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Chlamydia: Universal vs Selective Screening

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**CHLAMYDIA:
UNIVERSAL VS SELECTIVE SCREENING**

**By
Verneal Y. Glispie**

A THESIS

**Submitted to
Grand Valley State University
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ABSTRACT

CHLAMYDIA:

UNIVERSAL VS SELECTIVE SCREENING

By

Verneal Y. Glispie

Women, age 20 to 39, attending three family planning clinics within a Michigan health department, were screened for *Chlamydia trachomatis*. A nucleic acid hybridization test (Gen-Probe) was used to collect cervical specimens for seven consecutive months. A chlamydia risk assessment form, using Michigan Department of Community Health's selective screening criteria, was used to determine the client's risk group. A chi-square test with Yates correction was used for data analysis. The prevalence rates of high and low risk groups were compared with no significant difference ($p = .18$). The prevalence rates were 12.8% in Site A; 1.7% in Site B; 1.7% in Site C; and the mean prevalence rate was 3.0%. CDC's 5% prevalence rate, and Michigan's 1994 local out county, and state prevalence rates of 7.9% and 5.08% respectively, were used as guidelines for determining high risk populations. Universal screening was recommended and instituted for Site A, and selective screening was continued in Sites B and C.

Dedication

I dedicate this thesis to my mother, Cora Small Anderson. Encouraging her children to achieve their goals, in spite of all obstacles, was one of her gifts to us. Completing my Master's Degree in Nursing is a dream fulfilled.

Acknowledgment

This thesis was completed with the encouragement of my family and friends. I would like to express my deepest appreciation to my husband Thomas for his patience, understanding, and technical computer support throughout my graduate program.

My deep gratitude goes to my thesis advisors Dr. Patricia Underwood, Dr. Phyllis Gendler, and Dr. Johnine Callahan. Their professional expertise, gentle guidance, and encouragement gave me the confidence to fulfill the thesis requirements. Special appreciation to Linda Scott, my statistics advisor, for her patience and expertise, and also to Keith Tait for his assistance with the development of the risk assessment instrument.

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Table of Contents

List of Tables.....vii

List of Figures.....viii

List of Appendicesix

CHAPTER

1 INTRODUCTION.....1

2 LITERATURE AND THEORY.....5

Universal Screening.....6

Selective Screening.....12

Cost Versus Benefit.....21

Theoretical Framework.....28

Summary.....34

Definition of Terms.....35

Research Questions.....36

3 METHODOLOGY.....38

Research Design.....38

Human Subjects.....38

Instrument.....39

Table of Contents

(continued)

	Content Validity and Reliability.....	39
	Study Site and Subjects.....	40
	Procedure.....	41
4	DATA ANALYSIS.....	43
	Sample Characteristics.....	43
	Risk Factor Results.....	46
	Chlamydia Prevalence Rates.....	47
	Other Findings.....	49
5	DISCUSSION.....	51
	Summary and Conclusion.....	51
	Limitations and Recommendations.....	54
	Theoretical and Clinical Implications for Nursing.....	59
	APPENDICES	62
	REFERENCES.....	70

List of Tables

Table

1.	Chlamydia: Universal Screening Studies.....	8
2.	Chlamydia: Selective Screening Studies	14
3.	Chlamydia: Cost Versus Benefit Studies.....	22
4.	Chlamydia Testing and Treatment: Cost Under Each Decision Option at California Family Planning Clinics.....	25
5.	Cost Decision Analysis for <i>Chlamydia trachomatis</i> Screening in Colorado Family Planning Clinics.....	26
6.	Type Visits and Percentage of Co-Pay for Each Clinic.....	44
7.	Comparison of Demographic Data Prevalence Across Sites.....	45
8.	Chlamydia: Universal Screening Results.....	48
9.	Universal Screening Prevalence Rates.....	48
10.	Site A Client Demographics: With and Without Chlamydia.....	54
11.	Site A Client Risk Factors: With and Without Chlamydia.....	55

List of Figures

Figure

1. Neuman's Client System Model.....29
2. Format for Primary Prevention as Intervention Model.....32
3. Format for Secondary Prevention as Intervention Model.....33

List of Appendices

Appendix A. Human Research Review62

Appendix B. Chlamydia Risk Assessment.....63

Appendix C. Comparison of Chlamydia Risk Factor Prevalence Across Sites.....65

Appendix D. Risk Factors for Clients with Chlamydia.....66

Appendix E. Items Comprising the VD Education HBM Scale Dimensions.....67

CHAPTER 1

INTRODUCTION

Chlamydia trachomatis (chlamydia) is the most common bacterial sexually transmitted disease (STD) in the United States and causes more than four million infections annually (U.S. Department of Health and Human Services, 1994). Chlamydia has been described as the silent STD. Approximately 70% of clients with chlamydia are asymptomatic, and the infection may persist for up to 15 months. Serious complications associated with chlamydia make annual routine screening, for high risk populations, imperative. The most frequent complications of untreated chlamydia are pelvic inflammatory disease (PID) and infertility (Primary Care Update, 1994). An estimated 15% to 40% of women with untreated chlamydia develop PID. Twenty percent of women with PID become infertile, 18% develop prolonged pelvic pain, and 9% will have one or more ectopic pregnancies (Hillis, Black, Newhall, Walsh, & Groseclose, 1995).

Several research studies across the country have documented the benefit of universal chlamydia screening for high risk populations. Although the Michigan Department of Community Health (MDCH) (formally the Michigan Department of Public Health) made chlamydia a reportable disease in 1992, they have only allocated funds for selective or high risk screening. MDCH's high risk criteria are a) being less than 20 years of age, b) having

a history of STD in the past six months, c) having multiple partners, d) having a partner with multiple partners, e) having a new partner in the past six months, f) having a discharge or mucopurulent cervicitis (MPC), and/or g) having a friable cervix (MDCH, 1992). Instituting selective screening was a major step in the identification and early treatment of chlamydia, but the women who are not selected for testing may be at comparable risk. Universal screening could make the difference between spending an average of \$12 per client for screening and treatment, as opposed to spending hundreds of dollars on emergency, inpatient, and possibly surgical treatment.

Although MDCH has identified several high risk screening criteria, the client's risk may not always be accurately determined during an assessment interview. The client may be reluctant to acknowledge having more than one sex partner, recent treatment for an STD, or that her partner had more than one sex partner. Situations also occur in which the client may not be aware that her partner has more than one sex partner or that he had recently been treated for an STD. Therefore, unless the client is less than 20 years old or symptomatic, she may not be selected for screening.

Chlamydia testing is done by using culture or nonculture methods to test specimens obtained from the endocervical os. Cultures cost \$25 to \$50, with results returned in three to seven days. The nonculture test, which is the screening method used by most clinics, costs \$8 to \$12, with results available in three to four hours (Drolet, 1992). Due to the high cost of chlamydia screening, most providers do not routinely offer testing. Failure of providers to screen routinely for chlamydia leaves asymptomatic women vulnerable to developing unnecessary complications from this infection. Researchers have suggested

that preventing the complications of chlamydia could save states millions of health care dollars in outpatient and inpatient care for treatment of PID, ectopic pregnancies, or other complications. First year savings were estimated at six million dollars with five year savings reaching more than \$60 million (U.S. Public Health Service, 1991).

In the three-year period of 1992-1994, two family planning clinics in an urban health department selectively screened 1,077 females using MDCH protocol. Of those 1,077 female clients, 16 to 39 years of age, 118 tested positive for chlamydia. This represented a 16% prevalence rate at Site A, 9.7% at Site B and a mean prevalence rate of 11% (Wayne County Department of Health, 1994). The Centers for Disease Control (CDC) (1993) rates any prevalence $\geq 5\%$ as indicative of a high risk population. These retrospective data obtained from the local health department did not include data on the low risk population, and specific descriptive data were not available. The data did, however, provide good background information and were the basis for this study.

The National Health Promotion and Disease Prevention Objectives for the Healthy People 2000 initiative include a focus on reducing the spread of STD's. Effective methods of early identification and treatment of chlamydia were among those objectives (U.S. Public Services, 1991). After MDCH made chlamydia a reportable disease in 1992, it became imperative that all health care professionals serving sexually active clients take chlamydia seriously. The Michigan Department of Community Health (1994) reported 288 cases of chlamydia in 1992, 4,783 cases in 1993, and 17,688 cases in 1994. It is not clear if the previous figures represent a true increased prevalence or if they reflect increased screening and reporting practices in Michigan. Nevertheless, rates of 9.7% and 16% in

these family planning clinics were above the mean prevalence rate of 5.1% for Michigan family planning clinics in 1994 (MDCH, 1995). In order to evaluate the effectiveness of the present screening criteria, this study compared the prevalence rates of the low risk groups to those of the high risk groups in three health department family planning clinics. It used the prevalence rates found in each risk group to determine whether universal screening or selective screening protocols would be more appropriate for use in these clinics.

The purpose of this study was to determine if the selective screening protocol, currently used by the urban health department, was adequate for screening their clinic populations or if universal screening would be preferable. Despite multiple studies on high risk criteria for chlamydia, researchers remain unable to establish reliable positive predictors for this infection and recommend universal chlamydia screening for high risk populations (Phillips, Aronson, Taylor, & Safran, 1987). CDC, also, recommends sentinel or periodic universal screening to monitor the prevalence of chlamydia in target populations.

CHAPTER 2

LITERATURE AND THEORY

Chlamydial infections have become the most common sexually transmitted disease in the United States. Although the cost of early treatment is minimal, the cost of testing has prevented widespread screening (Weinstock et al., 1992). In the 1980's, multiple studies were conducted to determine risk factors that would serve as positive predictors for chlamydia, and to determine which nonculture test shows the highest specificity and sensitivity for this bacterial infection. The higher the specificity of the nonculture test the more likely a negative result indicates the infection is not present; thus, the test has a higher rate of true negatives and a lower rate of false positives. The higher the sensitivity of the nonculture test the more likely a positive result indicates the infection is present; thus the test has a higher rate of true positives and a lower rate of false negatives. In addition, reliable positive predictors would make selective screening an alternative to the higher cost of universal screening. In spite of the many studies done on chlamydia, researchers have been unable to establish highly reliable predictors for high risk populations. Thus far, the major savings have been by the use of nonculture chlamydia testing for mass screenings, reserving the more costly culture test for cases with legal implications.

The literature review showed three basic types of studies. These were universal screenings, selective screening, and cost benefit studies. Universal screening studies focused on the benefit of screening all clients in high risk populations. Selective screening studies focused on screening only clients meeting predetermined high risk criteria as a cost reduction measure. Cost benefit studies compared the direct and indirect cost of screening and treatment when needed. The direct cost related to the expense of screening and treatment of uncomplicated cases, and the indirect cost related to complications and treatment for untreated chlamydial infections. Key variables, which included the lower end of the screening test's sensitivity, the direct and indirect cost of testing and treatment, and the population's prevalence rate for chlamydia, were analyzed to determine at what prevalence rate the cost of universal screening would outweigh the cost of treating complications from undetected cases. Betty Neuman's Systems Theory was used as a basis for examining risk factors and prevalence rates of chlamydia. Her concepts of "Primary and Secondary Prevention as Intervention" (Neuman, 1995) are discussed as they relate to the importance of screening for chlamydia.

Universal Screening

Dr. Russell Phillips (1987), from Harvard Medical School, along with several other researchers recommended routine or universal screening in populations with a prevalence rate above 6% to 7%. Universal screening was recommended because a) 60% to 80% of clients who had chlamydial infections are asymptomatic, b) there is a high probability of obtaining inaccurate histories relating to the client's sexual partner(s), and c) highly reliable risk factors have not been established (Woolard, Canp, Larson, & Hudson, 1989). The

relationship of prevalence to screening protocols are discussed in conjunction with cost benefit analysis. Several universal screening studies were done in urban family planning and STD clinics. Included in this literature review were studies conducted in Midwestern USA, Ohio, California, Virginia, Colorado, New York, and Canada.

In the early 1980's, a chlamydia study was conducted by Woolard et al. (1989) at a Midwestern university campus (Table 1). The result of this study showed a prevalence rate of 12.6%, using Abbott's Chlamydiazyme nonculture test. CDC reports nonculture tests such as Chlamydiazyme to have a sensitivity of 67% to 95% and a specificity of 97% to 99%. Of the 419 females who were screened, 53 of them tested positive for chlamydia. Limitations of this study were cited as having a high possibility of a) false-positive results with the use of Chlamydiazyme nonculture test in low prevalence populations; and b) inaccurate historical data reported by the client, related to her own or her partner(s) history of past STD's, and the number of partners the client or her partner(s) have had in the past year. This study concluded that due to the high incidence of asymptomatic women found to have chlamydia, routine testing is strongly recommended in most college based family planning clinics.

A study conducted at Columbus Health Department screened 60,000 to 70,000 females annually for three years. Reports from this study showed a decrease in prevalence from 8.8% in 1985, to 5% in 1988 (Johnson, 1992). Although a nonculture test was used in this study, the type of test, sensitivity, and specificity were not reported. Johnson states that this study and others were limited by unsatisfactory collection of endocervical cells

Table 1.

Chlamydia: Universal Screening Studies

DATE OF STUDY / AUTHOR	LOCATION	TEST	POS	RATE	TEST USED	SEN	SPEC	CONCLUSIONS
1980's Woolard et al. (1989)	Midwestern University	419	53	12.6%	Chlamydiazyme (Abbott)	*67% to 95%	*97% to 99%	High % of asymptomatic clients & inaccurate hx's limits predictability for chlamydia. Routine (universal) screening was recommended for college women.
1985-88 Johnson, M. (1992)	Columbus Health Dept.	60,000-70,000 x 3 yrs	ukn	8.8% in 1985 to 5% in 1988	unspecified nonculture	*67% to 95%	*97% to 99%	Widespread universal screening decreased the prevalence rate by 43% in 3.5 yrs. Replication of this project, especially for teen & Black populations recommended.
1987-88 Weinstock et al. (1992)	San Francisco	1,348	124	9.2%	MicroTrak DFA	** 61%	98%*	Recommended universal screening in high risk populations and selective screening for use in low risk populations.
1987-88 Johnson, B. et al. (1990)	Virginia Commonwealth University	1,458	133	9%	MicroTrak DFA	*61% to 90%	98%*	No current selective screening model yet proven to be reliable. Verification of this or other study model needed before selective screening is effective for use in high risk populations.

Note. *Manufacturer's or CDC's data ** Data reported in study Pos = Positive Sen = Sensitivity Spec = Specificity DFA = direct fluorescent antibody EIA = enzyme immunoassay

Table 1. (continued)
Chlamydia: Universal Screening Studies

Date of Study AUTHOR	LOCATION	TEST	POS	RATE	TEST USED	SEN	SPEC	CONCLUSIONS
1988 Zimmerman et al. (1990)	Colorado Springs	2,437 males - females	419	17%	MicroTrak DFA	** 90%	** 98%	20.5% positives identified via contact-tracing, 59.7% via routine screening, & 19.8% presented to clinic with symptoms. Increased reporting would facilitate contact follow-up
1988 Holmes et al. (1993)	New York City Correctional Institution	101	27	27%	Unspecified cell culture	** 80%	* nearly 100%	Combination of 3 high risk indicators only identified 70% of women positive for chlamydia. Recommend routine screening for all inmates on admission.
1980-81 Embil & Pereira (1985)	Halifax, Canada	355	29	8.2%	Unspecified cell culture	* 80%	* nearly 100%	All clients screened were asymptomatic. Chlamydia was much more prevalent in women under 25 years. Chlamydia was also higher in women with multiple partners.
1989-90 Sellors et al. (1992)	McMasters University Ontario	1,002	70	7%	Chlamydiazyme EIA (Abbott)	** 78.6%	*97% to 99%	Use of 4-5 predictors was effective for screening low prevalence populations. Saving gained in reduced cost of selective screening are lost with the increased cost of treatment for missed cases in high prevalence populations.

necessary for proper analysis. An average of 15% to 30% of unsatisfactory specimens may be found with widespread testing. To reduce this problem, the Columbus project sponsored in-service training to participating providers. Johnson concluded that the widespread universal screening done in the Columbus Health Department decreased the prevalence rate by 43% in about three years. Therefore, he recommends the replication of this project wherever possible, especially in high risk, teen, and predominately Black populations.

During a 1987-1988 study in San Francisco, Weinstock, Bolan, Kohn, Balladares, Back, and Oliva (1992) screened 1,348 females for chlamydia. With 124 women testing positive, the prevalence rate was 9.2%. A direct fluorescent antibody test, with a sensitivity of 61% as compared to 99% with cultures, was reported as a limitation of this study. Although no additional data were presented, the use of cytobrushes to collect endocervical specimens was felt to improve the sensitivity of the nonculture test. Weinstock et al. felt that due to the low sensitivity of the nonculture test, universal rather than selective screening should be used in high risk populations to increase the numbers screened, thus increasing the number of positive cases detected.

In a study conducted at Virginia Commonwealth University, 1,458 females were screened, and 133 tested positive for a prevalence rate of 9% (Johnson, Poses, Fortner, Meier, & Dalton, 1990). A direct fluorescent antibody (DFA) nonculture test was also used in this study, but no sensitivity or specificity data were reported. Since the cost of universal screening was a major concern for the Virginia Commonwealth University Clinic, a selective screening model designed to identify high, moderate, and low risk

clients was developed. The researchers admit that models so far have not been reliable but feel that one will be developed in the foreseeable future.

In Colorado Springs, a study of 2,437 males and females reported 419 positive tests and a prevalence rate of 17% for chlamydia (Zimmerman, Potterat, Dukes, Muth, Zimmerman, Fogle, & Pratt, 1990). In this study the MicroTrak DFA's sensitivity was reported as 90%. Contact-tracing was responsible for identifying 20.5% of the positive chlamydia cases, 59.7% were identified by routine screening, and only 19.8% of clients presented to the clinic with symptoms. Zimmerman et al. advised that increased reporting of chlamydia cases to public health officers would facilitate contact follow-up.

A 1988 study, conducted at New York City's Rikers Island Correctional Institution, found that of 101 females screened, 27 of them tested positive, with a prevalence rate of 27%. An unspecified cell culture with a sensitivity of 80% was used in this study. Since only 70% of the infected inmate population would have been identified using selective screening criteria, testing or offering presumptive treatment to all new female inmates was suggested (Holmes, Safyer, Bickell, Vermund, Hanff, & Phillips, 1993).

Canadian studies have shown similar findings. During 1980 and 1981 in Halifax, 355 females were screened, and 29 of the women tested positive for chlamydia. The prevalence rate was 8.2%. Chlamydia was found to be more prevalent in women less than 25 years old and higher in women with multiple partners (Embil & Pereira, 1985).

In a study conducted at the McMaster University Student Clinic in Ontario, 70, out of 1,002 females screened, tested positive, thus having a prevalence rate of 7%. Abbott's Chlamydiazyme enzyme immunoassay (EIA) nonculture test was used and reported to

have a sensitivity of 78.6% in that study. Canadian researchers agreed that in low prevalence settings, selective screening offered an efficient strategy compared with universal screening. Whereas in high prevalence settings, the increased costs incurred by treating the sequelae among missed cases reduced any savings associated with a selective screening program. The opportunity cost principle recognizes the existence of other cost-effective services that compete for women's health resources. It also recognizes that the limited resources of health care systems were the main forces propelling efforts to efficiently screen women for this disease (Sellors et al., 1992).

Universal screening studies in these urban areas all showed that despite the individual's risk factors, when nonculture tests were used for routine screening, the prevalence rates ranged from 5% to 27% with a mode rate of 8% to 9%. Several high risk indicators for chlamydia were identified in all of the studies, but no single indicator was consistently found to be a determinant for the presence of the chlamydial infection. All studies were limited by the use of convenience samples as opposed to random sampling. Using only clients who came into the clinics for services may not have produced an accurate sample of the target population at large.

Selective Screening

Multiple selective screening studies have been conducted to identify specific high risk indicators of chlamydia. Finding one or more reliable indicators would allow providers to screen only those clients at risk for the infection, thereby saving the cost of routinely screening all clients (Addis, Vaughn, Holzhueter, Bakken, & Davis, 1987). Researchers looked at several high risk factors identified in universal screening studies and used them

to develop selective screening protocols. Although both culture and nonculture tests were used in various studies for purposes of comparison, this literature review primarily focused on prevalences obtained using nonculture tests (Table 2).

Between 1980-1982, a study was conducted at a University of California / Los Angeles (UCLA) Student Health Center. Six hundred and thirty-eight females, with some predetermined high risk factors, were selectively screened for chlamydia. Using the Eagle cell culture, 42 students tested positive, and the prevalence rate was determined to be 6.6%. Risk factors for those testing positive included a mean age of 23.5, multiple partners, a partner with a recent history of urethritis, and/or the use of contraceptives. No associations were found between a positive chlamydia test and a history of testing positive for sexually transmitted diseases including gonorrhea, chlamydia, syphilis, or genital herpes. Nor was there any association with *Trichomonas* or *Gardnerella*; dyspareunia; abnormal vaginal discharge, burning, or odor; dysuria; or cervicitis on examination by clinicians. Although there are few reliable clinical markers that would identify positive chlamydia cases, clients with multiple partners and partners with nongonococcal urethritis (NGU) were the most common indicators in this UCLA clinic population (Weismeier, Lovett, & Forsythe, 1984). No specific recommendations were made regarding universal versus selective screening in this study, but the previous statement regarding multiple partners and NGU gives some direction in support of selective screening.

Table 2.

Chlamydia: Selective Screening Studies

	UCLA Student Health Center, 1980-82 (Wiesmeier et al., 1984)	Seattle Public Health Clinic, (unspecified year) (Handsfield, et al., 1986)	Wisconsin F.P. Clinic, 1985 (Addiss et al., 1987)	Milwaukee Community & Urban Health Center, 1986 (Addiss et al., 1990)	New York State Public Health Clinics, 1985-86 (Han et al., 1993)	San Diego County Public Health Centers, 1989-93 (CDC, 1994)
# Tested & Age Range	638 Unspecified	1,059 ≥ 14 yrs	335 14-37 yrs	751 13-49 yrs	1,531 16-27 yrs	11,044 n/a
Prevalence Rate	6.6% (42)	9.3% (98)	10.7% (36)	12.4% (93)	13.6% (208)	10.0% in 1989 to 1.9% in 1993
Test(s) used	Eagle Culture	MicroTrak DFA	DFA Chlamydiazyme EIA	MicroTrak - DFA & EIA	MicroTrak-DFA Chlamydiazyme - EIA by Abbott (A-EIA)	MicroTrak - EIA (M-EIA) 3/91-3/93
Sensitivity	n/a	*DFA 92%	**89%-90	**DFA - 77.4% **A-EIA - 83.9%	*DFA - 92% *A-EIA 83.9%	*M-EIA 93%
Specificity	n/a	*DFA 98%	**97%-98%	**DFA - 96.8% **A-EIA - 97%	*DFA - 98% *A-EIA 97%	*M-EIA 99%

Note. n/a = not assessed in this study NR = no relationship found in this study * Manufacturers or CDC data **data reported in this study
 ***Screening criteria recommended at conclusion of this study Direct fluorescent antibody (DFA) Enzyme immunoassay (EIA)
 Nongonococcal urethritis (NGU)

Table 2. (continued)

Chlamydia: Selective Screening Studies

	(Wiesmeier et al., 1984)	(Handsfield et al., 1986)	(Addiss et al., 1987)	(Addiss et al., 1990)	(Han et al., 1993)	(CDC, 1994)
Age	*** mean age 23.5	< 24 yrs*** mean age 21.8 12.4%	15% <20 yrs*** 16% <20 6.7% ≥ 20	<20 yrs 19.65 ≥ 20 yrs 9.5	*** <20 yrs 17.9% 12.3% ≥ 20yrs mean age 21	*** <20 yrs 8.4%
Recent new partner	n/a	17.3%*** < 2 months	17.5% ***	***23.1% < 3 months	n/a	*** < 3 months
Hx of >1 sex partners or partner with >1 partner in the past 2 months to 1 yr	30% ***	8.3% 0-1 partners *** ≥ 2 partners past two months 15.6%	29.2%***	*** >1 partner <3 months 25.3% >1 past yr 21.6%	*** >1 partner <6 months 12.7% none or one 10.5%	*** > partner < 3 months
Partner with hx of NGU < 30 days	***33%	n/a	100% ***	***28.1%	n/a	n/a
Nonbarrier methods	n/a	*** 25.8%	n/a	none, rhythm or withdrawal 13.9%	6%	***
Hx of GC	NR	NR	LR	***Partner - GC <30 days 40%	NR	n/a
Current GC	0.8%	1.2%	0.3%	***36.4%	NR	n/a
MPC	NR	23.3%***	***40%	*** mucoid 11.3% purulent 25.8%	*** 17.7%	***

Table 2 (continued)

Chlamydia: Selective Screening Studies

	(Wiesmeier et al., 1984)	(Handsfield, et al., 1986)	(Addiss et al., 1987)	(Addiss et al., 1990)	(Han et al., 1993)	(CDC, 1994)
Friable cervix	n/a	19%***	***26.5%	***20.9%	n/a	n/a
Symptomatic	6.6%	8.7%	11.3%	n/a	***16.9%	n/a
Inflammation on Pap smear	n/a	n/a	*** Inflammatory changes on current Pap 42.9% last Pap 28.2%	≥ 5 lymphocytes on 400x field 22.0% <5 = 11.5% 3+-4+ PMN 29.9% 0 - 2+ 10. = 9%	*** 25% pos in one clinic 13% neg in same clinic	n/a
Conclusions	Few reliable clinical markers that could identified positive cases. Multiple partners & partners with NGU were the most common indicators in this university population	No single risk factor identified. Which supports other studies recommendations for universal screening. Selective screening recommended for women with ≥ 2 risk factors*** as a cost-effective means for early detection of chlamydia	No single symptom or cluster of symptoms were reliable predictors of a positive DFA. Major finding: client's reason for visit not predictive of positive test. Recommend all clients be assessed for risk.	No one variable had sufficient predictive value for use as only criterion to selectively screen this population for chlamydia. Proposed criteria would screen 43% of clients & identify 71% of infections.	Selective screening is useful in directing limited testing funds to those most likely to be infected.	Recommends universal screening for all initial exams and selective screening for annual and other visits

A Seattle public health clinic universally screened 1,059 females to determine high risk factors. Using the MicroTrak DFA nonculture test, 98 clients tested positive for a prevalence rate of 9.3%. Significant characteristics of those testing positive included a) being ≤ 24 years of age, b) two or more sexual partners in the past two months, c) a recent new partner, d) an abnormal vaginal discharge, e) a mucopurulent cervicitis, f) a friable cervix, and g) cervical ectopy (ectropion). Nonsignificant predictor characteristics for chlamydia in this study included race, age at the onset of sexual intercourse, recent history of STD's, complaints of vaginal itching or irritation, urinary tract symptoms, lower abdominal pain, or pain with sex. The study concluded that no single risk factor was identified as a positive predictor for chlamydia, which supports other studies' recommendations for universal screening. However, as a cost-saving measure, Handsfield, Jasman, Roberts, Hanson, Kothenbeutel, and Stamm (1986) recommended selective screening for women with two or more of the risk factors identified in this study.

In a study conducted at four Wisconsin family planning clinics, 335 females were selectively screened. DFA and Chlamydiazyme EIA nonculture tests, with a sensitivity of 89% to 90% and a specificity of 97% to 98% respectively, resulted in 36 positive tests and a prevalence of 10.7%. Risk factors similar to those used in previous studies were used to determine the predictive criteria for this study. The major correlated factors included having a new sexual partner, a partner with urethritis, a partner with more than one partner, a friable cervix, a mucopurulent discharge, or being less than 20 years old. A likely relationship between a current history of gonorrhea and a current positive chlamydial infection was found in this study. It also noted that younger women were more

prone to cervical ectropion than older women. Cervical ectropion is a condition in which more columnar epithelial cells are exposed and thus makes women ≤ 24 years old more susceptible to chlamydia (Addiss, Vaughn, Holzhueter, Bakken, & Davis, 1987) The client's reason for visiting the clinic was not found to be predictive of chlamydia. Nor was there any relationship found between chlamydia and the client's race, educational level, marital status, history of STD's (other than gonorrhea), genitourinary related symptoms, or the use of oral contraceptive pills (OCP's). No single symptom or cluster of symptoms was found to be a reliable predictor of chlamydia. Addiss et al., however, recommended high risk selective screening, that would detect 89% of clients with chlamydia by testing only 58% of the clinic population.

In 1986, two Milwaukee, Wisconsin family planning clinics conducted a study. Universal screening was done on 751 females who were assessed as having similar high risk factors. Ninety-three of them tested positive, for a prevalence of 12.4% using the DFA and 13.1% using the EIA. The DFA's had a sensitivity of 77.4%, resulting in 22.6% false negatives; and a specificity of 96.8%, resulting in 3.2% false positives and a predictive value positive (PVP) of 77%. EIA had a sensitivity of 83.9% (thus a false negative rate of 16.1%), a specificity of 97% (thus a false positive rate of 3%), and a PVP of 80%. When high risk criteria were used including a) cervicitis; b) positive GC; c) partner with NGU, epididymitis, or GC within the past 30 days; and d) more than one sexual partner, or a new partner within the past 3 months, 43% of the 751 clients were identified as high risk and tested. This resulted in identifying 71% of clients actually having a positive chlamydia test. Although Addiss, Vaughn, Golubjatnikov, Pfister, Kurtycz, and

Davis (1990) recognize selective screening as an effective cost saving alternative, they still recommend universal screening for adolescents and women seen in high risk areas, if resources are available.

A study conducted in ten clinics outside New York City screened 1,531 females for chlamydia. Positive tests were reported for 208 of those tested, yielding an overall prevalence rate of 13.6% (Han, Morse, Lawrence, Murphy, & Hipp, 1993). A prevalence of 17% was reported for the eight high risk family planning and STD clinics. In the two low risk private and college clinics, the prevalence rate was 5.6%. Six high risk indicators observed in this study were clients less than 20 years old, multiple partners, the use of OCP's, MPC, inflammation on Pap smear, and symptomatic reason for their clinic visit. No relationship with race or history of other STDs was found. The authors of this study believed that the relationship between use of OCP's and chlamydia was explained by the tendency of estrogen and progesterone to foster the growth of chlamydia and an increase of ectropion in women using OCP's. This study also discussed the possibility that the use of antibiotics, vaginal creams, and douches may have masked the presence of chlamydia, thereby increasing the chances of obtaining false negative results. Han et al. state that selective screening is useful in directing the limited testing funds to clients most likely to be infected.

A five year study, conducted in six San Diego County public health centers, found that after screening 11,044 females during routine initial or annual visits, the prevalence decreased from 10.0% in 1989, to 1.9% in 1993. Ninety-one percent of those screened were asymptomatic. At the start of the study, from March 1989 through February 1991,

the Ortho Diagnostic Systems enzyme-linked immunoabsorbent assay (ELISA) test was used for screening. Although no reason was documented for the change in collection and testing methods, in March of 1991 the MicroTrak EIA was used to complete the testing. No sensitivity or specificity data were documented in this report. The high risk indicators in this study were being of the Black race and being less than 20 years old. Other indicators included having multiple partners or a new partner in the past three months, using a non barrier method of contraception, and having mucopurulent cervicitis. The results of this study led to the implementation of policy by the California Office of Family Planning in August 1993, which requires universal screening on all initial examinations and selective screening for annual and other clinic visits (CDC, 1994).

Selective screening studies have consistently identified several high risk factors that were predictive of a chlamydial infection. The one factor that consistently showed the highest risk was women less than 20 years old. Other factors associated with high risk were having multiple partners or a new partner in the past three months, a partner with multiple partners, single status, abnormal vaginal discharge, cervicitis, failure to use condoms, a recent history of gonorrhea, and symptoms of an urinary tract infection. However, no single factor or group of risk factors were shown to be highly reliable predictors in replicated studies. As a result, most clinics adopt a set of high risk characteristics identified in their study of choice and accept the selective screening predictive value "positive" of 77%, to save the cost of universally screening all clients. The weakness of this strategy is that 23% of clients with chlamydia are missed, and many go on to have long term complications from an untreated infection.

Cost Versus Benefit

Cost benefit studies were done primarily to determine at what prevalence rate the cost of selective or universal screening pays for itself. Although the cost of screening in dollars is an inescapable factor, providers should not ignore the serious consequences this STD can inflict on a very vulnerable population. Statistics show that within five years of an infection, many clients with untreated chlamydia suffer from PID resulting in chronic pelvic pain (due to adhesions), infertility, and/or complications of pregnancy (Hillis et al., 1995). These facts support the Phillips et al. (1987) study which recommends routine screening in high risk populations, defined by CDC as a prevalence $\geq 5\%$.

A 1984 study conducted in Boston determined the break-even prevalence rate for nonculture tests to be 7% and 14% for culture tests, when direct and indirect costs of treatment were considered (Table 3). The cost of using nonculture tests such as the DFA and EIA rapid test was \$15, and treatment with doxycycline was \$2. The sensitivity and specificity for DFA and EIA reported in this study were 80% and 98% respectively. Only the cost of the test and the medications were considered because the other costs would normally be included in the cost of a routine family planning visit. Phillips, Aronson, Taylor, and Safran (1987) determined that the cost of screening and treatment will pay for itself if the prevalence rate is greater than 7%.

Neddleman and Jones (1988) evaluated the prevalence rate of a college population to be 7.9%, and the cost-effectiveness prevalence rate to be 7.94%. A direct antigen nonculture test, with a sensitivity of 53% and a specificity of 96%, was used in this study.

Table 3.

Chlamydia: Cost Versus Benefit Studies

	Location Date Type clinic Number screened	Break -even prevalence rate	Rate Pos	Test used	Sen	Spec	Cost of test & Treatment	Conclusions
Phillips et al. (1987)	Boston 1984	7% nonculture 14% culture	7%	DFA EIA	80%** 80%**	98%** 98%**	Nonculture test - \$15 Meds \$2	Only the cost of test and meds were considered. Other costs are charged to a routine F.P. visit. Thus if prevalence rate ≥ 7 , screening & tx pays for itself
Neddleman & Jones (1988)	1985-6 college clinic 434	7.94%	7.9%	Direct Antigen	53%**	96%**	\$12 Meds \$1.09	The use of a low-cost direct antigen test, more effective than not testing and or treating
Trachtenberg, et al. (1988)	California 1986 F.P. clinics 400,000 annually	(as low as 1.84% to 2.59%) Baseline 5.98%	9.8%	Micro- Trak	90%**	98%**	\$6.75 test \$2 - meds \$16- return visit \$20 -visit & tx for partner	Universal screening cost effective if prevalence >6%

Table 3. (continued)

Chlamydia: Cost Versus Benefit Studies

	Location Date Type clinic Number screened	Break - even prevalence rate	Rate Pos	Test used	Sen	Spec	Cost of test & Treatment	Conclusions
Humphreys, et al. (1991)	Colorado 1988 F.P. clinics 11,793	2%	7.7%	Chlamy- diazyme EIA	79%**	97%**	Not screening \$0.00 Selective Screening \$82,500.00 Universal Screening \$203,500	Universal screening would decrease morbidity for clients with chlamydia & significantly reduce health care cost
Marrazzo (1994)	Region X 1990 F.P. clinic 11,141	1.8% 1.9% to 3.5%	6.6%	DFA LCR	75%** 95%**	*97% to 99%	\$5 \$10 - \$25	Require 56% be tested 78% detected. Selective screening is cost effective in low prevalence populations

Note Pos = positive Sen = sensitivity Spec = specificity DFA = direct fluorescent antibody EIA = enzyme immunoassay
LCR = ligase chain reaction

The cost of the direct antigen test was \$12, and the cost of the medication was \$1.09.

The authors concluded that the use of a low cost direct antigen test was more effective than not testing or treating clients for chlamydia.

California's state-funded family planning clinics, with a reported prevalence rate of 9.8%, were studied in 1986 using a decision tree. The purpose was to determine the total cost of universally screening or not screening the estimated 400,000 women, annually seen in California's state family planning clinics. The total cost of universal screening was \$7,307,717 (Table 4). They compared this with the cost of \$20,347,401 required to pay for hospitalization, surgical procedures, and medications for treatment of PID, ectopic pregnancies, infertility, and neonatal pneumonia and conjunctivitis, when no chlamydia screening was done. Break-even prevalence rates were determined to be as low as 1.84% to 2.59% using the MicroTrak nonculture test, with a sensitivity of 90% and specificity of 98%. The MicroTrak test cost \$6.75, medication per person was \$2, the cost of a return client visit was estimated to be \$16, and the cost of a contact partner visit and treatment was \$20. As a result, universal screening was determined to be cost effective if the prevalence rate was greater than 6% (Trachtenberg, Washington, & Halldorson, 1988).

A 1988 study conducted in 22 Colorado family planning clinics found that of 11,793 females tested 913 tested positive, which calculated the prevalence rate to be 7.7%. The total cost of not screening for chlamydia in this study was \$0 for direct cost and \$1,370,000 for the indirect cost (Table 5). Indirect cost included outpatient and inpatient treatment related to PID, ectopic pregnancy, tubal infertility, epididymitis, and neonatal pneumonia and conjunctivitis. Although the selective screening criteria were not specified,

Table 4.

Chlamydia Testing and Treatment: Cost Under Each Decision Option at California Family

Planning Clinics

	Screened (\$)	Unscreened (\$)
Testing	\$2,700,000	\$0
Treatment	1,529,856	0
Complications	127,488	0
Women with PID	-----	-----
Outpatient Rx	255,780	1,764,000
Hospitalization	1,270,928	8,765,022
Surgery	255,780	1,764,000
Epididymitis, outpatient	11,368	78,400
Epididymitis, inpatient	40,947	282,391
Ectopic pregnancy	327,342	2,257,528
Tubal infertility	746,025	5,145,000
In births to infected women:		
Neonatal pneumonia	39,078	269,500
Neonatal conjunctivitis	3,126	21,560
TOTAL COSTS (1986 Dollars)	\$7,307,717	\$20,347,401

Source: Trachtenberg et al. (1988). A cost-based decision analysis for chlamydia screening in California family planning clinics. Obstetrics and Gynecology, 71, 104.

Table 5.

Cost Decision Analysis for *Chlamydia trachomatis* Screening in Colorado Family Planning Clinics

Scenario	Screening Cost Dollars (Direct Cost)	Total Health Cost Dollar (Indirect Cost)	Total Cost Per Protocol
No Chlamydia Screening	\$0	\$1,370,000	\$1,370,000
Selective Screening	\$82,500	\$1,120,000	\$1,202,500
Universal Screening	\$203,500	\$607,000	\$810,500

Source: Humphreys et al. (1991). Cost-benefit analysis of selective screening criteria for *Chlamydia trachomatis* in women attending Colorado family planning clinics. Sexually Transmitted Diseases, 19, 51.

the direct cost was \$82,500, the indirect cost of selective screening was \$1,120,00 for a total cost of \$1,202,500. This figure was based on the a) cost of testing using the Chlamydiazyme EIA nonculture test with a sensitivity of 79% and a specificity of 97%, b) treatment as needed for those selectively screened, and c) the cost of treating complications in clients not screened who were subsequently found to have chlamydia. Universal screening was estimated at \$203,500 for direct cost and \$607,000 for indirect cost, with a total of only \$810,500. This low cost was attributed to the cost of routine testing and early treatment of chlamydia, which eliminated or reduced the occurrence and cost of treating complications. This study was based on the application of the

Trachtenberg decision model, used in California in 1986, to determine the total cost of screening versus the cost of not screening, using a break-even point of a 2% prevalence rate. Although state and federal funds only support selective screening at this time, Humphreys, Henneberry, Rickard, and Beebe (1991) noted that universal screening would decrease the morbidity for clients with chlamydia and significantly reduce health care cost.

Region X conducted a study in 1990. Their family planning clinics, located in Washington, Oregon, Alaska, and Idaho, selectively screened 11,141 females. Seven hundred-thirty-five subjects tested positive, for a prevalence of 6.6%. They found that selective screening would require testing 56% of the family planning clients, and that 78% of chlamydia infections would be detected. Cost effectiveness was based on the prevalence of chlamydia in the target population, the sensitivity of the screening criteria, the sensitivity of the diagnostic test, and the cost of the diagnostic test used. It was determined that, in a predominantly asymptomatic family planning population, selective screening is cost-effective if the prevalence rate is low. They defined low in this study to be less than 1.8%, using the DFA which had a sensitivity of 75% and cost \$5 per test. However, 1.9% to 3.5% was the breaking point when the ligase chain reaction (LCR) test was used, which had a sensitivity of 95% and cost \$10 to \$25 (Marrazzo, 1994).

Cost versus benefit analysis were affected by the prevalence rates of each individual study, when compared to the direct and indirect cost of testing and treatment. The prevalence rates were influenced by the sensitivity and specificity of the nonculture test, which was most widely used for screening high risk clinic populations. In spite of these

differences, studies showed that the break-even prevalence point still averaged 6% to 8% in high risk populations.

Theoretical Framework

Betty Neuman's Systems Theory provided the conceptual framework for this study. Her concept of secondary prevention as intervention relates to the early detection and treatment of physiological health problems. Her concept of health is the maintenance of a stable state. Neuman's client system model (1989) (Figure 1) represents a wholistic view of the client. This system's core is conceptualized as being protected by three sets of concentric rings. The core represents basic survival factors that relate to genetic response patterns, ego structure, cognitive ability, along with the strengths and weaknesses of body organs. The concentric rings consist of the flexible line of defense, the normal line of defense, and the lines of resistance. A dynamic flexible line of defense represents the outer concentric ring. The more distance between the flexible line of defense and the normal line of defense, the greater buffer it provides for the client's normal or stable state of health. The flexible line of defense constitutes the individual's immediate response to stressors. The normal line of defense is the next level of protection in Neuman's client system model. It lies between the flexible line of defense and the lines of resistance and represents the client's ability to maintain a dynamic equilibrium. It includes those resources for adapting to internal and external stressors that have been developed over a lifetime. Neuman (1995) states, " . . . when the normal line of defense has been penetrated, the client presents with symptoms of instability or illness, caused by one or more impacting

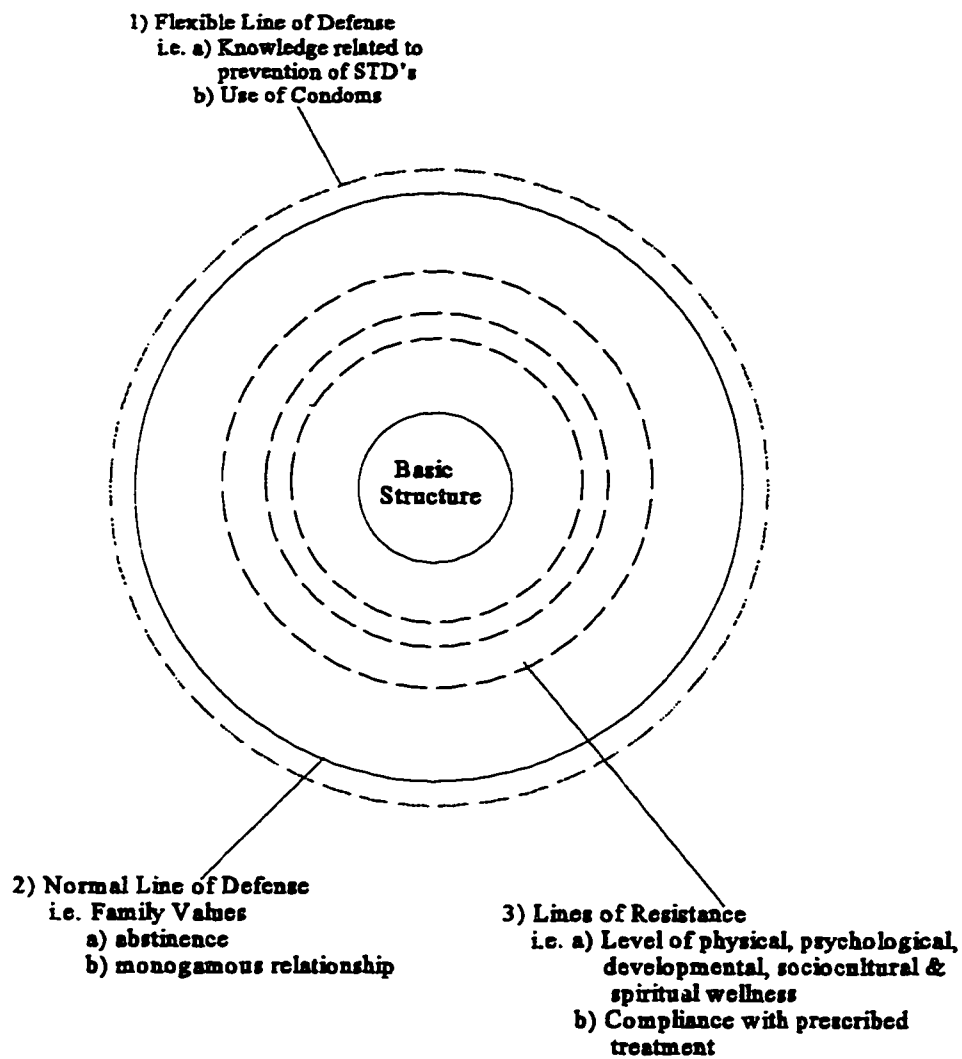


Figure 1. Neuman's client system model.

Source: Neuman, B. (1995). Systems and nursing: Conceptualization of the Neuman Systems Model. The Neuman Systems Model (3rd ed.) (p.28), Norwalk, CT: Appleton & Lange. Adapted with permission.

stressors " (p. 27). Protecting the core is the innermost concentric ring, called the lines of resistance. When stressors invade the normal line of defense, the lines of resistance are involuntarily activated in an attempt to stabilize the client's system by restoring its normal line of defense.

Neuman's (1995) concept of stressors includes intrapersonal, interpersonal, and extrapersonal sources. Each source includes physiological, psychological, developmental, sociocultural, and spiritual variables. Betty Neuman further focused on her concepts of primary, secondary, and tertiary prevention as interventions and on reconstitution (Reed, 1993). Intrapersonal stressors relate to the client's physical functioning. For example, the immaturity of the adolescent and young adult female's reproductive tract makes her more susceptible to contracting a chlamydial infection (Touchstone & Davis, 1992). Also the use of drugs and/or alcohol reduces inhibitions that consequently may increase the incidence of multiple partners and decrease the likelihood of barrier protection being used. Interpersonal stressors relate to the client's interaction with her external environment. For example, having multiple partners or having a partner with multiple partners increases the likelihood of being exposed to chlamydia. Extrapersonal stressors are also part of the client's external environment but are more abstractly related, such as a lack of education related to the transmission of chlamydia, and the media hype which portrays promiscuous sexual encounters to be desirable. For example, a client's flexible line of defense may be her knowledge related to the prevention of STD's or her use of condoms. Her normal line of defense may be her family values (abstinence or a monogamous relationship) and the environment in which she lives (a community that provides easy access to routine health

care). Her lines of resistance may be the maintenance of a high degree of physical, psychological, sociocultural, developmental, and spiritual wellness, and the compliance with treatment of sexually transmitted diseases when needed (Neuman, 1995).

Neuman's Systems Theory states that once the client's normal line of defense is broken, instability (infection) occurs. The primary concern of health care professionals is prevention. Therefore, Neuman's primary prevention as intervention is of prime interest. The purpose of primary prevention as intervention is to promote client wellness by prevention of stress and the reduction of risk factors (Neuman, 1995) (Figure 2). The first goal is to encourage the client to protect her normal line of defense by "...a) increasing her flexible line of defense's ability to withstand environmental stressors", for example, the use of condoms for protection; and by "b) decreasing risk factors" (Reed, 1993, p.14), by remaining abstinent, maintaining a mutually monogamous relationship, or by decreasing her number of partners. Primary prevention interventions include providing risk reduction education and counseling and making condoms readily available.

When primary interventions are not utilized or are ineffective, secondary prevention as intervention must be mobilized (Figure 3). Early, secondary prevention as intervention prevents more severe illnesses from occurring (CDC, 1993). In this study, secondary prevention as intervention refers to selective screening or early testing for chlamydia and providing early treatment when needed. Early treatment allows clients to return to a stable state as soon as possible thus preventing the long term consequences of an unidentified, untreated chlamydial infection (Neuman, 1995).

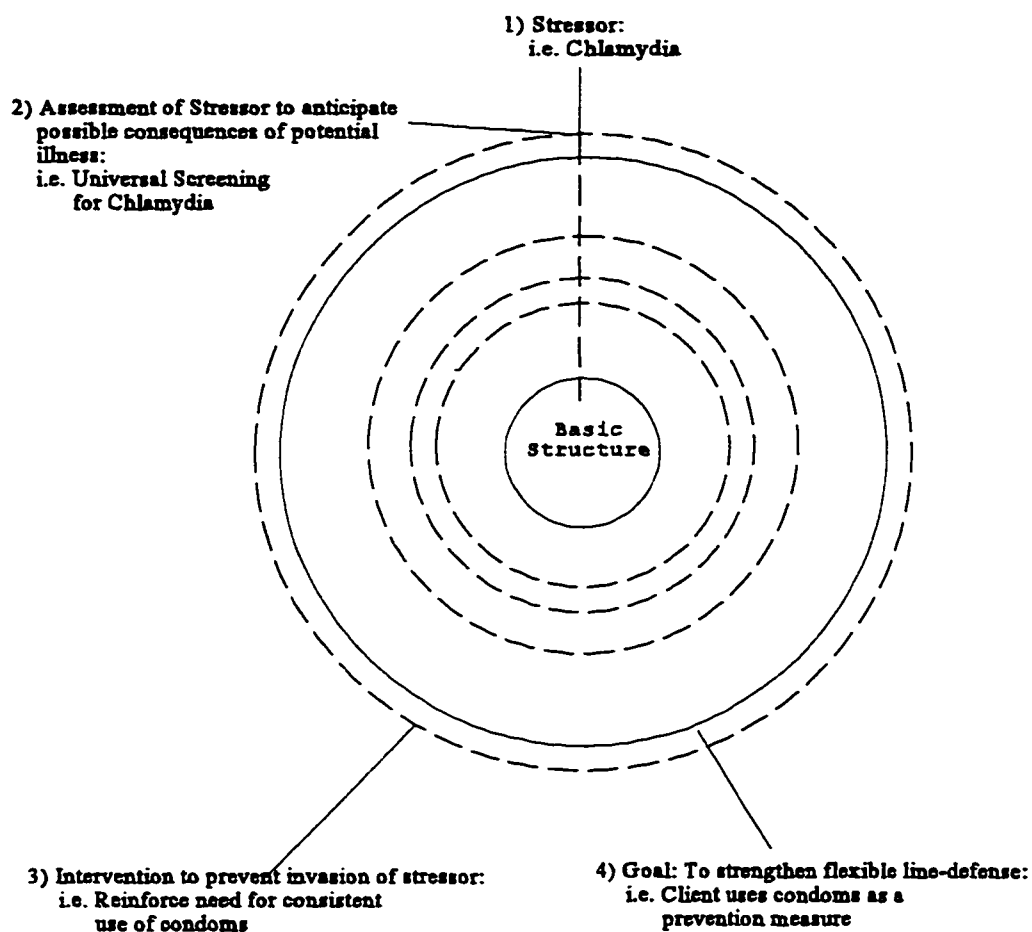


Figure 2. Format for primary prevention as intervention model.

Source: Neuman, B. (1995). *Systems and nursing: Conceptualization of the Neuman Systems Model*. The Neuman Systems Model (3rd ed.) (p.34), Norwalk, CT: Appleton & Lange. Copyright 1980 by Betty Neuman. Adapted with permission.

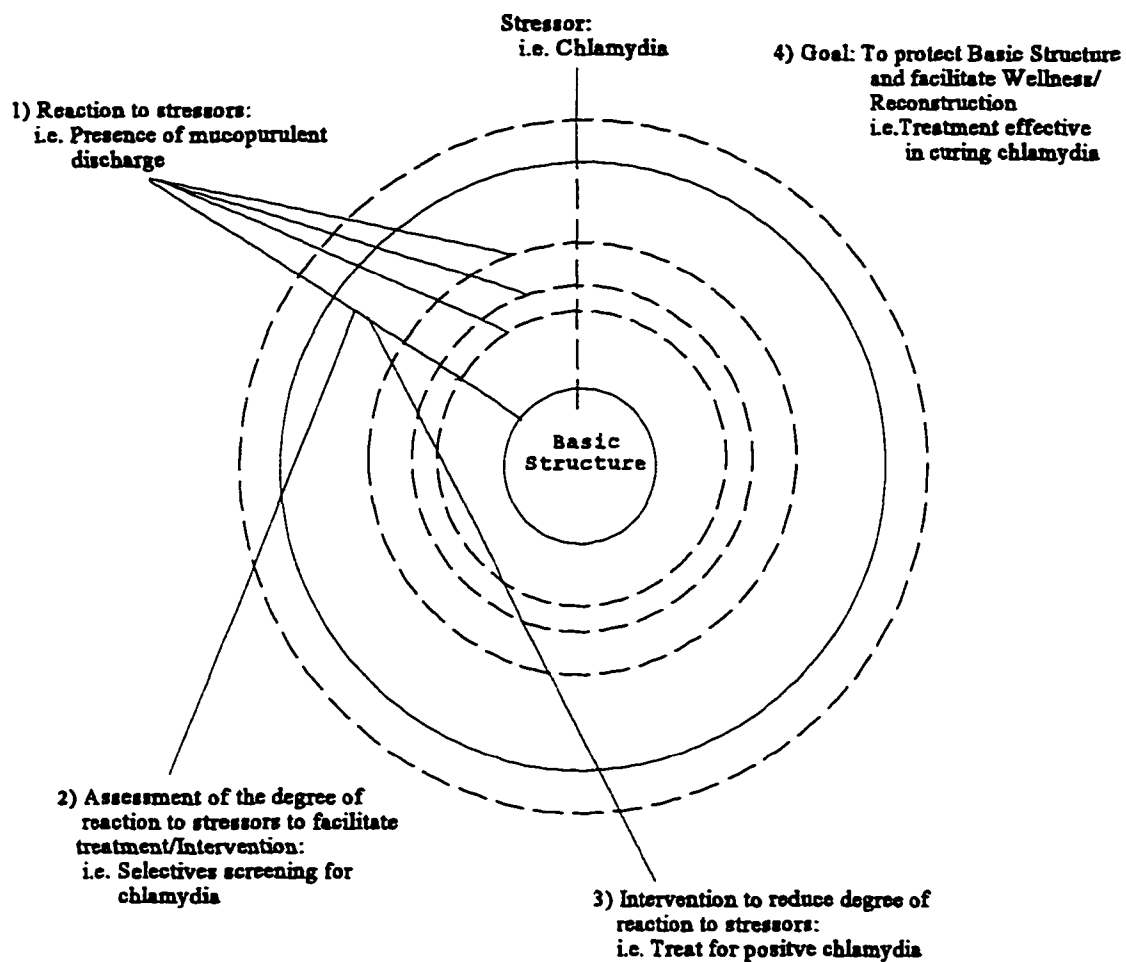


Figure 3. Format for secondary prevention as intervention model.

Source: Neuman, B. (1995). Systems and nursing: Conceptualization of the Neuman Systems Model. The Neuman Systems Model (3rd ed.) (p.35), Norwalk, CT: Appleton & Lange. Copyright 1980 by Betty Neuman. Adapted with permission.

The final phases of Neuman's Systems Theory are reconstitution and tertiary prevention as intervention. Once the client is successfully treated for the chlamydial infection, tertiary intervention is needed for reconstitution to be maintained. Education and counseling focused on compliance with prescribed treatment and prevention of future infection were examples of tertiary prevention in this study, and reconstitution was the return of the client's system to its pre-infectious state of well-being.

Summary

This literature review, which included universal screening, selective screening, and cost benefit analysis studies, pointed to the cost effectiveness of selective screening in low prevalence populations, when nonculture test were used. Selective screening, however, was not found to be cost effective in high prevalence populations. According to the CDC (1993), the Gen-Probe nonculture test has a comparable sensitivity to the DFA and EIA nonculture test. In a 1989 article, Dr. Russell Phillips stated "In any patient population where the prevalence of chlamydial infection is greater than 7%, routine (universal) screening of all patients would be cost effective" (p.93). The Centers for Disease Control states that "... a prevalence of <5% is considered to be low prevalence" (p. 17), and that "High = $\geq 5\%$ " (p. 14). Although CDC acknowledged that the 5% prevalence rate is arbitrary, it is based on the use of nonculture tests such as Chlamydiazyme EIA, and MicroTrak DFA, which all have approximate specificities of 99% and sensitivities of 80%. Because universal screening was recommended for use in high risk populations, CDC's 5% guideline was used in this study to determine whether these family planning clinics should be designated as low or high risk populations.

According to the Prevention Centers of Disease Control in Atlanta (Hillis et al., 1995), unlike viral infections such as HIV, herpes, and genital warts; bacterial infections, including gonorrhea and chlamydia, can be cured. It was pointed out that in Sweden, PID has been nearly eradicated due to collaborative efforts among health care providers, policy makers, educators, the media, as well as other related parties. If the Healthy People 2000 objective to reduce the spread of STD's in the United States is to be met, federal, state and local authorities must allocate funds to provide widespread screening and treatment of chlamydia. Researchers believed that the cost of treating PID and infertility, which are the primary complications of chlamydia, far outweigh the cost of universally screening low risk clients in high risk populations (Sellors et al., 1992).

Definition of Terms

High Prevalence Population - A population with a chlamydia prevalence rate equal to or greater than five percent ($\geq 5\%$).

High Risk Group - Clients who have one or more risk factors, as assessed by the Chlamydia Risk Assessment Tool, using the MDCH guidelines.

Low Risk Population: A population with a chlamydia prevalence rate that is less than five percent ($< 5\%$).

Low Risk Group - Clients who do not have any risk factors, as assessed by the Chlamydia Risk Assessment Instrument, using the MDCH guidelines.

P- Value - The probability that the results obtained are not due to chance alone.

Prevalence Rate: - The number of identified cases of chlamydia divided by the total sample population after the study period of seven consecutive months.

Risk Factor - A single characteristic statistically associated with, although not necessarily causally related to, an increased risk of contracting chlamydia.

Screening - The collection and laboratory testing of endocervical epithelial cell tissue specimens for the presence of *Chlamydia trachomatis*, using a Gen-Probe collection kit.

Selective Screening - The testing of clients who have one or more risk factors for chlamydia as defined by MDCH's selective screening protocol. The risk factors were a) having more than one sex partner in the past 6 months, b) having a new sex partner in the past 6 months, c) having a history of an STD in the past 6 months, d) having a discharge or mucopurulent cervicitis, or e) having a friable cervix.

Selective Screening Prevalence Rate - The number of identified cases of chlamydia, using MDCH's selective screening protocol, divided by the total sample population at a specific time.

Universal Screening - The testing of all clients for *Chlamydia trachomatis* who were seen in one of three health department family planning clinics for an annual or initial examinations.

Universal Screening Prevalence Rate - The number of identified chlamydia cases, using universal screening protocol, divided by the total sample population after the study period of seven consecutive months.

Research Questions

1. What is the prevalence rates of chlamydia in the low risk young adult females seen in this health department's family planning clinics?

2. What is the prevalence rates of chlamydia in the high risk young adult females seen in this health department's family planning clinics?
3. Is there a significant difference in the prevalence rates between young adult females who were considered low risk and those who were considered high risk for chlamydia?

CHAPTER 3

METHODOLOGY

Research Design

This study used a descriptive two group comparison *ex post facto*/correlation design and a convenience sample to examine the risk for chlamydia. The independent variable was the risk category as determined by the Chlamydia Risk Assessment Instrument. The dependent variable was the outcome of the chlamydia test. Each client was given a self-report questionnaire that assessed her risk category for the chlamydial infection. The questionnaire was reviewed by the nurse during the client's routine pre-exam assessment interview. The clinician documented on the questionnaire the presence or absence of high risk factors observed during the physical examination. An independent laboratory determined the results of the nonculture chlamydia test.

Human Subjects

Approval for the *ex-post facto* portion of this study, which involved the review, assessment, and analysis of related client records, was also given by Grand Valley State University's Human Research Review Committee (Appendix A). To maintain client confidentiality, the client's clinic identification number was deleted from the questionnaire after the result were recorded and reviewed for completeness by the researcher. A sequential record number was then assigned. When the clinic visit was completed, the risk

assessment information was used for statistical purposes only and did not become a part of the client's chart. All information was handled confidentially by the health department staff. All reasonable efforts were made to maintain client confidentiality and to maintain an unbiased, accurate collection and analysis of the data.

Instrument

A chlamydia risk assessment instrument (Appendix B) was developed by the author as a questionnaire to collect general, demographic, and risk assessment data for each client. General information included the clinic location, client identification number, type of visit, and payment category. Demographic data, necessary to accurately describe the characteristics of the sample population, included age, race, educational level, and marital status. To assess the client's risk category, questions relating to new partners, multiple partners, recent gonorrheal infections, presence or absence of genital discharge, and presence or absence of a friable or mucopurulent cervix, were included. To assess other possible risks, questions related to the presence of urinary tract symptoms, abdominal or pelvic pain, and the use of antibiotics or vaginal products were asked.

Content Validity and Reliability

The content validity and reliability of this instrument was based on the fact that the general, demographic and risk factors questions were all previously tested. Another contributing factor was the limited number of people involved in specimen collection and data analysis. The general and demographic information was the same information collected by the health department for all client visits. Seven of the risk factors assessed, relating to partners and clinical findings, were the same factors used by the Michigan Department of Community Health for selective screening purposes. Additional questions

relating to pain and the use of condoms were taken from other selective screening studies as possible high risk factors. The question, relating to the use of antibiotics and vaginal preparations was also taken from other studies and used to determine possible causes of negative results. This questionnaire and those used in other studies were limited by the information shared with us by the clients and by the estimation that 50% to 80% of clients with chlamydia are asymptomatic.

Several colleagues with experience developing questionnaires reviewed the instrument. It was pilot tested during two family planning clinic sessions at one clinic site.

Modifications made were to have clients specify age, rather than select from an age group and to specify a co-pay category, rather than select from a co-pay range group.

There was only one nurse practitioner and one physician collecting specimens in this study, and the nurse practitioner was the only researcher involved in the study. Both the nurse practitioner and the physician were trained in the proper technique for specimen collection, according to the Gen-Probe manufacturer instructions. The results were determined by an independent laboratory.

Study Site and Subjects

In 1996, the health department conducted a study that assessed the risk factors of their family planning clinic populations, to reevaluate their current selective screening protocol for chlamydia. Two of their urban clinics (having the highest prevalence rates from 1992-1994) and one rural clinic (prevalence rate unknown) were chosen for this study. Four hundred and three female subjects were screened for chlamydia. All were clients between 20 to 39 years of age who were seen for an initial or annual examination, during the seven consecutive months of this study. The Michigan Department of Community Health

supported this study by making the chlamydia nonculture specimen collection kits (Gen-Probe) available to the health department at a reduced cost and assumed the cost of the laboratory testing.

Procedure

When the client came into the clinic for her scheduled initial or annual family planning examination, she was given a self-report questionnaire to complete along with other clinic forms. A clinic nurse reviewed the questionnaire with each client during her routine pre-exam assessment interview. Explanations and/or clarifications were provided by the nurse as needed. Each client was then seen by a nurse practitioner or physician, and an endocervical specimen was taken during a routine pelvic examination. A Gen-Probe specimen collection kit, containing two Dacron swabs with diluent, was used to collect each specimen. The chlamydia specimen was taken before other specimens such as the Pap smear or gonorrhea culture. Excess cervical mucous was removed with the first swab and discarded. The second swab was used to collect the chlamydia specimen. To insure the collection of sufficient endocervical cells necessary for an accurate test, the Dacron swab was placed into the cervical os and rotated for 30 seconds. Gen-Probe has a sensitivity of 90% and a specificity of 100% (Miettinen, Vuorinen, Varis, & Hallstrom, 1995). After placing the second swab into the collection bottle with the diluent, the top of the swab was broken off near the top of the container and the cap screwed on tightly. The specimen was labeled with the client's name, identification number, and date. After completing each examination, the clinician recorded the presence or absence of a friable or mucopurulent cervix on the bottom of each survey. The specimen was mailed to the processing

laboratory at the end of that clinic day. Within five to seven working days the laboratory mailed the results back to the clinic and the results were recorded on the questionnaire.

CHAPTER 4

DATA ANALYSIS

This study compared the chlamydia prevalence rates of the low and high risk groups, within a health department's family planning clinic, using the Gen-Probe nonculture test. The purpose of this study was to determine a) the prevalence rates of chlamydia in designated low risk groups, b) the prevalence rates of chlamydia in designated high risk groups, and c) if there was a significant difference between the prevalence rates of these two groups.

Sample Characteristics

The sample consisted of 403 adult females, aged 20 to 39, seen in one of three family planning clinics within a local health department. During a period of seven consecutive months, all nonpregnant clients who were seen in these clinics for annual exam (60.8%) or an initial examination (39.2%), were included in this study (Table 6). All of the clinics were located outside a metropolis. Sites A and C were urban clinics having 47 and 297 participants respectively, and Site B was a rural clinic with 59 participants. Family incomes were as follows a) 80.9% had incomes of <100% of the poverty level, which qualified them for no cost family planning services, as identified by a 0% co-pay; b) 18.1% had incomes of 100% to < 175% of poverty and were billed 20% to 60% of the total visit cost, and c) 1% had incomes >175% of poverty and were billed 80% to 100% of the clinic

Table 6.

Type Visits and Percentage of Co-Pay for Each Clinic

	Site A 11.7% (n = 47)	Site B 14.6% (n = 59)	Site C 73.7% (n = 297)	All Sites 100% (N = 403)
Type Visits				
Initial	38.0%	57.6%	35.7%	39.2%
Annual	61.0%	42.4%	64.3%	60.8%
% of Co-Pay				
0%	91.5%	76.3%	80.1%	80.9%
20%- 60%	8.5%	22.1%	18.8%	18.1%
80%-100%	0%	1.7%	1.0%	1.0%

cost. All fees and co-pays were assessed on the date of their clinic visit using the 1996 WCHD/ Federal guidelines (Department of Health & Human Services, 1996). Forty-five percent of the total sample were between the ages of 20 and 24 years of age and 54.8% were 25 years and older (Table 7). The mean age was 25.97, with a standard deviation of 4.7. The racial makeup consisted of 65.5% White, 31.0% Black, and 3.5% other. Of all the subjects in this study, 13.3% of them had not completed high school, 36.1% were high school graduates, 43.9% had completed some college credits, and 6.8 % were college graduates. The largest percentage of the sample were single, not living with their partner (49.9%). The rest of the sample were more evenly distributed with 19.2% single, living with partner; 16.2% married; and 14.6% were separated, divorced or widowed.

Table 7.

Comparison of Demographic Data Prevalence Across Sites

	Site A	Site B	Site C	All Sites
Clients	11.7%	14.6%	73.7%	100%
Age				
20 - 24 years	45.2%	44.1%	46.5%	45.2%
> 25 years	54.8%	55.9%	53.5%	54.8%
Race				
Black	91.5%	13.6%	24.9%	31.0%
White	8.5%	83.0%	71.0%	65.5%
Other	0%	3.4%	4.1%	3.5%
Education				
<11th grade	0%	22.0%	13.6%	13.3%
High school grad	25.5%	40.4%	36.9%	36.1%
Some college	66.0%	33.3%	42.4%	43.9%
College graduate	8.5%	3.5%	7.1%	6.8%
Marital status				
Single not living with partner	68.1%	42.4%	48.5%	49.9%
Single living with partner	14.9%	16.9%	20.3%	19.2%
Married	6.4%	25.4%	15.9%	16.2%
Sep/Div/Wid	10.6%	15.3%	15.2%	14.6%

Demographically Sites B and C were quite similar. Seventy-one percent to 83% were White, 42.4% to 48.5% of the clients were single and not living with their partner, and 33.3% to 42.4% had some college education. Also noted was that 76.3% to 80.1% had a

0% co-pay. Site A identified a much higher percentage of Black participants (91.5%), a slightly higher percentage of 0% co-pays (91.5%), with 68.1% of the clients identified as single and not living with their partners. In addition, Site A had a higher percentage of subjects with some college (66.0%) and a slightly higher percentage of college graduates (8.5%) than Site C. Site C was shown to have 7.1% college graduates, according to the self-report questionnaire, and Site B reported the lowest percentage (3.5%) of college graduates.

Risk Factor Results

Although having sex without using a condom is not one of MDCH's criteria for selective screening, failure to use condoms was assessed as a possible risk factor for chlamydia. Of the 403 subjects screened, the mean prevalence for those who had sex without using condoms, sometime in the last six months, was 72.3% (290).

Seven risk factors were used to differentiate the high risk groups from the low risk groups (Appendix C). The most frequent MDCH selective screening risk factor, identified in this health department, was having a new partner (20.6%) in the past six months. The prevalence of risk factors among those clients who tested positive for chlamydia were as follows a) having a new partner in the past six months (45.5%) (Appendix D); b) having more than one partner in the past six months (25.0%); c) having a friable cervix on examination (16.7%); d) the client or her partner having an unusual discharge (16.7%); e) having a partner who has had more than one partner in the past six months (9.1%); f) having a mucopurulent cervical discharge on examination (8.3%); and g) the client or her partner having had gonorrhea in the past six months (8.3%). If none of the previous

risk factors were identified, the client was designated as low risk. If any of the previous risk factors were identified the client was designated as high risk. If there were no response checked (yes or no) on any one of the risk factor questions, and no other high risk factor was indicated, the case was counted as missing.

Chlamydia Prevalence Rates

The prevalence rates for chlamydia in the low risk groups were Site A, 6.4%, Site B, 0%, Site C, 0.3%, and the mean low risk prevalence rate was 1.0% (Table 8). The mean high risk group prevalence rate was 1.8%. Site A's high risk group prevalence rate was 6.4%; Site B 1.8%, and Site C was 1.0%. The total chlamydia prevalence rates of each clinic (Table 9), which included both the low risk and the high risk groups, were Site A, 12.8%, Site B, 1.7%, Site C, 1.7%, and the mean rate was 3.0%.

A chi-square test with Yates correction was used to compare the test outcome with the risk designator. There was no significant difference in the diagnosis of a chlamydial infection, between the clients who were designated as low or as high risk, in any of the clinics or in the combined population. (Chi Square =1.8, df = 1, p = .18). The total clinic prevalence rates in Site B of 1.7% and Site C of 1.7% were well below the 5% prevalence rate that CDC uses as a guideline to determine the low risk from the high risk groups. Site A however, whose prevalence rate was 12.8%, was well above 5%. Also their low risk group's prevalence rate (6.4%) was equal to that of their high risk group's prevalence rate (6.4%). According to Dr. Phillips (1989), as well as multiple other universal and selective screening studies, Sites B and C fit into the selective screening category based on their low prevalence rates, even though there was no significant difference between their

Table 8.

Chlamydia: Universal Screening Results

	Low Risk Positive	High Risk Positive	Low Risk Negative	High Risk Negative	Totals
Site A	6.4% (3)	6.4% (3)	46.8% (22)	40.4% (19)	100% (47)
Site B	0% (0)	1.8% (1)	56.1% (32)	42.1% (24)	100% (57)
Site C	0.3% (1)	1.0% (3)	62.0% (183)	36.7% (108)	100% (297)
Combined Sites	1.0% (4)	1.8% (7)	59.4% (237)	37.8% (151)	100% (399)

Note. Missing cases: Site B (2) negatives
Site C (1) negative & (1) positive

Table 9.

Universal Screening Prevalence Rates

	Total Participants	Total Positives	Prevalence Rates
Site A	47	6	12.8%
Site B	59	1	1.7%
Site C	297	5	1.7%
Combined Sites	403	12	3.0%

low risk and high risk groups. Site A, however, fits into the universal screening category based on their prevalence rate of 12.8% being well above 5%, and because there was no significant difference between their low risk and their high risk groups.

Other findings

Additional questions were added to assess other possible high risk factors for those testing positive for chlamydia. Included were clients who had a) sexual intercourse at anytime in the past six months without using condoms (91.7%); b) used antibiotics, vaginal medications, or douched in the past 48 hours (18.2%); c) lower abdominal or pelvic pain at the time of examination (8.3%); or d) pain, burning, or frequency of urination (0%).

In order to determine if a lack of knowledge relating to their partners history had an influence on the subjects ability to accurately respond to some of the questions on the risk assessment form, a "don't know" category was added to two of the questions. The first question asked was had their "partner had more than one partner in the last six months?" A third (36.4%) of the participants answered "don't know". The second question asked was had their "partner had a positive test for gonorrhea in the past six months?" A smaller percentage (16.7%) of those responding indicated that they didn't know.

There were no significant differences in the other chlamydia prevalence rates or in the risk factors used to predict the risk for the low and high risk groups. One point of focus was that 72% of the total client sample population reported having had sexual intercourse without using condoms at least once within the last six months, but only 35.4% reported being married or living with their partner. Eleven (91.6%) of those testing positive admitted to having sex without a condom at sometime during the past six months, but one subject denied doing so. This supports the belief that chlamydia can persist for up to 15 months as stated in the Primary Care Update (1994).

When looking at other factors, all clients with a positive test were in the 0% co-pay category, indicating that they reported an income below poverty level. Seventy-five percent were single, and none were college graduates. Although there was a total of 403 participants in this study, the total number of subjects with a positive test for chlamydia (12) was too low to adequately test the risk assessment screening criteria.

CHAPTER 5

DISCUSSION

Summary and Conclusion

Adult females (N=403) from three clinical sites were universally screened for chlamydia risk factors, using a self-report chlamydia risk assessment form. Clients were accustomed to filling out the HIV risk assessment questionnaire, as part of the health departments routine interviewing process. This may have contributed to their cooperativeness in completing this chlamydia risk assessment instrument. The risk assessment tool also provided the nurses with a more structured format in which to discuss this, often silent, STD.

Based on the client's responses on the questionnaire, she was placed in either a low risk or a high risk group and tested to determine if a chlamydial infection was present. Twelve (3.0%) subjects tested positive. The primary purpose of this study was to determine if the use of the risk assessment tool to classify clients as low or high risk would accurately predict the results of a test for *Chlamydia trachomatis*. The secondary purpose was to determine the chlamydia prevalence rate at each clinic. Each clinic was then categorized as a low or high risk population, using CDC's 5% guideline. After analyzing the results, 241 (60.4%) were classified as low risk while 158 (39.6%) were placed in the high risk category with four missing cases. Four (1.0%) of the 12 subjects with chlamydia

were in the low risk group and seven (1.8%) were in the high risk group with one missing case.

The conclusion was that the mean prevalence rate of the health department's family clinics was 3% which categorized it as a low risk population. Sites B and C both had prevalence rates of 1.8% each, which is consistent with the mean rate categorization. Site A, however, had a prevalence rate of 12.8%. Having a rate $\geq 5\%$ places Site A in the high risk category, and should, therefore, be evaluated independent of Sites B and C.

Having less than a ninth grade education was reported by Holmes et al. (1993), to be a risk factor for chlamydia; however, Addiss et al. (1987) stated there is no relationship between a positive chlamydial infection and education. In addition, none of the other studies, documented in this literature review, assessed this relationship. In this study, Site A with a prevalence of 12.8%, reported the highest rate of clients with college degrees or with some college education (74.5%). This was compared to 49.5% at Site C and 36.8% at Site B, even with almost identical mean ages.

Also of interest are the findings related to race. In the literature review Handsfield et al. (1986), Addiss et al. (1987), and Han et al. (1993) reported no relationship existed between race and a chlamydial infection. Only CDC (1994) reported the presence of a relationship. Although five of the six clients with a positive test in Site A were Black, the prevalence was only 11.6%, while the prevalence for Whites was 25%. The greater number (5 out of 6) was most likely related to the fact that 91.5% of the clients at Site A were Black.

Another point of interest was the relationship between low income and the presence of chlamydia. Although it was not discussed in the literature reviews, it was noted that all the clients with a positive chlamydia test in this study, and 91.5% of Site A's total sample group reported incomes below the poverty level. Again, because there were only 12 cases of chlamydia identified in this study, no determination of differences in physical or socioeconomic risk factors could be made between those with or without chlamydia or among the three sites.

Taking a closer look at the clients at Site A who had chlamydia, compared to those who did not have chlamydia, the following data was noted for demographic variable categories (Table 10). Of those with chlamydia, 66.7% were age 24 or younger, while only 34% of those without chlamydia were in this age bracket. Thirty-three percent of clients with chlamydia were single and living with a partner. None were married or divorced. Of those without chlamydia, 12% were single and living with a partner, while a similar percentage were divorced, separated or widowed, and 7% were married. White clients comprised 16.7% of those with chlamydia and 7.3% of those without chlamydia. There was approximately the same percentage of clients with chlamydia as those without who were Black, high school graduates, or with some college education, and those who were single and not living with their partner. The most prominent social risk factor was having sex without using a condom (83.3% vs 53.7%), as compared to those who did not have chlamydia (Table 11). Other risk factors were a) having multiple partners (33.3% vs 17.1%), b) having a partner with multiple partners (16.7% vs 9.8%), c) having a new sexual partner (33.3% vs 22%), and d) having an unusual discharge (33.3% vs 22%).

Table 10.

Site A Client Demographics: With and Without Chlamydia

	With Chlamydia n = 6	Without Chlamydia n = 41	Total Site A n = 47
AGE 20 - 24 years	66.7% (4)	34.1% (14)	38.3% (18)
≥ 25 years	33.3% (2)	65.9% (27)	61.7 (29)
RACE Black	83.3% (5)	92.7% (38)	91.5% (43)
White	16.7% (1)	7.3% (3)	8.5% (4)
EDUCATION			
High school graduate	33.3% (2)	24.4% (10)	25.5% (12)
Some college	66.7% (4)	65.9% (27)	66.0% (31)
College graduate	(0)	9.8% (4)	8.5% (4)
MARITAL STATUS			
Single not living with partner	66.7% (4)	68.3% (28)	68.1% (32)
Single living with partner	33.3% (2)	12.2% (5)	14.9% (7)
Married	(0)	7.3% (3)	6.4% (3)
Sep/Div/Wid	(0)	12.2% (5)	10.6% (5)

Limitations and Recommendations

The fact that only 12 subjects tested positive was a major limitation of this study. The number of subjects with chlamydia was too low to statistically test the risk assessment tool's ability to accurately predict test results. However, the fact that Site A had a 12.8% prevalence rate indicated that it should be considered a high risk population at this time.

Table 11.

Site A Client Risk Factors: With and Without Chlamydia

	With Chlamydia n = 6	Without Chlamydia n = 41	Total Site A N = 47
New partner < 6 months	33.3% (2)	22.6% (9)	23.4% (11)
Multiple partners (mp) < 6 months	33.3% (2)	17.1% (7)	19.1% (9)
Partner with mp Yes	16.7% (1)	9.8% (4)	10.6% (5)
Don't know	33.3% (2)	22% (9)	23.4% (11)
Gonorrhea - self or partner tx < 6 months Yes	16.7% (1)	2.4% (1)	4.2% (2)
Don't know	16.7% (1)	12.2% (5)	12.8% (6)
Unusual discharge	33.3% (2)	22% (9)	23.4% (11)
Sex without condoms No	16.7% (1)	46.3% (19)	42.6% (20)
Yes	83.3% (5)	53.7% (22)	57.4% (27)
Pain, burning or frequency of urination	(0)	7.3% (3)	6.4% (3)
Abdominal/pelvic pain	16.7% (1)	24.4% (10)	23.4% (11)
Antibiotics, vaginal meds, or douching <48 hours	16.7% (1)	14.6% (6)	14.9% (7)
Mucopurulent cervicitis (MPC)	16.7% (1)	14.6% (6)	14.9% (7)
Friable cervix	(0)	14.6% (6)	12.8% (6)

Both the prevalence rates of the high risk group in Site A (6.4%, 3) and the low risk group (6.4%, 3) were equal. This indicates that further study is needed to determine if the assessment tool, based on the MDCH screening criteria, is adequate to determine who should or should not be screened. It was, therefore, recommended that universal screening be continued at Site A until that determination can be made. Although there was no

significant difference between the low risk and the high risk groups at Sites B or C in relation to the number of positive results obtained, their mean prevalence rates fell well below the 5% prevalence rate. Therefore, universal screening was terminated and selective screening protocols were resumed.

Because Site A is a high risk population (12.8%), as opposed to the low risk populations of Sites B and C (1.8% each), future study using the Health Belief Model was recommended to assess the beliefs, values, and attitudes of that population toward sexually transmitted diseases and the use of primary prevention measures. The Health Belief Model (HBM) assumes that the client must a) believe that her health is in jeopardy, b) perceive the potential seriousness of having complications related to an untreated chlamydial infection, c) believe that the benefits from the recommended behavior outweigh the costs or inconvenience and are within her ability to do, and d) have a "cue to action" that makes her feel the need to use primary preventive measures (Green & Kreuter, 1991).

According to Simon and Das (1984), it is helpful to assess data on a group's perception of various aspects of the HBM prior to developing an educational program for a particular group, such as Site A. These authors recommended the use of the Venereal Disease (VD) Education Health Belief Model Scale Dimensions in analyzing similar populations. This model uses a 5-point scale ranging from strongly agree to strongly disagree to rate several questions in five major scale categories. These scales are the Susceptibility Scale, Seriousness Scale, Barrier Scale, Benefit Scale, and the Likelihood Scale (Appendix E). Examples of questions on these scales are a) Susceptibility Scale:

I am too young to have venereal disease, b) Seriousness Scale: an attack of gonorrhea might make me unable to have children, c) Barrier Scale: I am too embarrassed to go for VD checkups, and d) Benefit and Likelihood Scale: telling my sexual partner(s) if I suspect that I have VD. Once this data has been collected and assessed, health professionals can tailor a program more suited to the specific needs of Site A's high risk population. Although this model by Simon and Das is an excellent model, it is recommended that it be updated to reflect the change in terminology from the use of Venereal Disease (VD) to the current use of Sexually Transmitted Disease (STD). Also recommended is a change reflecting the current recommendation for yearly physical examinations, unless otherwise indicated.

Other limitations of this study included the use of convenience sampling, whereby clients were self-selected by coming to one of the three pre-selected clinics, pre-designed for use by low and no income clients. Due to the limited number of available participants, random sampling was not recommended.

Prior studies have shown that although there are many risk factors that may place a client in the high risk category for chlamydia, the only consistent demographic risk factor found is being less than 20 years of age (Wiesmeier et al., 1984; Handsfield et al., 1986; Addiss et al., 1987; Han et al., 1993, & CDC, 1994). Because there has been no single physical risk factor or group of risk factors identified as a positive predictor for this sexually transmitted disease, further studies are needed. One of the most frequent recommendations is for further development of less costly, less invasive, and more sensitive test that would make widespread universal screening practical. At the present

time the development of a more sensitive rapid stat test would be beneficial. Due to the difficulty encountered with client follow-up such as a) contacting clients in a confidential manner, especially with the new caller id, b) inaccurate phone numbers and/or addresses given by the clients, c) the transient nature of clients, as well as d) clients who do not return for treatment when notified, having a rapid stat test, whereby results can be available (in < 30 minutes) while the client is still in the clinic, would be a major advantage. This would facilitate providers in prescribing immediate treatment based on a more definitive diagnosis as opposed to treatment based on a presumptive diagnosis, or delaying treatment while chlamydia results are pending. The current rapid stat test, however, detects all three chlamydia species, has a high false-positive rate, and has a sensitivity of only 48.5% (Hook III, Spitters, Reichart, Neumann & Quinn, 1994).

Although several high risk factors have been identified, no one factor or group of factors has been found to be a reliable positive predictor for chlamydia. Unfortunately, most of the risk factors are based on client self-report of their own behavior as well as their knowledge of and willingness to report their partner's behavior over the past six months. For example, clients are asked a)"Have you had a new sexual partner?" b)"Have you had more than one partner?" c)"Has your partner had more than one partner?" and d)"Have you or your partner had a positive test for gonorrhea or an unusual discharge?" Sharing such confidential information with virtual strangers is frequently difficult for some and unthinkable for others. If there was some way to elicit more reliable responses from clients, it would most likely increase the positive predictive values of the current risk factor criteria. Establishing a more trusting climate, whereby the client is able to share

sensitive information more openly, whether it is written or verbal, is the crucial first step. Some clients may be willing to share the requested information but may not be reliable because they have not discussed these issues with their partner(s), or their partners have not been truthful with them. Encouraging clients to establish better communication between them and their partners, so that they are more knowledgeable about their partners, is another necessary step. The third step is to reduce the cost of testing so that it is available to all sexually active clients as part of their routine gynecological examination. Doing so would minimize the risk of developing complications of an untreated chlamydial infection. The fourth step is to follow up on client contacts, as recommended by the CDC (1993), so that asymptomatic partners do not go untreated and unknowingly spread the infection to others.

Theoretical and Clinical Implications for Nursing

Extensive selective screening studies have been done, and several high risk factors have been identified for the chlamydial infection. Betty Neuman's concept of primary prevention as intervention can, therefore, be used as a basis for educating the public in general and the client in particular about risk reduction methods. Primary prevention focuses on the protection of the flexible line of defense from invasion by a stressor such as *Chlamydia trachomatis*. The challenge to health professionals is to a) provide education as needed, b) activate client acceptance and/or motivation, and c) assist clients in developing or mobilizing skills needed to negotiate partner cooperation in utilizing primary prevention measures. For example, maintaining a mutually monogamous relationship and/or the consistent use of condoms are the primary means of risk reduction for

chlamydia and other STD's. Therefore, the more effective health professionals are in assisting clients to utilize these primary preventive measures, the greater impact they will have in reducing the prevalence rate of chlamydia. In line with Neuman's primary prevention model, many states have mandated low income family planning and STD clinic services for local communities. Providing flexible hours and user friendly clinic services will enhance the clients desire and willingness to use them when needed. Neuman's secondary prevention as intervention focuses on early detection of diseases, such as chlamydia, and provides for treatment prior to or at the early onset of symptoms. Universal and selective screening can be utilized to detect sexually transmitted diseases prior to the onset of symptoms. Selective screening can be used to detect chlamydia and provide treatment when symptoms first occur. Because chlamydia has been labeled the silent STD, selective screening for contact follow-ups is the best means for early treatment of asymptomatic partners. Neuman's Systems Model can be effectively used by health care professionals in developing services for the prevention, early detection and treatment of chlamydia and other sexually transmitted diseases.

Chlamydial trachomatis is a bacterial infection that can be easily treated with one oral dose of Azithromycin or by taking Doxycycline twice a day for seven days. Therefore, it is up to all health care providers to offer screening and treatment to their sexually active clients. Universal screening is recommended if their site prevalence rate is $\geq 5\%$, and selective screening if their prevalence rate is $< 5\%$. Failure to do so places clients at undo risk, and the money saved by failing to screen clients will be lost in treating clients who experience complications such as PID or infertility.

As a result of this study, the Michigan Department of Community Health approved universal screening at Site A, which is currently in effect. This decision was based on Site A's high prevalence rate of 12.8%, as compared to the 1994 local out county and state prevalence rates of 7.9% and 5.08% respectively. Selective screening was subsequently resumed at the low prevalence Sites B & C.

APPENDICES

APPENDIX A
Human Research Review



1 CAMPUS DRIVE • ALLEDALE MICHIGAN 49401-9403 • 616/885-0811
September 9, 1996

Verneal Y. Glispie
19591 Nadol Drive
Southfield, MI 48075

Dear Verneal:

The Human Research Review Committee of Grand Valley State University is charged to examine proposals with respect to protection of human subjects. The Committee has considered your proposal, "*Chlamydia Screening: Universal vs. Selective Screening Protocol*", and is satisfied that you have complied with the intent of the regulations published in the Federal Register 46 (16): 8386-8392, January 26, 1981.

Sincerely,

[Redacted Signature]

Howard Stein, Acting Chair
Human Research Review Committee

APPENDIX B

Wayne County Department of Health

(Page 1 of 2)

Location:

_____ 1) Highland Park

Client ID# _____

_____ 2) Sumpter

_____ 3) Westland

Date _____

Chlamydia Risk Assessment

This information is completely voluntary and strictly confidential. It will not be part of your medical record here. This information will be helpful for statistical and planning purposes. Do not write your name on this sheet.

1) City of residence: _____ Zip Code _____.

2) Type of visit: (1) Initial _____, (2) Annual _____, (3) Other _____.

3) Age: _____, Birth date: _____.

4) Race/Ethnicity (1) Black _____, (2) White _____, (3) American Indian _____,

(4) Asian/Pacific Islander _____, (5) Alaskan Native _____, (6) Hispanic _____,

(7) Arabic _____, (8) Other _____.

5) Highest grade completed: (1) Less than 8th _____, (2) 8th-11th _____,

(3) High School Grad _____, (4) Some College _____, (5) College Grad _____.

6) What percentage of your family planning bill are you expected to pay? Ask clerk

(1) 0% __, (2) 20% __, (3) 40% __, (4) 60% __, (5) 80% __, (6) 100% __.

7) Marital Status:

(1) Single (not living with partner) __, (2) Single (living with partner) _____,

(3) Married __, (4) Separated __, (5) Divorced _____, (6) Widowed _____.



- 8) Have you had a new sexual partner in the last six months?--- (0) No __ (1) Yes __
- 9) Have you had more than one sex partner in the last six months? (0) No __ (1) Yes __
- 10) Has a partner of yours had more than one partner in the last six months?-----
----- (0) No __, (1) Yes __, (2) Don't know ____
- 11) Have you or a partner had a positive test for gonorrhea in the last six months? -----
----- (0) No __, (1) Yes __, (2) Don't know ____
- 12) Do you or a partner have an unusual discharge?----- (0) No __ (1) Yes __
- 13) In the last six months, have you ever had sexual intercourse without using a
condom?----- (0) No __ (1) Yes __
- 14) Do you have frequent, burning, or painful urination ? --- (0) No __ (1) Yes __
- 15) Do you have lower abdominal or pelvic pain ? ----- (0) No __ (1) Yes __
- 16) Have you used any type of antibiotics, vaginal creams, jellies, suppositories or
douches in the past 48 hours?----- (0) No __ (1) Yes __

If you have any additional questions or concerns, you may discuss them with the staff during your visit today. Please return this sheet to one of the health care providers today. Thank you for helping us to help you.

!!STOP HERE!!

Interviewing Nurse _____

****TO BE RECORDED BY Physician/Nurse Practitioner:**

****17) Mucopurulent discharge present?_____ (0) No __ (1) Yes __**

****18) Friable cervix ? ----- (0) No __ (1) Yes __**

19) RESULTS of chlamydia test----- (0) Negative __ (1) Positive __

20) Risk level ----- (1) Low __ (2) High __

VYG&KAT/04/9



APPENDIX C

Comparison of Chlamydia Risk Factor Prevalence Across Sites

		Site A n = 47	Site B n = 59	Site C n = 297	All Sites N= 403
Sex Without Condoms	Yes	(27) 57.4%	(47) 79.7%	(216) 73.2%	(290) 72.3%
	No	(20) 42.6%	(12) 20.3%	(79) 26.8%	(111) 27.7%
	Missing Cases (2)				
New partner	Yes	(11) 23.4%	(9) 15.3%	(63) 21.3%	(83) 20.6%
	No	(36) 76.6%	(50) 84.7%	(233) 78.7%	(319) 79.4%
	Missing Cases (1)				
Multiple Partners (mp)	Yes	(9) 19.1%	(4) 6.8%	(36) 12.1%	(49) 12.2%
	No	(38) 80.9%	(55) 93.2%	(261) 87.9%	(354) 87.8%
	Missing Cases (0)				
Partner with mp	Yes	(5) 10.6%	(1) 1.8%	(21) 7.1%	(27) 6.8%
	No	(31) 66.0%	(47) 85.5%	(222) 75.5%	(300) 75.8%
	Don't Know	(11) 23.4%	(7) 12.7%	(51) 17.3%	(69) 17.4%
	Missing Cases (7)				
Unusual discharge	Yes	(11) 23.4%	(6) 10.3%	(25) 8.4%	(42) 10.5
	No	(36) 76.6%	(52) 89.7%	(271) 91.6%	(359) 89.5%
	Missing Cases (2)				
Abdominal / Pelvic pain	Yes	(11) 23.4%	(8) 13.6%	(48) 16.2%	(67) 16.6%
	No	(36) 76.6%	(51) 86.4%	(249) 83.8%	(336) 83.4%
	Missing Cases (0)				
Antibiotics, vaginal meds, or douching <48 hours	Yes	(7) 14.9%	(4) 6.9%	(31) 10.5%	(42) 10.5%
	No	(40) 85.1%	(54) 93.1%	(264) 89.5%	(358) 89.5%
	Missing Cases (3)				
Mucopurulent cervicitis	Yes	(7) 14.9%	(5) 8.5%	(11) 3.7%	(23) 5.7%
	Missing Cases (4) No	(40) 85.1%	(54) 91.5%	(286) 96.3%	(380) 94.3%

APPENDIX D
Risk Factors for Clients With Chlamydia

	Site A n = 6	Site B n = 1	Site C n = 5	ALL SITES N= 12
New partner < 6 months	(2) 33.3%	(1) 100%	(2) 50% 1 missing case	(5) 45.5%
Multiple partners (mp) < 6 months	(2) 33.3%	(0)	(1) 20%	(3) 25.0%
Partner with mp Yes	(1) 17%	(0)	(1) 20%	(1) 9.1%
Don't know	(2) 33.3%	(0)	(1) 25% 1 missing case	(4) 36.4%
Gonorrhea - self or partner tx < 6 months Yes	(1) 17%	(0)	(0)	(1) 8.3%
Don't know	(1) 17%	(0)	(1) 20%	(2) 16.7%
Unusual discharge	(2) 33.3%	(0)	(0)	(2) 16.7%
Sex without condoms No	(1) 16.7%	(0) 0%	(0) 0%	(1) 8.3%
Yes	(5) 83.5%	(1) 100%	(5) 100%	(11) 91.7%
Pain, burning or frequency of urination	(0)	(0)	(0)	(12) 100%
Abdominal/pelvic pain	(1) 17%	(0)	(0)	(1) 8.3%
Antibiotics, vaginal meds, or douching <48 hours	(1) 17%	(0)	(1) 25% 1 missing case	(2) 18.2%
Mucopurulent cervicitis (MPC)	(1) 17%	(0)	(0)	(1) 8.3%
Friable cervix	(0)	(1) 100%	(1) 20%	(2) 16.7%

APPENDIX E

Items Comprising the VD Education HBM Scale Dimensions

(Each item rated along a 5-point scale from Strongly Agree to Strongly Disagree)

1) Strongly Agree 2) Agree 3) Unsure 4) Disagree 5) Strongly Disagree

Susceptibility Scale

1. I cannot contract VD because I/my sexual partner(s) douche after sexual intercourse.
2. I am too young to have venereal disease.
3. I am very healthy so my body can fight off venereal disease.
4. I take a bath every day with soap and water, so I am not likely to catch venereal disease.
5. I can't catch venereal disease because I always use a clean toilet seat.
6. My religious teaching has been very good, so I cannot contract venereal disease.
7. My sexual partner(s) has/have resistance to venereal disease, so I cannot get VD.
8. I cannot contract VD because my sexual partner(s) use the pill (oral contraceptive).
9. People like me don't get VD.
10. I cannot contract VD because my sexual partner(s) is/are always very clean.
11. If I had a venereal disease and got treated, I could not contract it again.
12. If I had syphilis, I could not have gonorrhea at the same time.

Seriousness Scale

1. I think gonorrhea is a serious disease because it may damage my heart in the long run.
2. An attack of gonorrhea might make me unable to have children.
3. Venereal disease is more serious than most other diseases.
4. In my opinion gonorrhea is a serious disease because it may eventually cause arthritis.
5. I don't believe that VD is a serious disease because it is not going to kill me.
6. Contracting VD will disturb my peace of mind.
7. If I contracted VD, it would seriously disturb my family relations.

Barrier Scale

1. I don't go for VD checkups because I am afraid other people in the clinic might think I have VD.
2. I am afraid of pain during VD checkups.
3. I don't want to go for VD checkups because the examination might show that I have VD.
4. I don't go for VD checkups because I have no time to do so.
5. I am embarrassed to go for VD checkups.
6. I don't like to go for VD checkups because I'm afraid the doctor might not be considerate of me.
7. I don't go for VD checkups because I don't know the location of VD clinics.

Appendix E (continued)

Items Comprising the VD Education HBM Scale Dimensions

8. I am hesitant to go to VD clinics because the clinic workers may tell others about my visit.
9. I am unable to afford the cost of periodic VD checkups.
10. VD clinic hours are inconvenient for me.
11. If I were infected with VD, I would be reluctant to disclose the name of all my sexual partners to protect my privacy.
12. If I were infected with VD, I would be reluctant to disclose the name of all my sexual partners to protect their privacy.

Benefit Scale and Likelihood Scale

*These two scales comprise the same 14 items considered from a different perspective.

* For the Benefit Scale, the items were answered in response to "How strongly do you agree that the following actions are useful in controlling and preventing venereal disease?"

* For the Likelihood Scale the items were answered in response to "How likely are you are you to take the following actions in order to prevent the control of venereal disease?"

1. Refusing sexual activities with casual sexual partners who would not accept the use of a condom (rubber).
2. Avoiding sexual intercourse with persons who have many sexual partners.
3. Refusing sexual relations with anyone who I know has had VD.
4. Examining my genital area regularly for signs of VD infection.
5. Examining regularly the genital area of my sexual partner(s) for any sign of VD infection.
6. Carrying a condom (rubber) at all times for use whenever I have sexual intercourse with a casual sexual partner.
7. Seeking immediate medical advice if I suspect that I have contracted a venereal disease.
8. Telling my sexual partner(s) if I suspect that I have VD.
9. Washing the genital area with soap and water immediately after sexual intercourse.
10. Releasing the names of all my sexual contacts to the VD clinic authorities if I am diagnosed as having VD.
11. If infected with VD, avoiding sexual activities (even after treatment) until the cure is verified by a physician.
12. Encouraging anyone I suspect of having VD to seek immediate medical help.
13. Getting regular VD checkups a minimum of four times a year for early diagnosis of the disease.

Appendix E (continued)

Items Comprising the VD Education HBM Scale Dimensions

14. Encouraging my friends who are sexually active to have regular VD checkups a minimum of four times a year.

Source: Simon, K. & Das, A. (1984). An application of the Health Belief Model toward educational diagnosis for VD education. Health Education Quarterly, 415-416.

LIST OF REFERENCES

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Addiss, D., Vaughn, M., Holzhueter, M., Bakken, L., & Davis, J. (1987). Selective screening for *Chlamydia trachomatis* infection in nonurban family planning clinics in Wisconsin. Family Planning Perspectives 19, 252-256.

Addiss D., Vaughn, M., Golubjatnikov, R., Pfister, J., Kurtycz, F., & Davis, J. (1990). *Chlamydia trachomatis* infection in women attending urban midwestern family planning and community health clinics: Risk factors, selective screening, and evaluation of non-culture techniques. Sexually Transmitted Diseases 17, 138-146.

Centers for Disease Control and Prevention (1993). Recommendations for the prevention and management of *Chlamydia trachomatis* infections. Morbidity and Mortality Weekly Report 42, 1-32.

Centers for Disease Control (1994). Chlamydia prevalence and screening practices San Diego County, California, 1993. Morbidity and Mortality Weekly Report 43, 366-375.

Como, D. (Ed.). (1990). Mosby's pocket dictionary of medicine, nursing, and allied health. (3rd ed.). St. Louis: Mosby.

Department of Health & Human Services (1996). Federal Register. 61, Washington D.C. p. 8286.

Drolet, J., Patterson, S., & Williams, N. (1992). A national assessment of *Chlamydia trachomatis* screening at university and college student health services. Health Values. 16, 43-49.

Embil, J., & Pereira, L. (1985). Prevalence of *Chlamydia trachomatis* and genital mycoplasma in asymptomatic women. Canadian Medical Association Journal. 133, 34-35.

Green, L., & Kreuter, M. (1991). Health promotion planning: An educational and environmental approach (2nd ed.). Mountain View, CA: Mayfield.

Han, Y., Morse, D., Lawrence, C., Murphy, D., & Hipp, S. (1993). Risk profile for chlamydia infection in women from public health clinics in New York State. Journal of Community Health, 18, 1-9.

Handsfield, H., Jasman, L., Roberts, P., Hanson, V., Kothenbeutel, R., & Stamm, W. (1986). Criteria for selective screening for *Chlamydia trachomatis* infection in women attending family planning clinics. The Journal of the American Medical Association, 255, 1730-1734.

Hanson, M. (1992). Proficiency testing under CLIA '88. Syva Microtopics: Continuing Education for Syva MicroTrak Customers, 2, 1-8.

Hillis, S., Black, C., Newhall, J., Walsh, C., & Groseclose, S. (1995). New opportunities for chlamydia prevention: Applications of science to public health practice. Sexually Transmitted Diseases, 22, 197-202.

Holmes, M., Safyer, C., Bickell, N., Vermund, S., Hanff, P., & Phillips, R. (1993). Chlamydia cervical infection in jailed women. American Journal of Public Health, 83, 551-554.

Hook III, E., Spitters, C., Reichart, C., Neumann, T., & Quinn, T., (1994). Use of cell culture and a rapid diagnostic assay for *Chlamydia trachomatis* screening. The Journal of the American Medical Association, 272, 867-871.

Humphreys, J., Henneberry, J., Richard, R., & Beebe, J. (1991). Cost-benefit analysis of selective screening criteria for *Chlamydia trachomatis* infection in women attending Colorado family planning clinics. Sexually Transmitted Diseases, 19, 47-53.

Johnson, B., Poses, R., Fortner, C., Meier, F., & Dalton, H. (1990). Derivation and validation of a clinical diagnostic model for chlamydial cervical infection in university women. The Journal of the American Medical Association, 264, 3161-3166.

Johnson, M. (1992). Widespread screening seeks to lower chlamydia prevalence. Family Planning Perspectives, 24, 135-136.

Marrazzo, J., Celum, C., Fine, D., DeLisle, S., Mosure, D., Handsfield, H. (1994). Cost-effectiveness of selective vs universal screening for *Chlamydia trachomatis* infection in women attending family planning and STD clinics. 8th International Symposium on Human Chlamydial Infection, Paris, 63-66.

Michigan Department of Community Health (1995). An interval summary of gonorrhoeae and chlamydia testing results. Unpublished, 2-3.

Miettinen, A., Vuorinen, P., Varis, T., & Hallstrom, O. (1995). Comparison of enzyme immunoassay antigen detection, nucleic acid hybridization and pcr assay in the diagnosis of *Chlamydia trachomatis* infection. European Journal of Clinical Microbiology & Infectious Diseases, 14, 546-549.

Neuman, B. (1989). The Neuman Systems Model. (2nd ed.). Norwalk, CT: Appleton and Lange.

Neuman, B. (1989). Neuman's Systems Model. In J. Fawcett (Ed.), Analysis and Evaluation of Conceptual Models of Nursing (2nd ed.). (pp. 169-204). Philadelphia: Davis.

Neuman, B. (1995). The Neuman Systems Model. (3rd ed.). Norwalk, CT: Appleton and Lange.

Nettleman, M., & Jones, R. (1988). Cost-effectiveness of screening women at moderate risk for genital infections caused by *Chlamydia trachomatis*. The Journal of the American Medical Association, 269, 207-213.

Phillips, R., Aronson, M., Taylor, W., & Safran, C. (1987). Should tests for *Chlamydia trachomatis* cervical infection be done during routine gynecologic visits? An analysis of the cost of alternative strategies. Annals of Internal Medicine, 107, 188-194.

Primary Care Update (1994). Update: new weapons in the war against *Chlamydia trachomatis* infection. Consultant, 34, 103-6.

Sellors, J., Pickard, L., Gafni, A., Goldsmith, C., Jang, D., Mahony, J., & Chernesky, M. (1992). Efficiency of selective vs universal screening for chlamydial infection in sexually active young women. Archives of Internal Medicine, 152, 1837-1844.

Simon, K., & Das, A. (1984). An application of the Health Belief Model toward educational diagnosis for VD education. Health Education Quarterly, 403-416.

Touchstone, D., & Davis, D. (1992). Consider chlamydia. RN, 55, 32-37.

Trachtenberg, A., Washington, E., & Halldorson, S. (1988). A cost-based decision analysis for chlamydia screening in California family planning clinics. Obstetrics and Gynecology, 71, 101-107.

U.S. Public Health Service (1991). Curbing the increase in rates of STDs. Cancer Weekly, 12, 15-18.

Wayne County Department of Health (1995). [Chlamydia results from Wayne County Department of Health clinics]. Unpublished raw data.

Wayne County Department of Health (1996). Poverty income guidelines 1996 matrix: Family planning program sliding fee schedule. Wayne County Public Health Department: Community Mental Health Clinics / Management Information System User Guide. ml. 21.

Weinstock, H., Bolan, G., Kohn, R., Balladares, C., Back, A., & Oliva, G. (1992). *Chlamydia trachomatis* infection in women: A need for universal screening in high prevalence populations? American Journal of Epidemiology 135, 41-47.

Wiesmeier, E., Lovett, M., & Forsythe, A. (1984). *Chlamydia trachomatis* isolation in a symptomatic university student population. Obstetrics and Gynecology, 63, 81-83.

Woolard, D., Canp, Larson, J., & Hudson, L. (1989). Screening for *Chlamydia trachomatis* at a university health service. Journal of Obstetrical and Gynecological Neonatal Nursing, 145-149.

Zimmerman, H., Potterat, J., Dukes, R., Muth, J., Zimmerman, H., Fogle, J., & Pratts, C. (1990). Epidemiologic differences between chlamydia and gonorrhea. American Journal of Public Health, 80, 1338-1342.