

Abstract

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Chlamydia trachomatis is now considered to be the most prevalent sexually transmitted disease in the United States today. Demographic, behavioral, and clinical indicators associated with Chlamydia were examined in women attending a family planning program in order to: 1) determine the prevalence rate of Chlamydia, and 2) identify and refine criteria for selective screening. Chlamydia was isolated from the cervix of 41 (14.28%) of 287 women using the Microtrak[™] Chlamydia direct test. Since it is not economically feasible to screen every sexually active woman for Chlamydia, the development of a selective screening protocol seems to be a reasonable alternative.

Ten indicators were significantly associated with the presence of Chlamydia on univariate analysis: 1) number of partners in the last 3 months, 2) number of new partners in the last 3 months, 3) number of partners with multiple partners in the last three months, 4) young age, 5) length of time on oral contraceptives, 6) inflammatory cells on Papanicolaou smear, 7) abnormal vaginal discharge, 8) friable cervix, 9) pain with intercourse, and 10) bleeding with intercourse. A stepwise regression analysis was done and seven indicators were significant. Three of the indicators significant on univariate analysis persisted on multivariate analysis: 1) partners with multiple partners, 2) inflammatory cells on Papanicolaou smear, and 3) friable cervix. Four indicators significant on multivariate analysis were not significant on univariate analysis: 1) pain with urination, 2) abdominal pain, 3) previous abnormal Papanicolaou smear, and 4) vaginal odor. The last two variables, however, were negatively correlated with Chlamydia.

Behavioral and Clinical Indicators of Chlamydia
trachomatis in women

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CHAPTER 1

INTRODUCTION

In this chapter, the researcher discusses the scope of the problem, the research hypotheses and the significance of the study of *Chlamydia trachomatis*, a sexually transmitted disease.

Background

Chlamydia trachomatis is now recognized as the most prevalent sexually transmitted disease in the United States today (Shafer et al., 1984). Even though it is an organism that has been around for a long time and causes symptoms similar to gonorrhea, it has just recently been identified as an intracellular bacterium (Thompson & Washington, 1983). After the identification of the organism, it was still some time before a simple, inexpensive test was developed to allow the clinician to selectively screen sexually active individuals. We in Wisconsin are fortunate to be one of the states that require mandatory reporting to help facilitate the control of this insidious disease.

For women who rarely have noticeable symptoms, the outcome of the *Chlamydia* infection can cause salpingitis which can lead to infertility and/or ectopic pregnancy (Washington, Gove, Schachter & Sweet, 1985). Infants passing through the birth canal are at risk for developing conjunctivitis and pneumonia as a result of maternal infection (Heller 1984). For men, the outcome is equally as bleak with epididymitis and possible infertility as a complication of *Chlamydia urethritis*. Since

Chlamydia causes milder symptoms than gonorrhoea in men it is less likely that a man will seek treatment. This subsequently endangers his partner(s), preventing them from reaching treatment. Women with *Chlamydia* may harbor the organism for years and possibly infect a number of partners (Heller, 1984).

Recent research has identified a number of factors that can be elicited by history-taking to be positive predictors of women at high risk for *Chlamydia* infection. An age of 23 or younger seems to correlate with an increased risk (Harrison et al., 1985). A woman with multiple sexual partners in the last ninety days, a new partner, or a partner with multiple partners also appears to be at increased risk (Harrison et al., 1985). Clinical signs that have been suggested to be indicators of *Chlamydia* infection include muco-purulent cervical discharge, a friable cervix, and cervical ectopy (Chacko & Lovchik, 1984). Contraceptive method also appears to correlate; barrier methods offer some protection from *Chlamydia* whereas oral contraceptives appear to increase the risk of *Chlamydia* (Washington et al., 1985). This study and others have indicated, however, that it is not the hormones in the oral contraceptive but the ectopy that evolves from oral contraceptive use that is associated with the presence of *Chlamydia*. Other factors that are suspected to be associated with *Chlamydia* include inflammatory cells on Papanicolaou smear and abnormal bleeding patterns.

Until recently, the identification of *Chlamydia* was done primarily through ruling out gonorrhoea since the *Chlamydia* culture is expensive and has to be transported on ice to the State Laboratory of Hygiene within twenty-four hours of obtaining the specimen. Since that time, the

Chlamydia cultures have been reduced in price but still require special handling. A relatively new test, the monoclonal antibody test (Microtraktm) has been developed and can be acquired at a reasonable cost. It is easy to do and does not require special handling (Wingerson, 1983).

There have been relatively few studies published that have looked comprehensively at the indicators associated with *Chlamydia trachomatis* infection in women; therefore, many clinicians are not aware of those indicators of *Chlamydia* that have been identified - they are missing an opportunity to screen women who are at high risk of having the organism. In order to best serve the sexually active population and best utilize the health care dollar, it is necessary to continue to expand and refine the indicators most highly associated with *Chlamydia*.

Significance of the Study

In my practice as an Obstetrical/Gynecological Nurse Practitioner in a rural setting, this researcher has been concerned about the lack of information about *Chlamydia* and the high prevalence of the organism in the population of women served. It would be valuable to verify some of the indicators that have already been studied and also expand the study to include new factors that may be indicators of *Chlamydia* in women. One of the factors that this researcher wanted to look at was the sudden onset or increase in menstrual cramps in the previous three months. Another factor was the report of abnormal bleeding patterns such as "breakthrough bleeding" with the use of oral contraceptives, post-coital bleeding, and intermenstrual bleeding.

At this point, the screening of every sexually active woman is financially infeasible, so it is important to continue to search for indicators that would alert the clinician or client to the necessity for a *Chlamydia* test. Once the indicators most predictive of *Chlamydia* have been identified for the population of women attending Southwest Family Planning, a refined selective screening protocol can be implemented. This study will have implications for other health care providers in Southwest Wisconsin who are serving a population of women with similar characteristics and who need to develop criteria for selective screening.

Health educators have a responsibility to inform clients and the community about the known indicators and complications associated with the presence of *Chlamydia* to allow the health consumer to identify when she/he is at risk and seek diagnosis and treatment when appropriate. If the health care consumer is well informed about *Chlamydia*, seeks out appropriate diagnosis and treatment, many complications (including infertility) would be reduced significantly. A substantial proportion of health care dollars now spent on hospitalization for complications such as neonatal pneumonia, pelvic inflammatory disease, and infertility workups could be saved.

Health Educators also have a responsibility to provide continuing education to health care providers regarding the indicators and complications associated with the presence of *Chlamydia*. With well informed health care providers and consumers working together, *Chlamydia* would no longer have to be the potential threat that it now presents.

Statement of the Problem

Chlamydia trachomatis is the most prevalent sexually transmitted disease in the United States today. This research attempts to address the following problem: What are the demographic, behavioral, and clinical indicators associated with the presence of *Chlamydia* in women attending the Southwest Family Planning Program in Platteville, Wisconsin?

Research Hypotheses

This study addressed the following hypotheses.

Hypothesis One

There is a statistically significant relationship between the age of the client and the presence of a *Chlamydia* infection.

Hypothesis Two

There is a statistically significant relationship between the type of birth control used and the presence of a *Chlamydia* infection.

Hypothesis Three

There is not a statistically significant relationship between length of time on oral contraceptives and the presence of a *Chlamydia* infection.

Hypothesis Four

There is not a statistically significant relationship between a previously reported abnormal Papanicolaou smear and the presence of a *Chlamydia* infection.

Hypothesis Five

There is not a statistically significant relationship between previously reported inflammatory cells on a Papanicolaou smear and the presence of a *Chlamydia* infection.

Hypothesis Six

There is a statistically significant relationship between the number of sexual partners in the last three months and the presence of a *Chlamydia* infection.

Hypothesis Seven

There is a statistically significant relationship between the report of a new sexual partner in the last three months and the presence of a *Chlamydia* infection.

Hypothesis Eight

There is a statistically significant relationship between the report of a partner with multiple partners in the last three months and the presence of a *Chlamydia* infection.

Hypothesis Nine

There is a statistically significant relationship between the report of a partner(s) with symptoms of urethritis and the presence of a *Chlamydia* infection.

Hypothesis Ten

There is a statistically significant relationship between the increased frequency of menstrual cramps in the last three months and the

presence of a *Chlamydia* infection.

Hypothesis Eleven

There is a statistically significant relationship between the reported increase in menstrual flow in the last three months and the presence of a *Chlamydia* infection.

Hypothesis Twelve

There is a statistically significant relationship between the occurrence of bleeding between menstrual periods in the last three months and the presence of a *Chlamydia* infection.

Hypothesis Thirteen

There is a statistically significant relationship between the reported occurrence of bleeding with intercourse in the last three months and the presence of a *Chlamydia* infection.

Hypothesis Fourteen

There is a statistically significant relationship between the reported occurrence of pain with intercourse in the last three months and the presence of a *Chlamydia* infection.

Hypothesis Fifteen

There is no statistically significant relationship between the reported presence of an abnormal vaginal discharge and the presence of a *Chlamydia* infection.

Hypothesis Sixteen

There is no statistically significant relationship between the

reported presence of an abnormal vaginal odor and the presence of a *Chlamydia* infection.

Hypothesis Seventeen

There is no statistically significant relationship between the reported presence of lower abdominal pain and the presence of a *Chlamydia* infection.

Hypothesis Eighteen

There is a statistically significant relationship between the reported presence of pain/burning on urination and the presence of a *Chlamydia* infection.

Hypothesis Nineteen

There is no statistically significant relationship between the reported presence of frequency on urination and the presence of a *Chlamydia* infection.

Hypothesis Twenty

There is no statistically significant relationship between the reported presence of urgency on urination and the presence of a *Chlamydia* infection.

Hypothesis Twenty-One

There is no statistically significant relationship between the presence of a current abnormal Papanicolaou smear and the presence of a *Chlamydia* infection.

Hypothesis Twenty-Two

There is a statistically significant relationship between the presence of inflammatory cells on current Papanicolaou smear and the presence of a *Chlamydia* infection.

Hypothesis Twenty-Three

There is no statistically significant relationship between the color of vaginal discharge and the presence of a *Chlamydia* infection.

Hypothesis Twenty-Four

There is a statistically significant relationship between the degree of friability of the cervix and the presence of a *Chlamydia* infection.

Hypothesis Twenty-Five

There is a statistically significant relationship between the color of endocervical discharge and the presence of a *Chlamydia* infection.

Hypothesis Twenty-Six

There is a statistically significant relationship between the percent of ectopy on the cervix and the presence of a *Chlamydia* infection.

Assumptions

The following assumptions were made regarding this research. 1. The instruction received by this researcher through the State Laboratory of Hygiene provided the most consistently accurate way to obtain laboratory specimens for this study. 2. Each client told the truth regarding her medical history, symptoms, and sexual partners. 3. The

Wisconsin State Laboratory of Hygiene consistently practiced "quality control" to assure accurate test results. 4. There were no undiagnosed health conditions contributing to the positive responses given by clients on the interview questionnaire.

Limitations

The following limitations were placed on this study. 1. This study was limited to sexually active women who were between fourteen and forty-one years of age, and who were seeking reproductive health services at Southwest Family Planning. They may not be representative of all sexually active women. 2. Since this study was conducted in a rural setting in southwest Wisconsin, similar results may not be obtained in other settings that are more urban.

Delimitations

1. In order to focus this study on factors that are not obvious indicators of the need for *Chlamydia* testing, I did not look at clients who have partners with known *Chlamydia* infections, clients who are pregnant, or clients who had symptoms of a pelvic inflammatory disease. 2. This researcher did not evaluate cervical/vaginal discharge on all clients for the presence of white blood cells or organisms such as trichomonas, yeast, or bacterial vaginosis unless symptoms were present that suggested a vaginitis. 3. This study was delimited to sexually active women between the ages of fourteen and forty-one years of age who were seeking reproductive health services from Southwest Family Planning

in Southwestern Wisconsin. They may not be representative of all sexually active women.

Definition of Terms

The following is a list of definitions to facilitate the reader having a clearer understanding of how these terms were used in this research.

Breakthrough bleeding. The vaginal bleeding that occurs with oral contraceptive use while taking the active pills consistently and correctly.

Conjunctivitis. An inflammation of the membrane that lines the eyelids and covers the exposed surface of the eyeball.

Dysparunia. Pain with sexual intercourse.

Dysuria. Pain with urination.

Ectopy. The exposure of endocervical (columnar) cells on the surface of the cervix that can be visualized with speculum examination.

Endometritis. An inflammation of the lining of the uterus.

Epididymitis. An inflammation of the epididymis (an elongated mass at the back of the testis).

Friable cervix. The active bleeding that occurs with the routine swabbing of the cervix.

Muco-purulent discharge. A yellow or grey discharge present after swabbing the vagina or endocervical canal.

Peri-hepatitis. An inflammation of the peritoneal capsule of the liver and of the tissues around the liver.

Proctitis. An inflammation of the rectum.

Salpingitis. The inflammation of a salpinx (fallopian tube).

Urethritis. An inflammation of the urethra of either the male or female.

CHAPTER 2
REVIEW OF LITERATURE

This chapter provides information on the *Chlamydia* organism and its epidemiology, suspected indicators of *Chlamydia* infection, and the diagnostic tests used to determine the presence of *Chlamydia* in the female reproductive tract.

The Disease: *Chlamydia trachomatis*

The organism responsible for the disease, *Chlamydia trachomatis*, is an obligate intracellular bacterium. This means it can only live within cells and, in humans, typically inhabits columnar and pseudostratified columnar epithelium (Thompson & Washington, 1983). The organism basically exists in two forms: the elementary body and the reticulate body. The elementary body is the infectious particle that is metabolically inactive. It attaches to the cell membrane and is phagocytized into the cell. After about twelve hours, the elementary body reorganizes into the metabolically active form known as the reticulate body. The reticulate body undergoes binary fission many times and the resultant multitude of cells revert to elementary bodies. The host cell then undergoes lysis (cell rupture) which releases new infectious particles. The life cycle is complete in approximately forty-eight hours (Pruessner, Hansel and Griffiths, 1986).

Epidemiology of *Chlamydia trachomatis*

Chlamydia trachomatis is the most prevalent sexually transmitted disease in the adult population in the United States (Khurana, Deddish & delMundo, 1984). Shafer et al. (1984) has estimated the rate at four to eight percent in asymptomatic women and over twenty percent in women with lower genital tract infections. It has been estimated that three to four million Americans suffer from an infection caused by *Chlamydia* each year (Center for Disease Control, 1985). In Wisconsin there were 10,194 cases of *Chlamydia* reported in 1986 which was a 101% increase from 1985 (Katcher, Addiss, & Vaughn, 1986). Recent research done in a metropolitan area of Southeastern Wisconsin reported a 12.4% prevalence of *Chlamydia* (Addiss et al., 1986). *Chlamydia trachomatis* is considered to be at epidemic proportions by most sexually transmitted disease surveillance officers, and is of great epidemiologic concern.

Complications associated with *Chlamydia*

This research will only focus on the indicators and testing of women for *Chlamydia*, but there are also implications for men and infants with the disease. A male who has acquired *Chlamydia* will probably have milder symptoms of urethritis (burning and discharge from the penis) than if he had gonorrhoea. That may lead to a delay in seeking treatment. Before the *Chlamydia* organism was identified, men who presented with symptoms of gonorrhoea but did not have it were treated for non-gonococcal urethritis. Thirty-five to fifty percent of men who were diagnosed with non-gonococcal urethritis are thought to have had *Chlamydia* (Thompson &

Washington, 1983). Three percent of non-gonococcal urethritis progresses into epididymitis which could lead to sterility (Thompson & Washington, 1983). In addition to non-gonococcal urethritis and epididymitis, *Chlamydia* has also been implicated in post-gonococcal urethritis and proctitis in men.

For infants passing through a birth canal infected with *Chlamydia*, conjunctivitis and pneumonia are common sequelae. Thirty-five to fifty percent of infants with infected mothers will develop neonatal conjunctivitis within one to three weeks of birth. Ten to twenty percent will develop pneumonia within one to four months (Pruessner et al., 1986). Even though the majority of infant conjunctivitis resolves without permanent damage, corneal scarring can occur (Heller, 1984).

Asymptomatic women represent an important reservoir for the pathogen since they remain infected without seeking medical treatment (Harrison et al., 1985). It is believed that the vast majority of women have no noticeable symptoms which would prompt them to seek medical treatment until complications developed.

For women, cervicitis, urethritis, salpingitis, peri-hepatitis, endometritis, and pregnancy complications have been reported to be associated with the presence of *Chlamydia*. The complication of salpingitis is a very serious one. The infection of the salpinx (fallopian tube) results from either surface spread, invasion through the lymphatics, or via sperm (Friberg, Gleicher, Suarez & Confino, 1985). Twenty percent of cases of acute salpingitis are thought to be caused by the *Chlamydia* organism. In ten percent of salpingitis cases, unilateral or bilateral tubal closure will result (Thompson &

Washington, 1983). This damage to the fallopian tube with resultant infertility and/or ectopic pregnancy represents a major health problem. Peri-hepatitis (Curtis-FitzHugh Syndrome), which is secondary to salpingitis, is also associated with *Chlamydia* (Clair & Curtis, 1983). Without proper diagnosis a woman could have months or years of upper abdominal pain, an unnecessary discomfort which could be remedied with proper treatment.

Recent research has also shown an association between pregnancy complications and *Chlamydia*. Gravett et al., (1986) has shown an association between pre-term labor, premature rupture of membranes, and low birth weight with the presence of *Chlamydia*.

Indicators of *Chlamydia trachomatis*

The indicators that have been reported in the literature fall into three categories. These categories are demographic, clinical and behavioral.

Demographic

It has been generally agreed upon that *Chlamydia* is a disease of the young sexually active person. Research done with two family planning programs in a rural area of Southeastern Wisconsin reported a strong association between twenty years of age or younger and the presence of *Chlamydia* (Addiss, Vaughn, Davis, Holzhueter & Bakken, 1985). In a study done on university women in Tucson, Harrison & Washington (1985) reported a significant association between twenty-three years of age and under and the presence of *Chlamydia*. A study done in family planning

clinics in the Seattle area revealed a strong association between twenty-four years of age or younger and the presence of the *Chlamydia* organism (Handsfield et al., 1985).

The prevalence of *Chlamydia* in certain ethnic populations has not been demonstrated. Studies have shown that there does not seem to be any difference in the rates of *Chlamydia* between white and non-white populations (Handsfield et al., 1985). The only exception to that was a study done with adolescents in San Francisco where the Black population had a significantly higher rate of *Chlamydia* than the white population. The researchers could not account for the difference (Shafer et al., 1984). Marital status has been reported in a number of studies and has not been significantly related to the presence of *Chlamydia* (Addiss et al., 1985; Handsfield et al., 1985).

Clinical

Addiss et al., (1985) reported in his recent research that a woman with *Chlamydia* was five times more likely to have inflammatory cells on her Papanicolaou smear than a woman without *Chlamydia*. Other studies have also shown an association between inflammatory cells and the presence of *Chlamydia* (Shafer et al., 1984, 1985). It has been cautioned, however, that the Papanicolaou smear results should not be used as a diagnostic tool but rather as a possible indicator of the presence of *Chlamydia*.

The presence of muco-purulent cervical discharge has been strongly associated with *Chlamydia* infection (Addiss et al., 1985; Handsfield et al., 1985). Friability, described as the marked bleeding from the

cervical opening after swabbing, has also been positively correlated (Chacko & Lovchik, 1983). Friability associated with *Chlamydia* infection has also been substantiated by Addiss et al., (1985) and Handsfield et al., (1985) in their recent research. Harrison et al., (1983) in their study of university women in Tucson, calculated a "cervicitis" score giving one point each for any degree of erythema, ectopy, discharge, or friability of the cervix. One extra point was given if the discharge was thick and another if it was yellow or green in color. If one to four polymorphonuclear leukocytes were present in the vaginal discharge microscopically, another point was added. Two points were given if there were five or more leukocytes seen. A cervicitis score of four or above was significantly associated with the presence of *Chlamydia*.

Ectopy has also been reported in the literature as being highly correlated to *Chlamydia* infection (Chacko & Lovchik, 1984; Thompson & Washington, 1983). The generally agreed upon theory as to why ectopy is associated with *Chlamydia* is that the organism primarily inhabits columnar epithelial cells so that the greater the exposure of those cells to the organism, the greater the chance of becoming infected (Chacko & Lovchik, 1984). It is also thought that the greater the degree of ectopy, the easier it is to retrieve the organism upon testing (Washington et al., 1985).

The presence of five or more white blood cells per high-power microscopic field on a saline wet mount preparation of vaginal and/or cervical secretions has also been reported as significant (Harrison et al., 1985; Shafer et al., 1984). Since wet mount preparations are not a routine part of a gynecological examination, this indicator would be

limited to women presenting with lower genital tract complaints where a wet mount would be indicated. It could also assist in making a presumptive diagnosis of *Chlamydia* when treatment is necessary before test results return.

There has been limited research that has explored the role of pain as an indicator for *Chlamydia*. Addiss et al., (1985) did not find a correlation between abdominal pain, pelvic pain, dysuria, or dysparunia and the presence of *Chlamydia*. The reporting, however, was limited to one week prior to the clinic appointment. For those who had intermittent pain or who had not had intercourse in the week prior to the appointment, that information could be missed. Menstrual cramping that has recent onset may also be of significance but has not been examined closely.

Abnormal bleeding patterns such as intermenstrual bleeding, breakthrough bleeding while on oral contraceptives, and post-coital bleeding have had limited attention in the research. This researcher believes they deserve further attention.

Behavioral

A number of patterns of sexual behavior have been looked at as a determinant of increased risk of *Chlamydia* infection. Current multiple partners was reported as highly significant in a population of urban Baltimore adolescents (Chacko & Lovchik, 1984). That finding was corroborated by both Handsfield et al., (1985) and Addiss et al., (1985). A new partner in the last two or three months has also been shown to be significant (Handsfield et al., 1985). A partner who has

more than one sexual partner is significantly associated with an increase in *Chlamydia* infection (Addiss et al., 1985). Having a partner with urethritis symptoms has been reported to also be strongly associated (Addiss et al., 1985; Chacko & Lovchik, 1984). Age at first intercourse and increased years of sexual activity was found to be a significant factor by Shafer et al., (1984). Harrison et al., (1985) found an association between four years or less of intercourse and the presence of *Chlamydia*. Handsfield et al., (1985) found no association between *Chlamydia* and age at first intercourse. A past history of a sexually transmitted disease was not found to be correlated (Chacko & Lovchik, 1984), however, Harrison et al., (1985) did find a significance between the presence of *Chlamydia* and a past history of gonorrhea.

The association in the literature between oral contraceptive use and *Chlamydia* infection is striking. Twelve out of fourteen epidemiologic studies done between 1974 and 1984 demonstrated a high positive correlation (Washington et al., 1985). In several studies recently, however, oral contraceptives were not found to be associated with the presence of *Chlamydia* (Chacko & Lovchik, 1984; Handsfield et al., 1985). The generally agreed upon explanation as to why oral contraceptives appear to correlate with the presence of *Chlamydia* is that oral contraceptives induce ectopy, which is associated with a *Chlamydia* infection.

Diagnostic tests

There have been a number of studies that have been done to try to determine whether the Papanicolaou smear results can predict the

presence of *Chlamydia*. Shafer et al., (1984) reported that inflammatory changes on the Papanicolaou smear were found to be associated with infection. Even though dysplasia has been linked with *Chlamydia* in some studies, Schachter et al., (1975) found no association in his study. Addiss et al. (1985) noted a five fold increase in inflammatory cells on Papanicolaou smear with women who had *Chlamydia* versus those who did not. Another study done by Shafer et al., (1984) revealed that Papanicolaou smear testing was not a useful tool in making a definitive diagnosis, but the presence of inflammatory cells indicated an increased risk and need for further testing.

There are three tests that have been used to identify the presence of *Chlamydia*. The *Chlamydia* culture test, which is considered to be the "standard" culture test, requires stringent transport protocol, is time consuming for the laboratory, and has not been readily available (Quinn, Warfield, Kappus, Barbacci, & Spence, 1985). Also, the results take about four days to obtain, which delays treatment. The sensitivity and specificity of the culture are not known because no independent standard exists against which to measure it (Chernesky et al., 1986). It is generally agreed that the sensitivity is less than 100%, which means that the culture may not always indicate the presence of existing infection. The specificity, however, is believed to be almost always 100%, which means the culture will not indicate an infection when one is not present.

Two new tests have come on the market in the last three years that make screening for *Chlamydia* much more feasible. One of the new tests, Chlamydiazyme[™], (Abbott Laboratories, N. Chicago, Illinois) uses a

special solution to break down cell walls of epithelial cells and employs antibodies that detect antigens on the surface of the exposed *Chlamydia* organisms (Wingerson, 1983). It does not require special handling and laboratory results can be obtained in about three hours. The other new test, Microtraktm, (Syva Company, Palo Alto, California) detects the organism with a flourescein-labeled monoclonal antibody. It takes thirty minutes for the slide to be read under a special microscope. The sensitivty and specificity of this test has been reported to be 77%-90% and 95%-97%, respectively, depending on the prevalence of *Chlamydia* in the population being studied and the culture technique employed (Addiss et al., 1986) (Tam et al., 1984).

For this study, the Microtraktm *Chlamydia* direct test was selected because of the availability, lack of transport requirements, cost, and accuracy.

CHAPTER 3
METHODOLOGY

This research is a descriptive study designed to identify behavioral, demographic, and clinical characteristics of women that are associated with *Chlamydia trachomatis* infection.

Subjects

The population chosen were women attending the Southwest Family Planning program located in Platteville, Wisconsin. These are women aged 11 through 67 who primarily live in Grant, Iowa, and Lafayette Counties in Wisconsin. One-third of them are teenagers, and the majority of them are of the white race.

The selection of the sample was done by screening every consenting sexually active woman who met the criteria and attended the clinic from November 11, 1986 through April 9, 1987. The sample consisted of white women aged 14 through 41 years of age. There were 58 high school students, 23 vocational school students, 19 college students and 187 non-students.

Instrumentation

The tool used to acquire the data on *Chlamydia trachomatis* was an interview questionnaire designed and used by the researcher. All demographic, behavioral and clinical interview questions were completed by the researcher prior to the physical examination. The clinical

assessment responses were completed by the researcher after completing the physical assessment and pelvic examination. The necessary samples for testing of *Chlamydia*, gonorrhea, and cervical cell changes (Papanicolaou smear) were acquired at that time. See Appendix A for a copy of the instrument.

Equipment

The *Chlamydia* test that was used was the Microtraktm direct test by Syva Corporation. The gonorrhea culture medium was Martin Lewis Agar plates supplied by Gibco Laboratories.

Procedures

This researcher (Obstetrical/Gynecological Nurse Practitioner) received special training by the Wisconsin State Laboratory of Hygiene in conjunction with the Division of Health regarding the optimal collection of samples for *Chlamydia*, gonorrhea, and conducting Papanicolaou smears.

After the research proposal was presented to the "Use of Human Subjects" board and approved, the collection of data began.

The researcher interviewed each client by reviewing the self-reporting medical history and/or discussing the presenting complaint. A determination was then made if the client was a candidate for the study. Clients who had not had sexual intercourse in the last 2 years or had used antibiotic therapy in the last 4 weeks were not asked to participate. They were, however, offered a *Chlamydia* test. The researcher then explained the *Chlamydia* research project to the client

and asked her to participate. If the client declined to participate she was offered a *Chlamydia* test. If the client consented to participate, the researcher read the Informed Consent form to her (see Appendix B) and obtained her signature. The researcher then conducted the interview questionnaire recording all client responses regarding demographic, behavioral and clinical information (see Appendix A). As a visual aid, the client was provided with a three by five card which had all possible responses from the questionnaire.

To determine the reliability of the questions in the behavioral and symptom section, each question was asked before and after the examination a total of thirty times. Of the 16 self-reported questions on the instrument, only 3 questions were not responded to identically in all 30 clients. There were at least 28 out of 30 responses to each question that were identical. The researcher determined that the questions were stable and proceeded to collect information before the exam, and only asked clients after the exam if they cared to change any of their responses. No client changed her response.

With the completion of the interview, a physical examination was performed which included a complete pelvic assessment. All clinical assessment information was recorded.

A score for friability of the cervix was pre-determined by the researcher using the following method:

- 0 No bleeding
- +1 Blood on endocervical swab
- +2 Oozing of blood from cervix
- +3 Free flow of blood from cervix
- +4 Free flow of blood from cervix with
 difficulty stopping after applying
 pressure with large swab.

The determination of color of vaginal and endocervical discharge was done by observing the color of the white swab after insertion into the vagina or cervix. The first swab of the vagina was used to determine the color of vaginal discharge, the first endocervical swab was used to determine endocervical discharge.

The specimen collection consisted of cleaning the ectocervix with a large swab to remove excess secretions. A sterile cotton-tipped applicator was then introduced into the endocervix to obtain a specimen for Papanicolaou smear. An ectocervical specimen was also obtained with a wooden scraper and plated on the same slide and sprayed with a fixative. A second endocervical swab was collected for gonorrhea which was plated out on a Martin Lewis Agar plate. A third endocervical specimen was then obtained for *Chlamydia* by introducing a dacron-tipped swab into the cervical opening, rotating and removing it after 15-20 seconds. The swab was then rotated onto the well of the Microtraktm slide and left to dry for fifteen to thirty minutes. The slide was then fixed with acetone and allowed to air dry before refrigeration. The

tests were then transported in styrofoam containers to the Wisconsin State Laboratory of Hygiene within twenty-four hours of collection via the United States Postal system. All results were obtained from the State Laboratory within two weeks.

Data Collection and Analysis

The data sheet was completed by the researcher except for the test results and placed in the front of the client folder. As the test results returned and were recorded on the client folder and data sheet, the data sheet was then returned to the researcher for analysis.

The data was collected between November 11, 1987 through April 9, 1987 with a minimum of thirty positive *Chlamydia* tests anticipated.

Upon examining the hypotheses, the following statistics were chosen.

The independent t-test was chosen for Hypotheses 1, 3, 6 through 9, and 26 because the dependent variable was interval/ratio in nature and the independent variable was dichotomous. The Mann-Whitney U test was chosen for Hypotheses 10 through 21, and 24 because the dependent variable was ordinal and the independent variable was dichotomous. The Chi-square test was chosen for Hypotheses 2, 4, 5, 22 through 23, and 25 because the independent and dependent variables were nominal in nature.

If statistical significance was found, appropriate measurements for the strength of the relationship was calculated (i.e., phi, eta squared, Glass rank biserial correlation coefficient).

For multivariate statistical analysis, a stepwise regression analysis was chosen. This analysis was chosen to be consistent with research done in the past. The variables were either dichotomous or interval/ratio in nature.

CHAPTER 4

RESULTS

Univariate and multivariate statistical analysis was used to identify demographic, behavioral, and clinical indicators associated with the presence of *Chlamydia trachomatis*.

Descriptive Statistics

Prevalence rates

Of the 287 women in this study, 41 of them had a positive test for *Chlamydia*. The prevalence rate was 14.28%, which is within the range reported by other Family Planning Programs in the United States. It is higher, however, than two studies done in Wisconsin which reported a prevalence rate of 10.7% in a rural area in Southeastern Wisconsin and a 12.4% prevalence rate in a Milwaukee study. It is possible that since *Chlamydia* tests were not available in this area until the last few years that we have a higher "pool" of *Chlamydia* that is just beginning to be identified.

The prevalence rate for clients from Grant County was 15% (30/200), Iowa County was 21.8% (7/32) and Lafayette County was 9% (4/44). There were 11 clients from outside the 3 Counties and none of them had a positive test result. There appears to be an increased prevalence of *Chlamydia* in Iowa County. Three of the seven cases, however, were high school students who had the same sexual partner later identified as

having a positive test result. Lafayette County appears to have a much lower prevalence rate.

Of the high school students who were tested, 15.5% (9/58) had a positive test result. Vocational school students had a 17.4% (4/23) rate and college students had a 21% (4/19) prevalence rate for *Chlamydia*. There were 187 non-students, 24 of whom had a positive test result (12.8%). Since the numbers for each group were relatively small, it is important to be cautious when making generalizations about the differences in each group.

A gonorrhea culture was performed on everyone who had a *Chlamydia* test. There was one positive gonorrhea test which was not a client with a positive *Chlamydia* test result.

Age

The age range for the sample of women in the study was 14-41 years. The mean age for women without *Chlamydia* was 21.7. The mean age for women with *Chlamydia* was 20 with an age range of 16-25.

Birth Control

Of the 287 women in the study, 191 (71%) reported using oral contraceptives as their method of birth control. Barrier methods (condoms, sponge, spermicides, diaphragm) were reported by 47 (17.5%) of the women, 1 (.4%) reported the use of the IUD and 30 (11.2%) reported no method of birth control.

Sexual Partners

The number of sexual partners reported in the previous three months ranged from 0 to 8; the mean and standard deviation were (\bar{x} =1.56; s.d.=1.32) for the *Chlamydia* positive group and (\bar{x} =1.08; s.d.=0.57) for the *Chlamydia* negative group.

The number of new sexual partners reported in the previous three months ranged from 0 to 5; the mean and standard deviation were (\bar{x} =0.58; s.d.=1.18) for the *Chlamydia* positive group, and (\bar{x} = 0.20; s.d.=0.46) for the *Chlamydia* negative group.

The number of partners reported with multiple partners in the previous three months ranged from 0 to 7; the mean and standard deviation were (\bar{x} = 0.75; s.d.=1.39) for the *Chlamydia* positive group and (\bar{x} = 0.15; s.d.=0.58) for the *Chlamydia* negative group.

The number of partners reported in the last three months who had symptoms of urethritis ranged from 0 to 1; the mean and standard deviation were (\bar{x} =0.048; s.d.=0.21) for the *Chlamydia* positive group, and (\bar{x} =0.01; s.d.=0.12) for the *Chlamydia* negative group.

Inferential Statistics

Each hypothesis is stated in null form below and the results of the statistical analysis are reported.

Hypothesis 1

Hypothesis 1 states: There is no significant relationship between the age of the client and the presence or absence of a *Chlamydia* infection.

A t-test was performed comparing the mean age of the two groups: *Chlamydia* positive group and *Chlamydia* negative group. The test results were statistically significant ($t=-2.57$, $df=74.78$, $p=0.012$), indicating the mean age of women with a positive *Chlamydia* test was lower than the mean age of women with a negative test result. The strength of the relationship as indexed by eta squared was .08. The null hypothesis was rejected.

Hypothesis 2

Hypothesis 2 states: There is no significant relationship between the type of birth control used and the presence or absence of a *Chlamydia* infection.

Table 1
The relationship between birth control methods and
Chlamydia test results.

Test results	Birth Control Methods		
	Oral Contraceptives	Barrier Methods	No Method
<i>Chlamydia</i> (+)	34	4	3
Column %	16.7%	8.0%	9.1%
Residual	4.9	-3.2	-1.7
<i>Chlamydia</i> (-)	169	46	30
Column %	83.3%	92.0%	90.9%
Residual	-4.9	3.2	1.7

Table 1 reflects the birth control methods used by Group 1 (positive test result) and Group 2 (negative test result). It does appear from

table 1 that there is an excess of oral contraceptive users in the group with the positive test result and an excess of barrier method users in the group with a negative test result. However, a chi-square test of independence was performed on the relationship between the type of birth control used and the presence or absence of *Chlamydia*, and it was not statistically significant ($\chi^2=3.33606$, $df=2$, $p=.1886$) indicating there was no significant difference in the two groups in regard to birth control method. The author failed to reject the null hypothesis.

Hypothesis 3

Hypothesis 3 states: There is no significant relationship between the length of time on oral contraceptives and the presence or absence of a *Chlamydia* infection.

Table 2 reflects the results of the difference between the *Chlamydia* positive group and the *Chlamydia* negative group with regard to the length of time on oral contraceptives.

Table 2

The relationship between the length of time on oral contraceptives and *Chlamydia* test results.

<u>Test Result</u>	<u>Length of time on Oral contraceptives</u>					
	<u>Number of cases</u>	<u>mean</u>	<u>S.D</u>	<u>t value</u>	<u>df</u>	<u>p</u>
<i>Chlamydia</i> (+)	41	24.9	16.7			
<i>Chlamydia</i> (-)	169	32.25	1.98	-2.10	69	0.04

A t-test was performed comparing the mean length of time on oral contraceptives for the group with a positive test result and the group with a negative test result. The t-test showed statistical significance ($t=2.10$, $df=69.18$, $p=.040$), indicating that the length of time on oral contraceptives was lower for the group with a positive test result than for the group with the negative test result. The strength of the relationship as indexed by eta squared was .09. The null hypothesis was rejected.

Possibly one of the reasons why a shorter length of time on oral contraceptives was significantly related to a positive test result was because of the younger age of the clients with *Chlamydia*. If the client is younger, she has probably been on orals for a shorter length of time, and, since those with *Chlamydia* infections were younger, they were more likely to be on oral contraceptives for a shorter length of time.

Hypothesis 4

Hypothesis 4 states: There is no significant relationship between a previously reported abnormal Papanicolaou smear and the presence or absence of a *Chlamydia* infection.

There were 247 women who had previously had a Papanicolaou smear. Of those women, 21 reported an abnormal finding. Only two of them had a current positive *Chlamydia* test.

A chi-square test of independence was performed to determine if there was a relationship between a previous abnormal Papanicolaou smear and the presence of *Chlamydia*. The chi-square was not statistically

significant, ($\chi^2 = 0.47031$, $df=1$, $p=0.4928$) indicating there was no difference in the two groups regarding the report of a previous abnormal Papanicolaou smear. The author failed to reject the null hypothesis.

Hypothesis 5

Hypothesis 5 states: There is no significant relationship between previously reported inflammatory cells on a Papanicolaou smear and the presence or absence of a *Chlamydia* infection.

Of the 247 women who reported a previous Papanicolaou smear, 33 reported previous inflammatory cells on the Papanicolaou smear. Of those, 7 had a current positive *Chlamydia* test. A chi-square test of independence was performed to determine if there was a relationship between previously reported inflammatory cells on Papanicolaou smear and a positive *Chlamydia* test. The chi-square test was not statistically significant ($\chi^2 = 1.29267$, $df=1$, $p=0.2556$), indicating there was no significant difference between the two groups regarding the report of previous inflammatory cells on Papanicolaou smear. The author failed to reject the null hypothesis.

Discussion of Hypotheses 4 and 5

In determining whether a previous abnormal Papanicolaou smear or inflammatory cells on Papanicolaou smear existed, the researcher checked the client record first. If there were no previous Papanicolaou results recorded, the client was asked to recall if she ever had inflammatory cells or any other abnormality on a Papanicolaou smear. All previous abnormal results were recorded regardless of how much time had passed.

Table 3
The relationship between sexual behaviors and
Chlamydia test results.

Behavior Test results	Mean	S.D	t value	df	p value
<u>Number of sex partners</u>					
<i>Chlamydia(+)</i>	1.56	1.324	2.25	42.52	0.03
<i>Chlamydia(-)</i>	1.08	0.036			
<u>Number of new partners</u>					
<i>Chlamydia(+)</i>	0.58	1.183	2.04	42.12	0.04
<i>Chlamydia(-)</i>	0.20	0.469			
<u>Number of partners with partners</u>					
<i>Chlamydia(+)</i>	0.75	1.392	2.75	42.37	0.00
<i>Chlamydia(-)</i>	0.15	0.584			
<u>Number of partners with symptoms</u>					
<i>Chlamydia(+)</i>	0.04	0.218	0.93	44.61	0.35
<i>Chlamydia(-)</i>	0.01	0.127			

Since most clinicians don't inform clients when inflammatory cells are reported on the Papanicolaou smear, it is probable that the amount of inflammatory cells on previous Papanicolaou smear were under-recorded from self-reported data. Clients may not have been accurate in recalling abnormal Papanicolaou smear results either. If only verified

Papanicolaou smear results were recorded for the last six months, the results may have been different.

Hypothesis 6

Hypothesis 6 states: There is no significant association between the number of sexual partners in the last three months and the presence or absence of a *Chlamydia* infection.

As reflected in Table 3, the mean number of sexual partners for the *Chlamydia* positive group was 1.56; the mean for the *Chlamydia* negative group was 1.08. A t-test was performed comparing the mean number of sexual partners for Group 1 and 2; the t-test was statistically significant ($t=2.25$, $df=42.52$, $p=0.03$). This indicates that Group 1, who had a positive test result, had a higher number of sexual partners than Group 2, who had a negative test result. The strength of the relationship, as indexed by eta squared, was .10. The null hypothesis was rejected that there is no significant difference between the number of sexual partners and the presence or absence of *Chlamydia*.

Hypothesis 7

Hypothesis 7 states: There is no significant relationship between the report of a new partner in the last three months and the presence or absence of a *Chlamydia* infection.

As reflected in Table 3, the mean number of new partners reported by the *Chlamydia* positive group was 0.58; the *Chlamydia* negative group had a mean number of new partners equal to 0.20. A t-test was performed comparing the mean number of new partners for both groups; the t-test result was statistically significant ($t=2.04$, $df=42.12$, $p=0.047$),

indicating that the group with a positive test result had a significantly higher number of new sexual partners than the group with negative test results. The strength of the relationship as indexed by eta squared was .08. The null hypothesis was rejected.

Hypothesis 8

Hypothesis 8 states: There is no significant difference between the report of a partner(s) with multiple partners in the last three months and the presence or absence of a *Chlamydia* infection.

As reflected in Table 3, the mean number of partners with multiple partners for the *Chlamydia* positive group was 0.75 compared to the *Chlamydia* negative group with a mean of 0.15. A t-test was performed to compare the mean number of partners with multiple partners of each group; the t-test result was statistically significant ($t=2.75$, $df=42.37$, $p=0.009$). This indicates that the group with *Chlamydia* had a significantly higher number of partners with multiple partners than the group without *Chlamydia*. The strength of the relationship as indexed by eta squared was .15. The null hypothesis was rejected.

Hypothesis 9

Hypothesis 9 states: There is no significant difference between the report of a partner(s) in the last three months with symptoms of urethritis and the presence or absence of a *Chlamydia* infection.

As reflected in Table 3, the mean number of partners for the *Chlamydia* positive group was 0.04 compared to the *Chlamydia* negative group with a mean of 0.01. A t-test was performed to compare the mean number of partners with symptoms for the two groups. The t-test result

was not statistically significant ($t=.93$, $df=44.61$, $p=0.35$) indicating the mean number of partners with symptoms of urethritis was not significantly different for the two groups. The author failed to reject the null hypothesis.

Discussion of Hypotheses 6 through 9

Of the four partner-related potential indicators for *Chlamydia*, the number of partner(s) with symptoms was the only one not significantly associated with the presence of *Chlamydia*. Since many males are asymptomatic, have sporadic urethritis symptoms, and may be reluctant to tell a partner that they have symptoms, it is not surprising that no significance was found. Since it is estimated that 30-50% of urethritis in men is caused by *Chlamydia*, it is essential that a female who reports having a partner with urethritis symptoms be tested for *Chlamydia*.

It is not surprising that the three other partner-related indicators were found statistically associated with *Chlamydia*. It would seem logical that the more partners one has, the more partners one has with multiple partners, and the more recent partners one has (assuming the partner(s) has been sexually active with others), the more chance one has of becoming exposed to a sexually transmitted disease.

Hypothesis 10

Hypothesis 10 states: There is no significant difference between the report of increased frequency of menstrual cramps in the last three months and the presence or absence of a *Chlamydia* infection.

As reflected in Table 4, the mean rank for the *Chlamydia* positive group was 107.08; the mean rank of the *Chlamydia* negative group, was

107.57. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=41) and Group 2 (n=246). The difference in ranks was not statistically significant (U=2823.5, p=.95) indicating that there was no significant difference between the two groups in regard to the report of increased menstrual cramps. The author failed to reject the null hypothesis.

Hypothesis 11

Hypothesis 11 states: There is no significant relationship between the reported increase in menstrual flow in the last three months and the presence or absence of a *Chlamydia* infection.

As reflected in Table 4, the mean rank for the *Chlamydia* positive group was 147.84; the mean rank of the *Chlamydia* negative group, was 141.60. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=41) and Group 2 (n=246). The difference in ranks was not statistically significant (U=4762.5, p=0.51) indicating there was no significant difference between the two groups in regard to the report of increased menstrual flow. The author failed to reject the null hypothesis.

Hypothesis 12

Hypothesis 12 states: There is no significant relationship between the occurrence of bleeding between menstrual periods in the last three months and the presence or absence of a *Chlamydia* infection.

As reflected by Table Four, the mean rank for the *Chlamydia* positive group was 138.43; the mean rank of the *Chlamydia* negative group was 144.93. A Mann-Whitney U test was applied to the ranked data for Group 1

(n=41) and Group 2 (n=246). The difference in the ranks was not statistically significant (U=4814.5, p=0.44) indicating there was no significant difference between the two groups in regard to the report of bleeding between menstrual periods. The author failed to reject the null hypothesis.

Table Four
Summary of results of Genito-Urinary symptoms I

Symptom		Mann-Whitney	
Test result	Mean Rank	U	p value
<u>Menstrual cramps</u>		2823.5	0.95
<i>Chlamydia</i> (+)	107.08		
<i>Chlamydia</i> (-)	107.57		
<u>Menstrual flow</u>		4762.5	0.51
<i>Chlamydia</i> (+)	147.84		
<i>Chlamydia</i> (-)	141.60		
<u>Bleeding between menses</u>		4814.5	0.44
<i>Chlamydia</i> (+)	138.43		
<i>Chlamydia</i> (-)	144.93		
<u>Bleeding with intercourse</u>		3738.0	0.00
<i>Chlamydia</i> (+)	147.67		
<i>Chlamydia</i> (-)	133.04		
<u>Pain intercourse</u>		4148.0	0.00
<i>Chlamydia</i> (+)	165.83		
<i>Chlamydia</i> (-)	140.36		

Hypothesis 13

Hypothesis 13 states: There is no significant relationship between the reported occurrence of bleeding with intercourse in the last three months and the presence or absence of a *Chlamydia* infection.

Bleeding with intercourse can occur because of a vaginitis due to trichomonas, yeast, or bacterial vaginosis. For this hypothesis, all confirmed cases of vaginitis were eliminated from this analysis. As reflected in Table 4, the mean rank for the *Chlamydia* positive group was 147.67; the mean rank for the *Chlamydia* negative group was 133.04. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=36) and Group 2 (n=233). The difference in ranks was statistically significant (U=3738, p=0.0033) indicating that there is a significant relationship between the report of bleeding with intercourse and the presence of *Chlamydia*. The strength of the relationship as measured by the Glass rank biserial correlation coefficient was .11. The null hypothesis was rejected.

Hypothesis 14

Hypothesis 14 states: There is no significant relationship between the reported occurrence of pain with intercourse in the last three months and the presence or absence of a *Chlamydia* infection.

Pain with intercourse can be caused by vaginitis, therefore all confirmed cases of vaginitis were eliminated from this analysis. As reflected by Table 4, the mean rank for the *Chlamydia* positive group was 154.93; the mean rank of the *Chlamydia* negative group was 131.92. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=36)

and Group 2 (n=233). The difference in ranks was statistically significant ($U=3476.5$, $p=0.0042$) indicating that there was a positive relationship between the report of pain with intercourse and the presence of a *Chlamydia* infection. The strength of the relationship as measured by the Glass rank biserial correlation coefficient was .17. The null hypothesis was rejected.

The following symptoms addressed in the next six hypotheses could develop as a result of vaginitis. All the confirmed cases of vaginitis have been eliminated from the analysis of these hypotheses.

Hypothesis 15

Hypothesis 15 states: There is no significant relationship between the reported presence of an abnormal vaginal discharge and the presence or absence of a *Chlamydia* infection.

Of the 28 women who reported some degree of abnormal vaginal discharge, 3 of them had a positive *Chlamydia* test result. As reflected by Table 5, the mean rank for the *Chlamydia* positive group was 132.46; the mean rank of the *Chlamydia* negative group was 135.39. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=36) and Group 2 (n=233). The difference in ranks was not statistically significant ($U=4102.5$, $p=0.69$) indicating there was no difference between the two groups in regard to the report of an abnormal vaginal discharge. The author failed to reject the null hypothesis.

Table Five
Summary of Genito-Urinary symptoms II

<u>Symptom</u>	<u>Values</u>		
<u>Test result</u>	<u>Mean Rank</u>	<u>U</u>	<u>p</u>
<u>Abnormal vaginal discharge</u>		4102.5	0.6907
<i>Chlamydia</i> (+)	132.46		
<i>Chlamydia</i> (-)	135.39		
<u>Vaginal odor</u>		4156.0	0.8667
<i>Chlamydia</i> (+)	136.06		
<i>Chlamydia</i> (-)	134.84		
<u>Abdominal pain</u>		3818.0	0.1234
<i>Chlamydia</i> (+)	145.44		
<i>Chlamydia</i> (-)	133.39		
<u>Pain urination</u>		3902.0	0.0807
<i>Chlamydia</i> (+)	143.11		
<i>Chlamydia</i> (-)	133.75		
<u>Frequency of urination</u>		4093.0	0.6381
<i>Chlamydia</i> (+)	137.81		
<i>Chlamydia</i> (-)	134.57		
<u>Urgency on urination</u>		3956.5	0.9264
<i>Chlamydia</i> (+)	131.04		
<i>Chlamydia</i> (-)	131.57		

Hypothesis 16

Hypothesis 16 states: There is no significant relationship between the reported presence of an abnormal vaginal odor and the presence or absence of a *Chlamydia* infection.

Of the 27 women who reported vaginal odor, 4 of them had a positive test for *Chlamydia*. As reflected by Table 5, the mean rank for the *Chlamydia* positive group was 136.06; the mean rank for the *Chlamydia* negative group was 134.84. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=33) and Group 2 (n=233). The difference in ranks was not statistically significant (U=4156.0, p=0.8667) indicating there was no significant difference between the two groups in regard to the report of vaginal odor. The author failed to reject the null hypothesis.

Hypothesis 17

Hypothesis 17 states: There is no significant relationship between the reported presence of lower abdominal pain and the presence or absence of a *Chlamydia* infection.

Of the 32 women who reported some degree of abdominal pain, 7 of them had a positive test result. As reflected by Table 5, the mean rank for the *Chlamydia* positive group was 145.44; the mean rank for the *Chlamydia* negative group was 133.39. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=33) and Group 2 (n=233). The difference in ranks was not statistically significant (U=3818, p=0.1234) indicating there was no significant difference between the two groups in regard to the report of lower abdominal pain. The author failed to reject the null hypothesis.

Hypothesis 18

Hypothesis 18 states: There is no significant relationship between the reported presence of pain/burning on urination and the presence or

absence of a *Chlamydia* infection.

Of the 14 women who reported the presence of pain/burning on urination, 2 of them had a positive *Chlamydia* test result. As reflected in Table 5, The mean rank of the *Chlamydia* positive group was 143.11; the mean rank for the *Chlamydia* negative group was 133.75. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=36) and Group 2 ((n=233). The differences in ranks was not statistically significant (U=3902.0, p=0.0807), indicating there was no difference between the two groups in regard to the report of burning/pain on urination. The author failed to reject the null hypothesis.

Hypothesis 19

Hypothesis 19 states: There is no significant relationship between the reported increase in frequency of urination and the presence or absence of a *Chlamydia* infection.

Of the 24 women who reported some degree of frequency of urination, 4 had a positive test result. As reflected in Table 5, the mean rank of the *Chlamydia* positive group was 137.81; the mean rank of the *Chlamydia* negative group was 134.57. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=36) and Group 2 (n=233). The differences in ranks was not statistically significant (U=4093.0, p=0.6381), indicating there was no significant difference between the two groups in regard to the report of frequency of urination. The author failed to reject the null hypothesis.

Hypothesis 20

Hypothesis 20 states: There is no significant relationship between the reported presence of urgency on urination and the presence or absence of a *Chlamydia* infection.

Of the 16 women who reported some degree of urgency on urination, 2 had positive *Chlamydia* test results. As reflected in Table 5, the mean rank for the *Chlamydia* positive group was 131.04; the mean rank of the *Chlamydia* negative group was 131.57. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=35) and Group 2 (n=227). The differences in ranks were not statistically significant (U=3956.5, p=0.9264), indicating there was no significant difference between the two groups in regard to the report of urgency on urination. The author failed to reject the null hypothesis.

Discussion of Hypotheses 10 through 20

Of the previous eleven genito-urinary symptoms analyzed, only two of them were statistically significant. Pain with intercourse and bleeding with intercourse were significantly associated with the presence of a *Chlamydia* infection. Of the clients who had a positive *Chlamydia* test result and presented with symptoms that were not found to be statistically significant, only one client (with abdominal pain) had no other statistically significant indicators. Since in some health care settings it is common practice to screen all women for *Chlamydia* who present with genito-urinary symptoms, it appears that using selective screening criteria would avoid unnecessary testing.

It is not surprising that only two genito-urinary symptoms were statistically significant since most women do not have symptoms of *Chlamydia* and most research report a lack of association between genito-urinary symptoms and the presence of *Chlamydia*.

Hypothesis 21

Hypothesis 21 states: There is no significant relationship between the presence of a current abnormal Papanicolaou smear and the presence or absence of a *Chlamydia* infection.

The Papanicolaou smear results were ranked from most severe (score=5) to negative (score=1). There were 254 negative Papanicolaou smear reports and 35 were positive for *Chlamydia*. Of the 11 reports of "benign atypia", 1 was positive for *Chlamydia*. The only report of dysplasia were three "mild dysplasia" reports and none of them had a positive *Chlamydia* test. The mean rank for the *Chlamydia* positive group was 131.18; the mean rank for the *Chlamydia* negative group was 135.02. A Mann-Whitney U test was applied to the ranked data for Group 1 (n=36) and Group 2 (n=232). The differences in ranks were not statistically significant (U=4056.5, p=0.47) indicating that there was no significant difference between the two Groups in regard to Papanicolaou smear result. I failed to reject the null hypothesis.

Hypothesis 22

Hypothesis 22 states: There is no significant relationship between the presence of inflammatory cells on current Papanicolaou smear and the presence or absence of a *Chlamydia* infection.

Of the 47 women who had a report of inflammatory cells on Papanicolaou smear, 14 of them had a positive *Chlamydia* test result. Of the 216 women who had a report of no inflammatory cells on Papanicolaou smear, 20 of them had a positive *Chlamydia* test result. A chi-square test of independence was performed on the relationship between inflammatory cells on Papanicolaou smear and the presence of *Chlamydia*. The chi-square was statistically significant ($\chi^2=11.91$, $df=1$, $p=.0006$) indicating there was a positive relationship between the presence of inflammatory cells on Papanicolaou smear and the presence of *Chlamydia*. The strength of the relationship, as measured by phi, was 0.21. The null hypothesis was rejected.

Hypothesis 23

Hypothesis 23 states: There is no significant relationship between the color of vaginal discharge and the presence or absence of a *Chlamydia* infection.

All confirmed cases of vaginitis were eliminated from this analysis. Of the 29 reports of women with abnormal (yellow/grey in color) vaginal discharge, noted by the researcher, 9 of them had a positive *Chlamydia* test. Of the 240 reports of women who did not have an abnormal vaginal discharge (white/clear/none), 27 had a positive *Chlamydia* test result. A chi-square test of independence was performed on the relationship between the presence of an abnormal vaginal discharge and the presence of *Chlamydia*. The chi-square was statistically significant ($\chi=14.05$, $df=2$, $p=0.0009$) indicating that there was a positive relationship between the presence of an abnormal vaginal discharge and the presence

of *Chlamydia*. The strength of the relationship, measured by phi, was .16. The null hypothesis was rejected.

Hypothesis 24

Hypothesis 24 states: There is no significant relationship between the degree of friability of the cervix and the presence or absence of a *Chlamydia* infection.

The friability score was ranked by the researcher from 0 to +4 with a +4 identifying the most severe bleeding. The mean rank for the *Chlamydia* positive group was 170.30; the mean rank for the *Chlamydia* negative group was 139.62. A Mann-Whitney U test was applied to the ranked data for group 1 (n=41) and group 2 (n=246). The difference in ranks was statistically significant (U=3964.5, p=0.0103), indicating that there was a positive relationship between the degree of friability of the cervix and the presence of *Chlamydia*. The strength of the relationship measured by the Glass rank biserial correlation coefficient was .20. The null hypothesis was rejected.

Hypothesis 25

Hypothesis 25 states: There is no significant relationship between the color of endocervical discharge and the presence or absence of a *Chlamydia* infection.

All clients with confirmed vaginitis were eliminated from this analysis. Of the 12 cases of abnormal (yellow/grey in color) endocervical discharge recorded by this researcher, 4 of them had a positive *Chlamydia* test result. Of the 257 cases of no abnormal endocervical discharge (white/clear), 37 had a positive *Chlamydia* test

result. A chi-square test of independence was performed on the relationship between the presence of abnormal endocervical discharge and the presence of a positive *Chlamydia* test. The chi-square test was not statistically significant ($\chi^2=2.69940$, $p=0.10$) indicating there was not a significant association between the presence of abnormal endocervical discharge and the presence of *Chlamydia*. However, the chi-square test was statistically significant before Yates Correction, ($\chi^2=4.31$, $p=0.03$). The null hypothesis was rejected.

Hypothesis 26

Hypothesis 26 states: There is no significant relationship between the percent of ectopy on the cervix and the presence or absence of a *Chlamydia* infection.

The ectopy scores were recorded in the following manner: 0%-1; 1 to 20%-2; 21 to 40%-3; 41 to 60%-4; 61 to 80%-5; and 81 to 100%-5.

The mean for the *Chlamydia* positive group was 2.6341; the mean for the *Chlamydia* negative group was 2.2073. A t-test was performed comparing the means of the two groups; the t-test result was not statistically significant ($t=1.53$, $df=48.20$, $p=0.131$). This indicates the means of the two groups did not differ significantly regarding the percent of ectopy on the cervix. The author failed to reject the null hypothesis.

Discussion of Hypotheses 21 through 26

The report of an abnormal Papanicolaou smear was not statistically associated with the presence of *Chlamydia* even though the presence of inflammatory cells reported on a Papanicolaou smear was associated.

These results are consistent with much of the research reported in the literature.

The presence of abnormal vaginal discharge and friability of the cervix were associated with *Chlamydia*. These clinical findings have been highly associated with *Chlamydia* in most research studies. This researcher was not surprised that endocervical discharge was not found to be significant in this study since it was difficult to assess the endocervical discharge. The yellow/grey discharge that is characteristic of a *Chlamydia* infection is very thick and adheres to the mucous membranes. Even though the thick discharge could be seen, it was difficult to get it to adhere to the swab so that the color could be assessed.

Ectopy was not significantly associated with *Chlamydia* in this study but has been associated in previous research studies. Since ectopy is often found to be associated with oral contraceptive use and birth control method was not statistically significant in this study either, that could at least partially account for the result.

Multivariate Statistical Analysis

A stepwise multiple regression analysis was done which included 25 of the 26 variables. Birth control was not included because it was a categorical variable. All confirmed cases of vaginitis were eliminated from this analysis. Seven variables were significant (see Table Six). Three of the variables that were statistically significant on univariate analysis persisted on multivariate analysis. These variables were: 1) number of partners with multiple partners, 2) inflammatory cells on

Papanicolaou smear, and 3) friable cervix. The four variables that were not statistically significant on univariate analysis but were significant on multivariate analysis were: 1) previous abnormal Papanicolaou smear, 2) report of vaginal odor, 3) report of abdominal pain, and 4) pain with urination.

Two of these variables, previous abnormal Papanicolaou smear and vaginal odor, have a negative correlation with *Chlamydia*. One of the possible reasons a previous abnormal Papanicolaou smear would be negatively correlated to *Chlamydia* is that usually when a woman has an abnormal result, she is referred to a Gynecologist who does an assessment of the cervix. This might lead to *Chlamydia* diagnosis and treatment; therefore, a woman with a previous abnormal Papanicolaou smear would be less likely to have *Chlamydia*. It is also possible that women who are older are more likely to have an abnormal Papanicolaou smear result than younger women, and since *Chlamydia* is associated with younger age, women with an abnormal Papanicolaou smear result are less likely to have *Chlamydia*.

Vaginal odor may have been negatively correlated with *Chlamydia* because if a woman seeks help for the complaint of a vaginal odor, she probably has some other condition besides *Chlamydia*. Since vaginal odor is not associated with *Chlamydia*, she would be less likely to have *Chlamydia* than someone who did not have a vaginal odor.

Even though abdominal pain and pain on urination were not significant on univariate analysis, they were significant on multivariate analysis. This occurs when the correlation between variables causes a significance that was not seen looking at each

variable independently. The abdominal pain could be caused from a mild pelvic infection or endometritis which are known to be complications of *Chlamydia*. *Chlamydia* also can invade the female urethra causing burning on urination; this is often mistaken for a bladder infection.

The number of partners with multiple partners was the most significant variable (Table Six). Since the number of partners and number of new partners are closely related to this variable, they were probably not included in this analysis because number of partners with multiple partners already had explained the variability. This is probably true of other variables significant on univariate analysis but not on multivariate analysis such as vaginal discharge, age, bleeding with intercourse, and pain with intercourse.

Table Six
Variables in the Regression Equation

Variable	B values	Beta weights
Number of partners with multiple partners	-.148095	-.348636
Inflammatory cells	.151669	.163750
Friable	-.049183	-.127891
Previous abnormal Papanicolaou smear	-.127807	-.097826
Vaginal odor	.102956	.136961
Abdominal pain	-.061367	-.115551
Pain with urination	-.123558	-.110180
(constant)	2.114064	

As reflected in Table Six, the most significant variables, in order by weight, are: 1) number of partners with multiple partners, 2) inflammatory cells and 3) vaginal odor. The least significant variable is 7) previous abnormal Papanicolaou smear.

Table Seven
Analysis of Variance of
Final Regression Equation

Source	DF	Sum of Squares	Mean square
Regression	7	5.91734	.84533
Residual	261	25.26482	.09680

F = 8.73278 Significant F = <.0001 Adjusted R Square = .168

Table Seven shows the analysis of variance of the regression equation. The equation is highly significant ($p < .0001$), the adjusted R Square is .16804, which means that approximately 17% of the variability can be explained by the regression equation.

Discussion of Results

In this study, young age was significantly associated with the presence of *Chlamydia*. The mean age for the *Chlamydia* positive group was age 20, whereas the mean age for the *Chlamydia* negative group was age 21.7. None of the clients that had a positive test result were over 25 years of age even though the sample ranged from age 14-41. There has been a recent suggestion that immunity to the *Chlamydia* organism from

repeated exposure could at least partially account for the reason that young age is associated with the presence of *Chlamydia* (Schachter, Cles, Ray and Frank, 1983).

Even though birth control method was not significantly associated with the presence of *Chlamydia* in this study, other studies have associated the use of oral contraceptives with an increased risk and barrier methods as a protection from *Chlamydia*. It is generally believed that the association between oral contraception and the presence of *Chlamydia* is related to the cervical ectopy that is induced by oral contraceptive use. Ectopy has also been shown to be associated with the presence of *Chlamydia* in some studies but was not significantly associated in this study. Although birth control method was not found to be associated with *Chlamydia* in this study, it is important to keep in mind that spermicides and condoms have been shown to reduce the risk of acquiring sexually transmitted diseases. Clients who are participating in high risk behaviors such as having multiple sexual partners should be advised to use a barrier method of birth control to minimize their risk of developing *Chlamydia*.

The length of time on oral contraceptives was significantly associated with *Chlamydia* in this study. Clients with a positive *Chlamydia* test were on oral contraceptives for a shorter length of time than clients who had a negative test result. Since young age also is associated with a positive *Chlamydia* test result, the younger the client, the shorter the length of time she would have been on oral contraceptives.

The behavioral indicators that were significantly associated with the presence of *Chlamydia* were 1) more than one sexual partner in the last three months, 2) a new partner in the last three months, and 3) a partner with multiple partners in the last three months. Partners with multiple partners also remained statistically significant in multivariate analysis. A partner with symptoms was not found significantly associated with *Chlamydia* in this study, but 30-50% of urethritis in males is attributed to *Chlamydia*, so it is imperative that clients with partners who have urethritis symptoms be tested for *Chlamydia*. Since most female clients do not manifest symptoms, an accurate sexually history is essential.

Of the genito-urinary symptoms analyzed in this study, only pain with intercourse and bleeding with intercourse were significantly associated with the presence of *Chlamydia* on univariate analysis. All but one of the clients who had a positive test result and had pain and/or bleeding with intercourse also had indications of a cervicitis (abnormal discharge and/or friability). It is probable that the pain and/or bleeding with intercourse is associated with the presence of a cervicitis which is also associated with the presence of *Chlamydia*.

Abdominal pain and pain with urination were statistically significant on multivariate analysis. Abdominal pain is probably related to endometritis or pelvic inflammatory disease which are both associated with *Chlamydia* in women. Pain with urination, which has been a "presenting complaint" for a number of my clients, is just beginning to be recognized as an indicator for *Chlamydia* infection.

Even though bleeding between menstrual periods was not shown to be statistically significant in this and most other studies, in my practice I have found it to be the "presenting" complaint for a number of clients who had a positive *Chlamydia* test result. The bleeding could be due to friability of the cervix or endometritis, both of which are associated with *Chlamydia*. It is important that health care providers keep this in mind when evaluating clients to determine if they are a candidate for *Chlamydia* testing.

Inflammatory cells on current Papanicolaou smear was found to be significant on univariate and multivariate analysis in this study as well as other recent studies. Of the 14 clients who had inflammatory cells on Papanicolaou smear as well as a positive *Chlamydia* test result, only 2 of them did not have any other significant indicators. Health care providers need to determine if it is necessary for their clients who have inflammatory cells on Papanicolaou smear (but have no other significant indicators) to return for *Chlamydia* testing.

The abnormal (yellow/grey) vaginal discharge noted by the researcher was significantly associated with the presence of *Chlamydia* on univariate analysis. Friability of the cervix noted while swabbing the cervix was also shown to be significantly associated with the presence of *Chlamydia* on univariate as well as multivariate analysis. These characteristics are referred to as "muco-purulent cervicitis" which has been associated with *Chlamydia* in most research studies (Addiss et al., 1985, 1986; Chacko & Lovchik, 1984).

Table Eight
 Summary of indicators significantly associated with
Chlamydia trachomatis on univariate and multivariate
 statistical analysis

Indicators	p value for univariate test
Number of partners with multiple partners in last 3 months ***	<0.001
Inflammatory cells on Papanicolaou smear ***	<0.001
Friable cervix ***	0.01
Previous abnormal Papanicolaou smear ** (negative correlation)	0.71
Vaginal odor ** (negative correlation)	0.56
Abdominal pain **	0.28
Pain with urination **	0.08
Number of partners in the last 3 months *	0.03
Number of new partners in the last 3 months *	0.04
Abnormal vaginal discharge *	<0.001
Young Age *	0.01
Length of time on orals *	0.04
Bleeding with intercourse *	<0.001
Pain with intercourse *	<0.001

*** Significant on univariate and multivariate analysis

** Significant on multivariate analysis

* Significant on univariate analysis only

Summary

As reflected by Table Eight, there were 10 variables that were found to be statistically significant on univariate analysis; Only three variables remained significant on multivariate analysis. Two variables that were not significant on univariate analysis were positively correlated with *Chlamydia*. Two other variables that were not statistically significant on univariate analysis were negatively correlated with *Chlamydia* on multivariate analysis. Young age (20 vs. 21.7) and length of time on orals probably have little practical application. The others have potential benefit for selective screening for women at risk for *Chlamydia*.

CHAPTER 5

SUMMARY

Demographic, behavioral, and clinical indicators associated with *Chlamydia trachomatis* infection were examined in women attending Southwest Family Planning in order to determine the prevalence rate and to determine and refine criteria used for selective screening. *Chlamydia trachomatis* was isolated from the cervix of 41 (14.28%) of 287 women using the Microtrak[™] *Chlamydia* direct test.

Ten indicators were significantly associated with the presence of *Chlamydia* on univariate analysis. A stepwise regression analysis was done and three indicators remained significant. These indicators were: 1) number of sexual partners with multiple partners, 2) inflammatory cells on Papanicolaou smear, and 3) friable cervix. Two indicators that were not statistically significant on univariate analysis were significantly associated with *Chlamydia* on multivariate analysis. These indicators were pain with urination and abdominal pain. Two other indicators were negatively correlated with the presence of *Chlamydia*. They were 1) previous abnormal Papanicolaou smear and 2) vaginal odor.

CONCLUSIONS

The partner-related symptoms that were found statistically significant in this study were consistent with results of other studies. Addiss & Vaughn (1986) did not find a significance with partners with multiple partners. That could be the result of a reluctance of clients

to share that information or clients not being aware of a partner's sexual activities.

Symptoms, such as pain and/or bleeding with intercourse which were found statistically significant on univariate analysis but not on multivariate analysis, have not been shown to be significant in most studies. Pain with urination, which was significant on multivariate analysis but not univariate analysis, has also been rarely reported as significant. This researcher feels it is significantly associated with *Chlamydia*, since it has been the "presenting" complaint for a number of women who have had *Chlamydia*. The reason these symptoms may have been significant in this study but not in others may have to do with the fact that the researcher did an interview rather than have the client complete a written questionnaire. This allowed for more complete clarification of the questions and answers. Abnormal vaginal discharge color (yellow/grey), abnormal endocervical discharge color (yellow/grey), and a friable cervix have been repeatedly reported in the literature as significantly associated with *Chlamydia*. The presence of abnormal endocervical discharge probably did not show statistical significance because this researcher found it difficult to assess the endocervix discharge.

Young age has been reported consistently in previous research to be significantly associated with the presence of *Chlamydia*. This study was no exception, with the mean age of those with a positive *Chlamydia* test being lower than the mean age of those with a negative *Chlamydia* test result.

Length of time on oral contraceptives, which was significant on univariate analysis but not on multivariate analysis, has not been reported in any previous studies that this researcher is aware of. There is probably no practical application of this information.

Ectopy of the cervix, which was reported as significant in the majority of prior research, was not found to be significant. Harrison et al. (1985) recommended screening all adolescent clients with ectopy for *Chlamydia*. Since only approximately 1/3 of the clients in this study who had ectopy of the cervix also had *Chlamydia*, it is not a feasible recommendation.

Inflammatory cells on Papanicolaou smear was found to be associated with *Chlamydia* on univariate analysis and multivariate analysis. Addiss et al. (1985) found a five fold increase in inflammatory cells on Papanicolaou smear for women with a positive *Chlamydia* test compared to women with a negative test result. In the 1986 study, Addiss & Vaughn found a 3 fold increase in inflammatory cells for those with a positive test result, but did not find that clients were at higher risk of having *Chlamydia* unless other indicators were present. Of the 14 clients with *Chlamydia* who also had inflammatory cells on Papanicolaou smear in this study, 2 had no other risk factors.

Intermenstrual bleeding was not significantly associated with *Chlamydia* in this study or in most other studies, however, this researcher has also found this symptom to be a "presenting" complaint for some clients with a positive test result. The lack of association may have been due to the fact that during the study, this researcher saw

clients with this complaint at other times than normal clinic times so they were excluded from the study.

Application of the Study

Southwest Family Planning will be providing the results of this research study to all health care providers in Southwest Wisconsin as well as publishing the information in a professional journal. The results will also be published in a newsletter that will be provided to our clients, as well as news releases to local newspapers. This study will be presented at the Sixteenth Annual ObGyn Nurse Practitioner conference in August, 1988. This researcher will also be available to health care facilities wanting to provide more information and skills to their staff on client education, testing and treatment for *Chlamydia trachomatis*.

Recommendations for Health Care Providers

1) Interviewing the client rather than having her complete a questionnaire will facilitate more accurate information and allow for establishing a degree of trust prior to answering sexual questions.

2) Although a partner with symptoms of urethritis was not shown to be statistically significant in this study, 30-50% of men with urethritis have *Chlamydia*. It is important to include this indicator in selective screening protocol for women.

Recommendations For Further Research

1) More research needs to be done looking at different populations at risk of *Chlamydia*, since the majority of research has been done only in sexually transmitted disease clinics, family planning clinics, and student health centers.

2) Research needs to be done in regard to the "immunity factor" as an explanation for why young age has been associated with the presence of *Chlamydia*.

3) Research needs to be done to analyze the association between the client's positive test result and current sexual partner's test results.

4) Research needs to be done regarding the results of follow-up of males and females for "test of cure" to insure early detection of any resistant strains of *Chlamydia*.

5) Research needs to be done looking at new indicators of *Chlamydia* such as pain with bowel movement and semen characteristics in men. A number of clients have shared with this researcher these symptoms which they felt were associated with their episode of *Chlamydia*.

In conclusion, health care providers and/or researchers need to keep alert to the possible manifestations of *Chlamydia*. Selective screening criteria should allow for flexibility in testing.

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