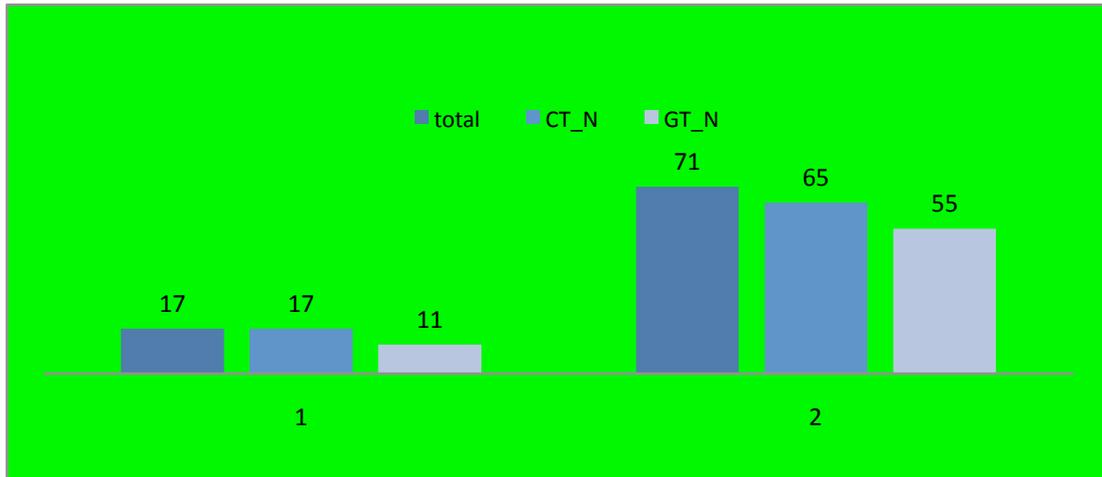


Figure 5. The negative test results for chlamydia (CT)_N and Gonorrhea (GT)_N and patients history of sexual abuse. The (1) represents positive history of sexual abuse and (2) represents no history of sexual abuse.

Figure 6: Negative Chlamydia and Gonorrhea Results & Age of First Pregnancy

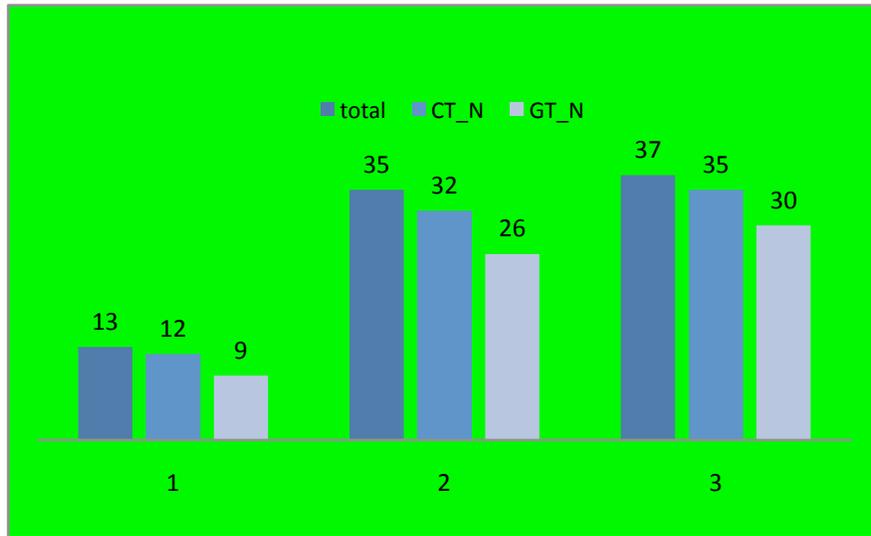


Figure 6. The percentage of negative test results for Chlamydia (CT)_N and Gonorrhea (GT)_N and age range of first pregnancy of the participants. The (1) defines first pregnancy between 10-15 years old, (2) defines first pregnancy 16-18 and (3) defines first pregnancy >19 years of age.

Appendix A: English Translation for Informed Consent

Informed Consent Form

Introductory Section:

You have been asked to take part in a research project described below. The researcher will explain the project to you in detail. Please feel free to ask questions. If you have more questions later, Camille Henson, the person mainly responsible for this study, will discuss them with you.

Description of the project:

The purpose of this study is to find out the prevalence of sexually transmitted infections in the community. The study will also determine the risk factors that contribute to females contracting Chlamydia and gonorrhea. These are two sexually transmitted infections that may cause you infertility.

Number of people that will take part of the study:

About 90 women will take part in this study.

What will be done:

During the course of the study you will undergo a vaginal and pelvic exam. Your specimen taken from the vaginal exam will be sent to the lab for testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. After analyze of the specimen you will be informed about the results of the test. If the results are positive you will be provided information about where you can receive treatment.

Benefits of this study:

The benefit of the study is the knowledge of your status about Chlamydia and gonorrhea. Testing, early diagnosis and treatment will prevent long term damage to the female

reproductive system. These diseases are possible causes of infertility.

Study Treatment:

Treatment will be a function solely of the clinic and is dependent upon you sharing the information with your primary care physician. At no time will the test result be shared with anyone outside of the principle investigator.

Follow-up care:

Follow-up appointments can be made according to clinic protocol. A follow up appointment can be made for each individual who has experienced adverse side effects from medication or secondary complications from diagnosis. Side effects from the treatment medications are rare. Each patient with a positive and negative diagnosis will be

provided information on prevention and have an opportunity to ask questions.

Risks or discomfort:

Some female patients find discomfort with pelvic exams but these exams routinely take less than ten minutes. You will be informed about the step-by-step procedures of a pelvic exam and will be given the opportunity to ask questions before each exam has begun.

This exam poses a minimal risk to pregnant women.

Confidentiality:

Patient identity will be anonymous. We will assign a code to you, and establish a code book that will be locked in a secure location. At no time will names be attached to any information associated with the research. All data will be destroyed within 12 months of the end of the study. We will not use your name in any speech or paper associated with the study. The primary investigator will be the only person with access to the records.

Cost and payment for being in the study:

There is no cost to you for being in the study. You will not have to pay for examination or laboratory tests that are part of this study.

You will not receive any monetary compensation for your participation in this study.

Your participation is voluntary. You will be provided standard medical care and treatment for sexually transmitted infections if you choose not to participate in the study.

In case of injury:

If you are hurt or injured in any way because you are taking part in this study, treatment will be provided by “Clinica Rural El Veron” under the auspices of SESPAS doctors who will provide treatment. By signing this consent form and agreeing to be in this study, you are not giving up any of your rights. If you believe that you have been harmed, please contact Camille Henson at Virginia College of Osteopathic Medicine by calling 540 231-4000 for information on your rights and advice on how to proceed.

Right to refuse and reasons for withdrawal:

Taking part in this study is voluntary. If you choose not to take part, it will not change your regular medical care. If you choose to be in the study, you may quit at any time without changing your regular medical care. If you quit the study, you may still be treated for gonorrhea and/or Chlamydia based on your voluntary request for care. If important new information is found that might change your decision to be in the study, we will tell you.

Persons to Contact

If you:

- Have questions about research study, contact “Clinica Rural El Veron” by visiting and reporting to the Clinic Director, the principal investigator Camille

Henson at (540) 231-4000 and/or the IRB chair Dr. Hara Misra (540) 231-4000.

- Have questions about your rights as a research subject, contact “Clinica Rural El Veron” by visiting and reporting to the Clinic Director, the principal investigator Camille Henson at (540) 231-4000 and/or the IRB chair Dr. Hara Misra (540) 231-4000.
- Think you may be having a problem from the pelvic exam in this study or feel you have been harmed by this study, contact, “Clinica Rural El Veron” and report to the Clinic Director, the principal investigator Camille Henson at (540) 231-4000 and/or the IRB chair Dr. Hara Misra (540) 231-4000.

Subject’s Statement

I have read and understand this consent form, and I volunteer to participate in this research study. I have had all my questions answered. I understand that I will receive a copy of this form. I hereby acknowledge the above and give my voluntary consent. I understand that my consent does not take away any legal rights. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Printed name of participant Signature of participant Date

When participant in a minor:

Printed name of parent Signature of parent Date

When subject is not able to provide consent:

Printed name of representative Signature of representative Date

Relationship of representative to participant

Should I have any pertinent questions about this research or its conduct, research subjects' rights, and whom to contact in the event of a research-related injury to the subject, I may contact:

List Investigator(s) Camille Henson
Phone & Email: (540) 231-4000, cahenson@vcom.vt.edu

For questions I may have about this study.

VCOM IRB Chairman
Hara P. Misra, D.V.M., Ph.D.
(540) 231-3693, misra@vt.edu

For questions I may have about my rights as a research subject.

This Informed Consent is valid from _____ to _____.

Appendix B: Spanish Translation for Informed Consent

Consentimiento Informado

Sección Introductoria:

Le han pedido participar en un proyecto de investigación descrito abajo. El investigador le explicará el proyecto a usted detalladamente. Puede hacer las preguntas que desee. La persona responsable de este estudio, Camilla Henson, estará dispuesta a responder cualquier interrogante que le surja durante el transcurso de dicho estudio.

Descripcion del proyecto:

El propósito de este estudio es descubrir el predominio de enfermedades transmitidas sexualmente en la comunidad. El estudio también determinará los factores de riesgo que contribuyen a que las mujeres contraigan infección por chlamydia y gonorrhea. Éstas son dos enfermedades de transmisión sexual que pueden causarle infertilidad.

Número de personas que participará en el estudio:

Cerca de 90 mujeres participarán en este estudio.

Qué será hecho:

Durante el curso del estudio usted experimentará un examen vaginal y pélvico. El espécimen tomado del examen vaginal será enviado al laboratorio para la investigación de *Chlamydia trachomatis* y *Neisseria gonorrhoeae*. Después de analizar el espécimen se le informarán los resultados de la prueba a usted. Si los resultados son positivos se nos proveerá información sobre dónde usted puede recibir el tratamiento.

Ventajas de este estudio:

La ventaja del estudio es el conocimiento de su estado sobre chlamydia y gonorrea. La prueba, el diagnóstico temprano y el tratamiento prevendrán daño a largo plazo al sistema reproductivo femenino. Estas enfermedades son causas posibles de infertilidad.

Tratamiento Del Estudio:

El tratamiento será una función solamente de la clínica y depende de usted sicomparte la información con su médico de atención primaria. El resultado de la prueba nunca será compartido con nadie y sólo tendrá conocimiento de éste el investigador principal.

Cuidado de seguimiento:

Las citas para darle seguimiento a la paciente se pueden concertar según el protocolo de la clínica. Una cita de seguimiento se puede concertar para cada persona que haya experimentado efectos secundarios de la medicación o complicaciones secundarias al diagnóstico. Los efectos secundarios de del tratamiento son raros. A cada paciente con un diagnóstico positivo o negativo le será proveída información sobre prevención y tendrá oportunidad de hacer preguntas.

Riesgos o malestar:

Algunas pacientes sienten molestias con los exámenes pélvicos pero estos exámenes rutinariamente toman menos de 10 minutos. A usted se le informará paso a paso sobre el procedimiento a seguir para un examen pélvico y tendrá la oportunidad de hacer preguntas antes del comienzo de cada examen. Este examen plantea un riesgo mínimo a las mujeres embarazadas.

Confidencialidad:

La identidad de la paciente no será dada a conocer. Le asignaremos un código, y establecemos un libro del código que será colocado en una localización segura.Los

nombres nunca serán anexados a ninguna información relacionada con la investigación. Todos los datos serán destruidos en el plazo de 12 meses del final del estudio. No utilizaremos su nombre en ningún discurso ni documento asociado con el estudio. El investigador primario será la única persona con acceso a los expedientes.

Costo y pago para estar en el estudio:

No se le cobrará dinero a usted para estar en el estudio. Usted no tendrá que pagar el examen o las pruebas de laboratorio que son parte de este estudio. Usted no recibirá ninguna compensación económica por su participación en este estudio. Su participación es voluntaria. A usted le serán dados asistencia médica y tratamiento estándares proporcionados para las enfermedades de transmisión sexual si usted elige no participar en el estudio.

En caso de lesión:

Si usted resulta lastimado o herido de cualquier manera porque usted está participando en este estudio, el tratamiento será proporcionado por la "Clínica Rural El Verón" bajo los auspicios de los doctores de SESPAS que proporcionarán el tratamiento. Firmando este consentimiento informado y acordando estar en este estudio, usted no está renunciando a ninguno de sus derechos. Si usted cree que ha sido perjudicada, por favor, entre en contacto con Camilla Henson en la Universidad de Virginia de Medicina Osteopática llamando al 540 231-4000 para información sobre sus derechos y consejos sobre cómo proceder.

Derecho a rechazo y razones para el retiro:

El participar en este estudio es voluntario. Si usted elige no participar, no cambiará su asistencia médica regular. Si usted elige estar en el estudio, usted puede parar en

cualquier momento sin cambiar su asistencia médica regular. Si usted para el estudio, usted puede todavía recibir tratamiento para gonorrhea y/o chlamydia basados en su petición voluntaria de atención. Si se encuentra información nueva importante que pudiera cambiar su decisión para estar en el estudio, le diremos.

Personas que puede contactar

Si usted:

- Tiene preguntas sobre esta investigación, contacte en la "Clínica Rural El Verón" al Director de la Clínica, a la investigadora principal Camilla Henson (540) 231-4000 y/o al Dr. Hara Misra al (540) 231-4000.
- Tiene preguntas sobre sus derechos como sujeto de la investigación, contacte en la "Clínica Rural El Verón" al Director de la Clínica, a la investigadora principal Camille Henson (540) 231-4000 y/o al Dr. Hara Misra al (540) 231-4000.
- Piensa que puede estar teniendo un problema por la realización del examen pélvico en este estudio o si siente haber sido perjudicado por este estudio, contacte en la "Clínica Rural El Verón" al Director de la Clínica, a la investigadora principal Camilla Henson (540) 231-4000 y/o al Dr. Hara Misra al (540) 231-4000.

Declaración del Participante

He leído y entiendo este consentimiento informado, y me me ofrezco voluntariamente a participar en este estudio de investigación. Todas mis preguntas han sido contestadas.

Entiendo que recibiré una copia de esta forma. Reconozco por este medio lo anteriormente escrito y doy mi consentimiento voluntario. Entiendo que mi

consentimiento no me quita ningún derecho legal. Entiendo además que nada en este consentimiento informado intenta reemplazar ninguna ley Federal, Estatal o local.

Nombre impreso del participante Firma del participante Fecha

Cuando participante es un menor de edad:

Nombre impreso del padre o madre Firma del padre o madre Fecha

Cuando el participante no puede proporcionar consentimiento:

Nombre impreso del representante Firma del representante Fecha

Relación del representante al participante

Si tengo cualquier pregunta pertinente sobre esta investigación o su conducción, los derechos del participante en la investigación o sobre a quién contactar en caso de una lesión al participante relacionada a la investigación , puedo contactar a:

Investigadora Camilla Henson
Teléfono & Email: (540) 231-4000, cahenson@vcom.vt.edu

Para las preguntas que pueda tener sobre este estudio.

VCOM IRB Chairman
Hara P. Misra, D.V.M., Ph.D.
(540) 231-3693, misra@vt.edu

Para las preguntas que pueda tener sobre mis derechos como participante de la investigación.

Este consentimiento informado es válido de _____ a _____.

Appendix C: Creole Translation for Informed Consent

Kondisyon pou aksepte

Seksyon entwodiksyon:

Ou te envite pou patisipe nan yon pwoje rechèch ki ekri pi ba. Envestigate a apral detaye pwoje a pou nou. Mete nou alez pou nou poze kesyon ki nesese. Si nou gen plis kesyon plita, Camille Henson, moun ki responsab etid sa a, apral diskite avèk nou.

Deskripsyon pwoje a:

Objektif etid sa a, se pou dekouvri predominans maladi ke moun ka pran nan fè sèks, ke yo rele maladi seksyèlman transmisib nan kominote a. Etid la ap detemine egzacteman faktè risk ki kontribye ak fanm yo ki pran trakomatis klamidya ak gonore de neseria. Se 2 maladi moun ka pran nan fe bagay ki koz yo pa ka fè pitit.

Kantite moun kap patisipe nan etid sa a :

En total nou gen 90 fanm kap patisipe nan etid sa a.

Sak pral fèt :

Pandan etid la yo pral gade bouboun ou. Y'ap pran specimen nan bouboun pou yo voye etidyel nan laboratwa pou yo kapab jwenn trakomatis klamidia ak gonore de neseria. Apre yo fi-n analize specimen yo, yo pral bay rezilta a. Si rezilta yo pozitif nap resevwa tretman.

Avantaj etid la:

Avantaj etid la se konesans wap genyen sou klamidia ak gonore. Eseyel diagnostikel pi bonè e tretman an ap anpeche w gen pwoblèm pou fè pitit. Paske maladi sa yo kòz ou pa ka fè pitit.

Tretman etid la :

Trètman an ap sèlman fèt nan klinik la, sa ap depann de ou menm pou w bay enfòmasyon ak medsen kap baw swen san pyès lòt moun pa konnen rezilta sòf envestigatè prensipal la.

Swen wap swiv:

Nou kapab pran randevou nan klinik lan selon jan yo ban noul . Nou kapab pran yon randevou apre pou chak moun apa .ki pwouve ke yo jwenn bagay defavorab nan medikaman an ou ki konplike sa yo genyen.Efè segondè medikaman an li trè ra . Chak moun ki prezante yon diagnostik pozitif oubyen negatif ap gen anpil enfòmasyon kòman pou yo anpechel.e yap gen okazyon pou yo poze kesyon.

Efè maladi a :

Gen yon seri de malèz femèl ke pasyan an jwenn nan egzamen pelvien yo, men egzamen sa yo kapab pran pa plis ke dis(10) minit. Wap enfòmè sou kijan pou swiv li yonn apre lòt.de yon egzamen pelvien e bay okazyon pou poze kesyon avan egzamen yo kòmanse .Egzamen sa yo pa gen anpil ris pou fanm ki gwovant.

Sa kap rete sekre:

Pyès moun pap konnen enfòmasyon sou moun ki malad la.Nap bay chak moun yon nimewo kòd,nap mete yon nimewo kòd kap fèmen ak kle nan yon kote ki bloke.okenn moun nan okenn moman pap gen aksè ak enfòmasyon sa yo. Tout enfòmasyon yo ap fini apre 12 mwa lè etid la fini. Nou pap site non moun nan pyès diskou.Envestigatè prensipal la sèlman kap gen aksè ak enfòmasyon yo.

Konbyen sa ap koute w :

Ou pap peye anyen pou w kapab nan etid la.Ou pa dwe peye ni ekzamen ni sa yap eseye nan laboratwa ki fè pati etid la.Ou pap jwenn anyen kòm rekonpans lajan pou

patisipasyon wap bay nan etid la .se yon patisipasyon volontè.Wap swen medikal e wap jwenn trètman maladi ke moun ka pran nan fè bagay, si w chwazi pou pa patisipe nan etid la.

Nan ka domaj :

Si w blese, oubyen w blese paske wap patisipe nan etid la , trètman ap fèt pa ‘‘El rural Veron de Clinica ‘’anba swen doktè SESPAS kapral bay trètman.Le w siyen akò saa ou aksepte nan etid saa ou pa bay anho pyes nan dwat ou yo.Si ou kwè ke sa kapab nwi w antre an kontak avèk nou tanpri.Camille hensen inivèsite vigini doktè de osteopatik, rele nan 540-231-4000 pou tout enfòmasyon sou dwa wè konsèy sou kouman ou kapab aji.

Dwa pou pa aksepte e rezon pou retire w :

Patisipe nan etid saa li volontè.Si ou chwazi pou pa patisipe,sa pap chanje swen medikal wap pran. Si w chwazi pou nan etid la ou ka kanpe nenpòt lè san w pa chanje swen medikal ou.Si w kanpe etid la, ou kapab toujou trete pou maladi gonorrhèe e chlamydia, sou menm volonte swen wap pran an .Si w jwenn enfòmasyon enpotan ki kapab chanje desizyon w nan etid la nap di w sa.

Moun pou kontakte

Si ou:

- Genyen kesyon sous rechèch etid sa, kontakte ‘‘El rural Veron de Clinica ‘’ e visite e fè rapè avèk direktè klinik la, investigate-a prensipal la, Camille Hesnon nan (540) 231-4000 e tet IRB la, dokte Hara Misra nan (540) 231-4000.
- Genyen kesyon sous dwa ou nan rechèch etid sa, kontakte ‘‘El rural Veron de Clinica ‘’ e visite e fè rapè avèk direktè klinik la, investigate-a prensipal la,

Camille Hesnon nan (540) 231-4000 e tet IRB la, dokte Hara Misra nan (540) 231-4000.

- Si Ou kwe ou wap gen problem ak exame pou bouboun ou nan rechèch etid sa, oswa ou santi yo te maltrete ou kontakte ‘El rural Veron de Clinica ‘ e visite e fè rapè avèk direktè klinik la, envestigate-a prensipal la, Camille Hesnon nan (540) 231-4000 e tet IRB la, dokte Hara Misra nan (540) 231-4000.

Mo Sijè-a

Mwen te lire e konprann konsanti papye saa, e mwen volontè pou-m patisipe nan rechèch etid saa. Tout kesyon mwen te genyen yo te repond yo. Mwen konprann map resevwa yon kopi de papye sa. Mwen konnen sa ki anwo a, e mwen bay konsanti mwen. Mwen konprann konsanti mwen pran dwa legal mwen. Pilwen mwen konprann anyen nan lentansyon papye sa ap retire nepot lwa ki relate pou biwo federal, eta, e lokal.

Non enprime a Sijè-a	Siyati a Sijè-a	Dat
----------------------	-----------------	-----

Le Sijè-a se yon timoun:

Non enprime a paran	Siyati a Paran	Dat
---------------------	----------------	-----

Le Sijè-a pa kapab bay konsanti

Non enprime a reprezantatif la	Siyati a reprezantatif la	Dat
--------------------------------	---------------------------	-----

Relasyon reprezantatif la ak Sijè-a

Si mwen ta genyen nepòt kesyon sous rechèch etid sa e jan li konduit, dwa etid yo, e moun pou kontakte si sije-a blese ou frape akoz etid sa, Kontakte:

Envestigate-a Camille Henson

Telefon e adres pou ecri sou internet la: (540) 231-4000, cahenson@vcom.vt.edu

Si mwen ta genyen nepòt kesyon sous rechèch etid sa.

VCOM IRB Moun ki nan Tet la

Hara P. Misra, D.V.M., Ph.D.

(540) 231-3693, misra@vt.edu

Si mwen ta genyen kesyon sous dwa mwen kon yon sije nan rechèch etid sa

Konsanti sa bon stat _____jis _____.

Appendix D: English Sociodemographic Questionnaire

Patient History and Assessment Form

Patient Identification

Date

Demographic Information

Date of Birth

Age _____

Marital Status:

Married _____

Single (Never Married) _____

Separated _____

Divorced _____

Cohabiting _____

Ethnicity: _____ **Dominican** _____ **Hispanic/Latino** _____ **Haitian** _____ **White**

American _____ **Black American** _____ **Indian** _____ **Asian** _____ **Other**

Occupation:

House Wife _____

Cook _____

Teacher _____

Childcare Worker _____

House Keeper/Maid _____

Hotel Service Worker _____

Healthcare Worker _____

Unemployed _____

Other _____

Can you read?

Yes _____

No _____

Can you write?

Yes _____

No _____

Highest **Educational** level

Completed 1-3 years _____

Completed 4-6 years _____

Completed 7-10 years _____
Completed 10-12 years _____
Graduated 12 years _____

Living environment: Population size

Small village <1000 _____
Moderate Village 1000- 3000 _____
Large Village 3000-5000 _____

Where do you live? _____

How many kilometers do you live from the clinic? _____

Living environment:

Do you have indoor plumbing?

____ Yes
____ No

Do you have running water?

____ Yes
____ No

Do you have electricity?

____ Yes
____ No

Chief Complaint, reason for visit:

Personal Medical History:

Medication Allergies/Intolerances:

General Health:

____ Good Health (Clinic visit once in past 12 months)
____ Fair Health (Clinic visit 3 times in past 12 months)
____ Sick Often (Clinic visit more than 6 times in past 12 months)
____ Poor Health (Clinic visit monthly in past 12 months)

Alcohol:

____ Yes
____ No

Illicit Drug: ___ Currently use cocaine, heroin, marijuana drugs ___ Does not use but has used drugs in the past

Medications and supplements:

Prescription medications: ___yes ___no If yes list:

Sexual History:

How often do you use condoms?

___ Always ___ Mostly ___ Sometimes ___ Rarely ___ Never

How many sex partners in the last 6 months? _____

How many new sex partners have you had in the last 12 months? _____

Have you had a sex partner that is more than 3 years older than you?

___ YES

___ NO

If yes, how old were you when that happened? _____ How old was he? _____

Are you still together?

___ YES

___ NO

Have you had other relationships with men more than 3 years older?

___ YES

___ NO

Have you ever been sexually abused?

___ YES

___ NO

How many relationships with men more than 3 years older than you? _____

Have you ever been diagnosed with a sexual transmitted disease?

___ YES

___ NO

Sexual Knowledge

1. You can contract a sexually transmitted disease by?

a. shaking hands

- b. sex
- c. bathing

2. Symptoms from Gonorrhea may cause

- a. coughing
- b. vaginal/penile discharge
- c. runny nose

3. Treatment for Chlamydia may include

- a. medication
- b. bathing
- c. resting

4. You learned about sexually transmitted diseases?

- a. family
- b. at school
- c. friends
- d. independently
- e. doctor or healthcare provider

Gestational History:

How many times have you been pregnant ? _____

How many live births? _____

Number of miscarriages? _____

Number of still births? _____

Number of planned abortions? _____

At what age did you have your first pregnancy?

10-12 _____

13-15 _____

16-18 _____

19-21 _____

22> _____

At what age did you have your first child?

10-12 _____

13-15 _____

16-18 _____

19-21 _____

22> _____

Physician Use Only:

Genital / Reproductive / Sexual Review of System:

Women: ___ Current discharge from Vagina
Ever tested for HIV: ___ Yes ___ No If yes results: _____
___ Difficulty with intercourse ___ Pain with intercourse ___ Infertility
Ever douched: ___ Yes ___ No
If Yes: Frequency ___ Once a month ___ Once every 3 weeks ___ Once every 2 weeks ___ More frequently
Women: ___ Age menses began Do you have menstrual periods: Yes ___ No ___ If no, age ceased: ___ Hot flashes: yes ___ No ___
Menses are ___ heavy ___ light ___ none Menses are ___ monthly ___ other than monthly (describe interval) _____
Date of last **pap smear** _____

Physical Exam:

Vitals:

_____ **B/P** _____ **P** _____ **Temp** _____ **Resp** _____ **Wght**
_____ **Hght**

Genital/Urinary: Women:

Vagina: ___ normal mucosa without discharge ___ inflamed mucosa ___ dry/atrophic mucosa ___ vaginal discharge
Labia: ___ normal ___ abnormal with lesions ___ abnormal with rash or inflammation
Urethra: ___ normal ___ abnormal ___ Urethrocele
Pelvic floor: ___ normal ___ rectocele ___ uterine prolapse
Ovaries: ___ normal ___ unable to palpate ___ mass or enlargement present
Uterus: ___ normal ___ unable to palpate ___ mass or enlargement present
Cervix: ___ normal appearance ___ inflamed with discharge ___ ulcerated appearance ___ lesions on cervix

Describe all abnormalities:

Appendix E: Spanish Sociodemographic Questionnaire

Formulario de evaluación e historia del paciente

Identificación Paciente

Fecha

Información Demográfica

Fecha de nacimiento _____

Edad _____

Estado marital:

Casado _____

Nunca Casado _____

Separado _____

Divorciado _____

Unión libre _____

Etnia: _____ **Dominicano** _____ **Hispano/Latino** _____ **Haitiano** _____ **Blanco**
_____ **Negro** _____ **Hindú** _____ **Asiático** _____ **Other**

Ocupación:

Ama de Casa _____

Cocinera _____

Profesora _____

Criada _____

Trabajadora del Hotel _____

Trabajadora en el área de la salud _____

Desempleada _____

Otro _____

¿Puede usted leer?

Sí _____

No _____

¿Puede usted escribir?

Sí _____

No _____

El nivel de enseñanza más alto :

Terminado 1-3 años _____

Terminado 4-6 años _____

Terminado 7-10 años _____

Terminado 10-12 años _____

12 años graduado de _____

Ambiente en que vive: Tamaño de la población

Comunidad pequeña <1000 _____

Comunidad Moderada 1000- 3000 _____

Comunidad Grande 3000-5000 _____

¿Dónde usted vive? _____

¿A cuántos kilómetros usted vive de la clínica? _____

Ambiente en que vive:

¿Usted tiene plomería en el interior?

____ Sí

____ No

¿Usted tiene agua corriente?

Do you have running water?

____ Sí

____ No

¿Usted tiene electricidad?

____ Sí

____ No

Principal Queja

Historial Médica Personal:

Medicación Alergias/Intolerancias:

Salud General:

____ Buena salud (ha visitado la clinica solo una vez durante los ultimos 12 meses)

____ Salud justa (ha visitado la clinica 3 veces en los ultimos 12 meses)

____ Enfermo a menudo (ha visitado la clinica mas de 6 veces en los ultimos 12 meses)

____ Salud Pobre (ha visitado la clinica mensualmente los ultimos 12 meses)

Alcohol:

____ Sí

___ No

Drogas ilícitas:

___ Utiliza actualmente la cocaína, heroína, marihuana

___ No utiliza ahora pero sí en el pasado.

Medicaciones y suplementos:

Medicamentos indicados por un médico: ___ Sí ___ No

Historia Sexual:

¿Con qué frecuencia usa condones?

Siempre ___ Casi siempre ___ A veces ___ Raramente ___ Nunca

¿Cuántos compañeros sexuales ha tenido en los últimos 6 meses? ___

¿Cuántos nuevos compañeros sexuales ha tenido durante los últimos 12 meses? ___

¿Usted ha tenido algún compañero sexual al menos 3 años mayor ?

___ Sí

___ No

¿Si sí, Qué edad tenía usted cuando esto sucedió? ___ ¿Quedad tenía él? ___

¿Están aún juntos?

___ Sí

___ No

¿Usted ha tenido relaciones sexuales con otros hombres al menos 3 años mayor que usted?

___ Sí

___ No

¿Ha sido abusada sexualmente alguna vez?

___ Sí

___ No

¿Con cuántos compañeros sexuales 3 años mayor que usted, usted ha estado ? ___

¿Le han diagnosticado alguna vez una infección de transmisión sexual?

___ Sí

___ No

Conocimiento Sexual

1. ¿Usted puede contraer una enfermedad sexual a través de
 - a. Un apretón de manos
 - b. sexo
 - c. Al bañarse

2. Los síntomas de gonorrhea pueden causar
 - a. Tos
 - b. Secreción vaginal/peneana
 - c. Mariz que moquea

3. El tratamiento para chlamydia puede incluir
 - a. Medicación
 - b. Bañarse
 - c. Descanso

4. ¿Dónde usted aprendió sobre enfermedades de transmisión sexual?
 - a. familia
 - b. en la escuela
 - c. amigos
 - d. independientemente
 - e. doctor o proveedor de salud

Gestational History:

¿Cuántas veces usted ha estado embarazada? _____

¿Cuántos nacidos vivos? _____

¿Número de abortos? _____

¿Número de partos muertos?

¿Número de abortos planificados? _____

¿A qué edad usted tuvo su primer embarazo?

10-12 _____

13-15 _____

16-18 _____

19-21 _____
22> _____

¿A qué edad usted tuvo su primer niño?

10-12 _____
13-15 _____
16-18 _____
19-21 _____
22> _____

For Physician Use Only (English)

Genital / Reproductive / Sexual Review of System:

Women: _____ Current discharge from Vagina
Ever tested for HIV: __Yes ___ No If yes results: _____
____ Difficulty with intercourse ____ Pain with intercourse _____ Infertility
Ever douched: _____ Yes _____ No
If Yes: Frequency _____ Once a month _____ Once every 3 weeks _____ Once every 2 weeks _____ More frequently
Women: _____ Age menses began
Date of last **pap smear** _____

Physical Exam:

Vitals:

_____ **B/P** _____ **P** _____ **Temp** _____ **Resp** _____ **Wght**
_____ **Hght**

Genital /Urinary: Women:

Vagina: __normal mucosa without discharge ____inflamed mucosa __dry/atrophic mucosa __ vaginal discharge
Labia: __normal ____abnormal with lesions ____abnormal with rash or inflammation
Urethra: __normal ____abnormal __Urethrocele
Pelvic floor: __normal ____rectocele ____uterine prolapse
Ovaries: __normal __unable to palpate ____mass or enlargement present
Uterus: __normal ____unable to palpate ____mass or enlargement present
Cervix: __normal appearance ____inflamed with discharge ____ulcerated appearance
__lesions on cervix

Describe all abnormalities:

Appendix F: Creole Sociodemographic Questionnaire

Fom Pou Moun Ki Malad La Ak Istwa Li

Idantifikasyon

Date

Enfomasyon moun nan :

Ki le li fet

Ki laj li _____

Kondisyon marital :

Marye _____

Senp _____

Separe _____

Divose _____

Viv avek _____

Kli ras : _____ **Dominiken** _____ **Ispano-latino** _____ **Ayisyen** _____ **blan**
meriken _____ **Ameriken nwa** _____ **Endyen** _____ **Azi** _____

Metye:

Fanm kay _____

Kizinye _____

Pwofese _____

Moun ki pran swen timoun _____

Fanm chay _____

Otelye _____

Manm pesonel _____

Moun ki pap travay _____

Lot _____

Eske-w konn li?

_____wi

_____non

Eske-w ekri?

_____wi

_____non

Nivo ki pi wo nan zafe edikasyon:

Fini klas 1-3 ane _____

Fini klas 4-6 ane _____

Fini klas 7-10 ane _____

Fini klas 11-12 ane _____

12 ane gradye _____

Kote wap viv :

Ti vil p piti ke <1000 _____

Vil modere 1000-3000 _____

Gran vil 3000-5000 _____

Kote -w rete ? _____

Konbyen kilomet ou fe pou rive nan klinik lan ? _____

Anviwènman vi a:

Ou genyen plombin?

____ Wi

____ Non

Ou genyen dlo kouri nan kay la?

____ Wi

____ Non

Ou genyen electricite?

____ Wi

____ Non

Plenyen ki prensipal la, rezon pu vizit la:

Listwa Medikal mwen:

Medikasyon Alergi/Pakapab Tolere:

Sante Jeneral:

____ Bon Sante (Vizite klink youn fwa **pandan 12 dènye mwa-yo**)

____ Jis Sante (Vizite klink 3 fwa **pandan 12 dènye mwa-yo**)

____ Malad anpil (Vizite klink plis de 6 fwa **pandan 12 dènye mwa-yo**)

____ Move Sante (Vizite klink chak mwa **pandan 12 dènye mwa-yo**)

Alkohol:

____ Wi

____ Non

Dròg anbachal: _____ Bwe drog cocaine, heroin, **marihuana** _____ Mwen pa sevi ak drog sa yo nan pandan 12 mwa

Medikasyon e supleman:

Medikasyon Prekripsyon: _____ wi _____ nom _____ si se wi, ecri pouki sa anba:

Istwa seks ou:

Konbyen fwa ou sevi ak proteksyon?

_____ Tout tan _____ Anpil Fwa _____ Gen de fwa _____ Raman _____ Jame

Konbyen moun wap fe seks ak pandan 6 mwa? _____

Konbyen moun nouvo wap fe seks ak pandan 12 mwa? _____

Eske-w te gen yon moun ke w te konn fe bagay avel ki gen 3 ane an plis oui?

_____ oui
_____ non

Si wi le sa te pase-a, ki laj ou te genyen? _____ ki laj li te genyen? _____

Eske w te ‘distillateur’ ansanm ?

_____ oui
_____ non

Eske w te konn fe bagay ak lot gason pandan 3 ane apre?

_____ wi
_____ non

Eske yo pa janm fe-w abi nan fe bagay?

_____ wi
_____ non

Eske-W gen relasyon nan 3 denie ane ki pase? _____

Eske-w pa janm dignotike avek yon maladi ou pran nan fe bagay?

_____ wi
_____ non

KONESANS NAN FE BAGAY :

1. Eske-w ka pran yon maladi yon moun ka pran nan fe bagay ?
 - a. Bay yon lot lamèn.
 - b. Fe bagay.
 - c. Benyen

2. Sentom maladi gonore-a kapab koz.
 - a. Tous
 - b. Dehaj nan bouboun
 - c. Nen dlo

3. Tretman pou maladi klamidya kapab genyen :
 - a. medikaman
 - b. benyen
 - c. repo

4. Ki kote yo pale-w de maladi ke moun ka pran nan fe bagay?
 - a. fanmiy
 - b. lekòl
 - c. zanmi
 - d. endepandan
 - e. dokte

Istwa sou avotman ou ped:

Konbyen fwa ou te anesent ? _____

Konbyen fwa ou te baby ki viv ou te fe? _____

Konbyen fwa ou pedi bebe-a le ou te anesent? _____

Konbyen fwa ou pedi bebe-a le ou te anesent, men ou pouse bebe -a ki mouri-a? _____

Konbyen fwa ou pedi bebe-a paski ou pa te vle anesent? _____

A ki laj ou te fe premye **ansent ou**?

10-12 _____

13-15 _____

16-18 _____

19-21 _____

22> _____

A ki laj ou te genyen **premye pitit ou**?

10-12 _____

13-15 _____

16-18 _____

19-21 _____
22> _____

For Physician Use Only (English)

Genital / Reproductive / Sexual Review of System:

Women: _____ Current discharge from Vagina
Ever tested for HIV: __Yes ___ No If yes results: _____
____Difficulty with intercourse ____Pain with intercourse _____ Infertility
Ever douched: _____Yes _____No
If Yes: Frequency _____ Once a month _____ Once every 3 weeks _____ Once every 2 weeks _____ More frequently
Women: _____ Age menses began
Date of last **pap smear** _____

Physical Exam:

Vitals:

_____ **B/P** _____ **P** _____ **Temp** _____ **Resp** _____ **Wght**
_____ **Hght**

Genital/Urinary: Women:

Vagina: __normal mucosa without discharge ____inflamed mucosa __dry/atrophic mucosa ____ vaginal discharge
Labia: __normal ____abnormal with lesions ____abnormal with rash or inflammation
Urethra: __normal ____abnormal __Urethrocele
Pelvic floor: __normal ____rectocele ____uterine prolapse
Ovaries: __normal __unable to palpate ____mass or enlargement present
Uterus: __normal ____unable to palpate ____mass or enlargement present
Cervix: ____normal appearance ____inflamed with discharge ____ulcerated appearance
____lesions on cervix

Describe all abnormalities:

Appendix G: Data Form for GC/CT Test Results

Laboratory Information

Patient Identification _____ **Date** _____

Disease Test +/-

Clearview Chlamydia	
Biostar OIA Gonorrhea	

Lab Error Noted

Appendix H: IRB Approval



Institutional Review Board
Dr. Hara Misra
Chairman
540.231.3693
misra@vcom.vt.edu

VCOM Institutional Review Board Notice of Review

January 7, 2008

Camille Henson, DO
PhD Candidate

RE: IRB#2007/043, Determining Risk Factors that Contribute to Transmission Rates of Chlamydia trachomatis and Neisseria gonorrhoea among Women in Veron, Dominican Republic

Dear Dr. Henson:

The proposed research is eligible for expedited review according to the specifications authorized by 45CFR 46.110 and 21 CFR 56.110. Your protocol has been reviewed via expedited procedure by two members of the VCOM IRB during the week of December 31, 2007. Your protocol has been **approved without changes**.

Federal guidelines dictate that IRB-approved research must be reviewed no less than once a year. Note that your continuation review will be January 7, 2009. Approximately 30 days before this date, you will receive a Progress Report Form from the IRB Coordinator. Please fill out this report and submit it to the IRB Coordinator at least two weeks prior to your review date.

Please remember that as the PI, you are responsible for promptly reporting to the IRB any proposed changes in the research activity prior to being implemented. You are also responsible for promptly reporting any injuries or adverse events or unanticipated risks to subjects.

Please be advised that the VCOM IRB will be conducting routine audits as a means of ensuring compliance with VCOM and federal policies in an effort to assure the protection of human subjects. Your project may, at any time throughout the approval period, be subject to this type of monitoring.

Thank you for your cooperation. If you have any questions or concerns, please do not hesitate to contact the IRB Coordinator, Sharon Kauffman at skauffman@vcom.vt.edu or 231-4512.

Sincerely,

Hara P. Misra, DVM, PhD
Chairman, VCOM Institutional Review Board

2265 Kraft Drive, Blacksburg, Virginia 24060
Phone: 540.231.4000 Fax: 540.231.5252

