THE RISK OF WOMEN IN MANITOBA ACQUIRING

PELVIC INFLAMMATORY DISEASE

FROM ONE OR MORE EPISODES OF GENITAL CHLAMYDIA TRACHOMATIS

OR NEISSERIA GONORRHOEAE INFECTIONS

BY

DAWN L. WUSKYNYK

A Thesis Submitted to the Faculty of Graduate Studies in Partial Fulfillment of the Requirements of the Degree of

MASTER OF NURSING

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Abstract

The association between being infected with the sexually transmitted infections (STIs), *Chlamydia trachomatis* or *Neisseria gonorrhoeae* and developing pelvic inflammatory disease (PID) is supported in the literature. Research also demonstrates an association between repeat infections with chlamydia or gonorrhea and acquiring PID. While there is some information from Canada on this topic, the majority of the research is from the United States and abroad. Additionally, there are few studies that have been able to examine the risk of acquiring PID utilizing a prospective study design.

The purpose of this study is to identify the risk of women in Manitoba acquiring PID from one or more episodes of genital chlamydia or gonorrhea. The length of time following a genital chlamydial or gonococcal infection where PID develops is explored. Obtaining information on the risks of acquiring PID, among women in Manitoba with genital chlamydia or gonorrhea, has important policy implications such as early detection and screening of STIs, treatment procedures, partner notification and contact tracing.

A surveillance system framework was used to guide the study. The data were acquired by linking administrative databases from Cadham Provincial Laboratory and Manitoba Health. Three cohorts of women were chosen, based on their history of testing positive or negative for STIs. Quantitative data analysis was completed through the use of the Statistical Analysis Software (SAS) program. Descriptive statistics and frequency distributions were completed for each variable to become familiar with the data. Since this is a cohort study, incidence rates and measures of association, such as the relative risk, were completed. Tests of statistical significance were also calculated. Study findings indicate that 15 - 24 year old women, in Manitoba with documented infections of genital

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Chlamydia trachomatis or *Neisseria gonorrhoeae* are at risk of acquiring PID. Compared to women infected with genital chlamydia, women infected with genital gonorrhea had a higher percentage of previous diagnosis of PID and experienced higher rates of hospitalization and outpatients visits related to PID. Recommendations related to practice and further research are made. Existing policies and future policies on testing and treatment of STIs within Manitoba will be more relevant by understanding the sequelae of chlamydia and gonorrhea.

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Dedication

To my parents, Marlene and Robert Wuskynyk for providing me with the skills, determination and confidence to pursue my academic aspirations

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Chapter One: Introduction

Sexually transmitted infections (STIs) have important implications for women. They are more easily transmitted to women than to men, infections in women are less likely to be symptomatic, are more difficult to diagnosis, and are more likely to cause serious long-term sequelae. If STIs are left untreated, they may lead to pelvic inflammatory disease (PID), ectopic pregnancy and infertility (Althaus, 1991; Egger, Low, Smith, Lindblom, & Herrmann, 1998). For the purpose of this project the focus will be on the association between STIs and PID. Additionally, of the studies reviewed on this topic, very few have been able to examine the risk of women acquiring PID utilizing a prospective study design.

The link between nursing, epidemiology and public health has played an important role in the management of communicable diseases, such as STIs. Nurses and other health care professionals are mandated by the *Public Health Act* to report communicable diseases, such as chlamydia and gonorrhea to provincial and federal health authorities (Public Health Act, 2003). Local health authorities have a responsibility to monitor, investigate disease outbreaks and participate in disease related research. Nurses support these responsibilities through the case management and eradication of STIs. Using the nursing process and epidemiological methods, primary, secondary and tertiary prevention interventions are implemented in order to decrease STIs (Malloy & Yiu, 2005).

Chapter One will introduce the problem under investigation, variable definitions and the proposed research questions. Assumptions around the research findings will be made and the relationship of this study to nursing will be discussed.

Statement of the Problem

The total population in Manitoba is approximately 1.1 million. Of this population, there are about 600 laboratory-confirmed cases of *Neisseria gonorrhoeae* and about 3000 laboratory-confirmed cases of *Chlamydia trachomatis* infection reported yearly. About three-quarters of the reported chlamydial infections occur in women and those between the ages 15 and 24 years are at greatest risk (Beaudion & Blanchard, 1996).

Untreated bacterial STIs, such as chlamydia and gonorrhea can cause serious complications, such as PID (Egger et al., 1998; Noble, 1990; Schachter, 1989). In Manitoba the hospitalization rate for PID in 1996 was 94.2 per 100,000 (Beaudoin & Blanchard, 1996). An estimated \$1.5 billion per year is spent on STIs related to direct and indirect costs (Schachter, 1989).

High-risk factors associated with chlamydial and gonococcal genital infections include young women, less than 20 years of age, single, inner city, low socioeconomic status, and multiple sex partners (Cates & Wasserheit, 1991; Graham & Blanco, 1990; Hillis, 1994). As a result of this, younger women (< 20 years old age) have twice the number of episodes of PID in comparison to older women (Graham & Blanco, 1990). Burst (1998) states that adolescents account for approximately 16 - 20% of the 1 million cases of PID reported each year. Faro (1991) further supports this by stating that approximately 20 - 40% of all sexually active women have been exposed to *Chlamydia trachomatis* and have positive antibodies to this organism.

Chlamydia is transmitted from person-to-person with particular ease through sexual intercourse, because approximately 70% of cases are asymptomatic and the patient is unaware of the infection, goes untreated, and continues to participate in unprotected sex with their partner(s), continues to transmit the infection to one another, therefore increasing the risk of transmission of STIs. Early identification of the signs and symptoms of Chlamydia *trachomatis* and *Neisseria gonorrhoeae* and early treatment of these STIs will reduce the duration of the infection and therefore the associated sequelae (Chinn, 2000; Graham & Blanco, 1990; Hillis & Wasserheit, 1996).

Most chlamydial infections are more common in women (Eng & Butler, 1992; Hillis, 1994) and women tend to be at greatest risk for chlamydial sequelae because their reproductive potential is at risk (Graham & Blanco, 1990). If chlamydia or gonorrhea is left untreated, the infection can further spread into the internal genital organs and cause PID. Since chlamydia, gonorrhea and PID can be asymptomatic, the infection can go untreated for a long time and cause tubal scarring, which can lead to infertility, partially blocked fallopian tubes or an ectopic pregnancy (Brunham et al., 1988).

Hillis and Wasserheit (1996) state that approximately 85% of women with PID delay seeking care and women with chlamydia are more likely to do so because their symptoms are minimal or absent. Women with gonorrhea or chlamydia associated PID who delayed care for three or more days were 2.6 times as likely to develop impaired fertility as those who sought care promptly (95% confidence interval 1.2, 5.9). Approximately 20% of women who delayed care suffered later infertility, compared with 8.3% who sought care promptly (Hillis et al., 1993).

Similarly, early detection of PID is important to prevent sequelae associated with PID, however, a clinical diagnosis of PID remains difficult due to the fact that the majority of cases are asymptomatic and even among experienced clinicians symptoms are correctly attributed to PID in only 65% of all cases (Temmerman, 1994).

Currently, there is little information on the incidence of PID acquired from *Chlamydia trachomatis* and *Neisseria gonorrhoeae* among women in Manitoba. Locally, Manitoba has the highest rate of chlamydia and gonorrhea infections among women of all provinces in Canada. The number of chlamydia cases in Manitoba for the 2003 calendar year increased by 9. 23% compared to 2002. For gonorrhea there was a 42.4% increase in the number of cases in 2003, compared to 2002 (Manitoba Health, 2003). The rationale for this increase in STIs is difficult to ascertain and the extent to which, more complete reporting of STIs that occur in Manitoba, compared to other provinces is unknown. If chlamydia and gonorrhea infections are left undiagnosed and untreated complications include, infertility, ectopic pregnancy and PID (Burst, 1998).

Cates and Wasserheit (1991) further support this by stating that numerous seroepidemological studies have confirmed the association between past infection with chlamydia and PID. While the rates of chlamydia and gonorrhea in Manitoba are known, the actual sequelae and number of PID cases associated with chlamydia and gonorrhea are unknown. The lack of this information makes policy formulation difficult. By demonstrating a more accurate account of sequelae associated with STIs in Manitoba women, the need for primary interventions with respect to STIs may be substantially supported. Failure to control these infections and decrease the number of cases of chlamydia and/or gonorrhea can have serious implications on the health of Manitoba women as well as the health care system. Brunham et al. (1988) state that the majority of PID cases are theoretically preventable by early recognition and treatment of uncomplicated cervical infections of chlamydia and gonorrhea (Burst, 1998; Chaudhry, Goel, Dhawan, & Aggarwal, 1997). The delay in treating STIs or PID can also lead to the

need for hospitalization, which is a huge financial burden on the health care system. Orr et al. (1994) state that in Manitoba in 1990, the hospitalization rate for PID was 71 per 100,000, while the outpatient physician visit rate was 463 per 100,000. Todd, Estany, and McLaren (1988) further state that in Canada in the mid 1980s, the total direct and indirect cost associated with PID, involuntary fertility and ectopic pregnancy was estimated to be over \$140 million per year. Thus the financial burden of STIs and PID is evident.

To prevent the sequelae of STIs, one must first look at the reducing the number of STI cases. Cates and Wasserheit (1991) and Aral and Wasserheit (1998) state that early identification of individuals infected with STIs, through widespread screening programs, and compliance with curative treatment procedures are effective in decreasing STIs. Magnusson et al. (1986) further support this and state that aggressive contact tracing and partner notification combined with the appropriate, current screening procedures would be effective in decreasing the incidence of STIs and therefore the incidence of PID.

As a Public Health Nurse and a former member of the Communicable Disease Control (CDC) Unit at Manitoba Health, the research questions associated with this topic were created based on my personal interest in this topic and the expectations set out by the CDC Unit. In Canada, provincial authorities have the responsibility to report the occurrence of communicable diseases, such as STIs to the Centre of Infection Disease Prevention and Control in Ottawa (Malloy & Yiu, 2005). Regional health authorities also have a responsibility to report communicable diseases to the CDC Unit at the provincial level, thus aiding in the case management of communicable disease control (Malloy & Yiu, 2005). The role of the Public Health Nurse (PHN) in the management of STIs is significant. The work of the PHN involves breaking the chain of infection related to STIS through partner notification, education and screening for STIs (Malloy &Yiu, 2005).

Definitions

Pelvic Inflammatory Disease (PID): Inflammatory condition of the female pelvic organs, caused by bacterial infections. Most common bacterial infections are chlamydia and/or gonorrhea (Glanze, 1986).

Chlamydia trachomatis: Sexually transmitted bacterial genital infection. Symptoms include mucopurulent discharge, burning on urination, itching. Most individuals are asymptomatic. Mode of transmission: sexual intercourse with an infected individual. Incubation period: poorly defined, approximately 7-14 days or longer (Chinn, 2000).

Neisseria gonorrhoeae: Sexually transmitted bacterial genital infection. Symptoms include purulent discharge, burning on urination, itching. Most individuals are asymptomatic. Mode of transmission: sexual intercourse with an infected individual. Incubation period: usually 2-7 days, sometimes longer with symptoms (Chinn, 2000).

Women in Manitoba: All women, 15 years and older who resided in Manitoba between 1984 and 2000. The women consisted of those who tested positive or negative for chlamydia and/or gonorrhea and also had a positive diagnosis of PID. Women, who had never been tested for Chlamydia or gonorrhea but had a positive diagnosis of PID, are also included. Women who were deceased or had cancelled their provincial health insurance coverage were excluded.

Research Questions

1. What is the risk of PID among women in Manitoba with previous documented episodes of chlamydial and gonococcal genital infections? What is the risk of acquiring PID: If tested negative for chlamydia or gonorrhea? If never been tested for chlamydia or gonorrhea?

2. What is the proportion of women diagnosed with chlamydia and gonorrhea who had a previous diagnosis of PID?

3. What is the survival time in months between the initial diagnosis of chlamydia and the initial diagnosis of PID? What is the survival time, in months between the initial diagnosis of gonorrhea and the initial diagnosis of PID?

4. What is the rate of hospitalization for PID among women who have chlamydia, gonorrhea or neither? What is the rate of outpatient visits for PID among women who have chlamydia, gonorrhea or neither?

5. What is the geographic distribution of chlamydia and gonorrhea? Are some municipalities more susceptible to these infections? What characteristics within a community effect the rates of chlamydia and gonorrhea?

Assumptions

It is expected that the incidence of chlamydia and gonorrhea will be higher in the 15-25 year age group and that this age group will be at a higher risk of acquiring PID compared to other age groups. Since the majority of PID cases are asymptomatic and many go untreated as a diagnosis of PID is difficult, it is assumed that women from the 15-25 age category who are expected to be infected with an STI, will also be at a

greater risk of being infected with PID, 10 - 15 years later, putting them at 30 - 35 years of age.

Women in Manitoba with one or more documented episodes of chlamydial and/or gonococcal genital infections will also be at a greater risk of acquiring PID compared to women who have never been infected with an STI. It is also expected that the rate of hospitalization for PID will be low in comparison to the number of chlamydia and gonorrhea cases as the majority of PID cases are asymptomatic, difficult to diagnose and the cases are expected to primarily be seen at the physicians' office on an outpatient basis.

Relationship of this Study to the Nursing Discipline

The CDC Unit at Manitoba Health is the provincial authority responsible for reporting communicable disease, such as chlamydia and gonorrhea to the Centre for Infectious Disease Prevention and Control in Ottawa (Malloy & Yiu, 2005). STIs, like chlamydia and gonorrhea, are considered notifiable diseases in Canada under the *Public Health Act* (Public Health Act, 2003). Health care providers are mandated to report all notifiable diseases to the Director of the CDC Unit by the fastest means possible (Public Health Act, 2003). Once these diseases are reported to the director of the CDC Unit, they are entered into a surveillance system to be monitored, analyzed and disease trends identified. This is information important to this research study since the data for this study was provided by Manitoba Health *Act*. For the purposes of this study, a secondary use of this data was to determine the risk among women in Manitoba in acquiring PID from infections with chlamydia or gonorrhea.

Since Florence Nightingale, nurses have played an important role in epidemiology, disease surveillance, case management and control of communicable diseases (Malloy & Yiu, 2005). As health professionals, nurses are mandated by the *Public Health Act*, Section 43(1), to report STIs and the names of contacts of an STI, or other communicable disease to the Director of the CDC Unit (Public Health Act, 2003). Through the use of epidemiology, the nursing process and research, nurses facilitate disease prevention, case management and the eradication of STIs (Malloy & Yiu, 2005).

Summary

To summarize, there is evidence that if STIs, such as chlamydia and gonorrhea, are left untreated serious long-term sequelae such as ectopic pregnancy, infertility and PID can evolve. Delay in treating these STIs and their sequelae can have serious implications on the health of women, as well as the health care system. Early identification and treatment of STIs will prevent the associated sequelae. Thus the purpose of this study is to identify the risk of women in Manitoba acquiring PID from one or more genital chlamydial or gonococcal infections.

The chapters that follow provide the following information. Chapter Two provides an overview of the literature on the study topic. The conceptual framework is discussed in Chapter Three. Chapter Four introduces the study methodologies, and Chapter Five is a presentation of the findings. Chapter Six, the final chapter, is a discussion of the findings and includes research and program recommendations, and policy implications.

Chapter Two: Literature Review

A review of the literature consisted of the available published studies that focused primarily on the sequelae associated with chlamydial and gonococcal infections. The literature identified studies from Canada, United States and abroad. The majority of research on this topic however has been conducted abroad, such as Sweden and in the United States. The following themes were identified: the incidence and sequelae of STIs, the incidence and sequelae of PID, the behavioral and sociodemographic risk factors associated with STIs and PID, the cost associated with STIs and PID, and recommendations that offer preventative and health promotion strategies to deal with the incidence of STIs and therefore PID. An overview of the Manitoba provincial STI program will also be discussed.

Incidence and Sequelae of STIs

The incidence of STIs; chlamydia and gonorrhea are on the rise worldwide. Chlamydia and gonorrhea are the most common STIs and more than 4 million STIs in the United States are caused by chlamydia and gonorrhea (Burst, 1998; Cates & Wasserheit, 1991; Egger et al., 1998; Graham & Blanco, 1990; Mgone, Lupiwa, & Yeka, 2002).

Of the two STIs, chlamydia is the most common and is higher in incidence than gonorrhea. While both chlamydia and gonorrhea have important implications on reproductive health sequelae, particularly in women, chlamydia tends to be the major cause of reproductive morbidity, compared to gonorrhea (Burst, 1998; Cates, 1999; Cates & Wasserheit, 1991; Chaudry et al, 1997; Egger et al, 1998; Faro 1991; Graham & Blanco, 1990; Kamwendo, Forslin, Bodin, & Danielsson, 1996; Magnusson et al., 1986; Mgone et al., 2002). Stated in the literature is the fact that chlamydia and gonorrhea are common in both men and women and are usually asymptomatic infections. Chlamydia tends to be asymptomatic in both men and women, while gonorrhea is more likely to be asymptomatic in women and symptomatic in men. While these infections affect both men and women, women are at a greater reproductive risk compared to men as these infections are asymptomatic and can go undetected for days, months, or years and can spread from partner to partner causing further spread of infection and further reproductive morbidity. Women with chlamydia who delayed seeking treatment for STIs were six times as likely to be diagnosed with an STI sequelae (Aral & Wasserheit 1998; Champion, Piper, Shain, Perdue, & Newton, 2001; Hillis, 1994; Mgone et al. 2002).

Some of the reproductive health sequelae associated with chlamydia and gonorrhea include chronic pelvic pain, PID, cervical cancer, tubule scarring and infertility (Burst, 1998, Cates, 1999; Cates & Wasserheit, 1991; Chaudhry et al., 1997; Egger et al., 1998; Faro 1991; Graham & Blanco, 1990; Kamwendo et al., 1996; Magnusson et al., 1986; Wang, Burstein, & Cohen, 2002). For the purposes of this study the literature review focused primarily on PID.

Incidence and Sequelae of PID

In the literature PID is described as a serious reproductive health condition that occurs due to a bacterial infection of the upper female genital tract, which includes the endometrium of the uterus, fallopian tubes and the ovaries (Aral & Wasserheit, 1998). As the incidence of STIs increases, the incidence of PID also increases. The majority of PID cases tend to occur from an infection with either chlamydia or gonorrhea, however a few PID cases have been associated with other causative agents, such as the use of the intrauterine device (IUD) (Aral & Wasserheit, 1998; Johnson, 1998: Khoiny, 1989; Noble, 1990; Risser, Risser, & Cromwell, 2002; Ross, 2002).

More than one million women contract PID yearly, resulting in more than 2.5 million out patient visits; 200,000 hospitalizations and 100,000 surgical procedures annually in the United States (Washington & Katz, 1991). Serological studies suggest that 20 - 60 % of PID cases may be attributed to chlamydia infections (Paavonen, 1980).

The prevalence of chlamydia is higher in the population compared to gonorrhea. Therefore, the prevalence of PID related to chlamydia is higher than the prevalence of PID related to gonorrhea. While the incidence of PID related to gonorrhea is lower, it is frequently associated with more severe clinical symptoms than chlamydia. Thus, the individual with gonorrhea is more likely to have a diagnosis of PID (Westrom, 1980). Some of the literature recorded the effects of recurrent infections with chlamydia and gonorrhea and also co-infection with both chlamydia and gonorrhea in the development of PID; and found that recurrent infections with chlamydia and gonorrhea put one at a greater risk of acquiring PID (Aral & Wasserheit, 1998). Primarily recurrent infections with chlamydia versus recurrent infections with gonorrhea seemed to be more important in the development of PID, while co-infections with both chlamydia and gonorrhea also played an important role in the development of PID (Aral & Wasserheit, 1998). Women with recurrent episodes of chlamydial infection, compared to women with one documented episode of a chlamydial infection, were at an increased risk for subsequent PID. Women with two chlamydia infections were four times as likely to be hospitalized for PID and those with three or more chlamydial infections were five to six times more likely to be hospitalized with PID (Aral & Wasserheit, 1998; Hillis et al.

1997). While recurrent and co-infections with chlamydia and gonorrhea seem to be important in the development of PID, only a few articles noted this in their research. A study conducted by the World Health Organization (WHO) (1995), found that women with past chlamydial and gonococcal infections or both were significantly more likely to acquire PID and the majority reported no history of PID symptoms. Ninety-three percent of women with PID had antibodies to chlamydia and/or gonorrhea. Twenty-nine percent of women with gonorrhea were less likely to report symptoms of PID, compared to 44% of women with previous chlamydial infections. Two-thirds of women with PID who had no evidence of previous infection with chlamydia or gonorrhea reported a history of abdominal pain and fever; symptoms associated with PID.

Similar to STIs, PID tends to be asymptomatic and can go undetected, therefore allowing the infection to spread further along the reproductive organs (Mgone et al., 2002). It is estimated that two-thirds of PID episodes are asymptomatic or mildly asymptomatic and therefore women do not seek medical care (Wolner-Hassen, 1995). Consequently, timely detection of PID is difficult and often is diagnosed as something else (Aral & Wasserheit, 1998; Marks, Tideman, Estcourt, Berry, & Mindel, 2002). The diagnosis of PID usually is based on clinical assessment verses a laboratory test which is often difficult and the margin of error is wide (Risser et al., 2002; Ross, 2002). If PID is not diagnosed and treated within an appropriate time frame, PID, like STIs, has serious sequelae.

Sequelae associated with PID include tubal scarring, chronic pelvic pain, tubal infertility and ectopic pregnancies (Hillis &Wasserheit, 1996; Lawson & Blythe, 1999). Tubal infertility is the inability to conceive and produce viable offspring. An ectopic

pregnancy occurs when the fertilized ovum is implanted outside the uterus instead of in the uterine wall (Miller, Caine, Rogers, Gribble, & Turner, 1999). The expense borne to both patients with STIs and the public for the management of STIs is largely associated with its sequelae PID and thus the sequelae associated with PID. Women with a history of PID have an increased risk of hospitalization and required surgery for numerous gynecological problems in the years following their PID infections (Buchan, Vessy, Goldare & Fairweather, 1993; Orr et al., 1994).

Washington and Katz (1991) state that more than 25% of women with a history of PID suffered with at least one of the sequelae associated with PID; chronic pelvic pain, infertility, or ectopic pregnancy. This is further supported by Hillis and Wasserheit (1996) who state that ectopic pregnancies are the leading cause of maternal death during the first trimester of pregnancy among American women and that this has increased in the last 20 years.

Most research studies have identified the importance of early diagnosis and detection of chlamydia and gonorrhea in order to prevent sequelae of PID. A 25-year study in Sweden, conducted by Kamwendo et al. (1996) demonstrated a steady decrease in the number of hospital admissions for PID during the last 10 years, which coincides with the nearly complete disappearance of gonorrhea and the decrease of chlamydia. These changes were seen in all age groups, however they were most pronounced in the 15-19, 20-24 and 25-29 year old groups. Another study by Scholes et al. (1996) provided strong evidence that the efficacy of screening for chlamydia prevents PID. Early identification and treatment of STIs is important and necessary, as it would prevent

sequelae like PID and in turn prevent chronic pelvic pain, infertility and ectopic pregnancy.

A study conducted in Manitoba, Canada by Brunham et al. (1988) demonstrated a relationship between being infected with an STI and acquiring PID among women in Manitoba. They also identified women with a poor fertility prognosis and related this to being infected with chlamydia. The researchers however, did not look at the effects of recurrent infections with chlamydia or gonorrhea in acquiring PID.

Behavioral and Sociodemographic Risk Factors Associated with Acquiring Chlamydia and/or Gonorrhea and their Sequelae

Various behavioral and sociodemographic characteristics associated with being exposed to and infected with STIs and PID were identified in the literature. Behavioral characteristics associated with being infected with STIs and PID included early age of first sexual encounter, young age (20% of 12-15 year old females), unmarried, multiple sex partners, new partners, high-risk sex partners, drug use, prostitution and engaging in unprotected sex (Aral & Wasserheit, 1998; Cates & Wasserheit, 1991; Huges et al., 2001; Manitoba Health, 2001b; Sionean et al., 2001; Voeten, Egesah, & Habbema, 2004).

Primarily females between 15 to 19 years and 20 to 25 years of age were at the greatest risk of acquiring STIs and it's sequelae; PID (Beaudion & Blanchard, 1996; Hiltunen-Back et al., 2003; Khoiny, 1989; Mgone et al., 2002; Wilson, 1985) because young women tend to have multiple partners, high frequency of partner change and engage in risky behavior compared to older women (Simms & Stephenson, 2000).

In 1995, the Center for Disease Control and Prevention in Atlanta, Georgia reported that the majority of positive chlamydia cases were young women. Of these

cases, 4% were 14 years or younger, 46% were 15-19 years, 33% were 20-24 years and 17% were 25 years or older.

The incidence of STIs is greatest among young adults (Hillis, 1994) and it is estimated that sexually active 10 to15-year-olds are 7 to 10 times more likely to contract PID than sexually active 20 to 24-year olds. Westrom (1980) reported that 70% of females with PID were younger than 25 years of age and that 33% experienced their first STI before the age of 19. A study by Suss, Homel, Hammerschlag, and Bromberg (2000) found that women with PID were significantly more likely than those without PID to show a younger age at first intercourse, older sex partners, chlamydial infections and involvement with a child protection agency.

Marital status was also identified as a behavioral risk factor in acquiring STIs and PID. Unmarried, single women were identified to be at a greater risk of acquiring STI and therefore the associated sequelae, PID, compared to those who were not diagnosed with STIs (Muylder et al., 1990). Women positive for chlamydia and/or gonorrhea were more often single (72.2%) compared to those women who were negative for chlamydia or gonorrhea (47.6%) (Magnusson et al., 1986). Single women were also more likely to have multiple sex partners, thus increasing the risk of acquiring STIs/PID. Multiple sex partners increase the risk of acquiring PID 4.6 times (Aral & Wasserheit, 1998; Burst, 1998; Graham & Blanco, 1989; Magnusson et al., 1986; Simms & Stephenson, 2000). The WHO Task Force on the Prevention and Management of Infertility (1995) also found that individuals with tubal infertility reported a greater number of partners compared to those without tubal infertility.

Sociodemographic characteristics such as low socioeconomic status, minority race/ethnicity, inner city residents, and remote rural residents were also identified (Aral & Wasserheit, 1998; Hiltunen-Back et al., 2003; Voeten et al., 2004). A study by Sionean et al. (2001) also identified a strong association between socioeconomic status and a high prevalence of gonorrhea. They found that adolescents whose parents were unemployed were twice as likely to report an infection of gonorrhea, compared to those residing with parents who were employed. This association remained even after controlling for potential confounding effects of parental monitoring, adolescents' sexual risk behavior and having a high-risk sexual partner. Another sociodemographic characteristic identified in a research article by Brunham et al. (1988) identified that women from Winnipeg, Manitoba, Canada who were positive for chlamydia and/or gonorrhea were significantly more often Native America Indians than any other ethnic background.

Costs Associated with STIs and PID

STIs and their sequelae, PID, as well as the sequelae associated with PID, not only have physical implications but also have proved to be a huge economic burden to individuals, the health care system and the economy. The physical implications associated with STIs and PID have already been mentioned; however include infertility, tubal scarring, chronic pelvic pain and ectopic pregnancies. These physical implications can put a great financial stress on the individual and the health care system. The substantial financial costs of genital chlamydial infection are a result of hospital treatment for PID, ectopic pregnancy and infertility (Simms & Stephenson, 2000; Taylor-Robbinson, 1994; Whiteside, Katz, Anthes, Boardman, & Peipert, 2001).

Direct and indirect costs associated with PID and its sequelae were estimated to be over \$4.2 billion in 1990 and projected to exceed \$10 billion in 2000 in the United States (Washington & Katz, 1991). Similarly, in Canada, the direct and indirect costs associated with PID in the mid 1980's were estimated to be over \$140 million per year (Todd et al., 1988). The hospitalization rate in Manitoba, Canada in 1990 for PID was 71 per 100,000 and the out patient physician visit rate was 463 per 100,000 (Beaudion & Blanchard, 1999). The implications associated with STIs and its sequelae; PID, affects society as a whole, physically and economically.

Recommendations from the Literature

Recommendations in the literature suggest preventative and health promotion strategies that would facilitate a decrease in the incidence of STIs and therefore a decrease in the sequelae associated with STIs. The recommendations include, early screening (diagnosing) of STIs, partner notification and utilization of a new advanced urine-based testing procedure.

The main goal of chlamydia screening and treatment is to prevent PID and its sequelae (Mangione-Smith, McGlynn, & Hiatt, 2000). Screening for chlamydia is recommended as 56 to 80% of individuals infected with STIs are asymptomatic and therefore do not attend for testing or treatment, thus allowing the infection to further spread along the reproductive tract and to their partners (Cates & Wasserheit, 1991, Chaudry et al., 1997; Mangione-Smith et al., 2000).

It is recommended that individuals with demographic risk factors (i.e., 15 - 19 years old and 20 - 25 years old, single, multiple sex partners and a history of STIs) associated with STIs be screened at each health care provider visit as this will have an

important impact on the incidence of STIs and their sequelae. This practice has proven to reduce STIs, as well as be cost effective (Graham & Blanco, 1990; Hart, 1993; Hillis, 1994; Katz, Fortenberry, Tu, Harezlak, & Orr, 2001; Mangione-Smith et al., 1999; Suss et al., 2000).

When patients are being screened for STIs, it is also an opportune moment to provide education and counseling on STIs, their sequelae, behavioral risk factors associated with STIs, selection of partners and the use of contraceptives, such as condoms for further protection against STIs and their sequelae (Hillis, 1994; Hillis et al., 1997; Huges et al., 2001; Katz et al., 2001). In Canada, Moses and Elliot (2002) found that physicians are missing opportunities for screening for chlamydia among young people. The majority of young men and women are seen by a physician at least one time a year and only one-quarter of women and less than 5% of men are tested for chlamydia. The reason for these low screening rates are due to a lack of awareness by both the physician and patient as to the importance of screening for chlamydia, as well as the inconvenience and discomfort associated with traditional testing methods for urethral and cervical infections; pelvic examination for women and urethral swab for men.

A study in Sweden demonstrated a decrease in hospital admissions for PID in the past 10 years that coincided with the nearly complete disappearance of chlamydia and gonorrhea. The decreased incidence in chlamydia and gonorrhea can be attributed to measures taken to control the spread of these infections. Such measures include making chlamydia and gonorrhea reportable to the local health authority through legislation. This legislation also required that both the patient and the physician were to be responsible for the screening, treatment, follow-up and partner notification related to STIs. Male partners of patients with PID were automatically provided with antibiotic treatment, because it was found that at least 60% of the male partners were infected with an STI. This study provides evidence that screening, treatment and partner notification are effective in decreasing STIs and their sequelae (Kamwendo et al., 1996).

Partner notification, also referred to as contact tracing in the literature, was recommended to decrease the incidence of STIs and PID. For the purposes of this study, the term partner notification will be used. Partner notification is the process of interviewing STI positive individuals for the names and contact information of their partner(s). A study by St. Lawrence et al. (2002) found that partner notification is not routinely performed by health care providers in the United States. The most common infection controls strategy was education of patients on safe sex practices and encouraging patients to inform their partners to attend for treatment. Only 20 - 30% physicians followed-up with their patients to confirm whether their partners attended for testing and treatment and only 9 - 16% of physicians collected information about the patient's partners and forwarded this information to the health department. The researchers recommended that a policy-level intervention, to increase case reporting and partner notification, be considered.

The use of a new screening test is being considered by some countries to detect chlamydia and gonorrhea; this is the urine-based nucleic acid amplification test. The urine-based nucleic acid amplification test screens urine and offers a non-invasive screening method that can be performed in the traditional clinical setting, as well as the non-traditional setting; out in the community (Risser et al., 2002; Shafer, Pantell, & Schachter, 1999). This non-invasive procedure may encourage more patients to be

screened and improve compliance with treatment and other preventative personal health care practices. Therefore, decreasing the incidence of STIs and their sequelae. The urine-based nucleic acid test has an increased sensitivity compared to other methods (Shafer et al., 1999).

Shafer et al. (1999) examined the cost of preventing PID and found that the urinebased nucleic acid screen compared to a pelvic examination was the most cost-effective procedure. The cost of preventing a case of PID is \$5,984 (US funds) utilizing the urinebased nucleic acid screen compared to \$11,044 (US funds) utilizing a pelvic examination. Thus the urine-based nucleic acid screen is being considered as an alternate screening tool to detect chlamydia and gonorrhea that has proven to be cost effective and less invasive, thereby preventing sequelae like PID.

Overview of the Manitoba Provincial STI Program

Since 1987, chlamydia and gonorrhea were required by provincial legislation to be reported to the public health authorities for case management and follow-up. The Public Health Act states that positive laboratory reports for chlamydia and gonorrhea and all STI notification of disease forms must be completed and reported to the Provincial Director of Communicable Disease Control (Manitoba Health, 2001a; Orr et al., 1994; Wylie & Jolly, 2001).

The provincial Communicable Disease Management Protocol policy states that all sexually active men and women should be screened for chlamydia, gonorrhea and syphilis and that the appropriate presumptive treatment be provided. The protocol also recommends that testing and counseling for the Human Immunodeficiency Virus (HIV) should be offered (Manitoba Health, 2001a). Testing for chlamydia and gonorrhea is
recommended for individuals with signs and symptoms of chlamydia and gonorrhea. STI screening of individuals with one or more of the following risk factors is also recommended: age, less than 25 years, history of previous STIs, multiple sex partners, new sexual partners, street involved individuals (injection drug use, prostitution, etc), pregnant women and unprotected sexual encounters (Manitoba Health, 2001b; Orr et al., 1994).

Case management of all positive STI cases and their partners, is the responsibility of the Regional Health Authorities throughout the province. The provincial Communicable Disease Management Protocol states that individuals positive for chlamydia and/or gonorrhea should be interviewed for a history of exposure to STIs, risk assessment, sexual partners and tested for STIs and HIV. The provincial protocol also recommends presumptive treatment. All STI positive individuals are required under the Public Health Act to be interviewed for exclosure of their sexual partners (Public Health Act, 2003). All sexual partners of symptomatic individuals, who were exposed to either chlamydia or gonorrhea, should be examined, tested for STIs and be provided presumptive treatment. Asymptomatic individuals should be interviewed for all sexual contacts from three months prior to the diagnosis. These contacts should be offered counseling, education, examination and testing, and presumptive treatment (Manitoba Health, 2001a).

Educational programs targeted at those individuals at the greatest risk of acquiring STIs are available throughout the province and is provided by the Regional Health Authorities. The programs are available at varying degrees as each Regional Health Authority has different populations and resources, both human and financial. The

education programs involve both individual and group counseling by Public Health Nurses and physicians (Orr et al., 1994).

To enhance screening of high risk individuals, Manitoba Health is in the process of introducing the new screening test; the urine-based nucleic acid amplification test for *Chlamydia trachomatis* for both men and women under the age of 25 and other risk factors (Moses & Elliot, 2002).

Summary

Identified in the literature review were the incidence of STIs, incidence of PID, demographic risk factors associated with acquiring STIs/PID, implications associated with STIs/PID and recommendations that offer preventative and health promotion strategies to decrease the incidence of STIs and therefore PID. While the above articles demonstrated a relationship between being infected with an STI and acquiring PID, the effects of repeat infections with an STI and acquiring PID was limited. Also, there was limited research on this topic using a prospective study design. Central to this research project is the demonstration of the risk of acquiring PID, <u>specific</u> to women in Manitoba with one or more repeated infections of either, or both genital chlamydia and gonorrhea. Knowledge of this information will have strong policy implications in Manitoba related to early detection and screening of STIs, treatment procedures, partner notification procedures, and the use of new testing procedures.

Currently, in Manitoba, under the *Public Health Act* (2003), chlamydia and gonorrhea are notifiable diseases and are reportable to the Director of the CDC Unit for data collection, and case management. PID is not considered a notifiable disease under the *Public Health Act* and thus, the actual number of PID cases in Manitoba is unknown. Therefore, this study will identify the risks of women in Manitoba acquiring PID from one or more episodes of genital chlamydia and/or gonorrhea infections. In Chapter Three, the conceptual framework utilized to guide this study is introduced and discussed.

Chapter Three: Conceptual Framework

A conceptual model of an epidemiologic surveillance system established by the Centres for Disease Control (CDC) in Atlanta Georgia is utilized to guide and address the etiology of STIs. A surveillance system framework was chosen to guide this study as Manitoba Health utilizes a similar framework to collect, manage, analyze and interpret data related to STIs and other communicable disease. Since the data for this study was provided by Manitoba Health and gathered utilizing a surveillance system framework, such a framework is appropriate to guide this study.

Nurses also utilize this framework during data collection, interpretation, case management and disease prevention of STIs. Following this framework allows the chain of infection, such as disease transmission to be broken and therefore preventing the spread of STIs (Malloy & Yiu, 2005). In this chapter, a definition of surveillance is presented, followed by a detailed explanation of the surveillance system and how it relates to this research.

What is Surveillance?

Surveillance is the systematic collection, analysis, and ongoing monitoring, and interpretation of health data to detect changes in health trends or distributions of diseases in order to plan, implement and evaluate public health practices (Klaucke et al., 1988; Valanis, 1999; Young, 1998).

Purposes and Goals of a Surveillance System

There are several purposes in using a surveillance system framework;

1. To detect a new or developing disease or health problems quickly and bring them under control.

2. To evaluate the effectiveness of control measures, interventions, programs and outcomes.

3. To monitor quality of care and define strategies (Valanis, 1999).

Surveillance systems are a very valuable and useful tool for health care providers. They provide quick awareness of potential problems, quick investigations, stimulates thought and reduces costs associated with morbidity and mortality studies (Valanis, 1999).

Since surveillance systems are developed to collect data on various health related issues, the surveillance systems can vary widely in terms of methodology, scope and objectives (Klaucke et al., 1988). Thus the need to understand the purpose of the surveillance system and being knowledgeable as to which surveillance data is necessary is important as it is helpful in establishing the goals of the surveillance system.

The goals of each surveillance system will depend on the purpose of the surveillance system. For instance, the purpose of a surveillance system may be to monitor the incidence of genital chlamydial and gonococcal infections. The goals should clearly specify what is required to achieve this purpose. The goals may include: a case definition of genital chlamydial and gonococcal infections, establishment of background rates from the current number of cases (if available), investigation of behavioral risk factors, and the implementation of appropriate prevention and control measures (Gregg, 1996; Valanis, 1999).

Explanation of the Surveillance System Framework

This epidemiologic surveillance system framework (Figure 1) consists of three important steps; diagnosis (by whom and how), reporting process, and data management (Valanis, 1999).



Figure 1. Surveillance System Framework. Adapted from the Centres for Disease Control in Atlanta Georgia (Valanis, 1999).

Diagnosis refers to the diagnosis of a disease or health event by a health care practitioner. This diagnosis is usually based on a scientific case definition that describes the signs and symptoms of a disease or health event (i.e., urethra discharge, burning on urination, etc.). Depending on the disease or health event, a diagnosis may be based on laboratory findings or other diagnostics tests. Once confirmation of a positive disease or health event has been made, this information is reported to the appropriate health authority.

As Figure 1 indicates, there can be a variety of reporting sources; physicians, laboratories, hospitals, schools, and vital records. To determine who the reporting source would be largely depends on the disease or the health event and the purpose and goals of the surveillance system.

The data recipients consist of three levels of government. In Figure 1, these three levels of government are listed as primary, secondary and tertiary levels. Since this framework is adapted from the CDC in the United States, the levels of government are labeled accordingly. However in applying this to Canada; at the primary level is the Regional Health Authority (RHA), at the secondary level is the provincial health authority and at the tertiary level is the federal health authority. While the surveillance system framework indicates that at the primary level the RHA would receive the disease information prior to the other levels of government; this is not always the case in Manitoba. The RHA may receive the information first and forward it to the provincial government. However the provincial government may be made aware of the information first and then forward it to the appropriate RHA.

The data recipients are responsible for data collection and entry, editing the data, analyzing the data, generating and disseminating reports on the data. The reports are then shared with the public in a variety of formats. It may be to notify a member of the public or a group within the public that they have or may have been in contact with a

communicable disease. Or, the information may be disseminated in the form of a surveillance report or a public education campaign.

How the Surveillance System Framework Relates to this Research

In applying this surveillance system framework to STIs, the process begins with the diagnosis of an STI by a health care provider, followed by reporting the STI to the appropriate provincial health authority (such as the Director of the Communicable Disease Control Unit). Once this data is received it is entered into the surveillance system database and provided to the appropriate RHA for case management and follow-up. Once the RHA collects all appropriate information, the information is forwarded back to the provincial health authority and this additional data is, again, entered into the surveillance system. During the data management step, the potential risk of PID acquired from STIs may be identified (through the signs and symptoms listed on the reporting form) and disseminated for further follow-up.

Communication and dissemination of information received is a two-way process: to the general public and back to the surveillance system. The information that the general public would receive would depend on how they relate to the surveillance system. For example, if a person is positive for an STI, they would be provided interventions for the treatment of the STI, be interviewed for their sexual contact(s) and provided information on prevention of STIs. If a person were named as a sexual contact to a person who is positive for an STI, they would be informed to visit their physician for testing and treatment, educated on prevention of STIs and how they should inform their partners of their potential risk of being infected with an STI, so that their partners may also be tested. The general public could also receive information on the STIs in the form of a public awareness campaign sponsored by the provincial health authority.

The surveillance system framework is an appropriate framework to guide this nursing research because nurses, particularly Public Health Nurses, have a responsibility to monitor, investigate disease outbreaks and participate in disease related research. Nurses play a major role in the management of STIs and through the nursing process, epidemiological methods, primary, secondary and tertiary interventions are implemented in order to decrease STIs (Malloy & Yiu, 2005).

Summary

By utilizing the surveillance system framework in the case management of STIs, health care professionals are able to quickly identify STIs and their potential sequelae, such as PID, and disseminate the information to the appropriate health authorities for investigation. Becoming aware of the number of cases of STIs and therefore the potential risk of PID within the province of Manitoba provides the province and RHAs the opportunity to identify risk factors (i.e., high risk populations, age, sexual behaviors, etc). This also provides policy makers and program planners with local epidemiologic data so that they may re-evaluate current policies and practices, thereby reducing STIs and their sequelae.

The research design is discussed in Chapter Four. Also described are the independent and dependent variables, data source and data collection procedure, privacy issues, data quality, study sample, data analysis, study limitations and ethical implications.

Chapter Four: Methodology

Research Design

This is an epidemiological study, which uses a matched cohort design. Epidemiology is "the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of heath problems" (Last, 1995, p. 55). A matched cohort design is an analytical method of epidemiologic study where subsets of a defined population can be identified who are, have been, or in the future may be exposed in different degrees to a factor or factors hypothesized to influence the probability of occurrence of a given disease. A cohort study allows for a large sample size to be observed over a long period of time. By matching cohorts, comparability among the cohorts is ensured and any potential cofounders are evenly distributed between the cohorts (Last, 1995; Polit & Hungler, 1999; Young, 1998). A cohort study design is an appropriate study for nursing research in that nurses provide care both to the individual, family and community; therefore the cohort study design allows for large populations to be studied.

The overall purpose of this study is to identify if women in Manitoba who are infected with genial chlamydia or gonorrhea are at risk of acquiring PID. The dependent variable is a diagnosis of one or more episodes of pelvic inflammatory disease (PID). A subject in this study can have 1 to 10 diagnosis of PID. This diagnosis can be made either as an outpatient or as a hospital diagnosis. Table 1 lists the dependent variable, variable labels and their measurements.

Dependent Variables

Variable Name	Variable Label in SPSS	Measure
PID date PID Diagnosis 1 – 10 PID Hospitalizations/ Outpatient Visits 1 – 10 Count	Dates of distinct PID events 1 – 10 diagnosis of PID events Date of Hospitalization/Outpatient visit Total number of PID events	Nominal Ordinal Nominal Nominal

Dependent Variables

The variables "PID date" and "PID Hosp/Outpatient Visits" are the dates of each PID event. These events are either a diagnosis of PID by outpatient visit or by hospitalization for PID. This variable is an actual date, supplied as day/month/year. There is no particular order to these dates and they vary in terms of time between the next test dates. Thus the level of measure for this variable is nominal (Last, 1995; Valanis, 1999).

The variable "PID Diagnosis" is the date of diagnosis. A person can have up to 10 dates of diagnosis of PID. Since not all women have 10 dates of diagnosis, the number of dates of PID diagnosis will vary from woman to woman. For each woman this information is provided in the order in which the diagnosis for PID is made. Thus, this variable is an ordinal measure (Last, 1995; Valanis, 1999).

"Count" is the variable that indicates the number of PID diagnoses for each person. There is no particular order to this variable since the number of PID diagnoses can vary from woman to woman. Thus the level of measure for this variable is nominal (Last, 1995; Valanis, 1999). The independent variables, variable labels and the measurement of the variables

are listed in Table 2, Independent Variables.

Table 2

Independent Variables

Variable Name	Variable Labels in SPSS	Measure
Case Municipal Code Case received Chlamydia positive	Municipal code of case Test received date of case	Nominal Nominal
Gonorrhea positive Muncd Case age Agegp	Manitoba Health Municipal code of control Age group of case Age group of control	Nominal Ordinal Ordinal

Independent Variables

The variable, "case municipal code" is the municipality code in which the case resided during the time of testing/treatment for STIs and when or if they were diagnosed with PID. Each municipality has a code to indicate the name of the municipality (i.e., 35 = the municipality of Fisher). There is no specific order to these codes and therefore the level of measure for this variable is nominal (Last, 1995; Valanis, 1999).

The variable "case received" is the date that the positive test for chlamydia and/or gonorrhea (of the case) was received by the laboratory. This variable is an actual date, supplied as day/month/year. There is no particular order to these dates and they vary in terms of time between the next test dates. Thus the level of measure for this variable is nominal (Last, 1995; Valanis, 1999).

"Muncd" is the municipality code in which the matched control resided during the time of testing for an STI or never being tested for an STI. Again, each municipality has a

code to indicate the name of the municipality (i.e. 35 = the municipality of Fisher). There is no specific order to these codes and therefore the level of measure for this variable is nominal (Last, 1995; Valanis, 1999).

The variables "Case age" and "Agegp" are the age groups of the cases and controls. The latter being the age grouping of the controls. The ages for both the cases and the controls are grouped into 5-year increments (i.e., 15 - 19 years, 20 - 24 years, etc.). The values for these 5-year increments are order as follows; 4 = 15 - 19 years, 5 = 20 - 24 years, etc. Since the 5-year increments are classified into ordered categories they are considered to be an ordinal level of measure (Last, 1995; Valanis, 1999).

Proxy Indicators for Independent Variables

Individual behavioral characteristics associated with the risk of acquiring STIs and their sequelae were presented in the literature. However, this information is not collected by Manitoba Health and therefore was not included in the initial data set. To obtain an estimate of the behavioral characteristics that effect the rates of chlamydia and gonorrhea, proxy indicators of community characteristics (Table 3) were developed. These proxy community characteristics were developed based on the 1996 Census, (Statistics Canada, n.d.) utilizing the municipal code variable; variable name, "muncd" for both urban and rural settings.

Variable Name	Variable Definition
Education (LTG9)	Percentage of 15+ non-institutionalized population with less than grade 9 education
Aboriginal (Abor)	Percentage of the total population (all ages) reporting either full or partial Aboriginal status
Family Income (FINC)	Average family income
Lone Parent Families (SPAR)	Percentage of families headed by a single parent (male or female)
Unemployment	Percentage of persons in the labor force (persons currently looking for work) who were unemployed
Immigrant Status (IMMIG)	No./1000 of total population (all ages) receiving landed immigrant status between 1980 and 1996
Urban	0 = All other Regions in Manitoba
Reserve	$1 = \text{Winnipeg region only} \\ 0 = \text{non-reserve} \\ 1 = \text{reserve}$

Proxy Indicators for Independent Variables

Source: Statistics Canada 1996 Census

Data Source and Procedure

Data was utilized from the Manitoba Health Administrative database and the Cadham Provincial Laboratory (CPL) database. Manitoba provides universal health insurance for Manitoba residents, which includes coverage for physician and hospital services. Since residents are not obliged to pay for health care coverage, non-participation in the health care plan is rare (Bernstein, Blanchard, Huston, & Wajda, 2001; Bernstein, Blanchard, Leslie, Wajda, & Yu, 2000). Manitoba Health's computerized administrative databases document the utilization of all health services within the province. These databases provide such information as physician services, hospitalization and hospital discharges, medical claims and a population registry for all persons registered with Manitoba Health Care Services. The hospital discharge database includes detailed information of all hospitalizations within Manitoba; patient demographic information, date of service and up to sixteen diagnosis and procedures performed while hospitalized. Each diagnosis is classified as a three-digit International Classification of Disease, Nine Edition Clinical Manifestation (ICD-9-CM) code (Bernstein, et al, 2000; J. Wylie, Personal Communications, December, 2001). Following hospitalization discharge, Manitoba hospitals forward an abstract to Manitoba Health, which includes, the name of the physician, patient's identification, date of hospital admission and discharge, and up to 16 diagnoses coded as six-digit ICD-9-CM codes (Bernstein et al, 2000).

During the mid 1980's, *Chlamydia trachomatis* became a reportable infectious disease under the Public Health Act and since then, approximately 90% of all diagnostic tests for chlamydia have been preformed at CPL. A large number of diagnostic tests for gonorrhea are also preformed at CPL, however the exact percentage of these tests could not be determined at the time of this study.

Computerized databases of all positive and negative test results for chlamydia and gonorrhea are maintained by CPL. This information has been imported into a Public Health Branch database, which enables linkages with other databases. Each record contains such information as the individual's Manitoba Health registration number, date of birth and postal codes, test results and diagnostic information.

In addition to the two previous mentioned databases, a population registry provides information on demographic data and registration status of Manitoba residents. A medical claims database registry also provides such information as diagnosis, procedures and the rationale for each patient's visit to the physician (University of Manitoba, Manitoba Centre for Health Policy, n.d.).

Since 1984, a personal health identification number (PHIN) has been assigned to each individual, and can be utilized to link various databases to create a longitudinal patient history (University of Manitoba, Manitoba Centre for Health Policy, n.d.). The Manitoba Health Administrative database and the CPL database were linked together utilizing the PHIN to create patient histories. The Information Technology Department and the Epidemiological Unit at Manitoba Health performed all data linkages.

Privacy

Since the Manitoba Health Administrative database and the CPL database is held by the government of Manitoba, an application was made to the Health Information Privacy Committee (HIPC) to receive approval to utilize the data (Manitoba Health, n.d.a). The purpose of the HIPC is to review requests for access to personal health information for research purposes to determine if the importance of the research outweighs the intrusion into privacy of individuals and whether the appropriate safeguards are in place to protect the confidentiality of the information (Manitoba Health, n.d.a). Personal Health information is any information that is recorded in any form, can be linked to an identifiable person and relates to an individuals health, health history, health care, personal health identification (PHIN) or other identifying information collected in providing care for an individual (Manitoba Health, n.d.b).

An application to the HIPC requesting permission to utilize data from the Manitoba Health Administrative database and the CPL database was made. The request

was made on a HIPC submission form May 2003 as per the submission process (Appendix A).

The HIPC reviewed the application and granted approval to access the data (Appendix B). Anonymized data for this study was provided by Manitoba Health in accordance with Section 24 of The Personal Health Information Act (PHIA). Section 24 permits disclosure of personal health information held by the government for research purposes if the project has been approved by HIPC (Manitoba Health n.d.b).

Data Quality

The data source and procedures demonstrate both a high internal validity and high external validity. Internal validity is the degree to which it can be inferred that the independent variable is responsible for the causal relationship of the dependent variable (Polit & Hungler, 1999). The findings within this study, demonstrate internal validity in that there is a strong association between being infected with an STI and acquiring PID. Additionally, this is unique to Manitoba, as it is Manitoba data and not data from another province, or country.

External validity is the degree to which results of the study can be generalized to other populations or settings other than the study (Polit & Hungler, 1999). External validity will be achieved in this study to the extent that the population of Manitoba and the delivery of health care services in Manitoba are comparable to other populations.

Often a concern with administrative databases is the reliability of the data. An important approach to measuring the reliability of the data is to compare information documented by separate professionals or organizations. For example, physician claims can be compared to hospital claims to ensure that the procedure and diagnosis is

consistent in each claim. Additionally, events that should logistically follow one another (i.e., a visit to a physician for a prenatal assessment should not logistically follow a hysterectomy) will be identified and inconsistencies located. As a result of these reliability measures, no artificial data is entered and missing data is minimal. Research regarding the reliability of data suggests that the data from administrative data bases have a high degree of reliability and accuracy (Roos, Roos, Cageorge, & Nicol, 1982; University of Manitoba, Manitoba Centre for Health Policy, n.d.). The data source and procedures in this study have high internal and external validity, thus ensuring that the adequate research control mechanisms are evaluated (Polit & Hungler, 1999).

Sample

Three groups of women were chosen based on their history of testing for chlamydial and gonococcal infections at CPL. Information was based on data from 1984 to 2000. The three groups consist of:

1. women who have tested positive for chlamydia or gonorrhea,

2. women who have never been tested for chlamydia or gonorrhea.

3. women who have tested negative for chlamydia or gonorrhea

Group one are the cases and groups two and three are the controls. Each case was matched with two controls based on the following criteria: age, time period of infection, region of residence, the number of positive or negative tests for chlamydia and gonorrhea, and had to be registered in Manitoba at the time the control was tested for chlamydia and/or gonorrhea. These criteria are independent variables and are identified and labeled in Table 1. Once matching was completed two cohorts were created. Cohort 1 consists of one woman who tested positive for chlamydia or gonorrhea matched with two women who were never tested for chlamydia or gonorrhea (Figure 2). Cohort 2 consists of one woman who tested positive for chlamydia or gonorrhea, matched with two women who tested negative for chlamydia or gonorrhea (Figure 2).



Figure 2. Diagram of Cohort 1 and Cohort 2

In this study, chlamydia cases and gonorrhea cases are used to refer to those women who tested positive for either chlamydia or gonorrhea. Cohort 1 will be used to refer to the women who had never been tested for an STI and cohort 2 will refer to those women who have tested negative for an STI.

The occurrence of PID among these cohorts was determined by linking individual patient records to the Manitoba Health hospital discharge claims and the medical claims files for 1984 through to 2000. Both hospital and outpatient events were assessed to ensure reliability of the data. Based on the available literature, it is acknowledged that many diagnoses of PID will go unrecognized and that many clinical diagnoses are erroneous, which may introduce possible biases (Temmerman, 1994). To ensure reliability of the data and to assess the extent of these possible biases, the Epidemiology

Branch at Manitoba Health completed a comparison of the diagnosis of PID within the medial and hospital claims.

The sample of cohorts selected is representative of the population in that it includes a sample of women from various geographic areas in Manitoba during the 1984 to 2000 period. The cohorts include women, of various ages who have tested negative and positive for STIs, as well as those who never have been tested for an STI. This sample also includes women from various municipal codes within Manitoba. Therefore the study has high external validity and the researcher will be able to generalize the results of this study to other populations or settings (Polit & Hungler, 1999).

Data Analysis

Data analysis was completed using a standard computer program called Statistical Analysis System (SAS), which is capable of performing a broad variety of statistical analyses to obtain study results (Polit & Hungler, 1999). The analysis was preformed by a qualified statistical consultant from the Biostatistical Consulting Unit, Department of Community Health Sciences, University of Manitoba. To become familiar with the data, descriptive statistics and frequency distributions were conducted on both the dependent and the independent variables (Gregg, 1996).

The incidence rate of PID among women in Manitoba was calculated. That is, the total number of new events of a diagnosis of PID was divided by the total number of person-years at risk for the event for each year of data. Incidence rates were calculated on the basis of person-years for follow-up for 1986-2000. Incidence rates were also calculated for chlamydia or gonorrhea. The total number of new cases of chlamydia or gonorrhea was divided by the Manitoba yearly population of adult women.

Research Question # 1 – What is the Risk of PID Among Women in Manitoba with Previous Documented Episodes of Chlamydial and Gonococcal Genital Infections? What is the Risk of Acquiring PID: If Tested Negative for Chlamydia or Gonorrhea? If Never Been Tested for Chlamydia or Gonorrhea? For question one, a relative risk calculation was completed to measure the strength of the statistical association between the exposure (chlamydial or gonococcal infections or both) and the health problem of interest (PID) (Gregg, 1996). To compute the relative risk, the incidence of those with an STI was divided by the incidence of disease among those without an STI. A relative risk was calculated for those who had tested positive for chlamydia or gonorrhea and those who were never tested for an STI.

In question one, the risk of acquiring PID based on the number of infected episodes of chlamydia and/or gonorrhea was measured, as well as the impact of testing negative or never being tested for an STI.

For question one, a relative risk was calculated to determine the association between the risk of those who never have been tested or have tested negative for an STI in acquiring PID. Additionally, tests of statistical significance were completed to determine how likely it was that the observed results occurred due to chance alone if the STIs was not related to PID (Gregg, 1996).

Research Question #2 – What is the Proportion of Women Diagnosed with Chlamydia and Gonorrhea who had a Previous Diagnosis of PID? For question two, the proportion of women who had a diagnosis of PID, prior to a diagnosis of chlamydia or gonorrhea, was calculated by dividing the total number women who had a diagnosis of PID before chlamydia or gonorrhea over the total number of women who tested positive for chlamydia or gonorrhea.

Research Question # 3 – What is the Survival Time, in Months Between the Initial Diagnosis of Chlamydia and the Initial Diagnosis of PID? What is the Survival Time, in Months Between the Initial Diagnosis of Gonorrhea and the Initial Diagnosis of PID? For question three, the mean and standard deviations were completed. A mean is a measure of central tendency. It is calculated by adding all the individual values in the group and dividing this by the number of values in the group (Last, 1995). Standard deviation is a measure of dispersion or deviation from the mean average of the group (Last, 1995; Valanis, 1999).

Research Question # 4 – What is the Rate of Hospitalization for PID Among Women who have Chlamydia, Gonorrhea or Neither? What is the Rate of Outpatient Visits for PID Among Women who have Chlamydia, Gonorrhea or Neither? For question four, a rate calculation was completed. A rate is the frequency with which an event occurs in a defined population (Last, 1995). Basically, the number of events of hospitalization for PID and the number of outpatient visits related to PID in a specified period of time was divided by the average population during that period of time, multiplied by 10.

Research Question # 5 – What is the Geographic Distribution of Chlamydia and Gonorrhea? Are Some Municipalities More Susceptible to these Infections? What Characteristics within a Community Effect the Rates of Chlamydia and Gonorrhea? For question five, the actual rates by municipalities and the relationship of STIs, and the variables in Table 3 were computed. A correlation matrix was produced to determine the relationship between all the variables and the rates of chlamydia and gonorrhea and to determine the difference between the urban and rural variables (Table 3). The effects of urban and rural variables on the rates of the chlamydia and gonorrhea were compared utilizing a *t test*. Finally a multiple regression was performed, weighted by the inverse of the variance, to determine which variables (Table 3) best explain the rates of chlamydia and gonorrhea.

Limitations

This study utilized secondary data to identify the risk of women in Manitoba acquiring PID from one or more infections with genital chlamydia or gonorrhea. A few limitations were identified in this study. By utilizing secondary data the scope of the analysis is limited to include only the information that is collected by these administrative databases. For instance the potential determinants of health and risk factors (i.e., sociodemographic information, behavioral risk-factors) are unknown, as this information cannot be obtained from the databases being used.

Secondly, even though a highly trained professional provides the diagnosis of PID, there is a possibility of under reporting due to the physiological nature of PID. Diagnosis of PID at times may be misdiagnosed or misclassified for other etiology. Additionally, it will be difficult to determine, from the data, if the diagnosis of PID is a result of an STI or due to another causative agent. By utilizing secondary data the true diagnosis of PID and the number of misdiagnosis of PID is unknown. Both of these issues are a limitation, as the true burden of PID may not be representative of the actual number of cases (Polit & Hungler, 1999).

Limitations associated with the matched cohort study design are that it is time consuming, it allows for only one or a few exposures to be studied and it is difficult to maintain a cohort due to loss of study subjects (Gregg, 1996; Young, 1998). In this particular study, databases are being linked as a source of data, therefore subjects will not be studied over a long period of time, nor will it be difficult to follow up and maintain study subjects.

A limitation associated with matching is that matching a factor prevents one from examining its association with disease. For instance matching the cohorts on age does not allow the researcher to evaluate age as a risk factor (Gregg, 1996). However, the sample size is large, and therefore representative of all age groups.

Ethical Implications

Since this project involved existing data collected for administrative purposes consent forms were not required. All database linkages were performed at Manitoba Health and only anonymized data was provided to the researcher. To further protect the anonymity and confidentiality of the individuals represented within the dataset, all identifying information was removed. For example, the postal code was converted to municipal codes which provided a much broader unit of geography and the date of birth was replaced by age group. The names and addresses of all study subjects and their physician's name was not a part of the dataset. Thus, all analysis and reporting was nonnominal. That is, data was provided by a scrambled PHIN rather than a person's name or date of birth. There were few ethical implications associated with this analysis. Ethics approval was received from the Education/Nursing Research Ethics Board (Appendix C).

Summary

In Chapter Four, a matched cohort design was presented. The sample consisted of two cohorts of women created from data received from the linkages of administrative data bases from Manitoba Health and Cadham Provincial Laboratory. Privacy and data quality issues related to the data set were discussed, the type of data analysis performed was reviewed and study limitations and ethical implications were addressed. The study findings, based on the analyses performed on each of the research questions are presented in Chapter Five.

Chapter Five: Study Findings

The purpose of this chapter is to present the outcomes of the analysis performed to answer each of the research questions as outlined in Chapter One. The findings include: a distinction of the cohort, a description of the study population; the risk of PID among women in Manitoba with previous documented infections with chlamydia and/or gonorrhea; the proportion of women diagnosed with chlamydia and gonorrhea who had a previous diagnosis of PID; the survival time between the initial diagnosis of chlamydia or gonorrhea and the initial diagnosis of PID; the rates of hospitalization and outpatient visits for PID among women with chlamydia or gonorrhea; the geographic distribution of chlamydia, and gonorrhea in Manitoba, as well as the community characteristics which have an effect on the rate of chlamydia and gonorrhea.

Cohort Distinction

The findings of this study are based on the comparison of two cohorts. Cohort 1 consists of one woman who tested positive for chlamydia or gonorrhea matched with two controls that were never tested for chlamydia or gonorrhea (Figure 2). Cohort 2 consists of one woman who tested positive for chlamydia or gonorrhea, matched with two controls that tested negative for chlamydia or gonorrhea (Figure 2).



Figure 2. Diagram of Cohort 1 and Cohort 2

To present the study findings, chlamydia cases and gonorrhea cases are used to refer to those cases who tested positive for either chlamydia or gonorrhea. Cohort 1 refers to those women who never have been tested for an STI and cohort 2 refer to those women who have tested negative for an STI.

Description of the Study Population

Cohort 1

In cohort 1 (n = 61,363), 17,910 were infected with chlamydia and 1,314 were infected with gonorrhea. The person-years of follow-up for chlamydia cases was 135,107 and was 12,821 for gonorrhea cases. For chlamydia controls, the person-years for follow-up was 254,079 and 23,191 for gonorrhea controls.

Cohort 2

In cohort 2 (n = 58,397), 18,691 were infected with chlamydia and 1,332 were infected with gonorrhea. The person-years of follow-up for chlamydia cases was 133,759 and was 12,442 for gonorrhea cases. The person-years of follow-up for chlamydia controls were 272,323 and 25,939 for gonorrhea controls.

Cohort 1 and Cohort 2

The age groups most commonly infected with chlamydia and gonorrhea between both

cohorts were among the 15 - 19 year olds and the 20 - 24 year olds (Table 4).

Table 4

Age Group	Chlamydia Incident rate per 1000 persons	No. Chlamydia Cases	Total Population	No. Gonorrhea Cases	Gonorrhea Incident Rate per 1000 persons
5 – 19	10.1079	6987	691239	543	0.78555
20 - 24	11.1603	8178	732776	518	0.70690
25 - 29	3.8507	2950	766085	238	0.31067
30 - 34	1.4249	1111	779686	131	0.16802
35 – 39	0.6039	453	750151	67	0.08932
40 - 44	0.3878	256	660062	29	0.04394
45 – 49	0.1760	98	556780	18	0.03233
Totals	0.406	20,033	49,336,779	1,544	0.3129

Population Estimates by Age Group*

*Note; the above data is not based on person-years

Findings to Research Questions

Research Question #1 – What is the Risk of PID Among Women in Manitoba with Previous Documented Episodes of Chlamydial and Gonococcal Genital Infections? What is the Risk of Acquiring PID: If Tested Negative for Chlamydia or Gonorrhea? If Never Been Tested for Chlamydia or Gonorrhea?

Cohort 1. In cohort 1, 3,341 women had a diagnosis of PID, among chlamydia cases, for an incidence rate of 24.7 per 1000 person-years. For gonorrhea cases, 397 women were diagnosed with PID, for an incidence rate of 30.9 per 1000 person-years (Table 5).

Chlamydia/Gonorrhea Cases and Controls	Patients with PID Diagnosis	Incidence Rate of PID per 1000 Persons	95% CI
Chlamydia Case	3,341	24.7	23.9 - 25.6
Chlamydia Controls	557	2.19	2.01 - 2.37
Gonorrhea Case	397	30.9	27.9 - 33.9
Gonorrhea Controls	77	3.32	2.58 - 4.06

Incidence of Pelvic Inflammatory Disease (PID) Among Women In Cohort 1

Among women in cohort 1, the risk of acquiring PID was 11.4 times higher among chlamydia cases and 9.25 times higher among gonorrhea cases compared to

controls (Table 6).

Table 6

The Risk of Acquiring Pelvic Inflammatory Disease (PID) Among Women In Cohort 1

Chlamydia/Gonorrhea Cases	Relative Risk	95% CI	P value
Chlamydia Case	11. 4	10.45– 12.93	<.001
Gonorrhea Case	9.25	7.24 – 7.39	<.001

Cohort 2. Among women in cohort 2, 3,335 diagnosis of PID were made in chlamydia cases, for an incidence rate of 24.9 per 1000 person-years. For gonorrhea cases, 401 women were diagnosed with PID, for an incidence rate of 32.2 per 1000 person-years (Table 7).

Chlamydia/Gonorrhea Cases and Controls	Patients with PID Diagnosis	Incidence Rate of PID per 1000 Persons	95% CI
Chlamydia Case	3,335	24.9	24.9 - 25.7
Chlamydia Control	3,754	13.8	13.3 - 14.2
Gonorrhea Case	401	32.2	29.1 - 35.3
Gonorrhea Control	445	17.2	15.6 - 18.7

Incidence of Pelvic Inflammatory Disease (PID) Among Women in Cohort 2

Among women in cohort 2, the risk of acquiring PID was 1.81 times higher in

chlamydia cases and 1.88 times higher in gonorrhea cases compared to the controls

(Table 8).

Table 8

The Risk of Acquiring Pelvic Inflammatory Disease (PID) Among Women In Cohort 2

Chlamydia/Gonorrhea Cases and Controls	Relative Risk	95% CI	P value
Chlamydia Case	1.81	1.73 - 1.90	<.001
Gonorrhea Case	1.88	1.64 - 2.16	<.001

A Comparison of Cohort 1 & Cohort 2. When comparing the two cohorts, those controls in cohort 2 (Those who tested negative) are at a greater risk of acquiring PID following infection with either chlamydia or gonorrhea (Chlamydia IRR 13.8 [95% CI 13.3 - 14.2]; (Gonorrhea IRR 17.2 [95% CI 15.6 - 18.7]) compared to controls in cohort 1 (never had been tested for an STI) (Table 9).

Chlamydia/Gonorrhea Controls	Patients with PID Diagnosis	Incidence Rate of PID per 1000 Persons	95% CI
Chlamydia Control			
(Cohort 2)	3,754	13.8	13.3 - 14.2
Chlamydia Control			
(Cohort 1)	557	2.19	2.01 - 2.37
Gonorrhea Control			
(Cohort 2)	445	17.2	15.6 - 18.7
Gonorrhea Control			
(Cohort 1)	77	3.32	2.58 - 4.06

A Comparison of the Risk of Acquiring PID between Women in Cohort 1 and Cohort 2

Research Question #2 - What is the Proportion of Women Diagnosed with Chlamydia and Gonorrhea who had a Previous Diagnosis of PID?

Cohort 1. Compared to controls, chlamydia cases, 2 338 (11.5%) had a previous diagnosis of PID. Of the women who tested positive for gonorrhea, 262 (16.5%) had a previous diagnosis of PID. In cohort 1, there was a significant difference in the proportion of women with a previous diagnosis of PID between cases and controls (Table 10).

Cohort 2. Among cohort 2, 2 301 (10.9%) women infected with chlamydia (chlamydia cases) had a previous diagnosis of PID. Also in cohort 2, 250 (15.7%) women infected with gonorrhea had a previous diagnosis of PID. In cohort 2, there was very little difference in the proportion of women with a previous diagnosis of PID between cases and controls (Table 10).

Chlamydia/Gonorrhea Cases and Controls	PID Before STI	Percent (95% CI)
C	ohort 1 (Never Tested for an ST	ΓΙ)
Chlamydia Case	2,338	11.5% (11.04 – 11.91)
Chlamydia Control	433	1.07% (0.97 - 1.17)
Gonorrhea Case	262	16.5% (14.6 – 18.3)
Gonorrhea Control	30	0.96% (0.62 – 1.30)
Col	nort 2 (Tested Negative for an S	STI)
Chlamydia Case	2 301	10.9% (10.4 – 11.3)
Chlamydia Control	3 881	9.7%(9.4 - 10.0)
Gonorrhea Case	250	15.7% (13.9 – 17.5)
Gonorrhea Control	300	10.4% (9.3 – 11.5)

The Proportion of Women with a Previous Diagnosis of PID

A Comparison of the Proportion of Women with a Previous Diagnosis of PID

Between Cohort 1 and Cohort 2. In both cohorts, chlamydia and gonorrhea cases had a higher proportion of women with a previous diagnosis of PID compared to controls (Table 10). Also, in both cohorts, the gonorrhea cases had a higher percentage of women (16.5% [95 CI, 14.6 - 18.3]) and (15.7% [95 CI 13.9 - 17.5]) with a previous diagnosis of PID compared to chlamydia cases (Table 10).

In comparing chlamydia and gonorrhea cases in cohorts 1 to chlamydia and gonorrhea cases in cohort 2, there was little difference in the proportion of women with a previous diagnosis of PID. However, both the chlamydia and gonorrhea controls in cohort 2 had a higher percentage of women with a previous diagnosis of PID compared to the controls in cohort 1 (Table 10). In cohort 1, 26.7 % of women had a previous diagnosis of PID within one month of a diagnosis of chlamydia, and 43.4% of women had a previous diagnosis of PID within one year of a chlamydia diagnosis.

For gonorrhea, 33.6% women had a previous diagnosis of PID within one month of the initial diagnosis of gonorrhea and 60.3% women had a previous diagnosis of PID within one year of a diagnosis of gonorrhea. Since there is very little difference in the proportion of women with a previous diagnosis of PID between cases in cohort 1 and cohort 2, these percentages may also be applied to chlamydia and gonorrhea cases in cohort 2.

Research Question #3 – What is the Survival Time, in Months Between the Initial Diagnosis of Chlamydia and the Initial Diagnosis of PID? What is the Survival Time, in Months Between the Initial Diagnosis of Gonorrhea and the Initial Diagnosis of PID?

For both cohort 1 and cohort 2, the cumulative probability of developing PID within 15 years (183 months) after a chlamydia diagnosis was 22.4% and half of such PID cases (11.2%) occurred within 3.4 years (41 months) of a chlamydia diagnosis (Figure 3).





Figure 3. Survival time between the initial diagnosis of chlamydia and the initial diagnosis of PID

For both cohort 1 and cohort 2, the cumulative probability of developing PID within 15 years (183 months) after a gonorrhea diagnosis was 22.4% and half of such PID cases (16.0%) occurred within 3.8 years (45 months) of a gonorrhea diagnosis (Figure 4).



Figure 4. Survival time between the initial diagnosis of gonorrhea and the initial diagnosis of PID

Research Question # 4 – What is the Rate of Hospitalization for PID Among Women who have Chlamydia, Gonorrhea or Neither? What is the Rate of Outpatient Visits for PID Among Women who have Chlamydia, Gonorrhea or Neither?

Cohort 1 - Rate of Hospitalization for PID. Among cohort 1, there was a total of 1, 193 chlamydia cases, for a hospitalization rate of 7.3 per 1000 person-years[95% CI 6.91 - 7.73] and a total of 166 gonorrhea cases for a hospitalization rate of 9.9 per 1000 person-years [95% CI 8.42 - 11.42]. Compared to controls, the rate of hospitalization for PID was significantly higher among gonorrhea cases (9.9 per 1000 person-years [95% CI 8.42 - 11.42]) and chlamydia cases (7.3 per 1000 person-years [95% CI 6.91 - 7.73]) (Table 11). Additionally, the rate of hospitalization for PID was higher among gonorrhea cases.

Table 11

Diagnosis	No. of cases	Hospitalization Rate	95% CI
Chlamydia Cases	1193	7.3	6.91 – 7.73
Gonorrhea Cases	166	9.9	8.42 - 11.42
Controls	290	1.03	0.91 – 1.15

Rate of Hospitalization for PID Among Women in Cohort 1

Cohort 1 - Rate of Outpatient Visits for PID. In looking at the outpatient rate for PID in Cohort 1, there was a total of 4,266 outpatient visits for chlamydia, for a rate of 26.2 per 1000 person years (95% CI 25.4 – 26.9). There was a total of 577 outpatient visits for gonorrhea for a rate of 34.5 per 1000 person-years (95% CI 31.7 – 37.3). Gonorrhea cases had a significantly higher outpatient rate of PID compared to chlamydia cases. Compared to controls, the rate of outpatient visits for PID was significantly higher among both chlamydia cases 26.2 per 1000 person years (95% CI 25.4 – 26.9) and gonorrhea cases 34.5 per 1000 person-years (95% CI 31.7 – 37.3) (Table 12).

Table 12

Diagnosis	No. of cases	Outpatient Rate	95% CI
Chlamydia	4, 266	26.2	25.4 - 26.9
Gonorrhea	577	34.5	31.7 - 37.3
Controls	507	1.8	1.6 – 1.9

Rate of Outpatient Visits for PID among Women in Cohort 1

Comparison of Hospitalization and Outpatient Visits for PID Among Cohort 1. In comparing the rates of hospitalization and outpatient visits for PID among cohort 1, the rate of outpatient visits for both chlamydia (26.2 per 1000 person-years; [95% CI 25.4 – 26.9] and gonorrhea cases (34.5 per 1000 person-years [95% CI 31.7 – 37.3]) was consistently higher. When comparing the controls in the hospital and outpatient settings, the rate of outpatient visits for PID (1.8 per 1000 person-years; [95% CI 1.6 – 1.9]) was slightly higher.

Cohort 2 – Rate of Hospitalization for PID. In cohort two, there was a total of 1197 chlamydia cases for a rate 7.4 per 1000 person-years [95% CI 7.0 – 7.9]) and a total of 167 gonorrhea cases for a rate of 10.2 per 1000 person-years [95% CI 8.7 – 11.7]). The rate of hospitalization for PID was significantly higher among gonorrhea (10.2 per 1000 person-years [95% CI 8.7 – 11.7]) and chlamydia cases (7.4 per 1000 person-years [95% CI 7.0 – 7.9]) compared to controls (Table 13). Additionally, the rate of hospitalization for PID among gonorrhea cases (10.2; [95% CI 8.7 – 11.7]) was higher compared to chlamydia cases (r = 7.4 [95% CI 7.0 – 7.9]) (Table 13).
Table 13

Diagnosis	No. of cases	Hospitalization Rate	95% CI
Chlamydia Cases	1197	7.4	7.0 - 7.9
Gonorrhea Cases	167	10.2	8.7 - 11.7
Controls	1793	5.4	5.2 - 5.7

Rate of Hospitalization for PID Among Cohort 2

Cohort 2 - Rate of Outpatient Visits for PID. In examination of the rate of outpatient visits for PID in cohort 2, there was a total of 4 215 outpatient visits for chlamydia, for a rate of 26.2 per 1000 person years [95% CI 25.4 – 27.0] and a total of 577 outpatient visits for gonorrhea for a rate of 35.2 per 1000 person-years [95% CI 32.4 – 38.0]. Additionally, gonorrhea cases had a significantly higher rate of outpatient visits for PID compared to chlamydia cases. Compared to controls, the rate of outpatient visits among chlamydia (26.2 per 1000 person years [95% CI 25.4 – 27.0]) and gonorrhea (35.2 per 1000 person-years [95% CI 32.4 – 38.0]) cases was significantly higher (Table 14).

Table 14

Diagnosis	No. of cases	Outpatient Rate	95% CI
Chlamydia Cases	4215	26.2	25.4 - 27.0
Gonorrhea Cases	577	35.2	32.4 - 38.0
Controls	4825	14.6	14.2 - 15.0

Rate of Outpatient Visits for PID among Cohort 2

Comparison of the Rate of Hospitalization and Outpatient Visits for PID Among

Cohort 2. When comparing hospitalization and outpatient visit rates for PID; the outpatient visit rates for PID in both chlamydia (26.2 per 1000 person-years ([95% CI

25.4 - 27.0]) and gonorrhea (35.2 per 1000 person-years [95% CI 32.4 - 38.0]) cases was consistently higher among women in cohort 2. Additionally, for both hospital and outpatient rates, gonorrhea cases were higher compared to chlamydia cases. When comparing the controls in the hospitalization and outpatient settings, the rate of outpatient visits for PID (14.6 per 1000 person-years [95% CI 14.2 -15.0]) was higher (Table 14).

Comparison of the Rate of Hospitalization and Outpatient Visits for PID Among Cohort 1 and Cohort 2. A comparison of the rates of hospitalization for PID among controls in cohort 1 and cohort 2, demonstrated that the rate of hospitalization among controls in cohort 2 was higher (10.2 per 1000 person-years [95% CI 8.7 - 11.7]). There is little difference in the rate of hospitalization among chlamydia and gonorrhea cases in both cohorts (Table 15).

Table 15

Comparison of the Rate of Hospitalization for PID Between Cohort 1 and Cohort 2

Diagnosis	Rate of Hospitalization For PID Cohort 1	Rate of Hospitalization For PID Cohort 2
Chlamydia Case	1.03	5.4
Gonorrhea Case	7.3	7.4
Controls	9.9	10.2

Similarly, the rates of outpatient visits for PID among controls in cohort 1 and controls in cohort 2 demonstrated that the rate of outpatient visits for PID is higher among controls in cohort 2 (14.6 per 1000 person-years [95% CI 14.2 -15.0]) (Table 16).

Table 16

Diagnosis	Rate of Outpatient Visits For PID Cohort 1	Rate of Outpatient Visits For PID Cohort 2
Chlamydia Case	26. 2	26.2
Gonorrhea Case	34.2	35.2
Controls	1.8	14.6

Comparison of the Rate of Outpatient Visits for PID Between Cohort 1 and Cohort 2

Research Question # 5 – What is the Geographic Distribution of Chlamydia and Gonorrhea? Are Some Municipalities More Susceptible to these Infections? What Characteristics within a Community Effect the Rates of Chlamydia and Gonorrhea?

The Pearson's Correlation Coefficient was utilized to determine the degree of the relation that exists between variables (Polit & Hungler, 1999). The relationship of the variables listed in Table 3 and the effects of these variables on the rates of chlamydia and gonorrhea were examined from three different perspectives:

1. All variables and the effect of these on the rate of chlamydia and gonorrhea.

2. All the variables and the effect on the rates of the chlamydia and gonorrhea in the non-urban setting (all regions except Winnipeg).

3. All the variables and the effect on the rates of the chlamydia and gonorrhea in the urban setting (Winnipeg region only).

All Variables and the Effect on the Rates of Chlamydia and Gonorrhea. To determine the degree of the relationship between all the variables listed in Table 3 and the rates of chlamydia and gonorrhea a correlation matrix was utilized (Appendix D). This correlation matrix demonstrated a moderate and positive relationship between all the variables listed in Table 3 (except for average family income and No/1000 of the total population receiving landed immigrant status) and the rate of chlamydia and gonorrhea. There was a negative relationship between the average family income and the No/1000 of the total population receiving landed immigrant status and the rates of chlamydia and gonorrhea. That is as the average family income and the number of individuals receiving landed immigrant status decreased, the rates of chlamydia and gonorrhea increased.

When examining the relationship of these variables on the rate of chlamydia alone, there was a moderate and positive relationship between the percent of families headed by a single parent; the percent of the 15 + non-institutionalized population with less than grade nine education; the percentage of the total population reporting either full or partial Aboriginal status; the percentage of persons in the labor force who were unemployed; and the rate of chlamydia. There was a moderate and negative relationship between the average family income; No/1000 of the total population receiving landed immigrant status and the chlamydia rate (Appendix D). That is as the average family income and immigrant status decreased, the rate of chlamydia increased.

All Variables and the Effect on the Rates of Chlamydia and Gonorrhea in the Non-Urban Setting (All Regions Except Winnipeg). When examining the extent to which the above variables were intercorrelated at the non-urban level (all regions expect Winnipeg) (n = 266), there was a moderate and positive relationship between the percent of families headed by a single parent; the percent of the 15 + non-institutionalized population with less than grade nine education; the percentage of the total population reporting either full or partial Aboriginal status; the percentage of persons in the labor

force who were unemployed; and the rate of gonorrhea. Similarly, there was a moderate and positive relationship between the percent of families headed by a single parent; the percent of the 15 + non-institutionalized population with less than grade nine education; the percentage of the total population reporting either full or partial Aboriginal status, the percentage of persons in the labor force who were unemployed and the rate of chlamydia (Appendix E).

Within the non-urban setting, there was a negative relationship between the average family income and No/1000 of the total population receiving landed immigrant status and the chlamydia rate.

To summarize, as the following characteristics within a community in the nonurban setting increase; (single parent families, the number of individuals with less than a grade nine education, Aboriginal status, and unemployment rate) so does the rate of gonorrhea. The rate of chlamydia increases as the following characteristics within a community in the non-urban setting increases; single parent families, less than grade education, Aboriginal status and unemployment rate. Both chlamydia and gonorrhea increase with a decrease in the average family income and immigrant status.

All Variables and the Effect on the Rates of Chlamydia and Gonorrhea in the Urban Setting (Winnipeg Region Only). Examining the intercorrelation of these variables in the urban setting (Winnipeg Region only) (n = 14) (Appendix F) there was a positive relationship between the following variables: the percent of the 15 + non-institutionalized population with less than grade nine education; the percentage of the total population reporting either full or partial Aboriginal status; the percentage of persons in the labor force who were unemployed and the rate of gonorrhea. A negative relationship existed

between percent of families headed by a single parent; No/1000 of the total population receiving landed immigrant status and the rate of gonorrhea (Appendix F). That is, as the number of single parent families and the total population receiving landed immigrant status decreased, the rate of gonorrhea increased.

Similarly, there was a positive relationship between; the percent of the 15 + noninstitutionalized population with less than grade nine education; average family income and chlamydia rates. A negative relationship existed between the percent of families headed by a single parent; the percentage of the total population reporting either full or partial Aboriginal status; the percentage of persons in the labor force who were unemployed; No/1000 of the total population receiving landed immigrant status and the rate of chlamydia (Appendix F).

A *t test* revealed that the rates of chlamydia and gonorrhea on reserve (chlamydia M= 24.68; gonorrhea M= 3.92) were significantly higher (chlamydia F = 19.5; t = -15.80; df = 60.7; p<.0001) (gonorrhea F = 169.50; t = -9.81; df = 59.2; p<.0001) than non-reserve (Appendix G).

A *t test* also revealed that the rates of chlamydia and gonorrhea in Winnipeg Region alone (chlamydia M= 3.28; gonorrhea M= 0.008) were significantly higher (chlamydia F = 23.65; t = 4.3; df = 60.9; p<.0001) (gonorrhea F = 921.66; t = 6.59; df = 274; p<.0001) than all other regions in Manitoba (Appendix H).

Analysis of Variance was utilized to determine whether the variables that exist in a community (Table 3) had an effect on the rates of chlamydia and gonorrhea. Initially, when examining the effects of these variables on the rates of chlamydia and gonorrhea, all variables were entered. Then to identify any confounding variables, each variable was

removed. When all the variables were considered, the effects of Aboriginal (F = 7.36; p,.0001), unemployment (F = 5.64; p<.0001), finance (F = 7.51; p<.0001) and reserve (F = 57.92; p<.0001) were significant on the rates of chlamydia and gonorrhea (Appendix I).

Effects of Community Variables on the Rate of Chlamydia. When the lone parent families variable was removed the effects of Aboriginal (F = 7.02; p<.0001), unemployment (F = 5.69; p<.0001), finance (F = 8.97; p<.0001) and reserve (F = 74.42; p<.0001) were statistically significant with the chlamydia rate (Appendix J).

When the education variable was removed, the effects of the variables; Aboriginal (F = 7.74; p<.0001), unemployment (F = 5.69; p<.0001), finance (F = 7.38; p<.0001) and reserve (F = 74.42; p<.0001) were statistically significant with the chlamydia rate (Appendix K).

Similarly, with the removal of the urban variable, the effect of Aboriginal (F = 7.28; p<.0001), unemployment (F = 7.5; p<.0001), finance (F = 15.06; p<.0001) and reserve (F = 75.36; p<.0001) were statistically significant with the chlamydia rate (Appendix L).

Removal of the immigrant variable also demonstrated that the effects of Aboriginal (F = 12.30; p<.0001), unemployment (F = 8.10; p<.0001), finance (F = 15.24; p<.0001) and reserve (F = 75.36; p<.0001) were statistically significant with the chlamydia rate (Appendix M).

Thus, following removal of the lone parent families, urban, non-urban, immigration, variables, all other variables were statistically significant. That is, as the following community characteristics increase (percent of the total population (all ages) reporting either full or partial Aboriginal status; the average family income; the percentage of the persons in the labor force who are unemployed; the number reserves increase) there is also an increase in the rate of chlamydia (Appendix N).

Effects of Community Variables on the Rate of Gonorrhea. In examining the effects of the variables on the rate of gonorrhea, when all the variables are considered, the effects of reserve (F = 19.70; p<.0001) was statistically significant. All other variables were not statistically significant (Appendix O).

When the following variables were excluded from the analysis of variance; finance, immigration, education, and urban, the effects of residing on a reservation (F = 24.63; p<.0001) were statistically significant on the rate of gonorrhea.

When the Aboriginal variable was removed; the effects of unemployment (F = 4.63; p<.001), reserve (F = 36.36 p<.0001) and lone parent family (F = 3.08; p<.0001) were statistically significant. All associations were positive, however the parametric estimate of the variable, lone parent family was -0.00001756, indicating that as the number of lone parent family increase, the gonorrhea rate decreases; therefore a negative relationship exists (Appendix P).

Therefore, when predicting whether the rate of gonorrhea in a community could potentially increase, the following characteristics are required; reserve and unemployment.

Summary

To summarize, in this chapter the outcomes of the analyses performed for each research question were presented. The study findings were based on the comparison of two cohorts of women. Cohort 1, consists of one woman who tested positive for chlamydia or gonorrhea matched with two women who were never tested for chlamydia

or gonorrhea (Figure 2). Cohort 2 consists of one woman who tested positive for chlamydia or gonorrhea, matched with two women who tested negative for chlamydia or gonorrhea (Figure 2).

Within the two cohorts of women, the study findings demonstrated that women in Manitoba between 15 - 19 years of age and 20 - 24 years old were at a greater risk of acquiring PID. Chlamydia and gonorrhea cases in both cohorts were at a greater risk of acquiring PID and were more likely to have a previous diagnosis of PID. Gonorrhea cases, compared to chlamydia cases had a higher proportion of women with a previous diagnosis of PID.

The rates of both hospitalization and outpatient visits related to PID were higher among women in cohort 2 (tested negative). The study also examined the effects that certain community characteristics had on the rates of chlamydia and gonorrhea and found that chlamydia rates were influenced by a number of characteristics, while the rate of gonorrhea was influenced by reserve and unemployment rates only.

As indicated in the literature, a number of similar behavioral characteristics effect the rates of chlamydia and gonorrhea equally; however this study found that different community characteristics effected the rates of chlamydia and gonorrhea differently. These issues are further discussed in Chapter Six, Summary and Discussion. Also, study limitations, research and program recommendations, and policy implications are discussed.

Chapter Six: Summary and Discussion

In this final chapter an overview of the study is provided. A summary of the study findings, discussion of study limitations, recommendations and implications are addressed.

Overview of Study

The purpose of this study was to determine the risk of women in Manitoba acquiring PID from chlamydia or gonorrhea genital infections. Prior research conducted on this topic identified an increased incidence of chlamydia and gonorrhea in North America. A review of the literature supported a relationship between testing positive for chlamydia and gonorrhea and acquiring PID (Temmerman, 1994).

Based on the literature review and the current number of laboratory confirmed cases of chlamydia and gonorrhea among women in Manitoba, the following research questions were studied:

1. What is the risk of PID among women in Manitoba with previous documented episodes of chlamydial and gonococcal genital infections? What is the risk of acquiring PID: If tested negative for chlamydia or gonorrhea? If never been tested for chlamydia or gonorrhea?

2. What is the proportion of women diagnosed with chlamydia and gonorrhea who had a previous diagnosis of PID?

3. What is the survival time, in months between the initial diagnosis of chlamydia and the initial diagnosis of PID? What is the survival time, in months between the initial diagnosis of gonorrhea and the initial diagnosis of PID?

4. What is the rate of hospitalization for PID among women who have chlamydia, gonorrhea or neither? What is the rate of outpatient visits for PID among women who have chlamydia, gonorrhea or neither?

5. What is the geographic distribution of chlamydia and gonorrhea? Are some municipalities more susceptible to these infections? What characteristics within a community effect the rates of chlamydia and gonorrhea?

Description of the Study Population

In describing the study population, the total numbers of chlamydia and gonorrhea cases presented in Table 4, were not captured in the total sample sizes for cohort 1 and cohort 2. This discrepancy presumably occurred during the matching of cases and controls from the Manitoba Health population registry and the hospital/physicians claims databases.

The Communicable Disease Control (CDC) Unit, Manitoba Health reported 3,704 chlamydia cases and 884 gonorrhea cases for the 2003 calendar year (Manitoba Health, 2003). Based on Manitoba Health's case numbers, it is evident that for the fifteen year study period, the total number of chlamydia cases (27, 7115) and gonorrhea cases (1, 544) presented in Table 4 are lower than expected, particularly gonorrhea. The rational for this lower than expected number of cases; particularly gonorrhea may be due to the fact that Cadham Provincial Laboratory (CPL) does not perform all diagnostic testing for chlamydia or gonorrhea in the province. CPL performs approximately 90% of all diagnostic tests for chlamydia and even a smaller proportion of diagnostic testing for gonorrhea. The exact percentage of diagnostic testing for gonorrhea performed at CPL

was not available at the time of the study. Diagnostic testing of gonorrhea is also completed at the Westman Region Laboratory in Manitoba.

Use of the CPL database to obtain chlamydia and gonorrhea cases could possibly introduce selection bias. Selection bias is "error due to systematic difference in characteristics between those who are selected for study and those who are not" (Last, 1995, p.153). Thus, any chlamydia or gonorrhea diagnostic testing performed at the Westman Region Laboratory would not have been included in this study thus under representing the actual number of chlamydia and gonorrhea cases in the province.

Discussion of Findings

Research Question # 1 – What is the Risk of PID Among Women in Manitoba with Previous Documented Episodes of Chlamydial and Gonococcal Genital Infections? What is the Risk of Acquiring PID: If Tested Negative for Chlamydia or Gonorrhea? If Never Been Tested for Chlamydia or Gonorrhea?

Previous studies have demonstrated the risk of acquiring PID from chlamydia and gonorrhea (Brunham et al., 1988; Burst, 1998; Chaudhry et al., 1997). The findings of this study are consistent with the literature, in that this study demonstrated that women in Manitoba, who tested positive for genital chlamydia and gonorrhea were at a greater risk of acquiring PID compared to controls who had never been tested or who had tested negative for an STI. Gonorrhea cases were slightly at a greater risk of acquiring PID compared to controls who had never been tested or who had tested negative for an STI. Gonorrhea cases were slightly at a greater risk of acquiring PID compared to chlamydia cases.

Since chlamydia and gonorrhea are asymptomatic, many women are not aware they have an infection and therefore do not attend for medical care, until they experience symptoms associated with an STI or PID, such as severe abdominal pain (Aral &

Wasserheit, 1998). Since the study subjects are positive for chlamydia or gonorrhea, it is assumed that they have received the appropriate treatment for the STI. Therefore, another rational for the risk of acquiring PID following an infection with chlamydia or gonorrhea is that the study subjects may be non-complaint with their treatment regime. Thus, allowing the infection to continue to spread and lead to sequelae, like PID.

If women do experience symptoms commonly associated with STIs, they may decide to "wait and see" if the symptoms persist. Additionally, their knowledge level related to STIs may be limited, therefore delaying them from seeking medical care and treatment, thus allowing the STI to spread and cause sequelae, such as PID (Aral & Wasserheit, 1998).

The finding that gonorrhea cases were at a higher risk of acquiring PID is consistent with the literature. The prevalence of chlamydia compared to gonorrhea is higher in the population, thus the prevalence of PID related to chlamydia is higher as well. However, PID caused by gonorrhea is frequently associated with more severe clinical symptoms and thus PID following gonorrhea would be expected to be higher (Westrom, 1980).

Similarly, those controls, which tested negative for an STI, were at a greater risk of acquiring PID compared to those who were never tested for an STI. It is expected that those who tested negative for an STI would be at a greater risk of acquiring PID, since they have attended for STI testing, therefore allowing the opportunity to detect other infections, such as PID. Also those who tested negative for an STI, may exhibit behavioral and socieodemographic characteristics, such as 15 -24 years age group, low income level, lower education level, etc, associated with STIs. Those women who tested negative for an STI may also be at a greater risk of acquiring PID due to false-negative test results. Manitoba Health's Communicable Disease Protocol Manual for Chlamydia and Gonorrhea recommends that contacts to a STI case be "tested and provided epidemiologic treatment" (Manitoba Health, 2001a, p. 5). A false negative result provides the individual with the impression that they are not infected, continue to engage in unprotected sex, allowing the infection to spread further in the reproductive tract and causing PID.

Research Question #2 - What is the Proportion of Women Diagnosed with Chlamydia and Gonorrhea who had a Previous Diagnosis of PID?

In both cohort 1 and cohort 2, there were a higher proportion of chlamydia and gonorrhea cases that had a previous diagnosis of PID, compared to controls. Similarly, there were a higher proportion of gonorrhea cases. Gonorrhea and chlamydia are asymptomatic, therefore individuals may not be aware that they are infected with an STI, and thus delay seeking medical care until severe abdominal discomfort is experienced or attend for a routine check-up. At this time a diagnosis of PID is made at the same time testing for chlamydia and gonorrhea has been done, causing the STI test result to follow the PID result.

The individual may also purposely not attend for STI testing due to lack of knowledge regarding the need for medical care related to STIs, lack of knowledge related to STI testing procedures, treatment, misapprehension of pain associated with testing procedures or personal embarrassment (Wayne & Hettler, 2005).

Research Question # 3 – What is the Survival Time, in Months Between the Initial Diagnosis of Chlamydia and the Initial Diagnosis of PID? What is the Survival Time, in Months Between the Initial Diagnosis of Gonorrhea and the Initial Diagnosis of PID?

For both cohort 1 and cohort 2, the cumulative probability of developing PID within 15 years (183 months) after a chlamydia diagnosis was 22.4% and half of such PID cases (11.2%) occurred within 3.4 years (41 months) of a chlamydia diagnosis. Similarly between the two cohorts, the cumulative probability of developing PID after 15 years (183 months) after a gonorrhea diagnosis was 22.4% and half of such PID cases (16%) occurred in 3.8 years (45 months) of a gonorrhea diagnosis. After 3.5 years, the percent of women (16.0%) infected with PID due to gonorrhea was higher compared to those who were infected with chlamydia. This is important to note and is consistent with the literature. The prevalence of chlamydia in the population is higher, thus the prevalence of PID related to chlamydia is higher than the prevalence of PID related to gonorrhea. Chlamydia is more likely to be asymptomatic; therefore the infection spreads to the upper genital tract and progresses to PID. However, PID as a result of gonorrhea is more severe and the incidence of PID following gonorrhea may also be higher (Westrom, 1980).

Chlamydia and gonorrhea can be asymptomatic and go undetected for a long time, therefore increasing the risk of sequelae, such as PID (Temmerman, 1994). Women may not attend for STI screening until they experience symptoms related to PID, such as severe abdominal pain at which time a diagnosis of PID is also made and the STI test results follow. Similarly, even amongst the most skilled medical professionals PID can be difficult to diagnose or be misdiagnosed as something else, therefore mistreated, allowing the infection to further spread and progress to sequelae such as tubal scarring (Temmerman, 1994).

As mentioned above an individual's knowledge level regarding STIs can also be an issue in delaying medical care (Wayne & Hettler, 2005). Individuals may not have access to appropriate transportation to attend for medical care thereby making it difficult to treat STIs, and increasing the risk of sequelae associated with STIs.

Research Question # 4 – What is the Rate of Hospitalization for PID Among Women who have Chlamydia, Gonorrhea or Neither? What is the Rate of Outpatient Visits for PID Among Women who have Chlamydia, Gonorrhea or Neither?

In both cohorts, the rate of outpatient visits for PID was higher compared to the rate of hospitalizations for PID. This is not surprising since the majority of cases are seen at the physicians' office on an outpatient basis and while PID is difficult to diagnose and often misdiagnosed by physicians (Temmerman, 1994), it is not necessary to hospitalize an individual in order to make a diagnosis of PID. A diagnosis of PID can be made within a physician's office without the need of expensive equipment.

In both cohorts, the rate of hospitalization and the rate of outpatient visits for PID were higher among those infected with gonorrhea compared to those infected with chlamydia. This is consistent with the literature in that, the prevalence of chlamydia in the population is higher, thus the prevalence of PID related to chlamydia is higher than the prevalence of PID related to gonorrhea. Chlamydia is more likely to be asymptomatic; therefore the infection spreads to the upper genital tract and progresses to PID. However, PID as a result of gonorrhea is more severe and the incidence of PID following gonorrhea may also be higher (Westrom, 1980).

Again, the individual's knowledge level related to STIs and interventions associated with STIs should be considered. Is the individual aware as to how they should care for themselves once a diagnosis of an STI or PID has been made? Are they aware of the risk factors associated with STIs?

The rate of hospitalization for PID was higher among those who tested negative for an STI, compared to those who never have tested for an STI. This is not surprising since those who tested negative for an STI are obviously attending for screening of STIs, due to risk behaviors or routine check-ups. Therefore testing and treatment for STIs can be offered and other diagnoses and findings made at those times. If one never attends for STI testing, there is no opportunity to detect STIs or their sequelae.

Additionally, those who test negative for STIs may fall within the risk behaviours associated with STIs, such as multiple sex partners, 15 - 24 years of age, female, sex trade workers, unemployed, etc. Thus causing them to be screened more often and therefore having a negative test.

Another reason for the high rates of hospitalization for PID among those who tested negative for an STI, may be due to false-negative test results. As previously mentioned, Manitoba Health's (2001a) Communicable Disease Protocol Manual for Chlamydia and Gonorrhea recommends that contacts to a STI case be "tested and provided epidemiologic treatment" (p. 5). A false negative result provides the individual with the impression that they are not infected, therefore they may not complete the entire course of prophylactic treatment, causing the infection to spread, resulting in the need for hospitalization.

In Manitoba, treatment for STIs are provided free of charge as part of the Provincial STI Program. Patients attending physician's offices for STI screening and treatment should receive the treatment at the physician's office, the same day. However, an evaluation of physician practices, STI drug utilization and compliance with screening and treatment guidelines in Manitoba found that physicians are noncompliant in following the STI treatment guidelines. Noncompliance with these guidelines was due to presumptive treatment that covered chlamydia, non-recommended treatment for gonorrhea and incorrect treatment of PID. Only 25% of women 15 - 24 years of age who attended a physician in 1997 were tested for chlamydia (Moses & Elliot, 2002). By physicians not following the STI treatment guidelines appropriately, this contributes to the incidence of STIs and their sequelae.

Research Question # 5 – What is The Geographic Distribution of Chlamydia and Gonorrhea? Are Some Municipalities More Susceptible to these Infections? What Characteristics within a Community Effect the Rates of Chlamydia and Gonorrhea?

It was identified in the literature review that the following behavioral characteristics put one at risk of acquiring an STI; 12 - 15 years old and 20 - 24 years old, unmarried, multiple sex partners, lower socioeconomic status, inner city and rural remote communities (Aral & Wasserheit, 1998, Cates & Wasserheit, 1991, Sionean et al., 2001). Since these behavioral characteristics were not available to the researcher from Manitoba Health, community characteristics that determine the rate of chlamydia and gonorrhea were created for this study (Table 3).

Based on community characteristics, this study found that the geographic distribution of chlamydia and gonorrhea in the province of Manitoba is higher among

urban and reserve settings. This finding is consistent with the literature in that inner city and remote rural residents were found to be more often associated with STIs (Aral & Wasserheit, 1998).

Additionally, these community characteristics effected the rates of chlamydia and gonorrhea differently. For instance, the following characteristics effected the rate of chlamydia; lone parent families, less than grade nine education, aboriginal, unemployed, family income and immigrant status. Whereas, reserve and unemployment characteristics effected the rate of gonorrhea. While the community characteristics that were created are consistent with those cited in the literature as influencing the rates of STIs, it was not identified, that the community characteristics effected the rates of chlamydia and gonorrhea differently. The findings in this study are different and may be due to the fact that community characteristics were created from 1996 Census data, thus providing only an estimate of what could effect the rates of chlamydia or gonorrhea in a community. Additionally, the variables received from Manitoba Health were based on an individual level and the community characteristics created were provided at a population level. Thus causing a difference.

In the urban setting, as the number of single parent families decreased, the rate of gonorrhea increased. This is inconsistent with the literature, which identified single parents as a sociodemographic characteristic associated with STIs (Sionean et al., 2001). Rational for this inconsistency, may be due to the fact that only 14 out of approximately 200 municipalities were randomly selected to represent the urban setting. Those municipalities that were selected may not have had a high number of single parent families residing in them.

Assumptions

In Chapter One, assumptions regarding the possible findings of the study were made. The assumptions were:

- Incidence of chlamydia and gonorrhea will be higher in 15 25 year olds
- Fifteen to twenty-five year olds are at a greater risk of acquiring PID
- Women with one or more episodes of chlamydia or gonorrhea are at a greater risk of acquiring PID compared to women who never have been tested for an STI.
- The rate of hospitalization for PID will be lower compared to the rate of outpatient visits for PID.

A few of the assumptions were founded within the study. The study findings demonstrate that incidence rates for chlamydia and gonorrhea are higher among women in Manitoba between 15 - 19 year olds and 20 - 24 year olds. While the risk of women in Manitoba acquiring PID could be calculated, the risk of acquiring PID by age groups could not be calculated as not every woman in the sample had a diagnosis of PID. This may have over represented or under represented some age groups.

The assumption that women who tested positive for either chlamydia or gonorrhea are at a greater risk of acquiring PID compared to those who never have been tested for an STI was also demonstrated and is consistent with the literature. Since, women testing positive for chlamydia or gonorrhea are already attending for screening of STIs it expected that other diagnostic findings will be made, compared those women who never attend for STI screening. Lastly, the assumption that the rate of hospitalization for PID is lower compared to the rate of outpatient visits for PID was also found within this study. Most diagnoses of PID are made within a physician's office and the more sever cases are made within hospital.

Conceptual Framework

The Surveillance System Framework presented in Chapter Three was utilized to guide this study. It was an appropriate framework in that the data set generated for this study was initially gathered based in a surveillance system framework. Chlamydia and gonorrhea cases are reported to public health authorities for case management, follow-up and appropriately reported to provincial and federal health authorities for documentation (Malloy & Yiu, 2005).

While the surveillance system is effective in determining the number of chlamydia and gonorrhea cases within a particular region and then forwarding the information to the three levels of government for case management and intervention, program planning and policy development; this process can only be applied to PID in theory. For PID to become a part of the surveillance system, it must become a reportable disease. That is, under the *Public Health Act*, it must pass legislation to be reportable to the Director of Communicable Disease Control (CDC). If this were done, the number of PID cases, based on a specific case definition could be reported to the Director of CDC and entered into a database, on a regular basis to capture the actual number of PID cases within the province. Other information could include socieodemographics of the population, such as risk factors, age, sexual practices. Knowledge of this information would provide the actual number of PID cases, provide program planners and policy

makers with raw data to support requests for new or enhancement of current STI prevention and/or interventions.

Study Limitations

A number of limitations were identified within this study. These limitations are related to the sample and the use of secondary data. While the study sample within the data set is representative of the population, it is not the entire population but rather a sample of the population. This can be an issue when referring to other research where the entire population was used as a sample, thus making it difficult to compare findings. This is also an issue of external validity in that the study findings may not be entirely generalizable to other populations.

There are also limitations when utilizing secondary data. While the data provided detailed information on the number of chlamydia and gonorrhea cases, age, geographic location, and the number of diagnosis of PID, etc., it lacked sociodemographic data. A disadvantage of secondary data is the lack of control over what the content is, in the data set (Black, 1995). Since the data was initially gathered for another purpose, information on socioeconomic status, education level, Aboriginal status, etc was not part of the data set and was not made available. The socioeconomic information was obtained through Statistics Canada; however this information was based on a population level as a whole rather than an individual level, in which the initial data set was provided. Having the information at an individual level allows more detailed, specific information about the socieodemographics of the women in Manitoba. The findings, based on the information received from Statistics Canada, provides the best estimate of the sociodemographic information per municipality in which each individual study sample resided.

Additionally, the data set was provided at the municipal code level for anonymity purposes. This allows for analysis of a very small geographic level thus the results may appear to be larger due to a smaller population size in some areas of the province.

Recommendations for Future Research

The findings of this study demonstrate that women in Manitoba with previous documented episodes of chlamydia and gonorrhea are at risk of acquiring PID, that the majority of women infected with chlamydia or gonorrhea is 15 - 25 years of age and that urban settings and reservations are more likely to be at risk of acquiring chlamydia or gonorrhea. Therefore, it would be important to examine existing STI programs within the province to evaluate their effectiveness in the prevention and treatment of STI and their sequelae.

Evaluation research, "involves finding out how well a program, practice, procedure or policy is working" (Polit & Hungler, 1999, p. 201). An evaluation of current primary prevention programs for STIs within Manitoba would identify the actual number of prevention programs that exist both in the urban and rural settings; the type of prevention programs available (i.e., primary, secondary, tertiary), and the target population that utilizes these programs. For instance, information on the age, sex, income and educational level of the population utilizing these programs would be helpful in determining if the appropriate populations are being reached. The evaluation would also identify the effectiveness of the program based on the number of chlamydia and gonorrhea cases within the geographical area in which the program is situated.

The evaluation could also look at how prevention programs are delivered. For instance, is the program primarily delivered by handing out pamphlets, drop-in, outreach

or billboards? An evaluation of the funding available to STI prevention programs would provide a better understanding of the extent of the services currently provided. Additionally, the identification of where the majority of program dollars, in relation to STI prevention (i.e., prevention, treatment) is spent would allow policy makers and program planners to reconsider if the best care and interventions for their money is being delivered.

Partner notification is another area related to STI treatment and care that should be evaluated. What percentage of partners are contacted and notified of their potential risk of an STI? How many of the partners attend for testing and treatment of STI? Knowing this information would allow policy makers and program planners the opportunity to identify the effectiveness of partner notification and if necessary change their programs and offer training sessions to physicians and nurses on conducting effective partner notification interventions.

In addition to offering training programs to physicians and nurses on partner notification, equally important is education for health care providers on STI screening and treatment guidelines within the province. An evaluation of physician treatment practices and compliance with screening and treatment guidelines conducted in Manitoba by Moses & Elliot (2002), found that physicians are noncompliant with STI treatment guidelines and that there is a need for education on the STI screening and treatment guidelines. As a result of noncompliance with the STI screening and treatment guidelines, physicians are missing opportunities to screen for STIs among the at risk groups.

Conducting qualitative research on those individuals who have been diagnosed with PID in order to obtain an understanding of their knowledge level related to PID, STIs, risk factors and prevention strategies is recommended. This would further enhance existing prevention programs in that program planners would have a better understanding of what their client's knowledge level is in relation to STIs, their complications, target populations, risk factors and preventative measures.

Program Recommendations and Policy Implications

The findings of this research demonstrate that women in Manitoba are at risk of acquiring PID from chlamydia and gonorrhea and those women between the ages of 15 - 25 years of age are at high risk compared to other age groups. Women who resided in the urban and reserve settings in Manitoba are also at a greater risk of acquiring chlamydia and gonorrhea. Based on these findings there are a number of implications that include the nursing profession and others; both at the program level and the policy level. *Program*

At the program level, given that the target population is women between 15 - 25 years of age, offering primary prevention initiatives within settings where this age group frequents would be appropriate. Currently, Public Health Nurses are assigned to a school where they offer services, however for the most part; are not available at the school on a regular basis. Offering primary prevention information in such settings as the school, post secondary institutions, recreation centers, etc would reach the appropriate target populations, educate them on STIs, risk factors and prevention strategies and therefore, potentially decreasing the risk of STIs and their sequelae. It is recommended to start primary prevention programs prior to fifteen years old, so that information is provided in

advance of the at risk age group so, that these individuals can make informed decisions related to their sexual behavior. Research has found that Canadian high school students exhibited a reasonable knowledge level on HIV; however were less informed about STIs, which they are at a greater risk of contacting (Hansen, Wong, & Perrin, 2003).

Additionally, since the majority of the population at risk resides in rural Manitoba, on reserve, delivery of how programs are offered should be considered. What works in the urban setting, may not necessarily work in the rural setting. In rural settings, transportation to and from the clinic may be an issue. In urban Manitoba, city center of Winnipeg region there is a "clinic on wheels". A van drives to communities where high risk individuals (i.e., target population, age, Aboriginal, etc.) reside, in order to deliver medical services related to a variety of issues. Offering, a similar service in rural Manitoba may enhance primary prevention services, as well as secondary and tertiary prevention initiatives. For instance, condoms and information on STIs can be provided through this service. Additionally, partner notification can also be achieved.

Cultural characteristics should also be taken into consideration. For instance, the development of culturally friendly material, (i.e., pamphlets) to aid primary prevention measures would be effective in decreasing the risk of STIs. This is especially true for marginalized groups that are at a greater risk of acquiring STIs, such as the Aboriginal population and new immigrants. Barriers, such as education, language and knowledge level of STIs, may discourage individuals from attending for treatment of STIs (Hislop et al., 2003). Wayne and Hettler (2005) state that many provinces lack services and resources that are translated into other languages, culturally sensitive and accessible.

One's cultural beliefs and values also influence how they care for themselves. Thus culturally appropriate material would aid in the prevention of STIs.

Also, at the program level, nurses need to be responsible for on-going education and further more, administration needs to be supportive of advancing education. The trends in the transmission, treatment and eradication of STIs have seen many changes over the past few years. Therefore keeping up-to-date on the most current practices is an important contributor to the reduction of STIs and their sequelae.

For centuries, the link between nursing, epidemiology and public health has a played an important role in the management of communicable diseases, such as STIs. Nurses and other health care professionals are mandated by the *Public Health Act* to report communicable disease, such as chlamydia and gonorrhea to provincial and federal health authorities (Public Health Act, 2003). Nurses, employed by local health authorities have a responsibility to monitor, investigate disease outbreaks and participate in disease related research. Nurses play a major role in the management and eradication of STIs. Through the nursing process and epidemiological methods, primary, secondary and tertiary prevention interventions are implemented in order to decrease STIs (Malloy & Yiu, 2005).

Policy

The findings of this study also have important implications for health care at the policy level. Women in Manitoba are at risk of acquiring PID following infections with chlamydia or gonorrhea. Manitoba Health's current STI screening and treatment guidelines recommend that those infected with STI be tested and treated for chlamydia and gonorrhea and also tested for syphilis (Manitoba Health, 2001a). Following these

guidelines, allows for the reduction of STIs and therefore a reduction in sequelae associated with STIs. Are health care providers following this policy? An evaluation of physician treatment practices and compliance with screening and treatment guidelines conducted in Manitoba found that there physicians are noncompliant with STI treatment guidelines and that there is a need for education on the STI screening and treatment guidelines (Moses & Elliott, 2002).

Alternate testing methods, such as urine based-testing offers non-invasive tests for STIs, therefore possibly increasing the number people who attend for STI testing. Urine based testing is currently being offered by Manitoba Heath. An evaluation of this program is an important aspect in determining the effectiveness of such a service. Has the number attending for STI testing increased with the introduction of urine-based testing? If so, is this the reason for the increase in chlamydia and gonorrhea rates?

An evaluation of where the majority of funds related to STIs in Manitoba are spent is important. If the majority of funds are already spent at the primary prevention level, this needs to be evaluated to determine why the rate of chlamydia and gonorrhea continues to increase. If there are a huge amount of dollars being spent on primary prevention efforts, what needs to change?

Summary of Recommendations

To summarize, the recommendations made within this chapter have implications for those health professionals working in research, program planning, and policy making related to STIs, and include:

Research Recommendations

1. Evaluation of the current primary prevention programs in Manitoba.

2. Evaluation of partner notification.

3. Qualitative research to gain a better understanding of the behavioral characteristics, knowledge of PID, STIs, risk factors and preventative strategies among women in Manitoba infected with STIs.

Program Recommendations

1. Program Planning – Offer primary prevention initiatives within schools, post-secondary institutions, recreational centers, where the target population would be found.

2. Program delivery in the urban verses rural setting.

3. Culturally sensitive educational material.

4. Continuing Education on STI trends and preventative strategies.

Policy Recommendations

1. Policy related to STI screening/testing procedures/methods.

2. Education of health care professionals on current Manitoba Health policy related to STIs.

3. Evaluation of funds spent on primary prevention initiatives.

Dissemination of Findings

It is important that the findings of this research study be shared with colleagues through a variety of venues. Some possibilities include scientific journals, such as *Sexually Transmitted Infections, Canadian Journal of Public Health* and the *American Journal of Public Health;* presentations at research symposiums, conferences, poster presentations and to local health authorities.

Summary

In conclusion, this chapter provided an overview and discussion of the study findings, limitations, recommendations for future research and implications. This study has contributed to an understanding of the risk of acquiring PID among women in Manitoba from genital infections with chlamydia and gonorrhea. More specifically, the study identified the target population at risk, the effects of one or more infections with chlamydia and gonorrhea in acquiring PID, the survival time from the initial diagnosis of chlamydia and gonorrhea to the initial diagnosis of PID, hospital and outpatient rates of PID and geographic factors associated with chlamydia and gonorrhea. Recommendations were made at several levels including research, program planning and policy making.

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Appendix A

Health Information Privacy Committee Application Form



Manitoba

Health

300 Carlton Street

HEALTH INFORMATION PRIVACY COMMITTEE

Winnipeg, Manitoba R3B 3M9

REQUEST FOR ACCESS TO HEALTH INFORMATION HELD BY THE GOVERNMENT OF MANITOBA

1. DATE OF REQUEST: May 30, 2003	2. REQUESTED BY: Dawn Krahn, Graduate Student, Masters of Nursing						
3. PRINCIPAL INVESTIGATOR(S):	Dawn Mann, Graduate Gudent, masters of Hussing						
Ms. Dawn Krahn Masters of Nursing Student, Faculty of	of Graduate Studies, University of Manitoba						
4. TITLE OF STUDY:							
The risk of pelvic Inflammatory disease among women i	in Manitoba with genital C.trachomatis or N. gonorrhoeae infection.						
5. STUDY DURATION:							
one year							
6. IS THERE MORE THAN ONE PHASE TO THE STU							
a) If yes, when will the subsequent phases be cond	ducted?						
N/A b) Will further data be required for subsequent pha	ses? If so, what data?						
N/A							

7. OBJECTIVES OF THE STUDY:

1) Estimate the incidence of PID among women with one or more documented episodes of chlamydia and gonococcal genital infections.

2) Estimate the relative risk of PID among women with previous episodes of chlamydia and genococcal genital infections in comparison to uninfected women.

3) Compare the incidence and relative risks of PID by age group, time since infection, number of infected episodes and presence of co-infection.

4) Estimate the rate of hospitalizations for pelvic inflammatory disease.

8. SPECIFIC DATA REQUIRED:

Cadham Provincial Laboratory testing data Manitoba Health administrative database

9. WILL DATA HELD BY A DEPARTMENT OR AGENCY OF THE GOVERNMENT OF MANITOBA BE LINKED/MERGED WITH DATA FROM ANOTHER DEPARTMENT OR EXTERNAL SOURCE(S)?

YES

NO If yes, state nature of linkage:

Data from the Manitoba Health administrative database and the Cadham Provincial Laboratory testing data will be linked together. A probabilistic linkage was preformed to locate the PHIN of those subjects who do not have one. A Deterministic linkage was performed on those subjects with PHINS. The linkage of data was performed using the following process; Probabilistic linkage to locate missing PHINS, created two matched cohorts with those who have tested positive for a sexually transmitted disease (STD); 1st cohort -match one women who tested positive for a STD with two women who tested negative for a STD from the same file; 2nd cohort - match one women who tested positive for a STD with two women from the general population who never have been tested for a STD. For each match cohort the frequency of persons-years from being tested for a STD to acquiring pelvic inflammatory disease between case and controls within each cohort will be identified.

10. WILL THE STUDY INVOLVE DIRECT ACCESS TO PATIENTS OR THE PUBLIC?

YES 🛛 NO

If yes, include copies of introductory letter(s) to the study individuals, as well as the consent forms and accompanying explanation for inclusion in the study.

	1. Minimal or no Intrusion: Aggregate statistical information or person specific information with no individua
	2. Potential Intrusion: Person specific information in anonymized form with data linkages that create the risk of
	identification of individuals. The degree of risk increases with the type of data linkage as follows:
	Identification of individuals;
	identification of individuals;
	 20. Initiage of Manitoba Health data files to other publicly available and aggregate level data sources neighbourhood-level data from the census) where all individual identifiers have been removed or modified; 2d. linkage of Manitoba Health data files to other person-specific data files where individual identifiers have been removed or modified, or in the case of surveys, no direct contact with the individual will be made (eg National Population Health Survey from Statistics Canada).
· 🖵	3. Moderate Intrusion: Person specific information such as patient charts, surveys or personal interviews will be u but the individuals affected will be asked for their consent prior to the disclosure of any personal health information the researcher. (Does not include cases where the population group or information concerned fails within category the researcher.
	4. High intrusion: Person-specific information involving linkage of Manitoba Health data files to other person-specifies for which the researcher has access to individual identifiers without consent, for example, patient information collected in clinical settings, specialized programs, and disease registry files with identifying information. (Does not include cases where the population group or information concerned fails within category 5.)
· •	5. Highly Sensitive: Requests for information which would otherwise fall into categories 3 or 4 where the populatio involved is vulnerable or dependent (eg. persons with mental disabilities, minors) or the nature of the information is highly personal and sensitive.
	PROVIDE A RATIONALE FOR YOUR CHOICE.
This pro individu the resu	oject involves database linkages with respect to information, which has already been collected; there are no al study subject consent forms. Once the database linkages are made, all individual identifiers will be removed fn ulting database. All analysis and reporting will therefore be unlinked and non-nominal.
12. HO of s	W WILL THE CONFIDENTIALITY OF THE DATA BE PROTECTED BY THE RESEARCHER(S)? Include discuss recurity measures, how will the data be destroyed, and other issues related to data.
No pers be remo	conal information will be available to the researchers. Once the data linkages are made, all individual identifiers wi eved from the resulting database. All analysis and reporting will therefore be unlinked and non-nominal.
Staff at Manitob Iinked d	the Epidemiology Unit, Manitoba Health who have signed Oaths of Confidentiality and have been authorized by a Health to access the computer network containing the databases, preformed all database linkages. Access to the atabase will be restricted to the principal research investigator who is working with the data.
It is requ analysis on the p	uested that permission be granted to take the research out of the province of Manitoba for the purpose of research as on the principal investigator who will be performing the data analysis resides in Alberta. Data will be analyzed resonal computer (PC) of Dawn Krahn at the following residence; 46 Halden Crescent, Spruce Grove Alberta T7) be above mentioned residence is secured by a home alarm manifered 24 hours a day by ADT Grove Alberta

12 Continued - Upon completion of the research study, data can be returned to Manitoba Health for destruction or destroyed by the researcher per direction from Manitoba Health.

13. DISCUSS THE IMPROTATICE OF THE RESEARCH IN RELATION TO THE LEVEL OF INTRUSION. Since the project does not involve individual study subjects, there is no intrusion into the personal lives of individuals. However the findings from the research project provide information on the pathogenesis of pelvic inflammatory disease and will have important program and policy implications for the control of sexually transmitted diseases.

14. WHO WILL BE RECEIVING STUDY RESULTS?

My Thesis committee; Dr. Lynn Scruby (Chair), Dr. Pamela Hawranik (Internal Member), and Dr. Stephen Moses (External Member)

15. WILL THERE BE ANY PUBLICATION OF THE STUDY RESULTS? (If yes, a copy must be sent to Manitoba Health prior to publication.)

Yes, my thesis will be made available as per the University of Manitoba policy (one copy of the thesis will be placed in the University of Manitoba Library).

16. OTHER INFORMATION RELEVANT TO THE SUBMISSION:

Ethical approval is to be sought July 2003. Once ethical approval is received, this information will be forwarded to the Manitoba Health Information Privacy Committee.

17. PLEASE PROVIDE:

a) Proof of funding for the project - N/A

b) Proof of Ethics Committee approval, including current status if updating a project. -Ethical approval is to be sought July 2003. Once ethical approval is received, this information will be forwarded to the Manitoba Health Information Privacy Committee.

Declaration

I declare that:

- This research complies with The Personal Health Information Act of Manitoba.
- It is important enough to outweigh any invasion of privacy involved; the project ensures the security of the personal health information and its destruction when finished; and the information requested is the minimum necessary to accomplish the purpose.
- All reports on the study will be submitted to the Health Information Management Branch of Manitoba Health for review
 prior to distribution or publication, to assure that the anonymity of respondents is preserved and that any references to
 Manitoba Health or other trustees are factually correct.
- A copy of all published reports will be provided to the Health Information Management Branch of Manitoba Health for its records.

Where identifiable health information is requested, I declare:

it cannot be done without using identifiable personal health information; and

it is impossible or impractical to obtain consent from the people the personal health information is about.

Date

Signature of Person Making Request

Marcal: 20, 2001

Health Information Privacy Committee Letter

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Manitoba

Health

300 Carlton Street Winnipeg MB R3B 3M9

HEALTH INFORMATION PRIVACY COMMITTEE

File No. 2003/2004-11

8 March, 2004

Dawn Krahn

Dear Ms. Krahn:

Re: The risk of pelvic inflammatory disease and ectopic pregnancy among women in Manitoba with genital C. trachomatis or N. gonorrhoeae

The Health Information Privacy Committee would like to thank you for providing the requested ethics approval and has *approved* this study

Please note that any significant changes to the proposed study design should be reported to the Chair for consideration. If you have any questions or concerns, please do not hesitate to contact Leonie Stranc at

Yours truly,

Dr R. Walker Chair

Please quote the file number on all correspondence

Cc: Louis Barre

Visit us on the web at www.gov.mb.ca/health/hipc

Ethics Approval Certificate



UNIVERSITY Of Manitoba RESEARCH SERVICES & PROGRAMS Office of the Vice-President (Research) 244 Engineering Bidg. Winnipeg, MB R3T 53-6 Telephone: (201): 174-8418 Eax: (204): 261-0325 www.innanabacarosearch

APPROVAL CERTIFICATE

5 February 2004

TO:Dawn Lynn Krahn
Principal Investigator(Advisor L. Scruby)FROM:Stan Straw, Chair
Education/Nursing Research/Ethies/Board (ENREB)Re:Protocol #E2004:013
"The Risk of Women in Manitoba Acquiring Pelvic Inflammatory
Disease from One or More Episodes of Genital Chlamydia
trachomatis or Neisseria gonorrhoeae Infections"

Please be advised that your above-referenced protocol has received human ethics approval by the **Education/Nursing Research Ethics Board**, which is organized and operates according to the Tri-Council Policy Statement. This approval is valid for one year only.

Any significant changes of the protocol and/or informed consent form should be reported to the Human Ethics Secretariat in advance of implementation of such changes.

Please note that, if you have received multi-year funding for this research, responsibility lies with you to apply for and obtain Renewal Approval at the expiry of the initial one-year approval; otherwise the account will be locked.

Get to know Research at your University

Appendix D

Correlation Matrix All Variables

	Simple Statistics											
Variable	N	Mean	Std Dev	Sum	Minimum	Maximum	Label					
gcrate1000	280	0.91160	2.11237	255.24865	0	15.93137						
chlrate1000	280	6.98973	10.76578	1957	0	62.50000						
SPAR	282	11.60152	6.67789	3272	3.52000	26.21910	SPAR					
EDUC	282	20.33725	8.23175	5735	3.79747	38.46000	EDUC					
ABOR	282	29.92466	37.89848	8439	0.22000	99.14000	ABOR					
UNEMP	282	11.11065	10.26565	3133	1.09000	38.40000	UNEMP					
FINC	282	40512	10559	11424341	21137	83904	FINC					
IMMIG1000	282	15.80003	19.78708	4456	0	153.04247	IMMIG1000					

		Pearsor Prob Nu	n Correlat > r unde mber of C	ion Coeffi er H0: Rho Observatio	cients)==0 ns			
	gcrate1000	chlrate1000	SPAR	EDUC	ABOR	UNEMP	FINC	IMMIG 1000
gerate1000	1.00000 280	0.86342 <.0001 280	0.56556 <.0001 280	0.56308 <.0001 280	0.71558 <.0001 280	0.70056 <.0001 280	-0.55765 <.0001 280	-0.29641 <.0001 280
chlrate1000	0.86342 <.0001 280	1.00000 280	0.70038 <.0001 280	0.63981 <.0001 280	0.85158 <.0001 280	0.82517 <.0001 280	-0.60679 <.0001 280	-0.36739 <.0001 280
SPAR SPAR	0.56556 <.0001 280	0.70038 <.0001 280	1.00000 282	0.61180 <.0001 282	0.87437 <.0001 282	0.89336 <.0001 282	-0.63977 <.0001 282	-0.29017 <.0001 282
EDUC EDUC	0.56308 <.0001 280	0.63981 <.0001 280	0.61180 <.0001 282	1.00000 282	0.75771 <.0001 282	0.77160 <.0001 282	-0.82738 <.0001 282	-0.28640 <.0001 282
ABOR ABOR	0.71558 <.0001 280	0.85158 <.0001 280	0.87437 <.0001 282	0.75771 <.0001 282	1.00000 282	0.95648 <.0001 282	-0.76954 <.0001 282	-0.46013 <.0001 282
UNEMP UNEMP	0.70056 <.0001 280	0.82517 <.0001 280	0.89336 <.0001 282	0.77160 <.0001 282	0.95648 <.0001 282	1.00000 282	-0.73173 <.0001 282	-0.38325 <.0001 282
FINC FINC	-0.55765 <.0001 280	-0.60679 <.0001 280	-0.63977 <.0001 282	-0.82738 <.0001 282	-0.76954 <.0001 282	-0.73173 <.0001 282	1.00000 282	0.34660 <.0001 282
IMMIG1000 IMMIG1000	-0.29641 <.0001 280	-0.36739 <.0001 280	-0.29017 <.0001 282	-0.28640 <.0001 282	-0.46013 <.0001 282	-0.38325 <.0001 282	0.34660 <.0001 282	1.00000

Appendix E

Correlation Matrix - Non-Urban (Rural Manitoba)

	Simple Statistics											
Variable	N	Mean	Std Dev	Sum	Minimum	Maximum	Label					
gcrate1000	266	0.95563	2.15839	254.19779	0	15.93137						
chlrate1000	266	7.18507	11.00037	1911	0	62.50000						
SPAR	268	11.45246	6.70844	3069	3.52000	26.21000	SPAR					
EDUC	268	20.96287	7.91606	5618	6.92000	38.46000	EDUC					
ABOR	268	31.19116	38.44416	8359	0.22000	99.14000	ABOR					
UNEMP	268	11.30422	10.47187	3030	1.09000	38.40000	UNEMP					
FINC	268	39672	9713	10632013	21137	63434	FINC					
IMMIG1000	268	13.68933	15.24325	3669	0	89.74000	IMMIG1000					

	Pearson Correlation Coefficients Prob > r under H0: Rho-0 Number of Observations													
	gcrate1000	chlrate1000	SPAR	EDUC	ABOR	UNEMP	FINC	IMMIG 1000						
gcrate1000	1.00000 266	0.86312 <.0001 266	0.58900 <.0001 266	0.57041 <.0001 266	0.71317 <.0001 266	0.69985 <.0001 266	-0.58879 <.0001 266	-0.34337 <.0001 266						
chirate1000	0.86312 <.0001 266	1.00000 266	0.72918 <.0001 266	0.65662 <.0001 266	0.85334 <.0001 266	0.82757 <.0001 266	-0.64996 <.0001 266	-0.43735 <.0001 266						
SPAR SPAR	0.58900 <.0001 266	0.72918 <.0001 266	1.00000 268	0.68773 <.0001 268	0.91319 <.0001 268	0.91464 <.0001 268	-0.72185 <.0001 268	-0.51976 <.0001 268						
EDUC EDUC	0.57041 <.0001 266	0.65662 <.0001 266	0.68773 <.0001 268	1.00000 268	0.76212 <.0001 268	0.79200 <.0001 268	-0.81958 <.0001 268	-0.22862 0.0002 268						
ABOR ABOR	0.71317 <.0001 266	0.85334 <.0001 266	0.91319 <.0001 268	0.76212 <.0001 268	1.00000 268	0.95861 <.0001 268	-0.80368 <.0001 268	-0.53864 <.0001 268						
UNEMP UNEMP	0.69985 <.0001 266	0.82757 <.0001 266	0.91464 <.0001 268	0.79200 <.0001 268	0.95861 <.0001 268	1.00000 268	-0.77209 <.0001 268	-0.49178 <.0001 268						
FINC FINC	-0.58879 <.0001 266	-0.64996 <.0001 266	-0.72185 <.0001 268	-0.81958 <.0001 268	-0.80368 <.0001 268	-0.77209 <.0001 268	1.00000	0.38159 <.0001 268						
IMMIG1000 IMMIG1000	-0.34337 <.0001 266	-0.43735 <.0001 266	-0.51976 <.0001 268	-0.22862 0.0002 268	-0.53864 <.0001 268	-0.49178 <.0001 268	0.38159 <.0001 268	1.00000 268						

Appendix F

	Simple Statistics												
Variable	N	Mean	Std Dev	Sum	Minimum	Maximum	Label						
gcrate1000	14	0.07506	0.07110	1.05086	0	0.26035							
chlrate1000	14	3.27835	2.26196	45.89690	1.18341	10.67430							
SPAR	14	14.45485	5.51349	202.36789	5.57103	26.21910	SPAR						
EDUC	14	8.36106	3.89112	117.05479	3.79747	17.07208	EDUC						
ABOR	14	5.68025	5.01034	79.52347	1.04586	19.08639	ABOR						
UNEMP	14	7.40524	3.17768	103.67343	3.84615	14.95527	UNEMP						
FINC	14	56595	13391	792328	34628	83904	FINC						
IMMIG1000	14	56.20492	42.90468	786.86891	9.59325	153.04247	IMMIG1000						

Correlation Matrix - Urban (Winnipeg Region only)

		Pearson Co Prob	rrelation (> r unde	Coefficien er H0: Rho	ts, N = 14)=0			
	gcrate1000	chlrate1000	SPAR	EDUC	ABOR	UNEMP	FINC	IMMIG
gcrate1000	1.00000	0.85007 0.0001	-0.00966 0.9738	0.43115 0.1238	0.12376 0.6734	0.03150 0.9149	-0.22712 0.4349	-0.15210 0.6037
chlrate1000	0.85007 0.0001	1.00000	-0.37581 0.1854	0.10965 0.7090	-0.16947 0.5624	-0.27879 0.3344	0.07016 0.8116	-0.37760 0.1832
SPAR	-0.00966	-0.37581	1.00000	0.72630	0.88824	0.91790	-0.82757	0.55885
SPAR	0.9738	0.1854		0.0033	<.0001	<.0001	0.0003	0.0378
EDUC	0.43115	0.10965	0.72630	1.00000	0.87099	0.86313	-0.80590	0.63839
EDUC	0.1238	0.7090	0.0033		<.0001	<.0001	0.0005	0.0140
ABOR	0.12376	-0.16947	0.88824	0.87099	1.00000	0.97774	-0.76198	0.62607
ABOR	0.6734	0.5624	<.0001	<.0001		<.0001	0.0015	0.0166
UNEMP	0.03150	-0.27879	0.91790	0.86313	0.97774	1.00000	-0.79974	0.72762
UNEMP	0.9149	0.3344	<.0001	<.0001	<.0001		0.0006	0.0032
FINC	-0.22712	0.07016	-0.82757	-0.80590	-0.76198	-0.79974	1.00000	-0.57683
FINC	0.4349	0.8116	0.0003	0.0005	0.0015	0.0006		0.0308
IMMIG1000	-0.15210	-0.37760	0.55885	0.63839	0.62607	0.72762	-0.57683	1.00000
IMMIG1000	0.6037	0.1832	0.0378	0.0140	0.0166	0.0032	0.0308	

Appendix G

t test Rates of Chlamydia and Gonorrhea on Reserve

0 = non reserve

1=reserve

					Statistic	s				2
Variable	Reserve	N	Lower CL Mean	Mean	Upper CL Mean	Lower CL Std Dev	Std Dev	Upper CL Std Dev	Std Err	Min
gcrate 1000	0	220	0.0591	0.09	0.1209	0.2125	0.2324	0.2564	0.0157	0
gcrate 1000	1	60	3.1425	3.9241	4.7057	2.5646	3.0256	3.6902	0.3906	0
gcrate 1000	Diff (1- 2)		-4.238	-3.834	-3.43	1.301	1.409	1.5367	0.2052	
chlrate 1000	0	220	1.8354	2.1652	2.495	2.2698	2.482	2.7385	0.1673	0
chlrate 1000	1	60	21.848	24.68	27.512	9.2926	10.963	13.371	1.4153	0
chlrate 1000	Diff (1- 2)		-24.09	-22.51	-20.93	5.0876	5.51	6.0095	0.8025	

		T-Tests					
Variable	Method	Variances	DF	t Value	Pr> t		
gcrate1000	Pooled	Equal	278	-18.68	<.0001		
gcrate1000	Satterthwaite	Unequal	59.2	-9.81	<.0001		
chlrate1000	Pooled	Equal	278	-28.06	<.0001		
chlrate1000	Satterthwaite	Unequal	60.7	-15.80	<.0001		

	Equ	ality of Va	riances		
Variable	Method	Num DF	Den DF	F Value	Pr>F
gcrate1000	Folded F	59	219	169.50	<.0001
chlrate1000	Folded F	59	219	19.51	<.0001

Appendix H

t test Rates of Chlamydia and Gonorrhea Urban

0 = non-urban (all regions except Winnipeg)

1 = urban (Winnipeg Region only)

	Statistics												
Variable	Urban	N	Lower CL Mean	Mean	Upper CL Mean	Lower CL Std Dev	Std Dev	Upper CL Std Dev	Std Err	Min			
gcrate 1000	0	266	0.6951	0.9556	1.2162	1.9892	2.1584	2.3592	0.1323	0			
gcrate 1000	1	14	0.034	0.0751	0.1161	0.0515	0.0711	0.1145	0.019	0			
gorate 1000	Diff (1-2)		-0.257	0.8806	2.0181	1.9458	2.1074	2.2984	0.5779				
chlrate 1000	0	266	5.8571	7.1851	8.5131	10.138	11	12.024	0.6745	0			
chlrate 1000	1	14	1.9723	3.2784	4.5844	1.6398	2.262	3.6441	0.6045	1.1834			
chlrate 1000	Diff (1-2)		-1.897	3.9067	9.71	9.927	10.751	11.726	2.948				

	T-Tests							
Variable	Method	Variances	DF	t Value	$\Pr > t $			
gcrate1000	Pooled	Equal	278	1.52	0.1287			
gcrate1000	Satterthwaite	Unequal	274	6.59	<.0001			
chlrate1000	Pooled	Equal	278	1.33	0.1862			
chlrate1000	Satterthwaite	Unequal	60.9	4.31	<.0001			

	Equ	ality of Va	riances		
Variable	Method	Num DF	Den DF	F Value	Pr > F
gcrate1000	Folded F	265	13	921.66	<.0001
chlrate1000	Folded F	265	13	23.65	<.0001

Appendix I

		Sum of	Mean		
Source	DF	Squares	Square	F Value	Pr>I
Model	8	10.15255	1.26907	120.05	<.0001
Error	257	2.71681	0.01057		
Corrected Total	265	12.86936			

Analysis of Variance - rate of Chlamydia - All Variables

	Parameter	Standard			
Variable	Estimate	Error	Type II SS	F Value	Pr > F
Intercept	-0.00286	0.00145	0.04136	3.91	0.0490
SPAR	-0.00003518	0.00005301	0.00466	0.44	0.5075
EDUC	0.00003058	0.00003127	0.01011	0.96	0.3291
ABOR	0.00006261	0.00002308	0.07777	7.36	0.0071
UNEMP	0.00021308	0.00008974	0.05960	5.64	0.0183
FINC	5.997906E-8	2.189182E-8	0.07935	7.51	0.0066
IMMIG1000	-0.00000958	0.00000701	0.01973	1.87	0.1731
URBAN	0.00096548	0.00063221	0.02465	2.33	0.1280
RESERVE	0.01195	0.00157	0.61230	57.92	<.0001

Appendix J

Analysis of Variance - Rate of Chlamydia - Lone Parent Families Variable Removed

	Ana	alysis of V	ariance		
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	7	10.14790	1.44970	137.43	<.0001
Error	258	2.72146	0.01055		
Corrected Total	265	12.86936			

Variable	Parameter Estimate	Standard Error	Туре II SS	F Value	Pr>F
Intercept	-0.00323	0.00133	0.06218	5.89	0.0159
EDUC	0.00003719	0.00002961	0.01663	1.58	0.2103
ABOR	0.00006054	0.00002285	0.07408	7.02	0.0085
UNEMP	0.00018170	0.00007620	0.05998	5.69	0.0178
FINC	6.352816E-8	2.120561E-8	0.09467	8.97	0.0030
IMMIG1000	-0.00000971	0.00000700	0.02029	1.92	0.1667
URBAN	0.00079987	0.00058025	0.02004	1.90	0.1692
RESERVE	0.01237	0.00143	0.78501	74.42	<.0001

Appendix K

Anal	lysis	of	Va	riance –	Rate	of	Chlam	ydia –	Edu	cation	V	⁄aria	ıble	e Removed	£
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Analysis of Variance								
Source	DF	Sum of Squares	Mean Square	F Value	Pr≥F			
Model	6	10.13126	1.68854	159.72	<.0001			
Error	259	2.73810	0.01057					
Corrected Total	265	12.86936						

Variable	Parameter Estimate	Standard Error	Type II SS	F Value	Pr > F
Intercept	-0.00215	0.00101	0.04739	4.48	0.0352
ABOR	0.00006333	0.00002276	0.08182	7.74	0.0058
UNEMP	0.00018199	0.00007628	0.06017	5.69	0.0178
FINC	5.198634E-8	1.913157E-8	0.07806	7.38	0.0070
IMMIG1000	-0.00000740	0.00000676	0.01265	1.20	0.2750
URBAN	0.00050379	0.00053078	0.00952	0.90	0.3434
RESERVE	0.01248	0.00143	0.80113	75.78	<.0001

Appendix L

Analysis of Variance – Rate of Chlamydia – Urban Variable Removed

	Ana	Analysis of Variance				
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F	
Model	5	10.12174	2.02435	191.56	<.0001	
Error	260	2.74762	0.01057	· .		
Corrected Total	265	12.86936				

Variable	Parameter Estimate	Standard Error	Type II SS	F Value	Pr>F
Intercept	-0.00271	0.00082476	0.11389	10.78	0.0012
ABOR	0.00006109	0.00002264	0.07697	7.28	0.0074
UNEMP	0.00020133	0.00007349	0.07931	7.50	0.0066
FINC	6.197888E-8	1.59714E-8	0.15914	15.06	0.0001
IMMIG1000	-0.00000400	0.00000574	0.00514	0.49	0.4862
RESERVE	0.01244	0.00143	0.79639	75.36	<.0001

Appendix M

Analysis of Variance – Rate of Chlamydia – Immigration Variable Removed

	Ana	lysis of V	ariance				
Source	DF	Sum of Squares	Mean Square	F Value	Pr>F		
Model	4	10.11660	2.52915	239.80	<.0001		
Error	261	2.75276	0.01055				
Corrected Total	265	12.86936					

Variable	Parameter Estimate	Standard Error	Туре II SS	F Value	Pr>F
Intercept	-0.00272	0.00082368	0.11523	10.93	0.0011
ABOR	0.00006891	0.00001965	0.12975	12.30	0.0005
UNEMP	0.00017233	0.00006054	0.08547	8.10	0.0048
FINC	6.226051E-8	1.595057E-8	0.16069	15.24	0.0001
RESERVE	0.01252	0.00143	0.81346	77.13	<.0001

Appendix N

Statistics for Removal DF = 1,261							
PartialModelVariableR-SquareF ValuePr > 1							
ABOR	0.0101	0.7760	12.30	0.0005			
UNEMP	0.0066	0.7795	8.10	0.0048			
FINC	0.0125	0.7736	15.24	0.0001			
RESERVE	0.0632	0.7229	77.13	<.0001			

Analysis of Variance - Rate of Chlamydia - Significant Variables

All variables left in the model are significant at the 0.1000 level.

Appendix O

	Ana	lysis of V	ariance		
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	8	0.55128	0.06891	28.02	<.0001
Error	130	0.31971	0.00246		
Corrected Total	138	0.87099			an an th

Analysis of Variance - Rate of Gonorrhea - All Variables

Variable	Parameter Estimate	Standard Error	Type II SS	FValue	Pr>F
Intercept	0.00006522	0.00047507	0.00004636	0.02	0.8910
SPAR	-0.00001736	0.00001372	0.00394	1.60	0.2079
EDUC	0.00000441	0.00001097	0.00039740	0.16	0.6884
ABOR	0.00000670	0.00000679	0.00240	0.98	0.3252
UNEMP	0.00002016	0.00002598	0.00148	0.60	0.4391
FINC	-4.985E-10	5.861283E-9	0.00001779	0.01	0.9324
IMMIG1000	-4.56598E-7	0.00000203	0.00012399	0.05	0.8227
URBAN	0.00009439	0.00014559	0.00103	0.42	0.5179
RESERVE	0.00213	0.00047964	0.04844	19.70	<.0001

Appendix P

Analysis of Variance - Rate of Gonorrhea - Aboriginal Variable Removed

	Ana	alysis of V	ariance		
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	3	0.54772	0.18257	76.24	<.0001
Error	135	0.32327	0.00239	-	
Corrected Total	138	0.87099			

Variable	Parameter Estimate	Standard Error	Туре II SS	F Value	Pr>F
Intercept	0.00004714	0.00011280	0.00041827	0.17	0.6767
SPAR	-0.00001756	0.00001000	0.00738	3.08	0.0814
UNEMP	0.00003840	0.00001784	0.01109	4.63	0.0332
RESERVE	0.00240	0.00039832	0.08707	36.36	<.0001

Appendix Q

Analysis of Variance - Rate of Gonorrhea - Significant Variables

Statistics for Removal DF = 1,135						
Variable	Partial R-Square	Model R-Square	F Value	Pr > F		
SPAR	0.0085	0.6204	3.08	0.0814		
UNEMP	0.0127	0.6161	4.63	0.0332		
RESERVE	0.1000	0.5289	36.36	<.0001		

All variables left in the model are significant at the 0.1000 level.