

An Epidemiologic Analysis of
Chlamydia trachomatis and *Neisseria gonorrhoeae*
Infections in Female Federal Prisoners

2002

Newman

Report Documentation Page

Form Approved
OMB No. 0704-0188

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1. REPORT DATE

2002

2. REPORT TYPE

N/A

3. DATES COVERED

-

4. TITLE AND SUBTITLE

An Epidemiologic Analysis of Chlamydia trachomatis and Neisseria gonorrhoeae Infections in Female Federal Prisoners

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Newman /Sara B.

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Uniformed Services University of the Health Sciences

8. PERFORMING ORGANIZATION
REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT
NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Infections caused by *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) are the most commonly reported bacterial sexually transmitted infections in the U.S. No studies have been conducted to determine the prevalence of these two infections in women federal prisoners. Information about the prevalence of and risk factors for the infections may assist the Federal Bureau of Prisons to implement a rational screening approach for CT and GC in female inmates. Two study phases were implemented as part of this protocol. The first study phase relied on qualitative techniques: focus groups and group-based cognitive interviews were implemented to assist in the design of the study instrument and study procedures to be used in the second phase of the study. For the second, quantitative phase, urine specimens and self-collected swabs were taken from 983 women incarcerated in two federal prison facilities in the U.S. Participants completed a self-administered questionnaire on sociodemographic characteristics, and sexual and clinical history. Another questionnaire was administered to participants after specimen collection on preferences for self-collected swab, urine collection and pelvic examination. Specimens were analyzed at the Johns Hopkins University Chlamydia laboratory using strand displacement amplification technology to detect the presence of CT and/or GC DNA. Prevalence of CT and GC was calculated for each of the prison sites. Potential risk markers associated with infection were assessed. Participants' preferences of self-collected swab and urine were also compared between the two sites. CT infection was found in 1.3% of the participants at one site where women are screened when they enter the prison, and in 2.3% at the other site, where women are not screened. One case of gonococcal infection was detected at the site where women are screened and no cases in the other site. Among women age 18-22, prevalence of CT infection was 8.5% in the prison with the highest prevalence of infection. Prevalence of CT infection among women age 30 and younger exceeded 3.5%. Screening women age 30 and younger would identify more than 60% of cases at an estimated cost of less than \$60,000 per year. Approximately 83% of infections could be detected if women age 35 and younger were screened, but the cost for screening would approach \$90,000. More than half of the participants (57%) found no difference between giving urine or swab samples in terms of ease of collection. Approximately 30% of participants said they would prefer to give a swab specimen in the future as compared to urine (21%), but nearly half of women expressed no preference for one method over the other. Most participants (60%) expressed a preference for doing a self-collected swab rather than having a pelvic exam (23%) to test for the infections in the future, but nearly 17% had no preference for one over the other. While prevalence among the study population was low, targeted screening in women age 30 and younger is recommended to detect more than half of the cases costeffectively. This study provided evidence that to inmates noninvasive screening techniques are acceptable alternatives to pelvic examination.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:

a. REPORT
unclassified

b. ABSTRACT
unclassified

c. THIS PAGE
unclassified

17. LIMITATION OF
ABSTRACT

SAR

18. NUMBER
OF PAGES

178

19a. NAME OF
RESPONSIBLE PERSON

DEDICATION

This dissertation is dedicated to my beloved husband, David. He is my greatest inspiration and advisor. I am deeply grateful to him for his constant support and understanding during this long process and for his enormous confidence in my ability. I also dedicate this work to my little Sharon Ana who has sacrificed lots of mommy time for me, and finally, to the little one growing inside me, who felt too much of my stress during these past few months but has endured it graciously.

ACKNOWLEDGEMENTS

I could never have accomplished this research without the many professors, colleagues, friends and family who have supported me throughout this endeavor. I am grateful to Dr. Heidi Friedman, my dissertation advisor, who encouraged me from the very beginning to take on this ambitious task, and who has given me tremendous support and advice through all of its challenges. I am also thankful to the rest of my dissertation advisory committee for their guidance and input throughout this process: Dr. Deborah Girasek; Dr. Paul Hshieh; Dr. Ann Jerse; Dr. Charlotte Gaydos from Johns Hopkins University; and Dr. Michael Nelson from the Federal Bureau of Prisons (BOP). I am thankful to Dr. Larry Laughlin, who served as Chair of my examination committee. I thank Dr. Newton Kendig of the BOP for providing me with the opportunity to conduct this study and to the prison staff for all of their support during our data collection. I am particularly grateful to Mary Ellen Rivers, Teresa Spicer and Don Tennant, as well as the many other prison health staff who went out of their way to help our data collection team. I appreciate the assistance of Dr. Kim Oh of the University of Alabama and Dr. Phillip Russell of Harvard University for providing me with copies of the surveys they used for research in jails and for reviewing my survey. I also greatly appreciate the assistance of Dr. Gordon Willis from the National Institutes of Health, who reviewed drafts of my survey and provided his expert input.

I am deeply indebted to members of my data collection team including Lisa Paul, Beth Maloney, and Heidi Friedman for taking time from their demanding schedules to assist me at the prison sites. I am especially thankful to Shilpa Hakre, who joined me at every prison site visit. She handled the collection and prepared the transport of more than 2000 specimens. Her precision and skill resulted in not one lost specimen. Finally, I am grateful to my incredibly talented mother, Gerda Freedheim, M.S.W., M.B.A., who facilitated all of my focus groups and joined me at every prison visit to serve on our data collection team. I am extremely fortunate to have had the opportunity to work so closely with my mother, whose skill I deeply admire and who continues to amaze me with her knowledge and expertise. She impressed me even further with her ability to cope under the supervision of her youngest daughter.

Abstract

An Epidemiologic Analysis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Infections in Female Federal Prisoners

Sara B. Newman, Dr. P.H., 2002

Dissertation directed by Heidi B. Friedman, Ph.D., Dr. Larry Laughlin, M.D., Ph.D., Deborah C. Girasek, Ph.D., Paul Hshieh, Ph.D., Department of Preventive Medicine and Biometrics, USUHS; Ann Jerse, Ph.D., Department of Microbiology and Immunology, USUHS; Charlotte A. Gaydos, Dr.P.H., Johns Hopkins University; Michael B. Nelson, D.O., Federal Bureau of Prisons.

Statement of the problem: Infections caused by *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) are the most commonly reported bacterial sexually transmitted infections in the U.S. No studies have been conducted to determine the prevalence of these two infections in women federal prisoners. Information about the prevalence of and risk factors for the infections may assist the Federal Bureau of Prisons to implement a rational screening approach for CT and GC in female inmates.

Methods: Two study phases were implemented as part of this protocol. The first study phase relied on qualitative techniques: focus groups and group-based cognitive interviews were implemented to assist in the design of the study instrument and study procedures to be used in the second phase of the study. For the second, quantitative phase, urine specimens and self-collected swabs were taken from 983 women incarcerated in two federal prison facilities in the U.S. Participants completed a self-administered questionnaire on sociodemographic characteristics, and sexual and clinical history. Another questionnaire was administered to participants after specimen collection on preferences for self-collected swab, urine collection and pelvic examination. Specimens

were analyzed at the Johns Hopkins University Chlamydia laboratory using strand displacement amplification technology to detect the presence of CT and/or GC DNA. Prevalence of CT and GC was calculated for each of the prison sites. Potential risk markers associated with infection were assessed. Participants' preferences of self-collected swab and urine were also compared between the two sites.

Results: CT infection was found in 1.3% of the participants at one site where women are screened when they enter the prison, and in 2.3% at the other site, where women are not screened. One case of gonococcal infection was detected at the site where women are screened and no cases in the other site. Among women age 18-22, prevalence of CT infection was 8.5% in the prison with the highest prevalence of infection. Prevalence of CT infection among women age 30 and younger exceeded 3.5%. Screening women age 30 and younger would identify more than 60% of cases at an estimated cost of less than \$60,000 per year. Approximately 83% of infections could be detected if women age 35 and younger were screened, but the cost for screening would approach \$90,000.

More than half of the participants (57%) found no difference between giving urine or swab samples in terms of ease of collection. Approximately 30% of participants said they would prefer to give a swab specimen in the future as compared to urine (21%), but nearly half of women expressed no preference for one method over the other. Most participants (60%) expressed a preference for doing a self-collected swab rather than having a pelvic exam (23%) to test for the infections in the future, but nearly 17% had no preference for one over the other.

Conclusions: While prevalence among the study population was low, targeted screening in women age 30 and younger is recommended to detect more than half of the cases cost-effectively. This study provided evidence that to inmates noninvasive screening techniques are acceptable alternatives to pelvic examination.

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by

Sara Beth Newman

Dissertation submitted to the Faculty of the Department of Preventive Medicine and
Biometrics Graduate Program of the Uniformed Services University of the Health

Sciences in partial fulfillment of the requirements for the degree of

Doctor of Public Health, 2002

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An Epidemiologic Analysis of
Chlamydia trachomatis and *Neisseria gonorrhoeae*
Infections in Female Federal Prisoners
Introduction and Review of the Literature

Sara Beth Newman

Introduction

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC) infections are the most common bacterial sexually transmitted infections in the United States. Signs and symptoms of both infections are nonspecific and a major proportion of women with proven infection of either bacterium are asymptomatic. The organisms may remain dormant for months or years in infected hosts who continue to serve as reservoirs for transmission to sexual partners^{1,2} For both CT and GC, untreated sequelae of infections are severe. They can include pelvic inflammatory disease, infertility and ectopic pregnancy. Both infections also have the potential for neonatal transmission. There is a large and growing literature on sexually transmitted diseases in the general population, including data from family planning clinics, sexually transmitted disease (STD) clinics, primary care clinics and even military populations. More recently, there have also been some published studies on STDs in jail settings.³⁻¹⁰ To date, however, there have been no published studies that focus on the sexual health of women prisoners in the federal prison system or in any other long-term incarceration facility. Because of the lack of data on STDs in the prison, the Federal Bureau of Prisons has been unable to establish a data-based policy for testing and treating women.

The purpose of the present research project was to provide the Federal Bureau of Prisons (BOP) with necessary data to develop a rational screening approach for chlamydial and gonococcal genital tract infection in female federal prisoners. The specific aims of this study were: 1) to estimate the prevalence of infection in women

prisoners in selected prison sites; 2) to identify demographic and behavioral characteristics that serve as potential risk factors and risk markers associated with the presence of infection; and 3) to compare participants' preferences for, and the effectiveness of, urine and self-collected swab specimens using a new, highly sensitive, non-invasive DNA amplification assay.

This study was designed with two distinct phases. Phase I relied on qualitative data collection techniques to assist in the design and implementation of the second, quantitative phase of the study. Phase II involved quantitative data collection in which study participants completed a survey and gave urine and vaginal swab specimens which were then tested for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) infections.

The starting point for managing the health needs of the female federal prison population is to establish an appropriate and rational screening protocol based on the prevalence of infection. There are a number of important reasons to screen for sexually transmitted infections (STIs) such as CT and GC, especially in populations where the infections are highly prevalent. First, these two infections are asymptomatic in most women, so most infected women are unaware they need medical treatment. Second, treatment of acute CT or GC infection can prevent significant tissue damage to the upper reproductive tract in cases where progression occurs. Third, the presence of STIs such as CT and GC can increase the risk of HIV transmission from between two to 20-fold.^{11,12} In addition, the continual movement of prisoners in and out of the penal system poses

increased risks of disease transmission to the general population. Consequently, access to prisoners provides an important public health opportunity for controlling the spread of infections in the general population. This is especially true because many incarcerated women have had limited or no access to medical services outside the prison. In many cases, their first, and perhaps only, encounter with medical care is in the prison.¹³

The BOP does not have a specific guideline for screening women for CT or GC in the prisons; consequently each prison has established its own screening policy. Of the country's six main federal prison sites for women, two screen all prisoners for CT and GC upon entry. The other prisons test women who present with clinical signs at their first physical exam upon entry. One of the women's prison sites is a referral prison that houses physically and mentally ill women, however, it was not considered an appropriate site for this study. To help the BOP establish a data-based policy for CT and GC screening and treatment of female inmates, it is necessary to first determine the prevalence of the two infections and to identify risk factors and markers for infection for targeted screening. Accurate prevalence data would assist the BOP in formulating appropriate screening guidelines.

Role of the Candidate

The candidate designed, carried out and managed all aspects of this study with guidance from her doctoral dissertation committee. For the qualitative study phase, the candidate carried out focus group discussions and group-based cognitive interviews with female inmates using an experienced facilitator. In preparation for the quantitative study

phase, the candidate also designed the questionnaire and prepared all informational material for inmates, including a brochure on chlamydial and gonococcal infection and an instructional booklet on specimen collection techniques. The candidate translated all necessary documents into Spanish and conducted all orientations for study participants in English and in Spanish, when necessary. She managed and carried out data collection. With support and collaboration from the Johns Hopkins University Chlamydia lab she also performed much of the laboratory analysis. She supervised the data entry, and carried out all the statistical analyses and data interpretation.

The candidate wrote the introduction, review of the literature, conclusions and recommendations and synthesized her findings in final manuscripts. The doctoral committee for this study provided guidance, advice and direct input throughout the study in the design, analysis, and final preparation of the documents. Each committee member revised drafts of the manuscript. Input from the members has been incorporated into the final dissertation.

Review of the Literature

The History and Biology of Chlamydial and Gonococcal Infection

Chlamydia trachomatis is one of four species within the genus *Chlamydia* which also includes *C. psittaci*, *C. pneumoniae* and *C. pecorum*. *Chlamys* is Greek for "cloak draped around the shoulder." This illustrates how the intracytoplasmic inclusions caused by the bacterium are "draped" around the infected cell's nucleus. The organism is a

bacterium with limited metabolic capability whose growth is restricted to within the intercellular environment of its parasitized host cells. Before 1960, chlamydiae were considered viruses, because of their small genome size of approximately 500-1000 kilobases and obligate intracellular parasitism. However, their outer membrane, similar to other gram-negative bacteria, ribosomes, DNA and RNA, and metabolic functions that confirm their bacterial nature.¹⁴ The infectious particle of chlamydiae is the elementary body (EB), which is a spore-like extracellular structure that is metabolically inert and enables the organism to exist outside the host.¹⁵ The EB represents the first stage of the chlamydia life cycle in which it adheres to a susceptible host and gains entrance into the host cell. Once the EB has entered the cell, it undergoes a metamorphosis and becomes a reticulate body (RB). By way of a mechanism that is still unknown, the RB reproduces to form more EBs. Once the EBs are released, they can infect new host cells.

C. trachomatis is restricted to human hosts and was first recognized as a sexually transmitted infection in the early 1900s. Colonization of *C. trachomatis* begins with attachment to sialic acid receptors on the conjunctiva and mucosal surfaces of the throat or genitalia. It persists at body sites that are inaccessible to phagocytes, T-cells, and B-cells. It also exists as 15 different serotypes known as serovars. These serotypes cause four major diseases in humans: endemic trachoma (caused by serotypes A through C), unogenital tract infections and inclusion conjunctivitis (caused by serotypes D through K), and lymphogranuloma venereum (caused by serotypes L1, L2, and L3). Endemic trachoma leads to blindness, whereas inclusion conjunctivitis is associated with the sexually transmitted serotypes and does not lead to blindness.

C. trachomatis (serotypes D-K) is transmitted through infected secretions only. It infects mainly mucosal membranes, such as the endocervix, rectum, urethra, throat, and conjunctiva. It is primarily spread via sexual contact and may manifest as acute or chronic inflammation at the infected site or it may be asymptomatic.

Symptoms due to infection are variable. Up to 80% of women and up to 50% of men with *C. trachomatis* genital tract infections show no symptoms and others may show mild symptoms.^{14, 16} The incubation period of CT is generally 5-10 days. Infection in women usually begins in the endocervix. Symptoms can include increased vaginal discharge, burning during urination, irritation of the area around the vagina, including lower abdominal pain, and abnormal vaginal bleeding. In men, the main symptoms include clear, white, or yellow discharge from the urethra, burning and pain during urination, and tingling or itching sensations. Another infection caused by *C. trachomatis*, lymphogranuloma venereum, is characterized by a swelling of the lymph nodes in the groin area. This can lead to proctitis in men and in women it can lead to rectal narrowing.

Neisseria gonorrhoeae (gonococci) is a gram-negative, nonmotile and nonspore-forming diplococcus closely related to *N. meningitidis* (meningococci).¹⁷ *N. meningitidis* infections have a low prevalence and high mortality, whereas *N. gonorrhoeae* infections have a high prevalence and low mortality.

Gonorrhoea is one of the oldest known human diseases, whose existence dates back to biblical times. It was understood to be a venereal infection as early as the 13th century. It was not until the 19th century, however, that Alvert Ludwig Siegmund Neisser (1879) described the organism in stained smears of purulent exudates from patients with cervicitis, urethritis, and ophthalmia neonatorum. The bacteria was then cultivated in 1882 by Loeffler and Leistikow.^{17, 18} The pathogenic mechanism involves the attachment of the bacterium to mucosa of columnar epithelial cells via pili (fimbriae) and the production of endotoxin. The organism then penetrates the cells and multiplies on the basement membrane. Porin is the most abundant gonococcal surface protein. One of the two porin serotypes is often associated with disseminated gonococcal infection (DGI). *N. gonorrhoeae* is a relatively fragile organism, susceptible to temperature changes, drying, UV light, and other environmental conditions. The incubation period of GC is between 1-14 days, the average is 2-5 days.

As is the case with CT, GC infection is generally limited to superficial mucosal surfaces lined with columnar epithelium. The areas most frequently involved are the urethra, endocervix, rectum, pharynx, and conjunctiva. Squamous epithelium, which lines the adult vagina, is not susceptible to infection by either GC or CT. However, the prepubertal vaginal epithelium, which has not been keratinized under the influence of estrogen, is susceptible to infection by either organism.

The endocervix is the most common infection site for uncomplicated gonorrhoea in women. Such infections are usually characterized by vaginal discharge and sometimes by

dysuria (burning urination). About 50% of women with cervical infections are asymptomatic. Although most men with gonorrhea develop symptoms, asymptomatic infections occur in males, as well. Both males and females with asymptomatic mucosal infections are an important reservoir for transmission and are at increased risk for developing complications if infections are left untreated.¹⁹

Epidemiology of Infection

CT infection is the most commonly reported bacterial STD in the US and is likely one of the most ubiquitous.^{14,20} The U.S. Public Health Service estimates that between 3-5 million new cases of CT infection occur annually in the US.^{14,21} GC is the second most commonly reported bacterial STD in the United States and is also a major cause of serious sequelae in women. An estimated 800,000 new GC infections occur each year.²² Although there was a decline in the prevalence of gonorrhea from the mid- 1970s to the mid-1990s, STD surveillance data from the Centers for Disease Control (CDC) indicate a 9% increase from 1997 to 1999.²² Furthermore, the current rate of gonococcal infection is still well above goals of the Healthy People 2010. The U.S. has the highest infection rate of any industrialized country.²⁰

CT and GC are highly contagious organisms transmitted primarily by sexual contact. The organisms can also be transmitted as a result of perinatal exposure. When properly treated, the infections have no long-term sequelae. If infection from either organism is left untreated, however, the long-term consequences may be serious. CT and

GC can cause infection in men; however the major burden of disease falls on women who are more likely to suffer from serious sequelae of untreated infection.

In the case of CT, in 20 to 40% of untreated cases the infection ascends to the upper genital tract. This may result in pelvic inflammatory disease (PID), which in turn can lead to ectopic pregnancy, infertility, chronic pelvic pain and, rarely, death.^{23,24} CT is the most common cause of neonatal conjunctivitis and can cause pneumonia in infancy. Infants with chlamydial pneumonia are at greater risk for chronic respiratory disease.²⁵ Various studies have provided evidence that between 50 and 75% of infants born to an infected mother will acquire chlamydial infection during delivery.²⁶⁻²⁹ CT is the leading single cause of pneumonia in the first six months of life.³⁰

Untreated GC in a woman can also infect the uterine lining or fallopian tubes leading to PID, ectopic pregnancy, infertility, and chronic pelvic pain.³¹ In addition, untreated gonococcal infection can spread through the bloodstream to infect the joints, skin, bone, tendons and other parts of the body.³¹ Disseminated GC infection is the number one cause of arthritis in young adults. Another major consequence of both chlamydial and gonococcal infections is the increased risk of contracting HIV.^{11,12,32-35}

GC predominately affects young, nonwhite, unmarried less educated, urban populations.³⁶ The infection is more efficiently transmitted from males to females than from females to males.³¹ Asymptomatic males and females are a major problem as

unrecognized carriers of GC. This occurs in the U.S. at a rate of over one million cases per year.

Health Services and Epidemiology of CT and GC in Female Prisoners

There are currently six main federal prison facilities that house women exclusively. Between 750 and 1500 women reside in each facility and approximately 6,000 of the nearly 11,000 female inmates are confined in these six sites. One of the six sites, an institution with 1,000 female inmates is for physically or mentally ill women requiring continuous medical attention. In addition to the inmates in women only prison, there are another 5,000 female inmates residing in 16 other mixed gender institutions throughout the U.S. Female inmates serve an average of five years, the majority for drug related offenses, such as the possession and distribution of drugs. Other crimes committed by women include robbery, property offenses, extortion, bribery, fraud, weapons offenses, and immigration offenses. The median age of the female inmate is approximately 36 years old and nearly two-thirds of women in prisons are African American, Hispanic and other (4%) (Table 2).

Once admitted to a federal prison, women go through an intake medical interview to collect general information. Within two to four weeks of residence in the prison, women are given a complete physical examination and a medical history is obtained. The examination includes at least:

- A gynecological and obstetrical history, including sexual activity and any recent rape history;
- Serology, CBC (differential if indicated), urinalysis (microscopic when indicated), pregnancy test (urine or serum), and other tests as clinically indicated;

- Measles, mumps and rubella vaccine is offered to inmates of childbearing age;
- Breast and pelvic examinations are offered; and
- A Papanicolaou (Pap) smear, gonorrhea or other endocervical cultures from vaginal and/or other orifices when clinically indicated.

The BOP does not currently have a specific guideline for screening women for CT or GC in the prisons, therefore each prison site has established its own screening policy. Of the five main, non-medical prison institutions for women, two universally screen prisoners for CT and GC upon entry. The other three prisons screen women who present with clinical signs at their first physical exam upon entry (Table 3). As described earlier, reliance on clinical indicators alone is not sufficiently sensitive to capture all women who are likely to harbor either infection. In addition, even at prisons where screening is universal or mandatory, the diagnostic method used to screen for infection (GenProbe™) may not have the sensitivity to identify all true positives.

Limited data exist on STD prevalence in the federal prison population. There is no centralized surveillance system for STDs in the federal prisons and the individual sites do not maintain databases of STD incidence or prevalence. Data collected from city and county jails and detention centers provide evidence of high rates of chlamydial and gonococcal infection in women entering jail.^{3,4} Using urine-based DNA amplification tests, investigators found infection rates between 10 and 13% for CT and between 5 and 9% for GC.^{3,4} Juvenile detention centers had much higher rates of infection, ranging from 16 to 27% for CT.^{3,4} A study conducted in 1992 to assess prevalence of CT in a New York City jail found a 27% prevalence of CT in female inmates.³⁷ The federal prison

population, however, is likely to differ from city and county jail inmates in terms of age, socioeconomic status, number of prior sex partners, and potential prior screening and/or treatment before BOP designation. It is therefore valuable to conduct a separate study to determine prevalence among women in the federal facilities.

The increase in the female prison population has introduced a new challenge to health providers within the system. Although female inmates comprise only 7% of the total federal prison population, there has been a 284% increase in the female federal prison population between 1990 and 2001 (Table 3). Because the majority of federal prisoners are male, most BOP facilities, policies and services are not designed with the unique needs of female inmates in mind.³⁸ Women have different and perhaps more complicated health problems than men, and their needs and demands for health care services are greater than men's.³⁹ Women tend to bear the burden of health risks associated with poverty and because most women who enter prison are of childbearing age, they require more health services than men. In addition, a greater proportion of women suffer from major depressive disorders.³⁹ Therefore, they require a different kind and quantity of health service delivery. The BOP has identified sexually transmitted diseases as an area requiring more examination for gender-specific testing policies and procedures. Women's health needs in prison are gaining increased importance as a public health issue and knowledge of prevalence levels and risk factors within the prison population will assist health planners to properly manage the problem.

Screening Approaches For CT and GC

Major concerns with CT and GC are that endocervical infections are asymptomatic in a majority of women and infection can persist for months or even years.⁴⁰ Therefore, screening programs that rely on the presence of symptoms as an entry point will leave the majority of infected women untreated. Two frequently studied and applied approaches to screening include universal screening and selective or targeted screening.⁴¹⁻⁴⁶

Although universal screening might be considered reasonable for detecting asymptomatic infections such as CT and GC, the approach can be costly in a large, low prevalence population. Selective screening or presumptive treatment are other alternative approaches to disease management. Selective screening involves the use of risk markers, in addition to symptoms and signs, as criteria for selecting the women for screening. It is the strategy implemented by most health service agencies. Selective screening is less costly than universal screening, but the cost savings must be weighed carefully against the consequences of missing infected women. Cost analysis suggests a benefit to universal screening of CT and GC at prevalence >3-6%, however many clinic settings use selective screening criteria to target specific sub-populations at highest risk.^{43,47} Key factors in determining the best approach to screening are prevalence of infection in the target population, and knowledge of risk factors and risk markers for disease among the target population.

Several symptoms and signs have been identified as useful components of selective screening programs for these sexually transmitted infections. The minority of women who might experience some of the symptoms described earlier (e.g., abnormal vaginal discharge, intermenstrual or postcoital bleeding, and dysuria) may be identified as good candidates for screening for these two infections. Urethral chlamydial infection may cause dysuria, frequency and hesitancy also known as "acute urethral syndrome."⁴⁸ Symptoms of PID can include pelvic, uterine or adnexal pain, but "silent PID" can also persist as an unrecognized sequelae of lower genital tract infection. Signs of infections detected by medical examination can also serve as markers for screening.

While an examination of the infected cervix may reveal easily induced bleeding, mucopurulent endocervical discharge, cervicitis, or edematous ectopy, the cervix appears normal in the majority of infected women. The finding of purulent (yellow or green) cervical discharge on a cervical swab is a possible sign of chlamydial and/or gonococcal infection.⁴⁹ Bleeding induced by gently swabbing is a sign more often seen in chlamydial infection.⁵⁰ It is not possible, however, to differentiate CT and GC from each other, or from vaginal infections, on the basis of symptoms or signs alone.^{51,52}

Identification of specific risk factors and risk markers for infection in a target population can be a necessary part of designing an appropriate screening protocol. A number of studies have assessed risk factors for CT and GC in women seen in family planning clinics, community health clinics, STD clinics and adolescent health clinics. Studies have consistently identified young age (<20 years), behavioral risks (e.g., recent history of a new sex partner, more than one partner and lack of use of barrier

contraceptive methods) and cervicitis as strong predictors of infection.^{41,42,53-55} Other risk factors found in numerous studies include unmarried status, black race, and poor socioeconomic conditions.^{31,56-57}

The Centers for Disease Control recommend that women who present with the following criteria be selectively screened: 1) mucopurulent cervicitis; 2) sexually active women less than 20 years of age; 3) women age 20-24; and 4) women over age 24 who meet the following criteria: inconsistent use of barrier methods, or new or more than one sex partner in the last 3 months. However, these screening criteria have been developed in geographically and clinically restricted settings without validation in other populations. For this reason, it may not be appropriate to simply apply criteria established in prior studies to the female federal prison population.⁴⁵

Diagnostic Testing for Chlamydial and Gonococcal Infections

An important challenge to the development of effective screening programs for CT and GC has been the lack of a sensitive laboratory assay appropriate for use on large numbers of clinical specimens. The lack of specific clinical symptoms and signs associated with either CT or GC mandates the use of laboratory methods for the diagnosis of infection. A medical history and physical exam of a patient does not provide the sensitivity or specificity needed to identify infected patients. Detection of either bacterium can be accomplished using both culture and non-culture tests (Table 4).

Laboratory Detection of C. trachomatis

For the past 25 years, cell culture has been the "gold standard" test for detection of chlamydiae because of its high specificity approaching 100%.²⁵ However, culture is becoming a less-preferred diagnostic method. Culturing is labor intensive, time consuming and costly. It requires stringent collection and storage of specimen. Specimen collection requires an experienced clinician to collect columnar epithelial cells from the endocervix. The clinician must use a dacron swab or a cytobrush for endocervical collection. Specimens also require specific cold chain transport and should be inoculated within 24 hours of collection, unless frozen at -70°C . After incubation, fluorescent monoclonal antibodies are used to detect chlamydial infection. While Gram, Giesma and iodine staining have been used in the past to visualize chlamydial inclusions in cell culture, these stains lack the sensitivity and specificity of fluorescent antibody staining and are therefore less relied upon.²⁵ Culture can only be performed in highly specialized laboratories and the sensitivity of the test is dependent on cell lines, growth medium and staining reagents as well as collection and transport techniques as described above.

The cost and difficulty of cell culture for CT detection has led researchers to explore other less costly and burdensome approaches. The most widely used are direct fluorescent-antibody assays (DFA) and enzyme immunoassay (EIA) tests. Rapid tests have also been used in clinical settings.^{2,25} The DFA stains elementary bodies in epithelial cell scrapings from infected sites, while the EIA is based on immunochemical detection of chlamydia lipopolysaccharide genus-specific antigen. Because test sensitivity of both DFA and EIA depend on the expertise of the technician and the adequacy of the specimen collection, the sensitivity of the tests range from 60% to 85%, with a specificity of about 98%.^{2,25,31} The EIA requires a confirmatory assay to rule out false positives.^{2,31}

Results of DFA and EIA tests can be obtained within two days. Although both tests provide results faster than culture (DFA approximately 30 minutes, EIA 3-4 hours) and do not require cold transport, a problem with the method is that it requires highly trained and experienced personnel.²⁵ Further, specimens collected by noninvasive means (i.e., using urine) yield low sensitivities.

Rapid tests, which employ EIA technology, are also available. Tests can be performed without sophisticated equipment in a physician's office within 30 minutes. These rapid tests generally have low sensitivities and specificities relative to culture: from 52-85% and a 95% specificity, respectively.²⁵

Laboratory Detection of N. gonorrhoeae

Culture generally has been considered to be the gold standard in the diagnosis of *N. gonorrhoeae*. However, even with culture there is a 10% false-negative rate (sensitivity to 90%). In addition, culture requires a CO₂ rich environment and specially grown medium agar to be cultivated in a laboratory. For GC the sensitivity of the test is also dependent on maintaining appropriate transport temperature and the needed CO₂ concentration. In women, culture specimens for gonococcal detection may be collected from the endocervix, rectum, or pharynx as well as from the endometrium, fallopian tubes, joint fluid or blood, if PID or DGI is suspected.¹⁹ As with culture collection in CT, specimen collection for GC requires experienced personnel to collect and analyze specimen in the laboratory. Stringent transportation requirements for culture specimens has also led to an increase in the utilization of nonculture assays for gonorrhea detection.

The endocervical Gram stain is the principal rapid diagnostic test in current clinical use for diagnosis of gonococcal infection. Gram stain and several other dyes (e.g., methylene blue and acridine orange) have been used to prepare clinical material for

microscopic examination of gonococci. The sensitivity and specificity of Gram-stained smears for detection of genital gonorrhea in women ranges from 50-75% and 95-100%, respectively, compared with culture.⁵⁸

Molecular Diagnostics for Detection of CT and GC

The most widely used test in public health laboratories in the United States to detect CT and GC is the Pace 2 nucleic acid hybridization (Gen-Probe™, San Diego, CA).⁹ The Pace 2 is a nonamplified test based on a single-stranded DNA probe. Like the nonculture tests described previously, it is a low cost test that is easy to use and transport, and it is able to detect both CT and GC. The assay has been found to have a sensitivity of 89-97% and specificity of 99% to detect GC.⁹ For CT, sensitivity ranges from 60 to 85% relative to culture. Gen-Probe™ has also developed a DNA probe test that detects both *C. trachomatis* and *N. gonorrhoeae* from a single specimen (PACE 2C).²⁵ Sensitivities have reached 89% with specificities of 95% for detection of CT and GC in high prevalent populations.²⁵

Another non-culture method available is the nucleic acid hybridization Hybrid Capture II CT/GC test (HCII Digene Corp., Beltsville, MD), which uses signal amplification to increase sensitivity.⁵⁹ The HCII can detect chlamydial or gonococcal DNA in cervical specimens. Sensitivity of this test for CT reached 93% in multicenter trials with specificities reaching nearly 99% compared to culture. For GC, sensitivity and specificity of the HC II method are 92% and 99%, respectively.¹⁶ However, these nonculture amplified and nonamplified hybridization techniques still require invasive cervical and urethral specimen collection and a skilled practitioner to take the specimen accurately.

The newest developments in diagnostic testing for both CT and GC rely on automated methods for detecting amplified nucleic acid sequence and can be applied to cervical, vaginal, urethral or urine specimens.³¹ The recent introduction of highly sensitive DNA-based laboratory tests to detect CT and GC promises to make widespread screening for these infections possible because of the ease of collection. In addition to their extreme sensitivity, these assays can be performed on self-collected urine and vaginal swabs.⁶⁰⁻⁶¹ These techniques minimize the need for highly skilled, costly healthcare providers, and offer a less invasive and painless collection method.

The most widely used assays are ligase chain reaction (LCR) and polymerase chain reaction (PCR) tests. While the specificity of both tests exceeds 99% for both GC and CT, their sensitivity varies depending on whether urine or cervical specimens are employed. In the case of chlamydial infection, the sensitivity of LCR, when applied to female first catch urine (FCU; the first 20 to 30 mL of stream), ranges from 69-96%, while the sensitivity with cervical specimens can range from 81-100%.⁶²⁻⁶⁷ PCR provides a sensitivity of 82-93% for FCU and 60 to 92% for cervical specimens.⁶⁸⁻⁶⁹ Performance of LCR and PCR on FCU indicate both are acceptable non-invasive techniques for diagnosing chlamydial infection of the urethra and cervix.²

To detect gonococcal infection using urine specimen, LCR has yielded sensitivities between 70-96% and specificities up to 99%, against culture.⁷⁰⁻⁷¹ When tested using endocervical swabs, LCR has yielded 96% sensitivities and 98% specificities, compared to culture.^{70,72} Use of PCR to detect GC has yielded sensitivities between 92-100% and specificities ranging from 96-99% on endocervical specimen.^{73,74} With use of urine specimens, PCR has yielded sensitivities ranging from 65 to 92% and 96-99% respectively, for GC detection.⁷⁴

An important limitation of PCR and LCR is that the tests may detect CT or GC nucleic acid remaining after therapy has been administered, yielding a false-positive result.^{75,76} This limitation suggests that the diagnostic test is useful for screening and research, but not as a test of cure until three weeks after treatment.⁷⁷ The PCR and LCR methods appear to be highly sensitive and specific for detecting *C. trachomatis* in female urine and endocervical specimen from females, making them both acceptable tests.

One of the most promising and newest of the nucleic acid amplification tests is the BDProbeTec ET systemTM (BD Biosciences, Sparks, MD), which detects CT and GC simultaneously. Recently cleared by the Food and Drug Administration, the BDProbeTec (BD-PT) uses Strand Displacement Amplification (SDA) technology for the direct, qualitative detection of CT and GC DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens. Recent studies to evaluate the performance of BD-PT using female urine against culture yielded sensitivities up to 100%, with specificities between 97 and 98% for CT. For GC, the sensitivity has ranged from 84 to 100%, with specificities reaching 99%.^{78,79} Data to determine the performance of BD-PT on self-administered swab (SAS) are not currently available. Comparisons of similar amplification assays, however, suggest that SAS performance is at least equivalent, if not superior, to urine and cervical culture for detection of CT and GC.^{61,80-81} A benefit of the BP-PT system is that both urine and swab specimen can be stored for a few days at room temperature before processing is required. In addition, both GC and CT can be detected simultaneously with BD-PT.

It is likely that women would prefer collecting their own vaginal specimen (SAS) to having a doctor's pelvic exam, and there is some evidence that women may prefer SAS

to urine collection. This may be especially true in the prison setting, where collection of urine may be raise suspicion of drug testing. In one study among military women, preference for SAS was especially high among those who had engaged in risky sexual behavior and among white women.⁸² Advantages of SAS over urine when using the BD-PT system are that SAS can be stored for up to six days at room temperature before processing, as opposed to the two days at room temperature for urine storage. In addition, SAS is easier to transport and requires less laboratory processing time than urine. This is particularly relevant for large screening programs. Comparison studies collecting both urine and SAS specimens are needed to further assess women's preferences and to determine the most accurate (i.e., most sensitive and specific) specimen type for diagnosis of these important pathogens.

CT and GC Treatment

For many years, standard treatment for *C. trachomatis* has been doxycycline given for seven days, two times daily. However, azithromycin is a single-dose alternative that has been proven effective and is now the drug of choice in some circumstances.¹⁶ Azithromycin is considerably more expensive than doxycycline, but greater compliance of a single-dose treatment versus a multiple dose treatment may make azithromycin a more cost-effective method. Tetracycline, chloramphenicol, rifampicin, and fluoroquinones are also effective treatments for CT.⁸³ Amoxicillin and erythromycin are safe alternatives for pregnant women.⁸³

For treatment of *N. gonorrhoeae*, ampicillin or amoxicillin are recommended. For non-pregnant persons infected with both organisms, a combination of antibiotics such

as ceftriaxone and doxycycline may be prescribed. Cefixime, ciprofloxacin, and ofloxacin are additional acceptable antibiotic regimens. Under current CDC guidelines, because patients infected with *N. gonorrhoeae* often are co-infected with *C. trachomatis*, those treated for gonococcal infection should also be treated routinely with a regimen effective against uncomplicated genital *C. trachomatis* infection.⁸³

Summary

Chlamydial and gonococcal infections can become serious health problems for women if they are left untreated. Because of their asymptomatic nature, it is critical that other means be applied to identify and treat infected women. The prison setting may provide an important public health opportunity to identify cases of infection and treat women who might otherwise not have access to health care or seek treatment for infection.

The present research project is the first study ever conducted in the federal prison system to identify the prevalence of and risk factors for CT and GC infection in female inmates. In addition, for the first time, this study introduces a new, noninvasive highly sensitive DNA amplification assay to test for infection. This study also explores women's preferences for non-invasive methods of specimen collection, which has been minimally explored even in the general population. Participation rates in this study exceeded 80% and results of the study provide important information for planning future screening programs for female federal inmates. Appendices A-E at the end of this manuscript, include the consent forms, surveys and informational materials used for this

study. All materials distributed to inmates were provided in both English and Spanish.

Materials in both languages are provided in the appendices.

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Table 1
Characteristics of Women in Federal Prison

Race/Hispanic Origin		Age		Marital Status		Education	
White	29%	24 or younger	9%	Married	29%	8 th grade or less	8%
Black	35%	25-34	35%	Widowed	6%	Some high school	19%
Hispanic	32%	35-44	32%	Separated	21%	High school graduate/GED	44%
Other	4%	45-54	18%	Divorced	10%	Some college or more	29%
		55 or older	6%	Never Married	34%		
		Median Age 36 years					

Source: Bureau of Justice Statistics, December 1999 Women Offenders (Greenfeld and Snell).

Table 2
Current Screening Protocol in the Eligible Female Prison Study Sites

Prison Site	Population	Screening for CT and GC	Method
Alderson, WV	868	Universal screening	Pelvic exam, endocervical swab
Bryan TX	777	Nearly all inmates screened	Pelvic exam, endocervical swab
Danbury, CT	1338	Screening only when clinically indicated	Pelvic exam, endocervical swab
Dublin, CA	1375	Screening only when clinically indicated	Pelvic exam, endocervical swab
Tallahassee, FL	1236	Screening only when clinically indicated	Pelvic exam, endocervical swab

Source: Information provided by Health Services Unit at each prison in September, 2001.

Table 3
Federal Prison Population

Year	General Population	Female Population	Percent of Females
1990	54,644	3,825	6.9%
1991	60,734	4,434	7.3%
1992	66,472	5,052	7.6%
1993	71,671	5,846	8.1%
1994	80,358	6,188	7.7%
1995	85,573	6,417	7.5%
1996	89,538	7,398	8.3%
1997	95,088	7,770	8.2%
1998	101,441	8,306	8.2%
1999	107,436	9,186	8.6%
2000	117,949	9,913	8.4%
2001	155,300	10,888	7.0%

Source: Data from 1990-2000 The Corrections Yearbook, Criminal Justice Institute, Connecticut and South Salem, NY (1990-2000).
2001 Data from the BOP website <http://www.bop.gov/>

Table 4

Diagnostic Tests To Detect Chlamydial and Gonococcal Infection

TEST TYPES	DETECTION PROCESS And SPECIMEN COLLECTION	CHLAMYDIA		GONORRHEA	
		Sensitivity	Specificity	Sensitivity	Specificity
CULTURE TESTS	Tissue culture for CT, mucosal surface for GC	70-85%	100%	90%	100%
NON-CULTURE TESTS					
Gram Stain	Rapid test for detection of GC	_____	_____	50-75%	95%
Direct Fluorescent Antibody	For CT detection only. Direct cytologic exam using fluorescent monoclonal antibody test. Directly stain organism in specimen using fluorescent-labeled antibody.	65-85%	98-99%	_____	_____
Enzyme immunoassay EIA	Colored product converted by an enzyme linked to an antibody Endocervical Specimen	60-80%	97-99%	_____	_____
CT Rapid Test	Rapid using enzyme immunoassay based system	52-85%	95%	_____	_____
Non Amplified DNA Probes	Uses DNA complementary to specific ribosomal RNA sequences Urogenital specimens	60-85%	95-99%	89%-97%	99%
DNA Amplification Methods					
Ligase Chain Reaction	Bacterial genes detected from epithelial cell specimens and urine.	69-96%, FCU* 81-100%- cervical	99.4-100%- FCU and cervical	70-96%- FCU 86-96% - cervical	99% -FCU and swab
Polymerase Chain Reaction Assay (PCR)	Nucleic Acid detection test able to detect a single gene copy from endocervical swabs and urine.	82-93% for FCU 60 to 92%- swab	100%	65-92% FCU 92-100% Swab	96%FCU and cervical
Strand Displacement Amplification	Uses homogeneous strand displacement amplification with an energy transfer chemistry. Urine	87-100%	97-98%	84-100%	98-99%

* FCU= First Catch Urine

First Manuscript

**Using qualitative methods to design an epidemiological study on sexually
transmitted diseases in female federal prisoners**

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This study was supported by a grant from the Uniformed Services University of the Health Sciences.

Abstract

BACKGROUND: Little is known about the sexual health of women in the federal prison system. Qualitative methods may be useful in designing quantitative studies of this and other minimally understood populations.

GOAL: To design a survey instrument and data collection procedures for an epidemiological study on sexually transmitted diseases in female federal prisoners.

STUDY DESIGN: Focus groups and group-based cognitive interview sessions.

RESULTS: Seven focus groups and six group-based cognitive interviews were conducted with 59 female federal prisoners age 18 to 60. Participants suggested population-appropriate terminology for a survey and related materials and assisted in rephrasing wording and structure of sensitive and complex questions (e.g., income, sexual abuse and drug use). They identified potential barriers to participation (e.g., confidentiality concerns, exclusion criteria, and lack of questions on female-to-female sexual activity) and recommended ways to overcome these barriers. Participants suggested data collection procedures to maximize participation rates.

CONCLUSION: Qualitative methods can inform survey instruments and study procedures and can contribute to question specific and study validity, and can increase participation rates.

Introduction

Qualitative research methods are well developed investigatory tools of the social sciences and related disciplines. Even in clinical medicine, practitioners rely on structured and unstructured interviews with patients to gather data for both practical application and research purposes.^{1,2} In contrast, western medical research historically has been grounded in quantitative data methods. More recently, however, researchers in the field of medical sciences and epidemiology have begun to use qualitative methods as part of a comprehensive research approach.³⁻⁹

Use of qualitative techniques is not actually new to epidemiology. In the mid-1800s, John Snow, the “father of epidemiology”, used a combination of qualitative and quantitative methods to identify the Broad Street pump as the causal link in a cholera outbreak in London. A century later, in a 1953 article on observation and experiment, Bradford Hill stressed the importance of Snow’s qualitative techniques, highlighting that Snow’s success was due to his observations of, and interviews with, residents and businessmen in the community. Hill noted “such reported observations may, of course, prove to be a most valuable indicator of a problem; they may be, thereby, the starting point of research.”¹⁰

Qualitative and quantitative methods have comparative strengths as tools in epidemiological research. While quantitative techniques serve to uncover distributions and typical characteristics for generalizing to populations, qualitative methods help the

researcher to gain insight into the complexities of human interaction and social meanings. An advantage of qualitative research methods is that they allow for an iterative process in which researchers can refine and improve their knowledge base and survey instruments. Qualitative research is especially useful for exploring little known phenomena or events, or for understanding the cultural perspective of a population that is minimally understood.^{5,7,11}

Female federal prisoners are one such population. Limited health research has been conducted in the federal prison system, with the exception of studies evaluating health services and general health conditions. Most of these studies were based on record reviews, however, and did not involve interaction with inmates.¹²⁻¹⁶ In particular, there is little information available on the health conditions and needs of women in the federal prisons, and to our knowledge, there is no published literature on sexually transmitted infections in this population. Although there have been some published studies on sexually transmitted infections in city and county jail settings, these data are not necessarily generalizable to the federal prison population.¹⁷⁻²⁵ Federal prisoners are generally older than jail inmates and are also confined to prison for greater lengths of time.

Two methods are particularly useful for gathering qualitative information -- focus groups and cognitive interviews. Focus groups first began to be used extensively in the 1950s by the market research community as a technique to obtain target-group perceptions to test market ideas and products.²⁶ More recently, the method has become

widely used in the social and behavioral sciences as a means of assessing needs, perceptions, and concerns of a specific population on a variety of social and/or health related issues.²⁷ Focus groups normally include between 6 to 12 participants and are led by an experienced facilitator who solicits participants' opinions on a particular issue.

The cognitive interview, developed in the 1980's in the Questionnaire Design Research Laboratory of the National Center for Health Statistics (NCHS), is used to detect covert and overt problems with a survey instrument by paying explicit attention to the mental processes that respondents use to answer survey questions.²⁸ In a cognitive interview, the interviewer asks the survey question, and after the subject has answered it, the interviewer asks for other, specific information to assess the validity and clarity of the question. For example, the interviewer may ask what the respondent meant when she answered the question and what the question meant to her.

The present study was designed to refine the questionnaire and survey protocol for an epidemiological study on the prevalence of and risk factors for chlamydial and gonococcal infection in female federal inmates. The draft questionnaire included sensitive questions about sexual behavior and was to be administered to a population that has not been studied in the past. Therefore, we employed focus groups and group-based cognitive interviews to gain an understanding of the population's perspectives and preferences. Our ultimate goals were to use these two techniques to design a more valid survey instrument and maximize study participation rates.

Methods

The study took place in three federal prison sites in the United States from December 2000 through May 2001. Because there are only six prison facilities that house female inmates exclusively, the names and locations of the study sites will not be revealed to preserve participant confidentiality.

Participants were recruited via a flyer displayed in common areas of the prison. The flyer requested that women interested in taking part in a discussion on women's health issues and sexually transmitted diseases (STDs) sign up with the Health Service Administrator at their prison. In prisons with a large Spanish-speaking population, the flyer was posted in English as well as in Spanish.

Draft surveys, prepared in both English and Spanish, were based upon survey instruments from previous epidemiological research on STDs, findings from the literature, and a preliminary focus group. An iterative process of refining and improving the survey instrument was implemented through a series of focus groups and group-based cognitive interviews. We made changes to the survey instrument after each group-based cognitive interview session and submitted the new version to the next session. In addition, focus groups were used to explore various methodological approaches and the knowledge base of participants in an attempt to gain a general view from all groups on specific topics related to sexual health. Focus groups and cognitive interview sessions

were conducted until we reached a point of saturation at which, we believed, additional sessions would not provide different or new insights gained from participants.

At the start of each focus group, the principal investigator and focus group facilitator met with volunteers to explain the nature and purpose of the discussion. Only women who provided written informed consent participated in the focus groups and the cognitive interview sessions. To help preserve confidentiality, women were encouraged not to use their real names during the discussion. No one from the prison staff was present in the room during either the focus group discussion or the cognitive interview session. Prison regulation did not permit us to tape record the sessions.

The Focus Groups

A total of seven focus groups were conducted in three prison sites. Six of the sessions were conducted in English and one was conducted in Spanish. The focus groups were facilitated by an experienced social scientist. She is a caucasian female in her mid-60s. The principal investigator, a bilingual Caucasian woman in her 30's, served as note taker for the focus group sessions and facilitated in Spanish.

Before beginning the session, the facilitator asked that women consider themselves consultants and explained that their opinions would be used to assist in the design and implementation plan of a future prison study on STDs. Women were informed that the session would assist in assuring that the language used on a questionnaire would be clear and understandable and in gaining insight to potential barriers facing the study.

The facilitator used a discussion guide to pose general and specific questions about sexual health and maintain uniformity across all focus groups. The facilitator set simple ground rules for discussion. She explained to participants that the discussion was confidential and urged them to respect the privacy of other women in the session. Women were told they could disagree with others if they felt differently about any matter, but were asked to speak one at a time. The facilitator used humor and a welcoming tone to build a rapport with the participants and to encourage an atmosphere of friendly and open discussion. The focus groups lasted for over an hour (range 90 to 120 minutes).

The purpose of the focus groups was to gain a better understanding of inmates' perspectives and knowledge of STDs, and preferred language when discussing sexual and other risk behaviors (e.g., drug use). For example, women were asked if they had heard of chlamydia and if they could describe symptoms associated with this infection. They were asked to describe what terms like "sexual intercourse" or "street drugs" meant to them.

A second goal was to discover potential barriers to data collection. The focus group facilitator explored women's perspectives on issues of privacy, and their willingness to answer sensitive questions truthfully. The sessions also aimed to determine the target population's preferences between types of specimen collection (i.e., urine versus self-collected vaginal swab). Receptivity to interviewer or self-administered questionnaires also was explored.

The Group-Based Cognitive Interview

Immediately following each focus group, the note taker from the focus groups took over the sessions and conducted a group-based cognitive interview with the same women. These sessions lasted approximately 90 minutes. The group-based cognitive interview was adapted from the cognitive interview technique.²⁸ This group-based format differs from the standard cognitive interview in that it does not involve a one-on-one interview, but is conducted in a group format so that women engaged in some discussion. As with cognitive interviews, the purpose of the group-based cognitive interview was to increase the clarity and acceptability of questions from participants' perspectives. Women were asked to complete the draft survey and make notes in the margin if a question was unclear, if they were unwilling to answer it, or if they had any question or problem with it as they completed the survey. All women completed the survey in approximately 20 minutes. After women completed the survey, the facilitator reviewed each survey question and asked each woman to explain her answer. The purpose of this was to examine whether the question and response categories had the same meaning to the respondent as they did to the researcher. For questions identified by any participant as difficult, unclear or too invasive, the facilitator asked for assistance to improve the question. For some questions, the facilitator probed participants' understanding of terms (e.g., "pelvic," "abdominal," "Pap smear"). When problem terms were encountered, women were asked to suggest alternatives. We made changes to the survey after each of the group-based cognitive interview sessions and submitted the revised version to the next group for further refinement, until we were satisfied that any potential problem areas were worded appropriately.

Results

A total of 59 women with a median age of 36 years participated in the focus groups and cognitive interviews (Table 1). A total of 7 groups were conducted at three prison sites (A, B and C); at least two sessions were held at each prison site. Each focus group had between 6 and 11 women.

Focus Groups With Female Inmates

Knowledge

Women were familiar with most STDs and could describe symptoms. Most, however, revealed misconceptions about how infections are transmitted and what were their symptoms. Several participants, for example, thought that chlamydia and gonorrhea were always symptomatic, describing symptoms such as “burning”, “itching”, and a “bad smelling” discharge. One woman believed that chlamydia was like a fungus and could be transmitted to others by touching feet. In the focus group with Latina inmates (Group 6), participants exhibited less knowledge about the types of STDs. They also expressed specific fears about transmission in the prison that revealed additional misconceptions. One participant stated, “We are at great risk being in this prison because we share toilet seats, we all eat together and we sleep very close to each other. We share our space so closely that we are sure to catch diseases easily.” Other women agreed with this statement.

Confidentiality

In each group, participants expressed a general belief that any Bureau of Prison (BOP) involvement in the study would deter women from participating and might reduce their willingness to provide honest answers to questions. Women said that the BOP should not be a visible part of the data collection process (e.g., recruitment, survey administration). One woman said, “No BOP staff should be connected in any way with this study to avoid people putting down false information.”

Overall, women did not believe that the information collected would be kept confidential. While they expressed a feeling of trust in the focus groups and seemed willing to be frank about difficult personal issues, they related that in a survey situation they would feel differently. Women expressed a general concern that any information they put down on paper could be traced back to them. Women conveyed that they would not be willing to take part in a study in which their name could be linked to their survey. Even when researchers explained that they would use unique identifiers on surveys and would keep results confidential, women said that they could not trust that the information would be protected.

This mistrust was further reflected in a woman’s commentary about her arrival to the prison. She said she was so distrustful that when she arrived at the prison and was asked to fill out a general health survey, she lied. She said that she now regrets having lied, because she has health problems and wishes she had been honest about her symptoms from the beginning to receive necessary treatment. She suggested that if women see that the results of the study will directly benefit them, or will change the

system to benefit others, that maybe they would be more willing to answer questions honestly. Other participants agreed.

Another aspect of trust related to inmates' opinions on how study test results should be handled by researchers. Women expressed a desire to be informed directly of their infection status after the study. Some women expressed a concern that if test results went directly to the health services at the prison, medical staff might not inform inmates who were infected. Others expressed concern that the test results would get out to other inmates.

Women also expressed a general fear of how the data would be used and how women might be personally harmed from study results. Women were concerned that the study might uncover a high prevalence of STDs in their prison, could call attention to current behavior of women at the site, and might result in more strict prison regulations. There was a general feeling of powerlessness expressed by the participants. One said, "The experience we have is that the more they know about us, the more they use it to hurt us. It's a mentality we struggle with everyday. We have no power. It's about you sitting over there in civilian clothes and us having to go to our cells." Distrust was not raised as an issue among the Latina focus group participants.

Sensitive Questions

A number of women in focus sessions expressed the view that any questions of a sensitive nature (e.g., about current behavior including drug use or sexual activity) would not be answered truthfully. Several women expressed that honesty to answers would depend greatly also on how the researchers behaved when they administered surveys. “If y’all come back and treat us like you are now, you’ll probably get people willing to answer your questions”, one woman said and others nodded in agreement. Women expressed an appreciation for being asked to participate in the design of the study and said that this would make them want to participate.

Income was another problematic topic. Some women said that inmates who are still under investigation for crimes related to their finances would certainly not be willing to answer these questions honestly. Other women said that the nature of their past lifestyle would make it impossible for them to answer questions about income. As one woman explained, “Some women will have difficulty reporting this because they don’t know. They earn income from different sources. Welfare recipients receive checks on a monthly basis and may not know their annual income. Drug dealers may know how much they have one day but not the next and cannot report on annual income.” Women suggested adding a “don’t know” option under income. They also advised that a question about income should distinguish between legal and illegal sources. Finally, they recommended that we ask questions such as whether women had been on welfare, or collected food stamps to gain a better picture of economic status.

In each session women expressed deep discomfort about any questions regarding sexual abuse or domestic violence. Women said that they would only be willing to

answer questions about sexual abuse in a general way. For example, they preferred an aggregate question about sexual, physical and emotional abuse. Latina women showed particular sensitivity about the nature of questions related to sexual issues. For example, women in the Latina group said they did not like being asked about their sexual behavior and the number of sex partners they have had. They expressed the belief that these kinds of questions implied that they were “dirty” and promiscuous.

Data Collection Procedures

Inmates were asked how they felt the survey should be administered. Women expressed a strong preference for it being self-administered in groups. They believed this method would make them less identifiable and provide an additional layer of privacy, in contrast to being singled out in a one-on-one interview. This view was espoused consistently in focus group discussions at all prison study sites. Women also said they would not want a BOP staff person to be in the room when they took the survey or provided a specimen.

Because women in prison frequently are required to provide urine samples for drug testing, we questioned whether participants would consider urine collection as a subterfuge for drug testing. Women did not express a concern about this. One woman said, “don’t mention anything about drug testing when you do the test, just don’t even put the idea in their heads.” . Others agreed. In general, women reacted positively to the idea of both urine and self-administered swab collection once they learned about the purpose of the study and that it could lead to the adoption of less invasive techniques for testing for chlamydial and gonococcal infection.

Women especially liked that these self-collected specimens could replace a doctor-administered examination. One woman said, “This would be a much cleaner technique than the tests they do now.” When asked what she meant by this, she expressed that she would trust the results more if she had collected the sample herself. Interestingly, it did not seem that Latina women shared this feeling. Overall, the Latinas expressed uncertainty about their ability to correctly collect their own specimen, and seemed to prefer a doctor-administered exam. “I am not sure I would know how to do it [the swab test] right if I did it myself. I am afraid I would make a mistake and then the test wouldn’t work.” Other participants in the Latina group agreed with this.

Exclusion Criteria

Another issue raised by participants had to do with the age-based exclusion in the STD study. When participants learned that only women age 35 and younger would be included in the study, many expressed opposition. Participants expressed the view that women older than 35 were highly sexually active and therefore at risk for STDs. Participants believed strongly that it was necessary to increase the age of eligibility, warning that women would be upset about being excluded.

Group-Based Cognitive Interview with Female Inmates

Following focus groups two through seven (see Table 1), women were asked to stay and discuss our draft survey instrument in detail. All agreed. Participants assisted in rewriting questions using phrasing that was familiar to them. For example, for questions about drugs, women suggested that we ask “what is your drug of choice?” rather than “what drugs did you use?” In addition, an early draft of the survey asked women about cocaine and crack use in the same question. Several women said they would refuse to answer a question with these two drugs placed together. One explained, “I would not answer this question, it’s offensive. I used cocaine, I was not a crack user. I am not a crack head.” Other women agreed.

A number of women expressed concern that the survey only included questions about sexual relations with men. Several participants for example, believed that women could pass infections to each other with sex toys. They recommended that questions about female-to-female sexual behavior be added. Women also suggested that ranges, instead of open-ended responses, be used for some of the questions, such as income and numbers of past sex partners. They believed women would be more likely to answer these questions truthfully with such categories. For questions about crimes committed, women expressed a preference for an open-ended response option. While some women knew what a “white collar” crime was, most said that the survey should allow women to specify their crime, and to describe multiple crimes.

In a number of instances, women expressed uncertainty about how to answer questions, because no time frame was provided. This was problematic for many whose

marital status, living conditions, drug use and sexual behavior had changed dramatically after their arrest.

Women expressed uncertainty about what “new” sex partner meant. They were not clear if this included someone they had never had sex with before or if a recent but also former sex partner could be considered new. They were also not certain if only a short-term sex partner should be considered a “new” partner. They suggested “non-regular sex partner” as a better term.

Women also provided input on the format and presentation of the survey. They expressed discontent about two specific items in earlier versions of the survey. They did not like a paragraph that appeared on the cover page of the questionnaire that discussed the confidentiality of the survey. They related that this paragraph made them overly concerned about the confidentiality and privacy of the survey. They suggested that the issue of confidentiality would be sufficiently addressed in the consent form and in an orientation to study participants. They also expressed immediate and collective aversion to a barcode that appeared on the front of the survey as a unique identifier. Women said this increased their suspicion about how data would be used and seemed to hide information from them.

Discussion

Valid measurement is a hallmark of good quantitative research. A survey instrument that is unclear to participants is likely to produce invalid data. In this study, focus groups and group-based cognitive interviews were used to design a more precise and accurate survey instrument. An iterative process was used in which new questions and terms were tested in subsequent focus groups and group-based cognitive interviews to ensure their clarity and meaning. The sessions led to numerous revisions of the wording, language, structure, and style of the survey that would be more likely to elicit valid responses from the participants. In addition, the sessions provided insight on how to maximize the participation of inmates overall and to minimize resistance to specific sensitive items. The sessions also helped identify preferences of inmates for certain study procedures that would lead to greater participation and more valid results. Results from this qualitative approach led us to change the questionnaire and methods in several ways.

The focus group participants assisted us in identifying specific ways to reduce the impact that distrust of the BOP could have on the study. Although prison staff were extremely cooperative at all participating sites and offered staff assistance to help us carry out the quantitative phase of our study, based on the focus group direction we declined any such assistance. No prison nurses would be in the room to assist in the specimen collection and staff would not assist in recruiting inmates.

In addition, based upon participant suggestions, our subject recruitment orientation emphasized the purpose of unique identifiers on survey materials and how data would be stored and labeled for confidentiality. In addition to providing a detailed consent form that described the risks and benefits of the study, we explained how data would be kept private at the orientation. We did this in lieu of including it on the cover sheet of the questionnaire, as recommended in sessions with participants. We also used numbers instead of bar codes on the survey.

Women were told that providing truthful answers would improve study quality and potentially improve service delivery for their fellow inmates. Women were also informed that no staff from their prison assisted in the design of the study or the survey. Additionally, they were informed that fellow inmates participated in the design of the survey instrument and data collection procedures. In addition, to increase their level of comfort, questionnaires were self-administered in large groups as recommended in focus groups.

Error in self-report of sexual behavior, particularly underreporting, is a continual concern in the field of sexual health.²⁹⁻³⁵ Clear guidelines exist in the literature to help investigators formulate sensitive and threatening questions.^{36,37} Our results indicated that in some instances these guidelines might not have been appropriate in this population. For example, it is recommended that using open-ended rather than close-ended questions increases the reporting of threatening behavior.³⁶ While our results suggest this might be true for some questions (such as crimes committed) for a number of sensitive questions

(e.g., number of sex partners, income levels) women believed that participants would be more likely to respond when closed-ended options were provided.

Our plan to exclude women older than 35 years from the quantitative study was another area of concern raised in the focus group discussions. The average age of female prison inmates is 36 years, yet young age (<20) is the most important risk marker for sexually transmitted infections. Nevertheless, several factors led us to increase the age limit of the study participants from 35 to 45 years. First, the strong sentiment expressed among focus group participants about including older women in the study was important. Women in focus sessions believed that excluding women above 35 years old would cause vocal opposition and anger among a large majority of inmates and could cause problems for implementing the study. Second, because an important purpose of the study was to address health needs and assess preferences for collecting specimens among all inmates, including a broader age range of women in the prison population could provide useful information for health service delivery in the future. Third, because there are no studies to date on STDs among women federal prisoners, increasing the age limit would provide necessary information about age as a risk factor in this study population.

Participants suggested that questions about women who have sex with women should be included in the final survey. Although literature is limited, there is some evidence that some sexually transmitted infections (herpes simplex, genital warts and bacterial vaginosis-associated organisms) are more common than expected in this population.³⁸⁻⁴² However, the implications of these results are unclear because of the

difficulty in identifying women who have only had female sexual encounters. Because women in prison do have sex with women, this setting provided a unique opportunity to explore sexual activity among women and collect valuable information for future research in this under-investigated area. Therefore, we chose to include questions in the survey on female-to-female sexual activity.

The focus group discussion and cognitive interviews with Latina inmates provided insight into possible differences between these women and their non-Latina counterparts. Although we conducted only one focus session with Latinas, the discussion revealed that survey questions about sexual topics were more sensitive and would be received with greater discomfort by this group. These findings are not surprising and are consistent with those of other studies.^{43,44} Additional research is required to better understand the health needs and knowledge of Latina women.

The group-based cognitive interview helped us understand the importance of distinguishing between circumstances of prisoners before arrest from their circumstances after arrest, but before being imprisoned. For example, a number of women related that immediately after arrest their behavior (e.g., sexual and drug-related) changed dramatically from their behavior before they were arrested. In addition, initially a question about the level of school completed did not specifically refer to that attained before prison. However, because many women attain their GED in prison, it was therefore necessary to specify our time frame of interest.

The focus groups and group-based cognitive interviews helped us understand the perspective of a population that has not been studied before, is socially isolated, and is minimally understood. The group-based format encouraged rich discussion about specific issues. Women worked together in rewording questions so that they made sense to them, were clear and met the needs of the research. Because a focus group was held prior to discussing the survey in detail, women gained familiarity with the subject matter and with the facilitators, and seemed comfortable speaking freely about survey questions. The inmates not only assisted in framing questions, but also raised insights that led us to reconsider issues related to study design.

There are general limitations of qualitative data and others specific to this study. Because focus groups do not include a random selection of women, involve small samples sizes, and stray from strictly standardized questioning, views of the participants should not be generalized to the prison population as a whole. An important methodological limitation in this study was our inability to tape-record the sessions. To compensate, the facilitator took some notes along with the note taker to capture as much information as possible. In addition, after each session, the facilitator and note taker compared notes and wrote full sets of session summaries.

Another possible limitation of the study relates to the change of facilitator for the Spanish-speaking focus group. It is possible that the differences noted between Latina and non-Latina groups may have been attributable to a change in facilitator. This seems unlikely, however, since our findings agree with published accounts that have been

identified between these ethnic groups. Finally, we did not validate the instrument produced by the process described, to ensure its superiority over our original draft survey. Validation of sexual behavior measurement tools is challenging⁴⁵ and beyond the scope of this investigation. Cognitive interviewing however, has been demonstrated to reduce erroneous survey responses in at least one prior investigation.⁴⁶ To our knowledge, the group-based cognitive interview format has not been validated.

Qualitative methods have much to contribute to epidemiological research and their inclusion should become customary. As with quantitative methods, qualitative techniques require both rigorous and systematic application. The field of Epidemiology should build on the best traditions of qualitative methods and recognize that special training and experience are essential to the application of these methods. The qualitative steps used here served not only to strengthen our subsequent quantitative study, but also provided insights into the target population that should be of use to other researchers.

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TABLE 1.**Characteristics of Female Federal Prisoners Who Participated in Focus Groups and Group-Based Cognitive Interviews**

Group	Prison	Number of Participants	Median Age	Race/Ethnicity
1*	A	8	34	3 Black, 3 White, 2 Asian
2	A	8	37	4 Black, 4 White
3	B	9	32	3 Black, 5 White, 1 Asian
4	B	9	39	5 Black, 4 White
5	C	8	33	2 Black, 4 White, 2 Latina
6□	C	11	39	10 Latina
7	C	6	35	3 Black, 1 White, 2 Latina

*A group-based cognitive interview was not held with group 1.

□Focus Group and group-based cognitive interviews conducted in Spanish.

Second Manuscript

Should Female Federal Inmates Be Screened for Chlamydial and Gonococcal Infection?

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This study was supported by grants from the Federal Bureau of Prisons and from the Uniformed Services University of the Health Sciences. Becton Dickinson donated Probetec ET™ assay kits for this study.

Abstract:

BACKGROUND: Insufficient data exist on the prevalence of *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) in female federal prisoners to design an appropriate screening approach for these infections.

GOAL: To determine the prevalence of and risk factors for chlamydial and gonococcal infections in one prison where women are screened at entry for the infections and another site where women are only tested for infection if they present with signs.

STUDY DESIGN: Cross-sectional study. Surveys were administered and urine and swab specimen collected from female federal prison study participants.

RESULTS: At the prison where women are screened at entry, 1.2% (4/323) of women tested positive for CT and 0.3% (1/323) tested positive for GC. At the prison where women are not screened, 2.3% of women (14/614) were positive for CT. No GC cases were identified. Young age (18-22 years) was the most important factor associated with infection in this site (OR 6.4), with a prevalence of 8.5% among this group. Prevalence of infection among women age 30 and younger exceeded 3.5%. Screening women age 30 and younger would identify more than 60% of cases at an estimated cost of less than \$60,000 per year. Approximately 83% of infections could be detected if women age 35 and younger were screened, but the annual cost for screening would approach \$90,000.

CONCLUSION: The overall prevalence of CT and GC infection at the study sites is low, therefore the female prisoners should be screened for infection based on age. Women at least 30 years of age and younger should be screened for infection in the prison sites.

Introduction

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC) are the two most common sexually transmitted bacterial pathogens in the United States. Approximately four million cases of CT infection and an estimated 800,000 new infections of GC occur each year.¹ Up to 80% of women with chlamydial or gonococcal infections are asymptomatic and in some cases women experience only mild or non-specific signs and symptoms. Serious long term consequences of untreated chlamydial and gonococcal infection include pelvic inflammatory disease (PID), ectopic pregnancy, tuboovarian abscess and infertility.²

The cost of managing untreated infections is burdensome to the U.S. health system, reaching approximately \$1.1 billion annually for gonorrhea and more than \$2 billion for CT and its sequelae.³ The CDC estimates screening and treatment programs can be conducted at an annual cost of \$175 million. Every dollar spent on screening and treatment saves approximately \$12 for the cost of complications that result from untreated CT.³ The CDC recommends screening all sexually active females under 20 years of age at least annually, and annual screening of women ages 20 and older with one or more risk factors for chlamydia (i.e., new or multiple sex partners and/or lack of barrier contraception). All women with infection of the cervix and all pregnant women should be tested.³ Screening programs to detect asymptomatic cases are important for the control of continued spread of infection, to prevent serious sequelae and to relieve the cost burden of these infections on the U.S. health system.

Universal screening may be appropriate in populations where the infections are highly prevalent. However, in lower prevalence populations, selective screening based on risk factors or risk markers may be a more cost effective alternative.^{4,5,6} Some of the important risk factors already identified in a number of studies include young age, black race, lower socioeconomic class, more sexual activity, and lack of barrier contraception.^{7,8}

Women incarcerated in short-term facilities such as city and county jails fit this high-risk profile; many are young, minority, unemployed single heads of household.⁹ Furthermore, many jailed women practice high-risk behaviors that predispose them to sexually transmitted infections.¹⁰ Recent studies conducted in U.S. jails support routine universal screening or offering presumptive treatment for women in jails where prevalence is high.^{11,12} While women incarcerated in long term facilities such as federal prisoners tend to be slightly older than city and county jail inmates, they fit a similar high-risk profile. To date, however, there have been no studies that have examined the prevalence of chlamydial and gonococcal infection in federal prisoners.

The objective of this study was to determine the prevalence of CT and GC infections in one prison site where women are universally screened for CT and GC at entry and in another female prison site where there is no universal screening. The purposes for including a prison in which universal screening is already in practice were to examine whether use of a new noninvasive highly sensitive DNA assay would identify cases not detected in the initial screening and to estimate the prevalence of infection in a screened population to determine if more periodic screening may be necessary.

Participants' urine and self-administered swab were tested for chlamydial and gonococcal infection and their demographic and behavioral data were collected to identify factors that might be associated with infection. The study was implemented to assist the BOP in designing a rational chlamydial and gonococcal screening protocol.

Methods

Study Population

A cross-sectional study was conducted at two women's federal prison sites, which house 40% of women incarcerated in female-only facilities. The two prisons included in the study will be referred to as the screening prison (SP) and the non-screening prison (NSP), to distinguish between the prison that universally screens prisoners and the prison in which women are only tested for infection if they present with signs at a routine physical examination conducted on all incoming inmates.

Women first learned about the study via flyers posted around the prison facility. Data collection began several weeks later between August and October of 2001, for a period of three to four days at each prison site. All women age 18-45 incarcerated in the two prison sites were invited to attend a "call out" to learn about the study. A "call out" is a routinely used system for calling inmates together for special group announcements or appointments. Every hour between 8:00 am and 3:00 pm a group of 20-30 women were called to the health center to learn about the study, hear an informational briefing about chlamydial and gonococcal infections and receive educational material about the two infections. Women who gave written consent were

asked to complete a questionnaire and provide urine and swab specimens. A trained interviewer administered the questionnaire to women unable to complete it because of illiteracy or disability. A total of approximately ten women at the two prison sites required questionnaires to be interviewer-administered. Women who attended call out but declined to participate were asked to complete an anonymous non-participation form with six general demographic questions to identify possible differences between study participants and non-participants. All study information was provided in English and Spanish. Institutional Review Boards of the Uniformed Services University of the Health Sciences, the Federal Bureau of Prisons, and the Johns Hopkins University approved the study protocol.

Data Collection

Participants completed a self-administered questionnaire, which included sociodemographic characteristics and sexual and clinical history. Information was also collected on the participants' age, marital status, race/ethnicity, years of education, and employment status prior to incarceration. Information about sexual activity prior to incarceration, history of sexually transmitted diseases, and current symptoms was also collected. The survey took approximately 30 minutes to complete.

After completing the questionnaire, women provided urine and swab specimens. To enhance accuracy of specimen collection, women were given an instructional brochure and diagram explaining how to provide the urine and vaginal swab specimens. Participants were instructed to insert a single swab one inch into the vagina, rotate it several times around, remove the swab and place it back in the tube. Following swab

collection, women were asked to provide approximately 20 ml of first catch urine into a sterile cup. Urine collection cups were marked at 20 ml to facilitate compliance. A Urine Processing Pouch® (Becton Dickinson, Sparks, Maryland) was placed into a collection tube. A lab assistant poured the urine specimen into the collection tube for storage and transport. Specimens were stored and transported at 4°C to arrive within four days for laboratory processing.

Laboratory Methods

Testing for chlamydial and gonococcal infection was performed using BDProbetec ET system (BD-PT, Becton Dickinson), which allows for the simultaneous detection of CT and GC DNA. BD-PT utilizes homogeneous strand displacement amplification (SDA) technology to amplify fluorescent energy transfer (ET) to detect the presence of CT or GC DNA in clinical specimens.¹³ The method provides high sensitivity and specificity, and can be performed on specimens obtained by noninvasive means.¹⁴ Four ml of urine were centrifuged at 2000xg for 30 minutes. The supernatant was decanted and 2 ml of sample diluent were added to the resultant pellet. The capped sample was vortex-mixed and placed into a lysing tray. Swab samples were eluted into 2 ml of sample diluent. All samples were lysed by heating at 114°C for 30 minutes and allowed to cool to room temperature for at least 15 minutes. Specimens were frozen at -70°C. All specimens were tested within two weeks of collection. Frozen specimens were thawed to room temperature and re-lysed at 114°C for 30 minutes and allowed to cool to room temperature. Processed samples were added to microwell strips to react with the SDA priming components. Samples remained in the priming wells at room temperature for at least 20 minutes and up to 6 hours. Priming was completed by

incubation at 72.5°C for exactly 10 minutes followed by transfer to amplification wells that had been preheated to 54°C. Plates were sealed and immediately placed into the BD-PT instrument. Amplification, fluorescence detection and data analysis occur by the instrument. Positive and negative controls were included in every batch of specimens tested. Women whose specimens tested positive by either swab or urine were considered to be infected.

Statistical Analysis

The prevalence of CT and GC was calculated for each of the prison sites. Potential risk markers associated with infection were assessed using χ^2 or Fisher's exact test.¹⁵ Correlations between risk factors were examined using χ^2 . Factors identified as associated with infection were selected as potential risk factors to build a multivariate Poisson regression model. The relative risk of infection was estimated based on the prevalence ratio. An exact Kappa statistic was used to test the percent and statistical agreement between urine and swab specimen test results. Statistical analyses were conducted using SAS (version 8.1 Cary, NC).¹⁶

Results

Study Population

In the two prisons, approximately 1,344 women were eligible to participate in the study. Of these, 1,230 (92%) attended call out. A total of 988 (80%) women who attended call out volunteered to participate. From the screening prison (SP), approximately 90% of women eligible to participate in the study attended call out and

93% of inmates from the non-screening prison (NSP) attended. Reasons for not attending call out included confinement in a secure housing unit (5%), illness, inability to be released from work, or personal choice. Participants included 625 women from the NSP and 363 women from the SP. Ninety-eight percent (614/625) of NSP volunteers and 89% (323/363) from the SP provided a urine and/or swab specimen. From the SP, three of the 363 study participants filled out a questionnaire in Spanish. At the NSP, which has a large Latina population, 232 of the participants (37%) completed the questionnaire in Spanish.

The median age of participants and non-participants at both study sites was 33 (Table 1). At the SP, 40% (16/41) of Latinas declined participation while at the NSP 4.2% (11/258) of the Latina population declined participation. In addition, at the SP 12.4% (24/194) of white women invited to participate in the study declined, whereas approximately 23% (32/140) of white women at the NSP declined study participation. At both prison sites, more than 20% of African American women declined participation [21% (43/201) SP, 28% (58/207) NSP]. At both sites, a larger proportion of study participants had graduated from high school than non-participants. In both prisons, single women were more likely to decline participation than married and divorced women. The median time previously served in years for current charge was the same for participants as non-participants at both sites.

Prevalence of *C. trachomatis* and *N. gonorrhoeae*

At the SP, CT was detected in 1.2% (4/323) and GC in 0.3% (1/323) of woman. None of the participants were coinfecting (Table 2). All five cases were detected by the swab specimen, but only one of the CT cases was additionally detected by urine (Table 2). The median age of those testing positive for infection at the SP was 27 years (range of 20 to 43 years). Because of the small number of cases at this prison site, we could not explore associations between infection and risk factors.

At the NSP, 2.3% of women (14/614) tested positive for CT. There were no GC cases. CT was detected in: both the swab and urine specimens of 10 of the 14 women, urine of three women who tested negative by swab, and one woman's swab whose urine specimen was negative.

The median age of those testing positive for CT at the NSP was 24 years (range 18 to 43 years). Nine of the positive cases were black women, four of whom were African American and five of whom were born in Africa or the Caribbean. Three other cases were Latina women and two cases were white. Of the women who tested positive for CT, approximately 77% were single and 23% were married. The prevalence of infection at the NSP was greater in the 18-22 year age group.

Univariate Analysis

At the NSP, CT was most common among women who had never been married ($p=.01$) and women between the ages of 18 and 22 ($p<.01$) (Table 3). Other factors

associated with infection included fewer years previously served in prison ($p=.03$), age younger than 17 years at first sexual intercourse ($p=.01$), and current unusual vaginal discharge ($p=.04$).

Factors considered but not associated with CT included level of education, race/ethnicity, a new sex partner before entering prison, multiple sex partners, income, history of sexually transmitted diseases, and use of barrier methods (not all data shown).

Of the 51 women age 18-22 who were tested, four were positive, providing a prevalence of 8.5% in this subgroup (Figure 1). Among women age 18-22 years, the only factors associated with infection were report of current vaginal discharge ($P=.04$) and vaginal itching ($P=.04$) (data not shown). No other risk factors including new sex partners, condom use and number of sex partners were significantly associated with women in this young age group, when compared to older women.

Multivariate Analysis

A final model was constructed using Poisson regression for rate data to determine which factors were associated with infection when controlled for other variables. The model included only risk factors that were found to be significantly associated ($p<.05$) with infection in the univariate analysis and were not highly correlated with other variables. We therefore eliminated years served in prison and marital status, because both these variables were highly correlated with age. Although age at first sexual intercourse was significantly associated with infection in univariate analysis, we had to eliminate it from the final model because all women testing positive were 17 or younger,

which caused complete separation and affected the viability of the model. The final model, therefore, included age and vaginal discharge. The Poisson regression model for rate data was the following: $\log(\mu/t) = \alpha + \beta x_1 + \beta x_2 + \beta x_3$; where μ = the number of cases; t = the combined number of subjects in each cell; $x_1 = 1$ if age = 18-22, 0 otherwise; $x_2 = \text{age}$ 23-30, 0 otherwise, $x_3 = 1$ if vaginal discharge is present, 0 otherwise. Only age (18-22) was associated with CT infection in this study population with an odds ratio of 6.4 (Table 4).

Discussion

The prevalence of *C. trachomatis* and *N. gonorrhoeae* observed in the study population is lower than that reported in studies conducted in jail settings where prevalence rates have been reported to reach as high as 27% in some sites.^{12,13} The greater age and length of stay of federal inmates as compared to inmates from jails and other short term facilities may explain this difference. In addition, because women who enter the federal facility may have come from other jails or prisons, they may have already been screened and treated for infection prior to entering the study site. The greater prevalence of chlamydial infection in the youngest participants is consistent with data reported in other studies.^{17,18,19} Information about prevalence of infection of CT and GC gathered from the two prison study sites can assist in making screening decisions.

Currently the BOP policy is that inmates are only tested for chlamydial and gonococcal infection if they present with signs at a routine physical examination. In the NSP between January and December of 2001, prison staff tested 17 women for GC and

CT, based on signs detected during a physical examination. Using Gen ProbeTM, a hybridization assay, no GC cases and one CT case was detected. While most prisons use these criteria for testing, two of the five prison sites for women conduct universal screening upon entry to the prison. At the SP, during ten months in 2001, five cases of CT were identified and one case of GC in 2,232 women screened at the prison, also using GenProbe assay. This represents a prevalence of 0.2% for both infections among the population screened. Data from these two sites leave us with two important questions: 1) Is universal screening the most cost effective method for detecting and treating chlamydial and gonococcal infection in the site where all women are screened? 2) Is sufficient screening being performed to ensure that most infections are detected at prisons where only women with clinical signs are tested?

In a population where prevalence is low, a strategy of selectively screening women at highest risk for infection is a cost-effective alternative to screening all women who enter the site. However using signs of infection at physical exam as screening criteria is not reliable, because most infections lack specific clinical signs. In this study, among women at the NSP, age was significantly associated with infection. Others have demonstrated age to be a cost-effective strategy for screening young women.¹⁹

At the SP, where an average of approximately 2,500 women are screened per year, the \$50 cost of screening each woman (\$16.50 for laboratory kit and testing, and \$33.50 for clinician's time) results in a \$125,000 cost to detect few CT and GC cases.²⁰ Based on data from this study and from this information provided by prison health staff, if the prison implemented an age-based screening policy, most infected women could be detected without having to screen all inmates (Table 5). For example, if the SP screened

all women age 30 and younger for CT/GC during 2001 using a highly sensitive test, the SP would have screened approximately 700 women and could have detected at least 7 of the 9 cases identified from our study (3) and from prison routine screening (6). Targeting screening to this age group would result in a cost of approximately \$35,000 instead of \$125,000. However, screening based on age would have resulted in 22% of the cases (2/9) being left undetected and untreated.

At the NSP, where signs at physical exam were used as markers to test for infection, it is likely that a number of cases are left undetected and untreated. At this site, although approximately 17 women were tested for CT and GC infection during a one-year period, only one case of CT was detected²¹ (Table 6). Age-based screening would have provided a more effective approach than relying on signs. Although the cost of age-based screening would greatly exceed the cost of screening based on signs alone, it would result in more cases detected, and a minimal difference in the cost per cases detected. Based on a prevalence of infection found in our data, screening women age 22 and younger would detect 30% of cases, screening women age 25 and younger would detect nearly half of cases and screening women 30 and younger would result in 62% of cases detected. While increasing the screening age at the NSP to 35 and younger would identify nearly 85% of all cases, this approach would greatly exceed the cost of screening younger age cohorts. This study provided evidence that gonococcal infection is not prevalent in the study population and therefore, it may be unnecessary to screen for gonococcal infection at these study sites.

Our study had some limitations. First, our study population may not be generalizable to the entire female federal prison population. The study included only two of the six main federal prisons exclusively for women and did not include the 5,000 additional female inmates who are confined in detention centers and other mixed gender facilities. In addition, at the SP, although there were few Latinas in the prison, 40% declined participation. At both prison sites more than 20% of black women declined participation and 20% of white women at the NSP declined participation. Also, single women and women with fewer years of education were more likely to decline participation. These factors could affect the prevalence of infection found in the NSP, and may have resulted in an underestimate of the prevalence of infection in these sites.

Another limitation to our study was identified in an earlier qualitative study in which we conducted focus groups with inmates. The study revealed that there was mistrust among inmates and that women may be reluctant to answer questions truthfully.²² Efforts were made, based on these focus groups, to increase inmates feeling of trust about the study. However, we should be cautious about the interpretation of the results.

Because of the small number of cases, we may have lacked the statistical power to reveal important associations between factors like condom use or multiple sex partners, which have been demonstrated by others. In addition, the low prevalence of infection in our prison sites has an impact on the positive predictive value (PPV) of our assay. In a population with a prevalence of infection of approximately 2%, the PPV of Probetec is estimated to be approximately 60%.²³ Because we used two methods to test for infection,

however, we were able to assess the agreement between the two tests. In the SP, of the 6 cases of infection detected, the overall percent agreement between the two tests is nearly 40%. Yet, while this indicates relatively poor agreement between the two tests the Kappa statistics resulted in a p-value of .01. We therefore conclude that there was significant agreement between the two tests, rejecting the null hypothesis that there was no agreement. At the NSP, the percent agreement between tests exceeded 80%, which represents excellent agreement.²⁴ The Kappa test at this site resulted in a p-value of less than .001, which results, again, in our rejection of the null hypothesis that the two tests do not agree, indicating significant concordance between the two tests. The significant agreement between these two tests at the prisons increases our confidence about the PPV of the assay.

Our findings reveal that age is an important risk factor for selecting women who are at greatest risk for CT infection in the prison sites under study. Therefore, based on the current study, we recommend that women age 30 and younger incarcerated in federal facilities be screened for CT infection. While screening women age 35 and younger would yield a greater detection, it should be recognized that the average length of stay of prisoners is 5 years and transmission of these two infections within prison is likely to be low. Therefore the cost of screening women in this age group may not outweigh the benefits. Prison health practitioners may determine, however, that women older than age 30 who present with signs, symptoms or report certain risk behaviors such as multiple sex partners or lack of use of barrier methods of contraception should also be tested for infection.

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Table 1
Characteristics of Participating and Non-Participating Female Federal Prisoners

Characteristics	Screening Prison		Non-Screening Prison	
	N (%)		N (%)	
	Participants N= 363	Non-Participants N=117	Participants N=625	Non-Participants N=123
Age				
Median	33	33	33	33
18-22	24 (6.6)	6 (5.1)	47 (7.5)	4 (3.3)
23-27	69 (19.0)	13 (11.1)	117 (18.7)	23 (18.7)
28-32	79 (21.8)	20 (17.1)	130 (7.5)	30 (24.4)
33-37	75 (20.7)	14 (12.0)	135 (21.6)	27 (22.0)
38-42	80 (22.0)	23 (19.7)	114 (18.2)	16 (13.0)
43+	34 (9.4)	10 (8.5)	66 (10.6)	21 (17.1)
Missing	2 (.6)	31 (26.5)	16 (2.6)	2 (1.6)
Race/Ethnicity				
African American	158 (43.5)	43 (36.8)	149 (23.8)	58 (47.2)*
White	170 (46.8)	24 (20.5)	108 (17.3)	32 (26.0)*
Hispanic	25 (6.9)	16 (13.7)	247 (39.5)	11 (8.9)*
Other†	2 (.6)	1 (.9)	70 (11.2)	15 (12.2)
Asian	0	2 (1.7)	11 (1.8)	3 (2.4)
Native American	6 (1.7)	0	14 (2.2)	4 (3.3)
Missing	2 (.6)	31 (26.5)	26 (4.2)	0
†African, Caribbean and other nationalities				
Time served for current charge				
Median	3 years	3 years	2 years	2 years
Number of Years				
0-1	93 (25.6)	20 (17.1)	186 (29.8)	25 (20.3)
2-3	83 (22.9)	16 (13.7)	180 (28.8)	42 (34.1)
4-7	44 (12.1)	16 (13.7)	90 (14.4)	20 (16.3)
8-19	17 (4.7)	5 (4.3)	25 (4.0)	10 (8.1)
Missing	126 (34.7)	60 (51.3)	144 (23.0)	26 (21.1)
School Level Achieved				
None	2 (.6)	0	9 (1.4)	0
Elementary	20 (5.5)	3 (2.6)	64 (1.4)	10 (8.1)
Some high school	88 (24.2)	37 (31.6)	164 (26.2)	64 (52.0)
High school Graduate	113 (31.1)	29 (24.8)	195 (31.2)	2 (1.6)
Some college	106 (29.2)	8 (6.8)	1362 (1.8)	31 (25.2)
College Graduate	28 (7.7)	1 (.9)	40 (6.4)	10 (8.1)
Postgraduate	5 (1.4)	1 (.9)	6 (1.0)	5 (4.1)
Missing	1 (.3)	38 (32.5)	11 (1.8)	1 (.8)
Marital Status				
Single (never married)	143 (39.5)	45 (54.9)	250 (40.6)	60 (48.8)
Married	124 (34.3)	19 (23.2)	251 (40.7)	42 (34.0)
Divorced	50 (13.8)	12 (14.6)	43 (7.0)	14 (11.4)
Separated	41 (11.3)	6 (7.3)	60 (9.7)	7 (5.7)
Widowed	4 (1.1)	none	12 (1.9)	none

Significant difference between participants and non-participants at $p < .05$ using χ^2

Table 2
Results of Laboratory Tests at the Screening and Non-Screening Prison

Tests	Screening Prison N=323	Non-Screening Prison N=614
<u>Chlamydia</u>		
Urine + /Swab+	1	10
Urine + /Swab-	0	3
Urine- /Swab +	3	1
Urine-/ Swab –	319	600
N (%)	4/323 (1.2%)	14/614 (2.3%)
<u>Gonorrhea</u>		
Urine + /Swab+	0	0
Urine + /Swab-	0	0
Urine- /Swab +	1	0
Urine-/ Swab –	322	0
N (%)	1/292 (0.3%)	

Table 3. Factors Associated with CT at the Non-Screening Prison

Factor	Total	Prevalence N (%)	Odds Ratio (95% CI)	P
Age Years				
31+	367	4 (1.1)	Referent	
23-30	195	4 (2.6)	2.4 (0.63 - 9.0)	.20
18-22	47	5 (8.5)	8.4 (2.0- 35.0)	.00
Race/Ethnicity				
White	136	2 (1.5)	Referent	
African American	147	4 (2.7)	1.9 (0.3- 0.4)	.47
Hispanic	248	3 (1.2)	0.8 (.14-5.0)	.83
Other	94	5 (5.3)	3.8 (.71- 20.0)	.12
Marital Status				
Married (or ever married)	366	3 (0.8)	Referent	
Single	250	10 (4.0)	5.0 (1.3-29.0)*	.01
Years confined in Prison				
3+	190	0	Referent	.03
<3	291	7 (2.4)	Cannot compute	
School				
High School Graduate	377	9 (2.4)	Referent	0.8
Non High School Graduate	237	4 (1.7)	.7 (0.2-2.6)*	
Pregnant				
Never been pregnant	85	11 (2.1)	Referent	
Ever been pregnant	531	2 (2.4)	.9 (.2-8.3)*	.74
Age First Sex				
18+	235	12 (3.6)	Referent	
<17	337	1 (0.4)	8.6 (1.2-370)*	.01
Number of sex partners 3 months prior to prison				
0-1	453	8 (1.8)	Referent	
2	113	4 (3.5)	2.3 (0.3-19.0)	.43
3+	44	1 (2.3)	3.6(0.4-32.0)	.24
Lifetime Number of Sex Partners				
0-4	254	4 (1.6)	Referent	
5-10	165	4 (2.4)	1.4 (0.4-5.1)	.60
11+	172	5 (2.9)	2.3 (0.6-9.5)	.24
Previously Treated for CT				
No	533	10 (2.0)	Referent	
Yes	92	4 (4.4)	2.4 (0.5-8.5)*	.14
Current symptoms:				
Unusual vaginal discharge	143	6 (4.2)	3.1 (1.1-10.0)*	.04
Vaginal itching	126	5 (4.0)	2.6 (0.6-9.7)*	0.1
Pelvic Pain	130	1 (0.8)	0.3 (0.0-2.3)*	1.0
Irregular Bleeding	54	0	0.9*	1.0
Pain on Urination (Dysuria)	39	0	0.9*	1.0
Does not use condom with Non- Regular partner	204	5 (2.7)	0.9 (0.3-3.6)*	0.7

*Indicates Fisher's exact odds ratio and exact confidence intervals were calculated, otherwise χ^2 test was used.

Table 4
Poisson Regression Final Model

Parameter	Relative Risk	95% CI	P value
Age 18-22 years	6.4	1.5 - 27.0	0.01
Age 23-30 years	2.0	0.5 - 7.5	0.4
Vaginal Discharge	2.3	0.7 - 7.3	0.2

Table 5
Annual Cost Estimate Of Different Screening
Options at the Screening Prison

Screening Criteria	Number Screened	Cases Detected* n (%)	Estimated Cost †	Cost/Case	Cases Left Undetected n (%)
Age <23	225	3 (33)	\$11,250	\$3,750	6 (67)
Age <26	300	3 (33)	\$15,000	\$5,000	6 (67)
Age < 31	700	7 (78)	\$35,000	\$5,000	2 (22)
Age <35	1,130	7 (78)	\$56,500	\$8,071	2 (22)
Universal Screening	2,500	9 (100)	\$125,000	\$15,625	none

*A total of nine cases is based on the six cases detected in universal screening during 2001 and an additional three cases detected from this study who entered the prison in 2001.

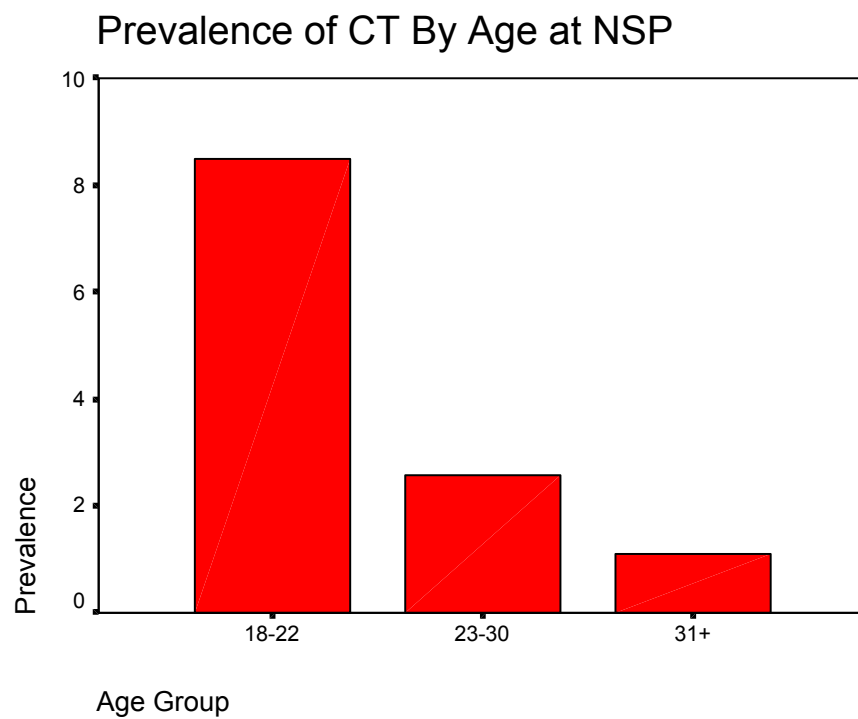
†Estimated cost is \$50 cost for the kit, laboratory work and physician time for specimen collection multiplied by number of people screened.

Table 6
Annual Cost Estimate of Different
Screening Options at the Non-Screening Prison

Screening Criteria	Number Screened	Prevalence* (%)	Cases Detected n (%)	Estimated Cost†	Cost/Case	Cases Left Undetected* n (%)
Signs	17		1 (2)	\$850	\$850	68 (98)
Age <23	225	8.5	19 (28)	\$11,250	\$592	50 (72)
Age <26	594	5.6	33 (48)	\$29,700	\$900	36 (52)
Age <31	1161	3.7	43 (62)	\$58,050	\$1,350	26 (38)
Age <36	1776	3.2	57 (83)	\$88,800	\$1,557	12 (17)
Universal Screening	3,000	2.3	69 (100)	\$150,000	\$2174.00	None

*Based on prevalence of infection determined in NSP prison site of all participants and within each age group.

†Estimated cost is \$50 cost for the kit, laboratory work and physician time for specimen collection multiplied by number of people screened

Figure 1

Third Manuscript

Female Prisoners' Preferences of Collection Methods to Test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infection

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This study was supported by grants from the Federal Bureau of Prisons and from the Uniformed Services University of the Health Sciences. Becton Dickinson donated Probetec™ assay kits for this study.

Abstract

BACKGROUND: There is an increasing reliance on noninvasive techniques to collect specimens for the detection of sexually transmitted infections. While there is greater understanding about the acceptability of these methods among the general population, there is little known about their acceptability among women confined in federal prison.

GOAL: To assess the preferences of female federal prisoners for self-collected vaginal swabs or urine collection and to compare preferences of prisoners between these techniques and a pelvic examination to detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

STUDY DESIGN: A cross-section of inmates incarcerated in a large federal prison provided urine samples and self-collected vaginal swab specimens. Women then completed a questionnaire regarding the ease of each method and their preferences for future specimen collection.

RESULTS: A total of 535 women between the ages of 18 and 52 (median age=33) participated in the study. More than half of the participants (57%) reported no difference between urine and swab in terms of ease of collection. Approximately 30% of participants said they would prefer to give a swab specimen in the future as compared to urine (21%), but nearly half of women expressed no preference for one method over the other. Most participants (60%) expressed a preference for doing a self-collected swab rather than having a pelvic examination (23%), but nearly 17% had no preference for one over the other.

CONCLUSIONS: The study population of female federal prisoners expressed no aversion to the self-collection of either vaginal swab or urine specimen for STD testing. A majority of participants expressed a preference for noninvasive techniques rather than a pelvic examination.

Introduction

New highly sensitive DNA tests provide opportunities for using noninvasive techniques such as self-collected urine or swab for widespread and cost-effective screening of sexually transmitted infections. While there is mounting evidence in the literature on the effectiveness of these collection methods compared with culture,¹⁻⁵ there are few peer-reviewed studies that have evaluated preferences of women for noninvasive techniques.^{6,7} Most studies that have been conducted explore preferences of adolescent girls rather than women.⁸⁻¹⁰ Results from these studies reveal a greater preference for noninvasive techniques over pelvic examination to detect chlamydial and gonococcal infection. These studies have provided useful information for designing widespread screening programs to detect these infections, especially among populations averse to getting a pelvic examination.

Cell culture has been the gold standard collection method for testing for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) and requires that a clinician take a small sample of cells from the endocervix during a pelvic examination.¹¹ More recently, research has identified highly sensitive and specific alternative nucleic acid amplification tests (NAATs) for chlamydial and gonococcal infection that allow for testing of self-collected specimens. NAATs such as polymerase chain reaction (PCR), ligase chain reaction (LCR), and strand displacement amplification (BDProbetecTM) are examples of techniques that have demonstrated efficacy for detection of chlamydial and gonococcal infections in self-collected distal vaginal swabs or urine.¹²⁻¹⁵

CT and GC infections are the most common bacterial sexually transmitted infections in the United States and globally. These infections are asymptomatic in most women and pose serious health consequences if left untreated. Minimal research has been conducted in federal prisoners, yet data from our study suggests that prevalence among female prisoners exceeds 8% in the youngest subgroup (18-22 years).¹⁶ In addition, there has been no research among prisoners to determine preferences for use of noninvasive techniques, which may provide a less costly, more acceptable alternative to a clinician-obtained specimen. One recent study found that a majority of adolescent girls (84%) prefer self-collection methods to the traditional gynecological examination.⁹ Adolescents are believed to be good candidates for these noninvasive methods because they might otherwise be reluctant to undergo pelvic examinations.¹⁰ A recent study conducted in adult women found that half had no preference for a self-collected swab compared to urine collection, and that the acceptability of these noninvasive methods among women suggests that they are an acceptable and suitable method for implementing widespread screening.⁶

Prisoners might also be good candidates for noninvasive collection methods. Mistrust of health care workers, loss of privacy and the discomfort of pelvic examinations may deter prisoners from consenting to standard STD testing, especially because pelvic examinations are voluntary in prison. In addition, although females comprise only 7% of the total federal prison population, between 1990 and 2001 there was an increase in the number of females in the federal prison from 3,825 in 1990 to nearly 11,000.¹⁷ This rapid growth in female prisoners strains the limited resources and time of prison health

staff. Noninvasive techniques may provide an effective alternative that frees the demands on highly skilled clinicians. Self-collected swab is an especially appealing method because it is easy to perform, can be more easily stored and transported than urine, and requires less laboratory processing time than urine.

While noninvasive techniques have been shown to be effective alternatives to culture, it is not known whether prisoners would prefer one noninvasive technique over another or if they would prefer to collect their own specimen (vaginal swab or urine), rather than undergoing a pelvic examination. Prisoners might consider urine collection a subterfuge for drug testing and could be averse to providing urine for STD testing. This study explores women's preferences for specimen collection techniques to assist in planning clinical management of STDs in the future.

Methods

This Institutional Review Board-approved study was part of a larger study to assess the prevalence of and risk factors for CT and GC infection in female inmates.¹⁶ It was conducted in one of the five main federal prisons for women in the United States during four days in October of 2001. All women incarcerated in the two prison sites age 18-45 years were invited to attend a "call out" to learn about the study. A "call out" is a routinely used system for calling inmates together for special group announcements or appointments. Approximately 30 women were called out at a time to learn about the study and informed consent was obtained. Participants completed a questionnaire on

demographic information, history of STDs, STD risk factors (e.g. number of partners, new sexual partners, barrier contraception use) and current gynecological symptoms.

Participants were then given a urine cup and swab (BDProbetec system, Becton Dickinson, Sparks, MD). A diagram and explanation of the collection technique was provided and research technicians were available to provide further explanation.

Participants were instructed to insert a single swab one inch into the vagina, rotate it several times around, remove the swab and place the swab back in the tube. They were asked to then urinate in a collection cup, which was marked at 20 ml to facilitate volume compliance. Specimens were kept at 4°C in coolers with ice packs and transported to the research laboratory within three days of collection where they were immediately processed. After processing, the samples were frozen at -70°C until testing by the BDProbetec assay according to manufacturer's instructions.

After specimen collection, participants were asked to answer a survey about their opinions concerning the self-collection techniques. Time limitations inhibited us from inviting all women to participate in this part of the study. The short questionnaire asked whether they found it easier to give the swab or the urine sample; why they chose one technique over the other, if they did; whether they would prefer to provide either a urine sample or self-collected swab specimen, given a choice in the future, and if so, why; and, whether they would prefer the self-collected swab to a pelvic examination in the future. We also asked women whether they were currently menstruating, to determine if this might influence women's choices and attitudes. Questions asking why women preferred a specific method to another were open ended and later coded into categories for

quantitative analysis. To assess the relation between demographic factors and preferences of women for collection methods, χ^2 tests were used and odds ratios were calculated to compare differences among subpopulations. Analyses were conducted using SPSS (version 10.1, Chicago, IL).

Results

Of the approximately 800 female inmates eligible to participate, a total of 748 (94%) came to the health center to learn about the study. Of these, a total of 614 (82%) women provided a specimen and completed an initial questionnaire. Most women who did not participate were either confined in a secure housing unit (5%), sick, unable to participate because of work conflicts, or declined participation. Of the women who provided a specimen, 535 (87%) were asked and agreed to answer the questionnaire about preferences.

The age (median 33 years), racial, and ethnic background of study participants varied little from the population of eligible inmates (Table 1).

Of 535 women who provided a specimen, nearly all, (97%) chose to provide both a urine and swab specimen. In terms of ease of the two methods, 57% (299/521) found no difference between urine and swab. Approximately 21% (108/521) of women reported that swab was easier and 23% (118/521) reported that urine was easier. Of the eight women who chose to provide a swab specimen but not a urine specimen, two said

they did so because they did not have to urinate. Of the ten women who declined to give a swab sample, six explained their decision saying they were afraid it would be uncomfortable. An additional three women said that they would not like, or were afraid, to insert something inside their vagina.

Asked what method of detection they would prefer in the future, nearly half of the women (48%, 256/535) said that it made no difference to them, 31% (164/535) said they would prefer the swab and 21% (110/535) said they would prefer the urine (Figure 1). Of the women who would prefer the swab, 41% said it is easier to do and cleaner than giving a urine specimen (Table 2). Nearly 20% of women said they preferred to give swab because they cannot always urinate on demand. Of women who preferred urine to swab, approximately half (45%) said that urine was easier to do or that the swab was too difficult. Seventeen percent of women who preferred urine said they do not like to insert something inside themselves. Thirteen percent of women said they found the swab method to be uncomfortable and five women said they were afraid they were not doing the swab correctly.

When asked whether they would prefer getting a pelvic examination or doing a self-collected vaginal swab in the future to test for infection, most women (60%, 314/535) reported that they would prefer to do their own vaginal swab collection, 23% (122/535) said they preferred a pelvic examination, and 17% (87/535) said that it did not matter to them (data not shown). Many of the women for whom the method did not matter, indicated a preference for the most effective collection method. Approximately 20

women also commented that they preferred the pelvic examination because the doctor could look for other health problems. Nearly 40 women also expressed preference for the pelvic examination, because they were not confident about their ability to do the self-collected swab method correctly.

Menstruation and Preferences

Nineteen percent (103/535) of participants were menstruating at the time of the study. A greater proportion of women who were menstruating expressed a preference for either swab or urine than women who were not menstruating. (Table 3 and Figure 2) Menstruating women were two times as likely as non-menstruating women to express a preference for using swab or urine in the future. (OR=1.8 CI 1.2-2.8). Although the difference was not statistically significant, 26% of menstruating women reported that the swab was an easier method than urine as compared to 19% of the non-menstruating women. More menstruating women displayed slight preferences for providing either a swab or urine specimen in the future than did non-menstruating women (Figure 3).

Demographic Factors and Preferences

Because of the large proportion of Spanish-speaking participants in the study (40%), we explored whether there were differences in preferences between Latina women and their non-Latina counterparts (Table 3). As with the rest of the population, more than half (56%) of the Latinas found no difference between swab and urine in terms of ease of the method (Figure 4). However, Latinas were nearly two times as likely as non-Latinas to prefer urine to swab (OR 1.5 C.I. 1.1,2.3). While a larger proportion of Latinas

showed a preference for future testing with urine rather than swab (24% vs. 20%), this difference was not significant (Figure 5). Differences between Latinas and non-Latinas in terms of preferences in the future for swab versus a pelvic examination were not statistically significant.

As with the rest of the population, more than half (54%) of African American women reported no difference between the swab and urine method in terms of ease. Differences in terms of preferences for future specimen collection differed slightly between African Americans and other races, but these differences were not statistically significant.

Participants' age also influenced preferences. Young participants (age 18-22) were more than twice as likely as all other women to report that swab was an easier method (OR=2.2, C.I. 1.1,4.6) (Table 3, Figure 6). In addition, 18-22 year olds were nearly three times as likely as all other women to express a preference for the self-collected vaginal swab in the future (OR=2.6, C.I. 1.3,5.1, Table 3, Figure 7). This 18-22 year old age group differed only slightly from older women with regard to future preferences for pelvic examination or self-administered swab (Figure 8).

Discussion

Until recently, optimal screening for bacterial sexually transmitted infections in women has required performance of pelvic examination and endocervical specimen collection. With the advent of DNA-based tests for the detection of CT and GC, alternate clinical specimens such as voided urine and self-collected swab perform as well as clinician-obtained specimens for STD diagnosis. They also provide noninvasive options that have been shown in previous studies to be preferred to pelvic examination.⁸⁻¹⁰ Yet, because most studies exploring preferences and acceptability of noninvasive techniques have generally included adolescent women, this study contributes to our knowledge about adult women's opinions.

Although women in this study could choose to provide either a urine or swab specimen, if they did not want to provide both, the fact that 97% of participants agreed to provide both specimens suggests that there was no strong aversion to either method. The results of this study suggest that female federal prisoners would generally favor noninvasive collection methods to invasive collection techniques. Half of the study population expressed no preference for urine or swab, finding both to be easy to perform. Inmates did not express aversion to urine collection, despite our concerns that they might suspect drug testing. In fact, a few women said that they preferred urine collection because they are so accustomed to it, and they consider it a routine or "normal" procedure.

To our knowledge, whether menstruation influences a woman's preference concerning collection method has not been explored in other studies. We found that menstruating women prefer self-collected swab to urine collection. Latinas were not as comfortable with the self-administered swab as other participants. This is consistent with focus group findings in which Latinas expressed a greater discomfort with the self-collected swab procedure than did their non-Latina counterparts.¹⁸ Young participants (18-22 years) showed an overall greater preference for doing a self-collected swab versus urine collection or pelvic examination, as compared to older populations. This preference by younger age women is consistent with findings in other studies in which youth express a preference for noninvasive techniques and may reflect a cohort difference in one age group over the other.^{8,9}

This study contributes to our understanding of women's preferences for STD specimen collection; in particular among women confined in long-term incarceration facilities. It may be important to note that one in four women preferred the pelvic examination to self-administered techniques. This differs from findings in adolescent girls, in which most expressed a preference for self-administered techniques over pelvic examination. This difference may be explained by age and experience. Whereas in our study population more than 75% of women reported having had a pelvic examination at least 12 months before incarceration, many of the young girls (nearly half) have never had a pelvic examination, and fear of the examination may make the noninvasive techniques more appealing.^{9,19}

In our study, women's concerns about the noninvasive techniques seemed to center around access to a more comprehensive examination and a lack of confidence about self-collection methods. Although women who are confined in prison have minimal input on the kinds of specimen collection techniques that are used, knowing that they do not have strong preferences for, or aversions to, certain collection methods may assist prison health planners to implement changes based on cost and manpower decisions.

Increasing evidence of the effectiveness of these noninvasive methods, may result in greater reliance upon them in future testing for a number of sexually transmitted infections.²⁰⁻²³ If prison health planners decide to rely on noninvasive techniques in the future, findings from this study provide evidence that female prisoners find them acceptable. While these techniques may provide an important opportunity to reduce the heavy demand on highly skilled clinicians, spare women from the discomfort of a pelvic examination, and provide a private, less invasive technique for finding infections, these techniques would not replace the health care attention of skilled practitioners that women may need when they are confined in prison.

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Table 1**Comparison of Race and Ethnicity of Study Participants with Eligible Population**

Racial/Ethnic Background	Study Population N (%)	Eligible Population N(%)
African American	123 (24)	207 (28)
White	87 (17)	140 (19)
Latina	219 (43)	258 (34)
Other*	62 (12)	85 (11)
Asian	10 (2)	14 (2)
Native American	10 (2)	18 (2)

*Other include Asian, Native American and Black women from Africa and the Caribbean

Table 2
Reasons For Preference of Collection Method

Preference	Study Participants N = 535 (%)
Reasons given by those who prefer swab:	
N=164/535 (29%)	n (%)
Swab is easier and cleaner to do	67 (41)
Can't always urinate on Demand	29 (18)
Seems like a better method	26 (16)
Urine messy/swab clean	18 (11)
Swab more comfortable	8 (5)
Swab is quicker	6 (4)
Gave no reason	10 (6)
Reasons given by those who prefer urine:	
N= 110/535 (19%)	n (%)
Urine is easier/swab difficult	50 (45)
Doesn't like to insert things in her vagina	19 (17)
Swab uncomfortable	14 (13)
Urine collection is more normal	9 (8)
Afraid of doing swab wrong	5 (5)
Seems like a better method	2 (2)
Gave no reason	11 (10)

Table 3
Comparison of Preferences In Different Groups of Women

Method	Menstruating N= 103 (19.2%) OR (95%CI)	Latina N=219 (41%) OR (95%CI)	Age 18-22 N=35 (7%) OR (95%CI)
Which Method Was Easier			
No Difference	0.7 (0.5- 1.1)	0.9 (0.7- 1.3)	0.6 (0.3- 1.1)
Swab	1.4 (0.9- 2.4)	0.7 (0.5- 1.1)	2.2 (1.1- 4.6)*
Urine	1.2 (0.7-1.9)	1.5 (1.1- 2.3)*	0.9 (0.4- 2.1)
Future Preference			
No Difference	1.8 (1.2- 2.8)*	1.1 (0.8-1.5)	0.4 (0.2-0.8)*
Swab	1.4 (0.9- 2.2)	0.8 (0.5-1.1)	2.6 (1.3-5.1)*
Urine	1.6 (1.0- 2.6)	1.3 (0.9-2.0)	1.1 (0.5-2.6)
Future Preference for Swab or Pelvic examination			
No Difference	0.5 (0.4- 0.9)*	1.5 (0.9- 2.2)	0.3 (.07-1.3)
Swab	1.1 (0.7- 1.8)	0.8 (0.5- 1.1)	1.6 (0.8- 3.3)
Pelvic	1.0 (0.6- 1.7)	1.1 (0.7-1.6)	1.2 (0.5- 2.6)

*Indicates statistically significant where $p < .05$

OR comparing menstruating and non-menstruating women, Latina and Non-Latina women and women age 18-22 with all other women.

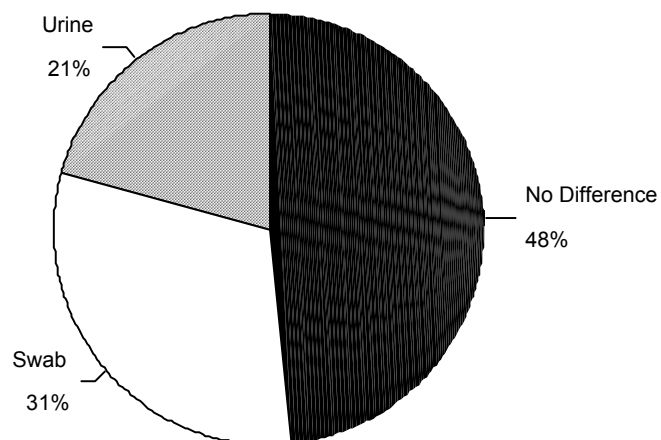
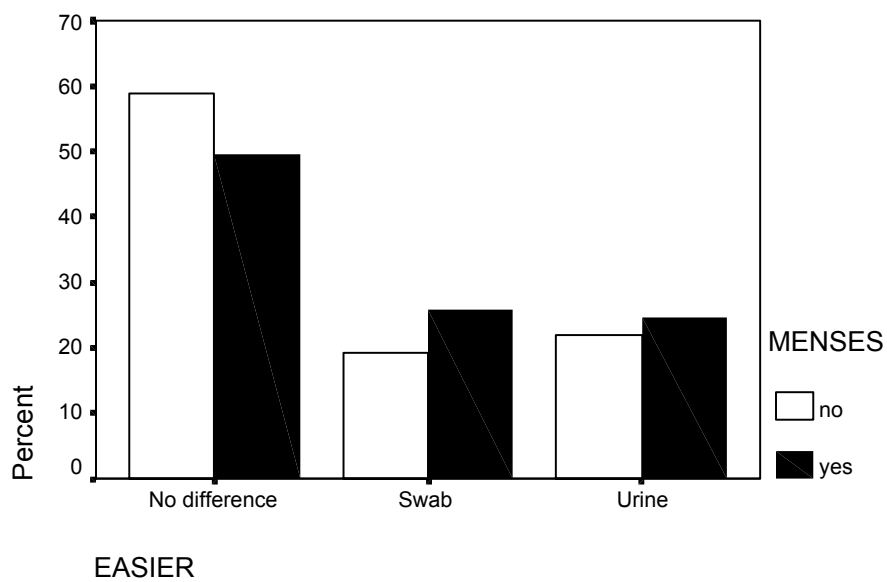
Figure 1**Preferred Future Collection Method****Figure 2****Self-Reported Ease of Method****By Menses**

Figure 3

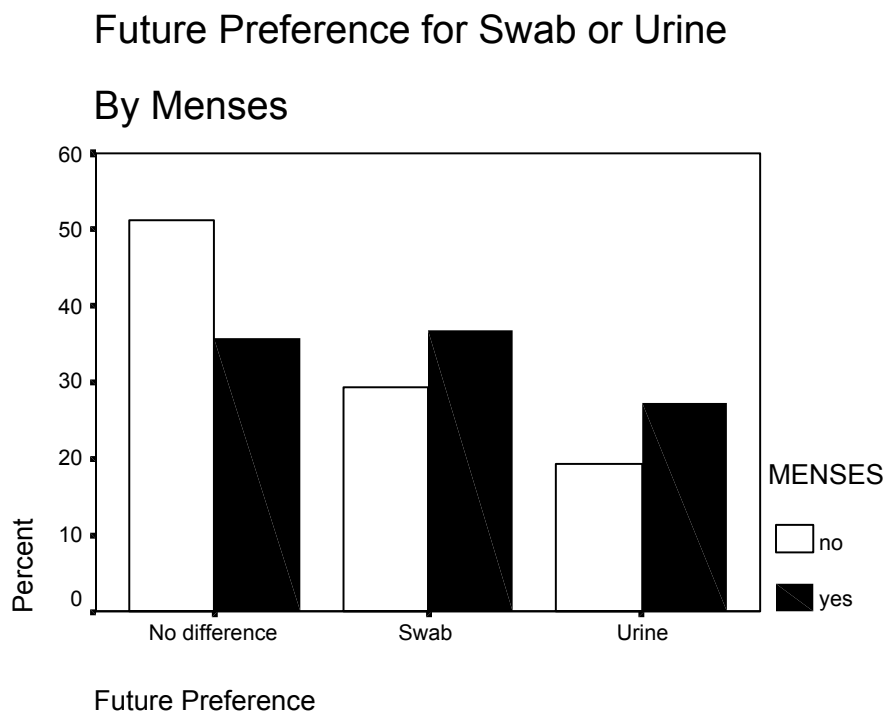


Figure 4

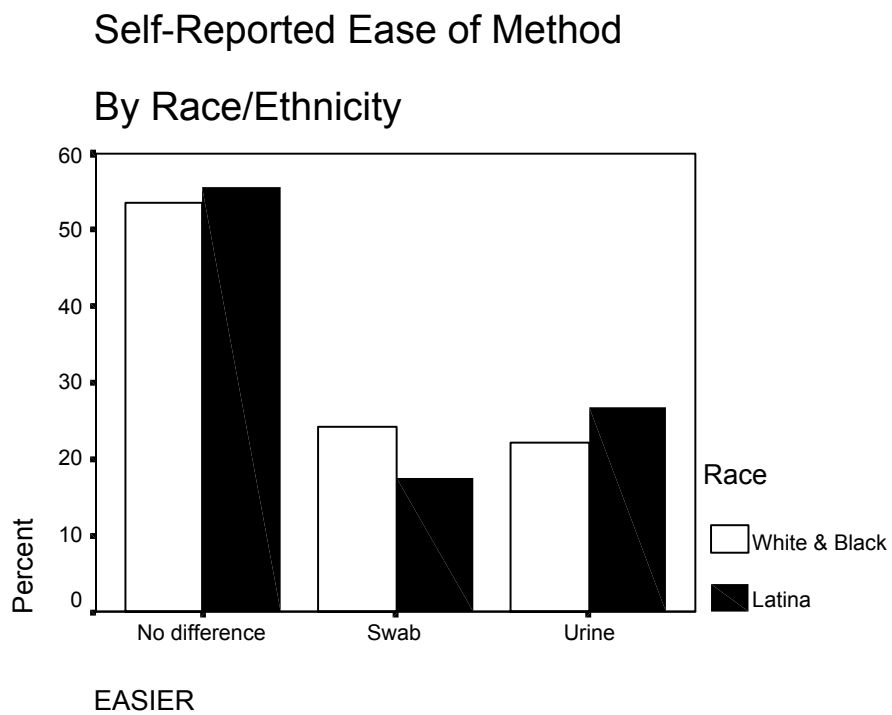


Figure 5

Future Preference for Swab or Urine

By Race/Ethnicity

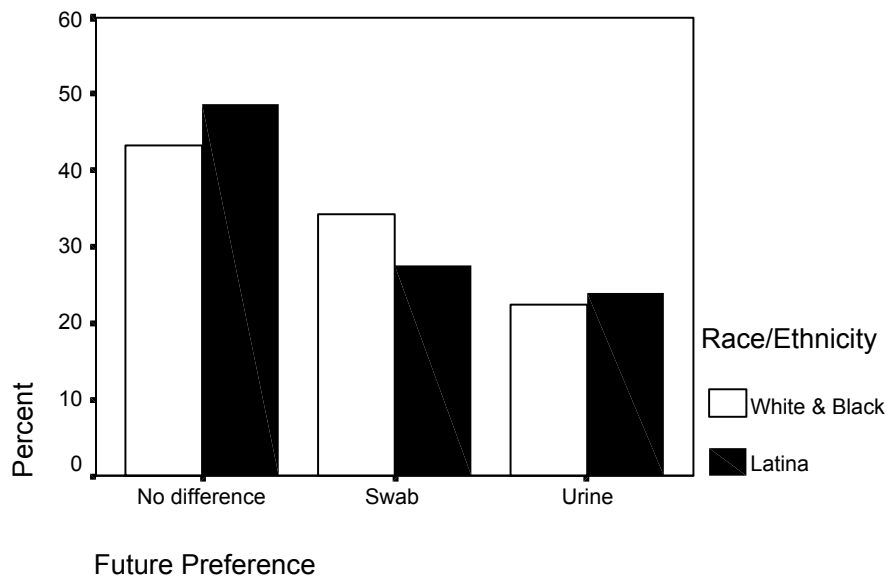


Figure 6

Self-Reported Ease of Method

By Age

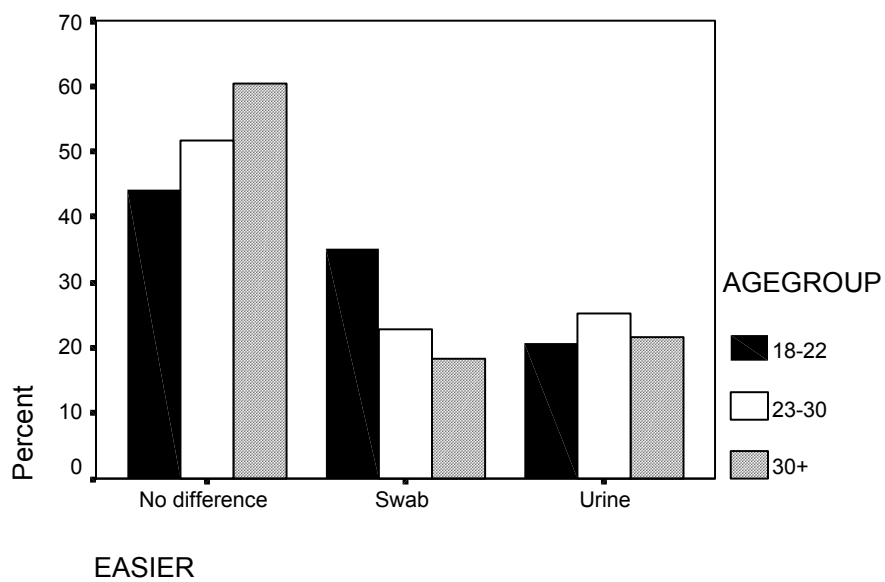
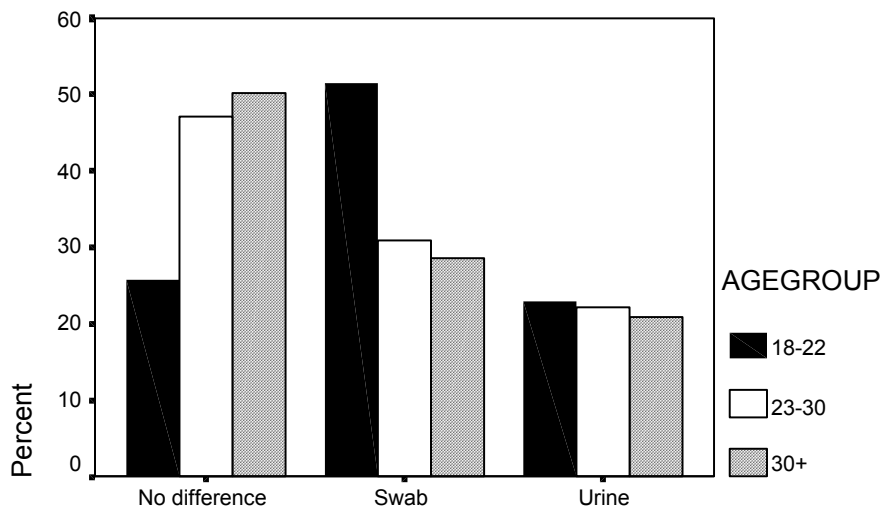


Figure 7

Future Preference for Swab or Urine

By Age Group

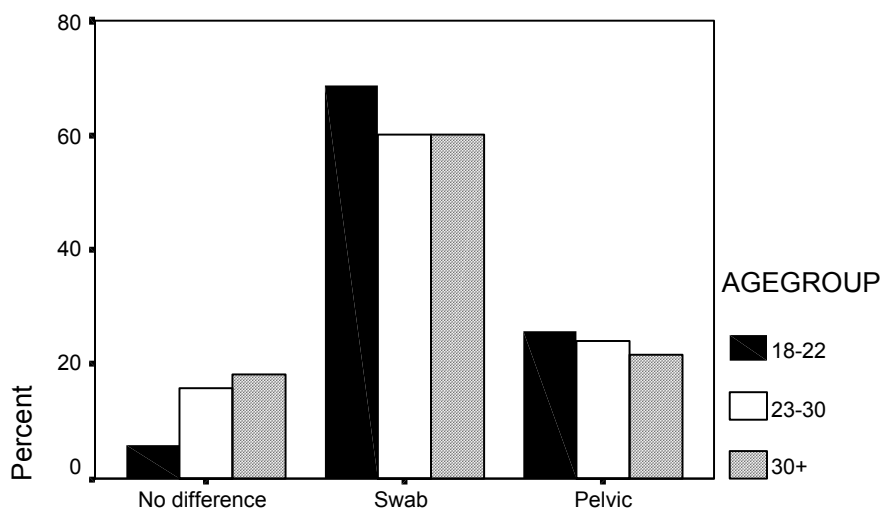


Preference in Future

Figure 8

Preference for Swab or Pelvic

By Age



Future Preference

Overall Discussion

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC) infections are highly prevalent sexually transmitted infections in the United States. Because infections caused by these two organisms are asymptomatic in most women, they often go undetected and untreated. Although treatment is easy and highly effective, untreated infections can contribute to upper genital tract infections, increased risk for contracting HIV/AIDS, and continued transmission to other partners. Screening programs have been proven to be effective for controlling chlamydial and gonococcal infections.¹ This study is the first that has been conducted to estimate the prevalence of and risk factors for the two infections in female federal prisoners. The study was undertaken in two large female prison facilities in the United States to determine the need for and to recommend approaches for screening women for CT and GC in prison.

Because there have been no previous studies conducted on female federal inmates on sexual health and behavior issues and other sensitive topics such as drug use and income, it was important to first use qualitative data collection methods to design a valid survey instrument. The qualitative study was also implemented to assist in overcoming possible barriers to data collection or participation in the study. Therefore, the study was designed in two phases; a qualitative phase and quantitative phase.

The qualitative phase of the study employed focus group discussions and group-based cognitive interviews to design a survey instrument and data collection procedures for the quantitative phase, which was an epidemiologic study on chlamydial and

gonococcal infection of female federal inmates. In the first study phase, inmates provided direct input on specific language used in the survey to improve the clarity and meaning of the questions. They also provided insight on possible barriers to data collection that allowed us to identify ways to maximize participation in our study.

Upon completion of the first phase of the study, we began the second study phase, which involved the collection of specimen and survey data. Information gained from the first study phase assisted us to achieve a participation rate that exceeded 80% in phase two. In addition, few participants skipped questions and logic tests of the completed surveys demonstrated consistency in answers, which may have resulted from our use of focus groups and cognitive interviews to identify population-appropriate language and a clear format for questioning. Results from the first phase of the study also contributed to our ability to obtain specimen from nearly 100% of women who agreed to complete a survey. Insights from the focus groups also helped us obtain both a urine and swab specimen from more than 95% of study participants. These results provide evidence of the importance and effectiveness of the first study phase for assisting in the design of the epidemiologic phase of the study.

The major objective of the second phase of our study was to estimate the prevalence of CT and GC infection in female prisoners and to identify risk factors that might be associated with infection in these women. Also, our use of self-collected urine and vaginal swab specimens to test for the infections provided an opportunity to explore women's preferences for these non-invasive methods for collecting specimen. While

preferences of these more recent techniques for collecting specimen for STD testing has been explored, most of the studies have been conducted in adolescent girls, and there are minimal data on the preferences of women for these techniques.²⁻⁵

Although results of this study revealed that prevalence of CT and GC infection is low among female federal inmates (2.3%), it was evident from the data that among younger inmates (18-22 years), CT infection is a more prevalent problem than among older inmates, with a prevalence among that group of 8.5%. In addition, compared with rates of CT infection in the general population of women in the United States, women incarcerated in the federal prison had higher rates of CT infection. The prevalence of infection among black non-hispanic women ages 30-34 in the general population is the highest among all other race/ethnic groups at 0.8%.⁶

When prevalence of infection is low, it leaves public health planners with a difficult dilemma. Because screening all women for infection is a costly option, it is probably better to selectively screen women who are most at risk. Targeting the highest risk groups, which in the case of the federal inmates is young age, some cases would still be left undetected and untreated. Of these women left untreated up to 30% could develop serious upper reproductive infections such as pelvic inflammatory disease. However, because the many infected women are 30 years of age or younger, it may be most cost effective to screen all women 30 and younger for infection. Selective screening by age is a better screening criteria than screening only women who present with symptoms or signs at exam, because most women do not exhibit signs or symptoms

with CT or GC infection. Although results from this study did not show any associations between number of sex partners or condom use and infection, as has been demonstrated in other studies, clinicians may still consider asking women who are older than 30 about their recent sexual risk behavior to determine their possible risk for infection.

Assessing women's preferences regarding methods for collecting specimen provides useful information for health planners who can structure screening programs to elicit greater participation rates. With an increasing reliance on less invasive collection methods such as urine, self-administered swab and tampons to test for a number of STDs, it is also important to determine how patients feel about these new techniques.⁷⁻⁹ Studies conducted which explore women's preferences have demonstrated a clear preference for non-invasive collection methods.²⁻⁵ This was also true in the prison population. Among female federal inmates, most (60%) expressed a preference for doing their own self-collected swab to test for chlamydial or gonococcal infection as compared to pelvic examination. Yet this preference for non-invasive techniques is not as great compared with other studies in which over 85% of women prefer noninvasive testing to pelvic examination.^{2,3} Age may be an important factor in this difference. Most studies exploring preferences have been conducted in adolescents and young women.²⁻⁴ This age difference was also found among prisoners, where a significantly greater proportion of the youngest prisoners expressed a preference for noninvasive techniques as compared to the rest of the female prison population.

Because this study only included approximately 40% of the female federal prisoners, it is important that health planners are careful not to generalize screening policy to the entire female prison population, but only for sites where prevalence data were collected. This is especially true among women housed in detention centers and shorter-term facilities where prevalence could differ greatly from those in the long-term facilities. This study could serve as a pilot for future studies in other federal prison facilities throughout the United States. The study also provides a basis for future research on sexual health of female federal inmates. Insights gained from the qualitative phase of the study will also be useful for future research and program planning in female federal prisons.

While this is the first study conducted in female inmates, there has also been minimal research on male inmates, and prevalence of these and other STDs in men is not known. Future research should include men in STD research in the prisons so that policies designed to manage STDs in federal prison are clear and appropriate for all federal inmates. It is also important that the BOP facilities maintain a data base on prevalence of infection obtained through routine screening in order to obtain a true measure of the burden of disease among federal inmates.

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Appendices

Appendix A

Informational Brochure on Chlamydia and Gonorrhea (English)
Informational Brochure on Chlamydia and Gonorrhea (Spanish)

Chlamydia

What Is Chlamydia?

Chlamydia (cla-mid-ee-a) is one of the most common sexually transmitted diseases (STD) in the world. It is caused by a germ, which can be passed between partners during sex. The infection can also be passed to a child born to a woman infected with Chlamydia. The baby could become infected in the eyes or lungs. Most women have no symptoms when they are infected with chlamydia so they are not aware of their infections and do not go to a doctor. If Chlamydia is not treated, it can cause serious damage to a woman's body so she can never have children or might suffer from long-lasting pain. A woman who has Chlamydia has a much greater chance of getting HIV if she has unprotected sex with a male partner who is HIV positive.

Can Chlamydia be treated?

YES. Chlamydia can be easily treated and cured, but it is important to diagnose the infection as early as possible. Treatment is as simple as taking a pill (antibiotic). If the untreated infection has spread to the pelvis, more treatment, and even hospitalization, may be necessary. But a person can get the infection again if they are exposed again.

Can Chlamydia be prevented?

The only way to prevent Chlamydia is to not have sexual intercourse with an infected partner. To reduce your chances of getting any STD you should limit your number of sexual partners. If used properly, latex condoms can prevent transmission of chlamydia during sexual intercourse. Using condoms with every act of intercourse will also provide protection against other STDs such as gonorrhea and HIV.

Who is most likely to get Chlamydia?

Teenagers (especially girls) are most likely to get infected, but all sexually active people can get Chlamydia. Women younger than 30 years old are more likely to be infected than women who are older than 30. Also people who already have other STDs are more likely to contract Chlamydia.

How can I find out if I have Chlamydia?

Very few women who are infected with Chlamydia will feel symptoms such as vaginal discharge, pain or burning when peeing, the urge to pee often, or burning or itching genitals. Even if you do not have these symptoms, you could be infected with Chlamydia. To detect Chlamydia infection, there is now a test using just a small sample of your urine or a vaginal swab that you do yourself. You do not need to have a doctor do the exam, and the test can detect both Chlamydia and Gonorrhea.

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Gonorrhea

What Is Gonorrhea?

Gonorrhea (gon-o-ree-a) is one of the most common sexually transmitted diseases (STD) in the world. It is caused by a germ, which can be passed between partners by close physical contact during vaginal, oral and anal sex. Other names for gonorrhea are GC, the clap, the drip or a dose. Gonorrhea can be passed to a baby during birth causing illness or blindness.

Most women have no symptoms when they are infected with gonorrhea so they are not aware of their infections, and may not seek health care. If gonorrhea is not treated, it can damage a woman's body so she can never have children or so she might suffer from long-lasting pain. If untreated, Gonorrhea can also cause pain and swelling in the knee or other joints, small red blisters on the skin and heart problems.

Can Gonorrhea be treated?

YES. Gonorrhea is usually easy to treat and cure with a pill. Most people who have gonorrhea also have Chlamydia so both infections can be treated at the same time.

Can Gonorrhea be prevented?

The only way to prevent Gonorrhea is to not have vaginal, oral or anal sex with an infected partner. To reduce your chances of getting any STD you should limit your number of sexual partners. If used properly, latex condoms can prevent transmission of gonorrhea during sexual intercourse.

Who is most likely to get Gonorrhea?

Teenagers (especially girls) have the highest rates of gonorrhea and are at greatest risk for infection, but all sexually active men and women are at risk.

How can I find out if I have Gonorrhea?

Very few women who are infected with gonorrhea will feel symptoms such as vaginal discharge, bleeding between monthly periods, burning or pain when peeing, or the urge to pee often. Even if you do not have these symptoms you may be infected with Gonorrhea. To detect Gonorrhea infection, there is now a test using just a small sample of your urine or a vaginal swab that you administer yourself. You do not need to have a doctor do an exam, and the test can detect both Chlamydia and Gonorrhea.

La Clamidia

¿Qué es la Clamidia?

La Clamidia causa una de las enfermedades de transmisión sexual más comunes. Es causada por un microbio que se puede pasar entre las personas durante el acto sexual. La infección puede ser pasada al niño que nace de una madre infectada. El bebé podría infectarse en los ojos o pulmones. La mayoría de las mujeres infectadas con clamidia no tienen síntomas, por lo tanto no se enteran de su infección y no van al médico. Sin tratamiento, la clamidia puede causar daño grave a la mujer. Es posible que ella no pueda tener niños y que sufra dolor vaginal por largo tiempo. Una mujer con clamidia tiene más probabilidad de contraer el SIDA si tiene sexo no protegido con un hombre con SIDA.

¿Se puede tratar la Clamidia?

Sí. La clamidia se puede tratar fácilmente y puede ser curada, pero es importante diagnosticar la infección tan temprano como sea posible. El tratamiento es la toma de una píldora (antibiótico). Si la infección no se trata y se esparce a la pelvis el tratamiento, incluyendo hospitalización es necesario.

¿Se puede prevenir la Clamidia?

La única manera de prevenir la clamidia es no tener el sexo con una persona infectada. Para reducir sus oportunidades de obtener cualquier enfermedad sexual se debe limitar el número de compañeros sexuales. Si se usan apropiadamente, los condones de látex se pueden prevenir la transmisión de la clamidia durante el sexo. El uso de condones en cada acto sexual proporcionará también protección contra otras enfermedades de transmisión sexual como la gonorrea y el SIDA.

¿Quién es más propenso a obtener la Chlamydia?

Los adolescentes (especialmente chicas) son más propensos de obtener la infección, pero toda la gente sexualmente activa puede obtener la clamidia. Las mujeres menores de 30 años son más propensas a estar infectadas que las mujeres mayores de 30. Gente que tiene otras enfermedades de transmisión sexual son más sensibles a contraer la clamidia.

¿Cómo puedo averiguar yo si tengo la Clamidia?

Algunas mujeres infectadas sentirán síntomas como; descarga vaginal, dolor o ardor cuando orinan, ganas frecuente de orinar, o ardor y picazón en los genitales. Uno puede estar infectado con la clamidia y no sentir estos síntomas. Existe una prueba para detectar la clamidia que usa una muestra pequeña de orina o un isopo vaginal. No se necesita un médico para hacer este examen, y la prueba puede detectar tanto clamidia como gonorrea.

⋮

La Gonorrea

¿Qué es la Gonorrea?

La gonorrea es una de las enfermedades de transmisión sexual más comunes. Es causada por un microbio que se puede pasar entre las personas durante el sexo vaginal, anal u oral. La infección puede ser pasada al niño que nace de una madre infectada. La mayoría de las mujeres no tienen síntomas cuando tienen gonorrea, por lo tanto no se enteran de que están infectadas y no van al médico. Si no se trata, la gonorrea, puede causar daño grave a la mujer, y es posible que no pueda tener niños y que sufra dolor vaginal por largo tiempo. Sin tratamiento, la gonorrea puede causar también dolor e hinchazón en la rodilla en otras articulaciones, y problemas de la piel y el corazón. Una mujer con la gonorrea tiene más probabilidad de contraer el SIDA si ella ha tenido sexo no protegido con un hombre que está infectado con el SIDA.

¿Se puede tratar la Gonorrea?

Sí. Normalmente se puede tratar fácilmente con una píldora (antibiótico). Muchas personas que tienen la gonorrea también tienen clamidia, y se pueden tratar las dos infecciones al mismo tiempo.

¿Se puede prevenir la Gonorrea?

La única manera de prevenir gonorrea es no tener relaciones sexuales con una persona infectada. Para reducir sus oportunidades de obtener cualquier enfermedad sexual se debe limitar el número de compañeros sexuales. Si se usan apropiadamente, los condones de látex puede, prevenir la transmisión de gonorrea durante el sexo.

¿Quién es más propenso de obtener la Gonorrea?

Los adolescentes (especialmente chicas) son más propensos a obtener la infección, pero toda la gente sexualmente activa puede obtener gonorrea.

¿Cómo puedo averiguar yo si tengo la Gonorrea?

Algunas mujeres infectadas con gonorrea sentirán los síntomas tal como; descarga vaginal, dolor o ardor cuando orinan, el hacer pipi con frecuencia, o sangre entre la regla. Uno puede estar infectado con gonorrea y no sentir estos síntomas. Para detectar la infección, existe una prueba que usa una muestra pequeña de orina o un isopo vaginal que usted puede hacer sola. Usted no necesita tener un doctor para hacerle el examen, y la prueba puede detectar tanto la clamidia como la gonorrea.

Appendix B

Consent Form (English)
Consent Form (Spanish)



INFORMED CONSENT FORM

Principal Investigator: Sara B. Newman, Uniformed Services University of the Health Sciences
Bethesda, MD (tel) 301-295-0305

Coinvestigators: Heidi B. Friedman, PhD
Uniformed Services University of the Health Sciences,
Bethesda, MD (tel) 301-295-9760
Charlotte A. Gaydos, DrPH
Johns Hopkins University, Baltimore, MD (tel) 410-614-0932

What is this study and why are you doing it?

Researchers at the Uniformed Services University of the Health Sciences are doing a research project called, "Prevalence of and Risk Factors For Chlamydial and Gonococcal Infections in Female Prisoners." We are studying what might be an easy way to diagnose chlamydia and gonorrhea infections.

We are asking women in this prison to take part in this study to find out how many women in the prison have chlamydia or gonorrhea infections. These infections are caused by germs (bacteria) in the penis of men and in the vagina of women. Both of these infections can be cured with medicine (antibiotics). The problem is, most women don't know they have an infection so they do not go to a doctor for treatment. If a woman has chlamydia or gonorrhea and does not receive medicine, these infections can cause permanent damage to a woman's female organs. They can also cause severe pain, make it hard to get pregnant, hurt an unborn baby, and be passed to a sex partner.

What do I have to do if I participate in this study?

If you decide to be in this study we will ask you:

- 1) to answer questions about your health that may be related to chlamydia or gonorrhea infections
- 2) to use a kind of cotton swab (Q-tip) to swab your vagina
- 3) to give a small amount of urine

Chlamydia and gonorrhea infections can be found in fluids in the vagina and urine. You will go into a bathroom alone and insert a long Q-tip one inch into your vagina, rub it around for a few seconds, and put the Q-tip into a plastic container. After that, you will pee into a special cup. We want to compare the urine sample and the Q-tip sample to see which is better at finding the infections.

Participant Initials: _____

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Expires: 15 NOV 01

Witness Initials: _____

Why should I participate in the study?

You may benefit after you participate in this study. Your urine and Q-tip samples will be tested to see if you have chlamydia or gonorrhea infections. The test results will be placed in your prison

medical file but no other information will go into the medical file. If the tests show that you have one or both of these infections, and if you want to be treated, prison medical staff may give you medicine that will cure the infection. You will not have to pay for the medicine. We will also give you more information about chlamydia and gonorrhea and other sexually transmitted diseases, and how to avoid getting them. We will also answer any questions you have about these infections. You may even feel good about helping other women.

Are there any risks or can I get hurt by participating?

You may feel embarrassed by some of the questions we ask you. You do not have to answer certain questions if you don't want to. You may feel nervous or embarrassed by giving a urine sample or the vaginal Q-tip sample, but neither one is a risk to you, even if you are pregnant.

Will I have to pay anything or will I receive anything for participating

It costs nothing to participate in this study. You will not be paid anything if you decide to participate.

How can I be sure that information I give you in this study is kept private?

The information we collect from you will be kept in locked files, without your name attached but with a special code that allows us to identify you if you test positive for infection and if you choose to be treated. Your questionnaire and specimens will be labeled with a code and will not have your name or any other identifying information and will be stored under laws of the State of Maryland. All information collected for this study, including your answers to questions or results of your tests will be used for research purposes only. Your name will not be in any report or publication resulting from this study. Prison staff who treat you if you have an infection will only know your disease status, but will not have any other information about you collected from this study. The only other people who will see your name in our research records are people whose job it is to protect your rights as a research participant. This might include people from the Bureau of Prisons human subjects review, Johns Hopkins University human subjects review, and the Uniformed Services University of the Health Sciences human subjects review. All of these people are also required to keep your identity confidential. The only exception to the guarantee of confidentiality is specific information about intent to harm yourself or someone else. We will keep the study information private to the extent possible by law.

Who do I contact if I believe I was harmed in this study?

If you think you have been hurt by being in the study, or not treated fairly, or have any questions about your rights in this study you can contact Heidi Friedman at the phone number on page 1 or Dr. Richard Levine at 301-295-3303. You may also use the BOP administrative remedy process.

Participant Initials: _____ **USUHS IRB APPROVED**
14 JUN 01 RRL Witness Initials: _____
Expires: *15 NOV 01*

What happens if I choose not to be in this study?

You are free to choose whether to be in this study. Being in this study will not affect your medical treatment in any other way. Being or not being in this study will not affect your release date or parole eligibility. Even if you decide to be in this study you may change your mind at any time. You may also decide not to do some parts of the study. However, it is most helpful to us if you complete all parts of the study.

Please feel free to ask me any questions if there is anything you do not understand.

Participant statement:

You will be given a copy of this form. By signing this form, you are agreeing that you understand the study and agree to take part in it. You are agreeing to do the following (please initial all those that you agree to):

_____ I agree to answer a survey

_____ I agree to provide a vaginal swab sample

_____ I agree to provide a urine sample

Signature of Participant

Typed/Printed Name

Date (M/D/Y)

Signature of Witness

Typed/Printed Name

Date (M/D/Y)

Investigator statement:

I certify that the research study has been explained to the above individual, by my research staff, or me, and that the individual understands the nature and purpose, the possible risks and benefits associated with taking part in this research study. Any questions that have been raised have been answered.

Signature of Investigator

Typed/Printed Name

Date (M/D/Y)

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Expires: 15 NOV 01



FORMULARIO DE CONSENTIMIENTO INFORMADO

Investigador Principal: Sara B. Newman, Uniformed Services University of the Health Sciences
Bethesda, MD (Tel) 301-295-0305

Coinvestigadores: Heidi B. Friedman, PhD
Uniformed Services University of the Health Sciences,
Bethesda, MD (Tel) 301-295-9760
Charlotte A. Gaydos, DrPH
Johns Hopkins University, Baltimore, MD (Tel) 410-614-0932

¿Qué es este estudio y por qué se esta haciéndolo?

Investigadores de la Universidad de Las Ciencias de Salud en Bethesda, Maryland están haciendo un estudio llamado "Prevalencia de Factores de Riesgo de Infección por Clamidia y Gonococo en Prisioneras". Nosotros estamos estudiando las posibilidades más fáciles para diagnosticar las infecciones de clamidia y gonorrea. Estamos pidiéndoles a las mujeres de esta prisión tomar parte en este estudio para averiguar cuántas mujeres en la prisión tienen infección por clamidia o gonorrea. Estas infecciones son causadas por gérmenes (bacterias) en el pene de los hombres o la vagina de las mujeres. Ambas infecciones pueden ser curadas con medicinas (antibióticos). El problema está, que muchas mujeres no saben que ellas tienen una infección y entonces no van al médico para recibir tratamiento. Si una mujer tiene clamidia o gonorrea y no toma medicina estas infecciones pueden causar daños permanentes en órganos genitales de la mujer. Ellas pueden también causar dolores severos, dificultad para quedar embarazada y ser transmitidas a su compañero sexual.

¿Qué tengo que hacer si yo participo en este estudio?

Si Ud. decide estar en este estudio nosotros le pediremos:

- 1) Responder las preguntas acerca de su salud que pueden ser relacionadas con infección de clamidia y gonorrea.
- 2) Usar un tipo de isopo de algodón para raspar su vagina.
- 3) Dar una pequeña cantidad de orina.

Las infecciones por clamidia y gonorrea pueden ser encontradas en los fluidos de la vagina y orina. Ud. irá a un baño sola y introducirá un isopo de algodón dentro de su vagina, muévalo alrededor de su vagina por algunos segundos y ponga el isopo en un recipiente de plástico. Después de eso Ud. orinará en un vaso especial. Nosotros queremos comparar la muestra de orina y la muestra vaginal del isopo para ver cual es la mejor para encontrar las infecciones.

Iniciales del participante: _____

Iniciales del testigo: _____

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14 JUN 01, RAC
Expires: 15 NOV 01

¿Por qué debería yo participar en este estudio?

Ud. puede beneficiarse después de participar en este estudio. Sus muestras de orina y vaginal serán examinadas para ver si usted tiene infección por clamidia o gonorrea. Si la prueba indica que usted tiene una de las infecciones y si usted quiere ser tratada, el personal médico de la prisión le dará medicina para curar la infección. Usted no tendrá que pagar por medicina.

Nosotros también le daremos más información acerca de clamidia y gonorrea y otras enfermedades de transmisión sexual y como prevenirlas. Nosotros también responderíamos cualquier pregunta que usted tenga acerca de estas infecciones. Puede ser que también usted se sentirá mejor al ayudar a otras mujeres.

¿Hay algún riesgo o puedo ser lastimada al participar?

Usted puede sentirse avergonzada por algunas de las preguntas que le haremos. Usted no tiene que responder a ciertas preguntas si usted no quiere. Usted puede sentirse nerviosa o turbada al dar las muestras de orina o vaginal, pero ninguna de las dos presenta un riesgo para usted, aunque usted esté embarazada.

¿Tengo que pagar algo o voy a recibir algo por participar?

No le va a costar nada participar en este estudio. No se le pagará nada si decide participar.

¿Cómo puedo yo estar segura que esta información que le doy a usted en este estudio se mantendrá en privado?

La información que nosotros recogemos de Ud. se mantendrá en un fichero con llave, sin su nombre pero con un código especial que nos permita identificarle. Si su prueba es positiva para alguna de las infecciones y si Ud. escoge ser tratada. Su cuestionario y muestras serán señaladas con un código y no tendrán su nombre o cualquier otra forma de identificación y serán protegidos bajo las leyes del Estado de Maryland. Toda información recogida por este estudio, incluyendo sus respuestas a las preguntas y resultados de sus exámenes serán usados para el propósito del estudio solamente. Su nombre no estará en ningún reporte publicado del resultado de este estudio. Sólo el equipo de la prisión que le tratará sabrá de su estado de la enfermedad, pero no tendrán ninguna otra información acerca de los datos obtenidos de Ud. en este estudio. Las únicas otras personas que pueden ver su nombre en este estudio son las personas que tienen el trabajo de proteger sus derechos como participante de este estudio. Esto puede incluir personas que revisan los derechos humanos en el BOP, la universidad de Johns Hopkins o la Universidad de las Ciencias de Salud. Todas estas personas tienen la obligación de mantener la confidencialidad. La única excepción de garantía de confidencia es información específica acerca de algún intento de hacerse daño a si mismo o a otra persona. Nosotros mantendremos la información privada de este estudio con las máximas garantías que la ley permite.

Iniciales del participante: _____

Iniciales del testigo: _____

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14 JUN 01 RPK
Expires: 15 NOV 01

¿A quién contactaría si yo creo que fui lastimada en este estudio?

Si usted piensa que ha sido dañada o tratada injustamente en este estudio o si usted tiene alguna pregunta acerca de sus derechos en estos estudios puede contactar con Heidi Friedman al teléfono en página 1 o al Dr. Richard Levine al 301-295-3303. Usted también puede usar el BOP proceso de remedios administrativos.

¿Qué pasa si yo decido no estar en este estudio?

Usted tiene la libertad de escoger si quiere estar en este estudio o no. El estar en este estudio no afectará su tratamiento médico en ninguna manera. Participar o no participar en este estudio no afectará su fecha de liberación o su elegibilidad de parole. Aunque usted decida estar en este estudio usted puede cambiar de idea en cualquier momento.

Usted debe saber que puede preguntarnos cualquier cosa que no entienda.

Reporte del Participante

A usted se le dará una copia de esta hojaforma. Firmando esta hoja, Ud. está aceptando que entendió el estudio y acuerda participar en él. Usted está aceptando hacer lo siguiente: (por favor escribe sus iniciales con las que esté de acuerdo.)

_____ Acuerdo responder a un cuestionario

_____ Acuerdo dar una muestra vaginal

_____ Acuerdo dar una muestra de orina

Firma del Participante

Nombre

Fecha (M/D/A)

Firma del testigo

Nombre

Fecha (M/D/A)

Reporte del Investigador

Yo certifico que el estudio de investigación ha sido debidamente explicado por mi equipo de investigación y por mi a esta participante con el objetivo que ella entienda el propósito, riesgos y beneficios posibles que están asociados con este estudio. Todas las preguntas hechas que ella tuvo fueron contestadas.

Firma de Investigador

Nombre

Fecha (M/D/A)

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14 JUN 01 RLR
Expires: 15 NOV 01

Appendix C

Questionnaire (English)
Questionnaire (Spanish)

Date _____

**Women Prisoners Health Study
Confidential Questionnaire**

Please Read These Instructions Carefully:

- Please answer the following questions by either writing your answer in the space provided or by checking the answer.
- Please note that most of the questions refer to what you did *before* you were arrested or entered prison.
- If you have any questions or need assistance, please ask the coordinator.

A. Background Information

1. What is your age? _____
Age

2. Are you? (*check all that apply*) ___ African American; ___ White; ___ Hispanic; ___ Asian;
___ Native American; ___ Other _____
(Please specify)

3. How long have you been incarcerated for your present charge? _____ Years _____ Months

4. What date did you enter the current prison site _____ / _____
(Month) (Year)

5. What was the highest level of school that you completed before you entered prison for this present charge?

___ None
___ Elementary School (Grades 1-8)
___ Some High School (Grades 9-11)
___ Graduated from High School or GED
___ Some College
___ Graduated from College
___ Postgraduate

6. What state and country were you born in? _____ / _____
State/Province Country

7. What state or country did you live in **right before** you entered prison? _____ / _____
State/Province Country

8. What was your marital status **right before** you entered prison?

___ Single (never married)
___ Married or living together as married
___ Divorced
___ Separated
___ Widowed

9. Who did you live with right before you were arrested for your present charge?
(*check all that apply*)

___ Alone
___ Your husband
___ Your boyfriend
___ Your female partner
___ Friends
___ Family members
___ Your children
___ Other _____
(please write in)

10. What was your housing situation before you were arrested?

- Owned your own house or apartment
- Rented
- Lived in a shelter or mission
- Lived on the street
- Other _____ (please specify)

11. Did you move in the 12 months **before** you were arrested?

- No
- Yes, **if yes** → How many times did you move in the 12 months before you were arrested?
(include any place where you lived for at least one month) _____
(number of times)

12. Including income provided by you and any other person living in your household (such as husband or other adult), which range of figures comes closest to your total household income (legal and/or illegal) the year before you were arrested?

- Less than \$10,000
- 10,000-15,000
- \$15,001-25,000
- \$25,001- \$50,000
- \$50,001-\$75,000
- more than \$75,000
- Don't know

13. How many people lived on this income? (including yourself)

- One (just you)
- Two
- Three
- Four
- Five
- More than five

14. Please indicate your working status before you were arrested (*check all that apply*)

- Employed full time
- Employed part time
- Received welfare payment
- Collected food stamps
- Earned illegal income
- None of the above

15. Please mark the kind of crime or crimes you were convicted of for your current prison sentence? (*check all that apply*)

- White Collar (for example, fraud or tax evasion) please specify _____
- Drug Related (for example, conspiracy, distribution) please specify _____
- Violent crime (for example, assault, robbery) please specify _____
- Other, please specify _____

B. General Health Section and Use of Substances

16. Have you taken any antibiotics in the past six months?

Don't Know

No

Yes, **if yes** → To treat what illness or illnesses? _____
(Briefly describe)

17. Were you treated for either Chlamydia or Gonorrhea when you entered prison?

Don't Know

No

Yes, **if yes** → **When were you treated?** _____
(Month/Year)

18. When was the last time you had a pelvic exam or Pap smear **before** you entered prison?

Never had these exams

Less than 12 months before I entered prison

12 months or more before I entered prison

I do not know.

19. Have you ever used any type of birth control method?

No

Yes, **if yes** → **what was the method of birth control you used in the 12 months before you entered prison?**

(Please check all types you used)

None

Norplant

Birth Control Pills

Condoms

Depo-Provera

IUD, coil, loop

Foams/gels

Rhythm method

Diaphragm

Female sterilization, tubes tied

Other _____

(please write in)

20. Have you ever been pregnant?

No

Not sure

Yes, **if yes** →

How many live births did you have? _____

How many miscarriages did you have? _____

How many abortions did you have? _____

In all, how many times have you been pregnant? _____

21. Have you ever been a regular (daily or weekly) user of illegal drugs or any controlled substance?

No

Yes, if yes → what were your drugs of choice?

(Check all that apply)

Marijuana

"Meth" (methamphetamines)

Crack

PCP

Cocaine

Barbiturates

Heroin

Other _____ (please specify)

LSD

22. About how often did you use each type of drug listed below during the **12 months before** you were arrested?

(Check the box under the answer that applies)

	Never	Monthly	Weekly	Daily
Marijuana	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Crack	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heroin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
"Meth"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LSD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PCP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(Please specify other) _____

23. About how often did you smoke cigarettes in the 12 months **before** you were arrested?

Never

Monthly or less

Weekly

Daily

24. When you were growing up, were you ever a victim of sexual, physical or emotional abuse by a family member?

No

Yes

25. Were either of your parents ever incarcerated in jail or prison?

- No
 Yes

26. Did either of your parents ever have a drug or alcohol addiction?

- No
 Yes

C. Sexual History

27. Have you ever had vaginal sex with a man?

- No
 Yes, if yes

→ How old were you when you first had vaginal sex with a man? _____ Age
→ When was the last time you had vaginal sex with a man? _____
Month/Year

28. How many men did you have vaginal sex with during the **3 months before** you entered prison?

- None
 One
 Two
 Three or more

29. How many men did you have vaginal sex with during the **12 months before** you entered prison?

- None
 One
 Two
 Three or more

30. How many men have you had vaginal sex with in your lifetime?

- None
 1-4
 5-10
 11-25
 26-50
 more than 50

31. Did you have a new sex partner 3 months before you entered prison?

- No
 Yes

32. Do you typically ask your new sex partners if they have a sexually transmitted disease (STD)?

- Never
 Rarely
 Sometimes
 Most of the time/always

33. Have you ever been told by a sex partner that he may have exposed you to an STD?
 No
 Yes, If Yes → **The most recent time this happened, did you go for a checkup or treatment?**

<input type="checkbox"/> No <input type="checkbox"/> Yes

34. Have you ever been treated for any of the STDs listed below?

(check all that apply)	
<input type="checkbox"/> No, I have never been treated for an STD	<input type="checkbox"/> HIV/AIDS
<input type="checkbox"/> Chlamydia	<input type="checkbox"/> Herpes
<input type="checkbox"/> Gonorrhea	<input type="checkbox"/> Warts/HPV
<input type="checkbox"/> Trichomoniasis	<input type="checkbox"/> Other _____
<input type="checkbox"/> Tube Infections (pelvic inflammatory disease- PID)	_____ (Please write in)
<input type="checkbox"/> Syphilis	<input type="checkbox"/> I don't know

The next four questions refer to sex with a woman. This includes using fingers, the mouth or sex toys in the vagina with women.

35. Have you ever had sex with a woman?
 No
 Yes, if yes → **when was the last time you had sex with a woman?** _____
Month/ Year

36. How many women did you have sex with during the **12 months before** you entered prison?

- None
 One
 Two
 Three or more

37. How many women have you had sex with in your lifetime?

- None
 1-4
 5-10
 11-25
 26-50
 more than 50

38. Do you typically ask your female sex partners if they have an STD?

- I have never had a female sex partner
 Never
 Rarely
 Sometimes
 Most of the time/always

39. Have you ever been told by a female sex partner that she may have exposed you to a sexually transmitted disease (STD)?

I have never had a female sexual partner

No

Yes, If Yes→ **The most recent time this happened, did you go for a checkup or treatment?**

No
 Yes

Questions 40-43 refer to sexual intercourse with a *non-regular* male sexual partner. A *non-regular* sex partner is a short term or one time male sex partner. A *non-regular* partner is **NOT a husband or a boyfriend.**

40. Before having sex with a non-regular sex partner do you typically ask him if he has an STD?

I have never had a non-regular sexual partner

Never

Rarely

Sometimes

Most of the time/always

41. Do you typically use a condom with a non-regular sex partner?

I have never had a non-regular sexual partner

Never

Rarely

Sometimes

Most of the time/always

42. Do you typically ask a non-regular sex partner to use a condom to protect yourself from getting an STD?

I have never had a non-regular sexual partner

Never

Rarely

Sometimes

Most of the time/always

43. Have you ever refused to have sexual intercourse with a non-regular sex partner if he didn't use a condom?

I have never had a non-regular sexual partner

No

Yes, If Yes→ **how often have refused sex if your non-regular partner will not wear a condom?**

Never
 Rarely
 Sometimes
 Most of the time/always

Now please think back on the times you have ever had sex with any partner...

44. How often did you typically use alcohol before having sex?

- Never
- Rarely
- Sometimes
- Most of the time
- Always

45. How often did you typically use street drugs before having sex?

- Never
- Rarely
- Sometimes
- Most of the time
- Always

46. How often did you have sex with someone who had used alcohol before having sex?

- Never
- Rarely
- Sometimes
- Most of the time
- Always

47. How often did you have sex with someone who had been using street drugs before having sex?

- Never
- Rarely
- Sometimes
- Most of the time
- Always

48. Have you ever exchanged sex for money or drugs?

- No
- Yes if yes, → Typically, how often did you use a condom?

- Never
- Sometimes
- Most of the time
- Always

D. Sexual Health Information

49. Do you think you currently have any of the following? (check each answer that applies)

- a. Abnormal or unusual (yellow or green) vaginal discharge No Yes
- b. Vaginal irritation, itch or unusual odor No Yes
- c. Lower abdominal pain or pelvic pain No Yes
- d. Vaginal bleeding or spotting different from your normal period No Yes
- e. Pain when you urinate (pee) No Yes

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE,
PLEASE DROP IT IN THE BOX

Fecha _____

Estudio de Salud de Mujeres Encarceladas Cuestionario Confidencial

Por favor Lea las instrucciones cuidadosamente:

- Por favor responda las siguientes preguntas escribiendo su respuesta en el espacio dado o marcando con un las respuestas.
- Por favor fíjese que la mayoría de las preguntas se refieran a lo que usted hizo antes de ser arrestada o encarcelada.
- Si Ud. tiene preguntas o necesita ayuda, por favor busque a la coordinadora

A. La Información del Fondo

1. ¿Cuál es su edad? _____
Edad
2. ¿Cuál es su raza ? ___ Negra; ___ Blanca; ___ Otra _____
(Por favor indique)
3. ¿Cuánto tiempo ha estado ud. encarcelada por su cargo actual? ___ Años ___ Meses
4. ¿Qué fecha entró ud. en esta cárcel? _____ / _____
(Mes) (Año)
5. ¿Cuál fue el último nivel escolar que usted realizó antes de entrar a la prisión?
___ Ninguna
___ Primaria (Grados 1-6)
___ Básico de secundaria (Grados 7-9)
___ Bachiller o equivalente (Grados 10-12)
___ Algo de universidad
___ Graduado en la universidad
___ Posgraduado
6. ¿En qué estado o provincia y en qué país nació usted? _____ / _____
Estado/Provincia País
7. ¿Dónde vivió usted **antes de que entrara** en la prisión? _____ / _____
Estado/Provincia País
8. ¿Cuál era su estado civil **antes de entrar** en la prisión?
___ Soltera (nunca casada)
___ Casada o union libre
___ Divorciada
___ Separada
___ Viuda
9. ¿Con quién vivía Ud. antes de que fuera arrestada? (marque la que corresponda)
___ Sola
___ Su esposo
___ Su novio
___ Amigos
___ Miembros de la familia
___ Sus hijos
___ Otro _____
(por favor escríbalo aquí)

10. ¿Cuál era su situación de vivienda antes de ser arrestada?

- Dueña de su propia casa o apartamento
- Alquilado
- Vivió en un edificio público
- Vivió en la calle
- Otro _____ (por favor especifique)

11. ¿Se trasladó de vivienda en los 12 meses antes que Ud. fuera arrestada?

- No
- Sí, **si es sí** → ¿Cuántas veces se trasladó en los 12 meses antes de ser arrestada? _____
(Incluye cualquier lugar donde vivió por lo menos un mes) (número de veces)

12. Incluyendo su salario y el de alguna otra persona viviendo en su casa (como su marido u otro adulto) ¿cuál de estas cantidades se acercan más al salario total anual (legal e ilegal) antes de que tu fueras arrestada?

- Menos de \$10,000
- \$10,001-15,000
- \$15,001- \$25,000
- \$25,001-\$50,000
- \$50,001-\$75,000
- más de \$75,000
- No sé

13. ¿Cuántas personas vivían con este salario? (incluyéndose usted)

- Uno (solo usted)
- Dos
- Tres
- Cuatro
- Cinco
- Más de Cinco

14. Por favor indique su situación de empleo antes de su arresto. (marque todo lo que le corresponda)

- Empleado tiempo completo
- Empleado medio
- Recibió pago del gobierno de EEUU (welfare)
- Colectó estampillas de comida?
- Acumuló dinero ilegal
- Ninguno de los arriba

15. ¿Marque por favor la clase del crimen o los crímenes por los que usted se cumple condena actualmente (marque todo que aplica)

- Criminales fiscals (por ejemplo, el fraude o la evasión fiscal) _____
- Drogas (por ejemplo, la conspiración, la distribución) _____
- Crimen violento (por ejemplo, el asalto, el robo) _____
- Otro (especifique por favor) _____

B. Salud General y Uso de Sustancias

16. ¿Ha tomado usted cualquier antibiótico en los últimos seis meses?

No sé

No

Sí, si es sí ¿Para tratar qué enfermedad o enfermedades? _____
(Describe Brevemente)

17. Recibió Ud. tratamiento para clamidia o gonorrea cuando entró en la prisión?

No sé

No

Sí, si es sí → ¿Cuándo recibió Ud. tratamiento? _____
(Mes/Año)

18. ¿Cuándo fue la última vez que Ud. tuvo un examen pélvico o Papanicolao antes de entrar en prisión?

Nunca tuve estos exámenes ever had these exams

Menos de doce meses de que entrara en la prisión

Doce meses o más antes de que entrara en la prisión.

No sé

19. ¿Has usado algún método anticonceptivo alguna vez?

No

Sí.....si es Sí → ¿Cuál fue el método del control de la natalidad que usó en los doce meses antes de entrar en la prisión?

(Por favor marque todos tipos que Ud. usó)

Ninguna

Pastillas anticonceptivas

Depo-Provera

Diafragma

Norplant

Condones

Dispositivo intrauterino

Método del ritmo

Amarre de Trompas

Otro _____

(por favor escriba dentro)

20. ¿Has estado embarazada alguna vez?

No

No estoy segura

Sí , si es Sí→

¿Cuántos nacimientos vivos ha tenido Ud.? _____

¿Cuántos abortos espontáneos ha tenido Ud. ? _____

¿Cuántos abortos provocados ha tenido Ud.? _____

¿En total cuántos veces ha estado Ud. embarazada? _____

21. ¿En su vida ha usado Ud. regularmente (diariamente o semanalmente) drogas ilegales o alguna sustancia controlada?

No

Sí.....si es Sí→ → ¿Cuáles fueron las drogas que usó?

(Marque todas que corresponden)

Marihuana

Crack

Cocaína

Heroína

"Meth" (metamfetaminas)

Otros _____

(por favor especifique)

22. ¿Con qué frecuencia ha usado Ud. cada tipo de droga del listado de abajo durante los 12 meses anteriores a su arresto?

(Marcar el cuadro de abajo con las respuestas que le corresponde)

	Nunca	Mensualmente	Semanalmente	Diariamente
Marihuana	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Crack	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaína	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heroína	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Metamfetaminas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Otros	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(Por favor especifique los otros) _____

23. ¿Más o menos cuántos cigarrillos fumaba en los doce meses antes de que ser arrestada?

Nunca

Mensualmente o menos

Semanalmente

Diariamente

24. Cuando usted era joven, ¿fue una víctima alguna vez de abuso sexual, físico o emocional por algún miembro de su familia?

No

Sí

25. ¿Alguna vez alguno de sus padres estuvo encarcelado?

- No
 Sí

26. ¿Alguno de sus padres fue adicto a la droga o al alcohol?

- No
 Sí

C. Historia Sexual

27. ¿Ha tenido Ud. sexo vaginal alguna vez con un hombre?

- No
 Sí.....si es Sí

→ ¿Cuántos años tenía Ud. la primera vez que tuvo sexo vaginal con un hombre? _____ Edad
b
→ ¿Cuándo fue la última vez que usted tuvo sexo vaginal con un hombre? _____ Mes/Año

28. ¿Con cuántos compañeros diferentes tuvo Ud. sexo vaginal con penetración durante los **3 meses antes** que entrara a prisión?

- Ninguno
 Uno
 Dos
 Tres o más

29. ¿Con cuántos compañeros diferentes tuvo Ud. sexo vaginal con penetración durante los **12 meses antes** que entrara a prisión?

- Ninguno
 Uno
 Dos
 Tres o más

30. ¿Con cuántos compañeros diferentes ha tenido sexo con penetración en su vida?

- Ninguno
 1-4
 5-10
 11-25
 26-50
 más de 50

31. Tuvó Ud. un nuevo compañero sexual durante los **3 meses antes** que entrara a prisión?

- No
 Sí

32. ¿Típicamente les pregunta Ud. a sus compañeros sexuales si ellos tienen alguna enfermedad de transmisión sexual.

- Nunca
 Rara vez
 Algunas veces
 Casi siempre/Siempre

33. ¿Alguna vez su compañero sexual la ha dicho a Ud. que él la expuso a Ud. a una enfermedad de transmisión sexual?
- No
- Sí.....si es Sí → La última vez que ésto pasó, fue Ud. a chequearse o tratarse?

<input type="checkbox"/> No
<input type="checkbox"/> Sí

34. ¿Alguna vez ha recibido tratamiento para algunas de las siguientes enfermedades de transmisión sexual?

(Marque las que correspondan)

- | | |
|--|---|
| <input type="checkbox"/> Nunca he recibido tratamiento para una enfermedad de transmisión sexual | |
| <input type="checkbox"/> Clamidia | <input type="checkbox"/> SIDA |
| <input type="checkbox"/> Gonorrea | <input type="checkbox"/> Herpes |
| <input type="checkbox"/> Sífilis | <input type="checkbox"/> Verrugas Vaginales |
| <input type="checkbox"/> Infección de la pelvis | <input type="checkbox"/> Tricomonas |
| <input type="checkbox"/> Otros _____ | |
| (por favor escribe dentro) | |
| <input type="checkbox"/> No sé si he recibido tratamiento | |

Las próximas cuatro preguntas se refieren a relaciones sexuales con una mujer. Esto incluye el uso de dedos, boca o juegos sexuales en la vagina.

35. ¿Has tenido relaciones sexuales con una mujer alguna vez?
- No
- Sí.....si es Sí → ¿cuándo fue la última vez que Ud. tuvo relaciones sexuales con una mujer? _____ (Mes/ año)
36. ¿Con cuántas compañeras sexuales diferentes ha tenido Ud. relaciones sexuales durante los 12 meses antes que Ud. entrara a la prisión?
- Ninguna
- Una
- Dos
- Tres o más
37. ¿Con cuántas compañeras diferentes ha tenido relaciones sexuales en su vida?
- Ninguna
- 1-10
- 11-25
- 26-50
- más de 50
38. ¿Típicamente pregunta Ud. a sus compañeras sexuales si ellas tienen una enfermedad de transmisión sexual.
- Nunca he tenido una compañera sexual
- Nunca
- Rara vez
- Algunas veces
- Casi siempre/Siempre

39. ¿Alguna vez su compañera sexual la ha dicho a Ud. que ella la expuso a Ud. a una enfermedad de transmisión sexual?
- No
- Sí.....si es Sí → La última vez que ésto pasó, ¿fue Ud. a chequearse o tratarse?

No
 Sí

*Las preguntas 40-43 se refieren a las relaciones sexuales con penetración que Ud. tuvo con un compañero **no regular**. Un compañero **no regular** es un compañero sexual por poco tiempo o solamente alguien con quien tuvo sexo una vez. Un compañero no regular **NO** es un esposo o un novio.*

40. ¿Antes de tener sexo con un compañero no regular, típicamente Ud. le pregunta si tiene una enfermedad de transmisión sexual?

Nunca he tenido un compañero no regular.

Nunca

Rara vez

Algunas veces

Casi siempre/Siempre

41. ¿Usa Ud. típicamente un condón con un compañero no regular?

Nunca he tenido un compañero no regular.

Nunca

Rara vez

Algunas veces

Casi siempre/Siempre

42. ¿Pide Ud típicamente a su compañero no regular que use condón para protegerse de una enfermedad de transmisión sexual?

Nunca he tenido un compañero no regular.

Nunca

Rara vez

Algunas veces

Casi siempre/siempre

43. ¿Alguna vez Ud. se negó tener relaciones sexuales con un compañero no regular si él no usaba el condón?

Nunca he tenido un compañero no regular.

No

Sí.....si es Sí → ¿típicamente, con qué frecuencia Ud. se nega a tener sexo con un compañero no regular si él no usa condón?

Rara vez

Algunas veces

Casi Siempre/Siempre

Ahora piense por favor en los tiempo que usted ha tenido el sexo con cualquier compañero.....

44. ¿Con qué frecuencia usó Ud. alcohol antes de tener sexo?

- Nunca
- Rara vez
- Algunas veces
- Casi siempre
- Siempre

43. ¿ Con qué frecuencia usó Ud. drogas antes de tener sexo?

- Nunca
- Rara vez
- Algunas veces
- Casi siempre
- Siempre

44. ¿ Con qué frecuencia Ud. tuvo sexo con alguien que ha tomado alcohol antes de tener sexo?

- Nunca
- Rara vez
- Algunas veces
- Casi siempre
- Siempre

45. ¿ Con qué frecuencia Ud. tuvo sexo con alguien que usó drogas antes de tener sexo?

- Nunca
- Rara vez
- Algunas veces
- Casi siempre
- Siempre

46. ¿Ha intercambiado el sexo por dinero o droga alguna vez?

- No
- Sí.....si es Sí, → ¿Usted usa un condón?

- Nunca
- Rara vez
- Algunas veces
- Casi siempre/Siempre

D. Información de Salud Sexual

47. ¿Piensa ud. que en este momento tiene uno de los siguientes síntomas? (marque cada respuesta que corresponde)

- a. Flujo vaginal anormal o inusual (flujo de color amarillo o verde) No Sí
- b. Irritación vaginal, picazón, o olor inusual No Sí
- c. Dolor abdominal o pélvico (la area reproductiva) No Sí
- d. Sangrado vaginal o manchas que son diferentes de su regla normal No Sí
- e. Dolor cuando Ud. orina No Sí

GRACIAS POR COMPLETAR ESTE CUESTIONARIO
POR FAVOR DEJELO EN LA CAJA

Non Participant

The following questions will help us know if the women in our study are similar to all women at the prison site. Thank you for helping us by filling out this anonymous form

1. What is your age? _____
Age
2. Are you? (*check all that apply*) _____ African American;
_____ White;
_____ Hispanic;
_____ Asian;
_____ Native American;
_____ Other _____ (Please specify)
3. How long have you been incarcerated for your present charge? _____
(Years and months)
4. When did you enter this institution? _____ / _____
(Month) (Year)
5. What was the highest level of school that you completed before you entered prison for this present charge?
_____ None
_____ Elementary School (Grades 1-8)
_____ Some High School or GED
_____ Some College
_____ Graduated from College
_____ Postgraduate
6. What was your marital status before you entered prison?
_____ Single (never married)
_____ Married or living together as married
_____ Divorced
_____ Separated
_____ Widowed

No Participante

Las preguntas siguientes nos ayudarán saber si las mujeres en nuestro estudio son semejantes a todas las mujeres de esta prisión. Gracias por ayudarnos llenando esta forma anónima.

1. ¿Cuál es su edad? _____
Edad
2. ¿Cuál es su raza ? ___ Negra; ___ Blanca; ___ Otra _____ (Por favor indique)
3. ¿Cuánto tiempo ha estado ud. encarcelada por su cargo actual? _____ Años
_____ Meses
4. ¿Qué fecha entró ud. en esta cárcel? _____ / _____
(Mes) (Año)
5. ¿Cuál fue el último nivel escolar que usted realizó antes de entrar a la cárcel?
____ Ninguna
____ Primaria (Grados 1-6)
____ Básico de secundaria (Grados 7-9)
____ Bachiller o equivalente (Grados 10-12)
____ Algo de universidad
____ Graduado en la universidad
____ Posgraduado
6. ¿En qué estado o provincia y en qué país nació usted? _____ / _____
Estado/Provincia País
7. ¿Cuál era su estado civil antes de entrar en la cárcel?
____ Soltera (nunca casada)
____ Casada o union libre
____ Divorciada
____ Separada
____ Viuda

Appendix D

How To Brochure for Urine and Specimen Collection (English)
How To Brochure for Urine and Specimen Collection (Spanish)

Test 2: The Urine Self Test

Note: Please do the vaginal swab test BEFORE you do the Urine test.

To obtain the urine specimen:

1. Place the cup under your vagina so you can catch the first stream of your pee.
2. Fill the cup to the line where it is marked on the cup.
3. Carefully hand the cup to the health care provider so that it does not spill.

This brochure, prepared by Sara B. Newman USUHS, Bethesda, MD 301-295-0305 is adapted from an instruction book by Polaneczky, M. et.al Use of self-collected vaginal specimens for detection of Chlamydia. *Obstetrics and Gynecology* 91:3:1998, 375-378.

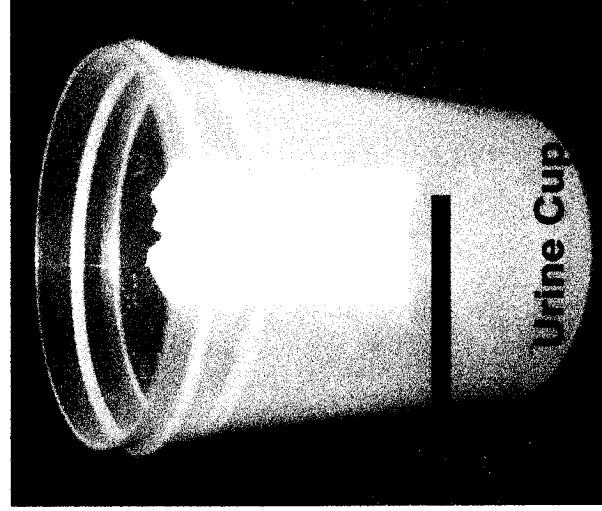
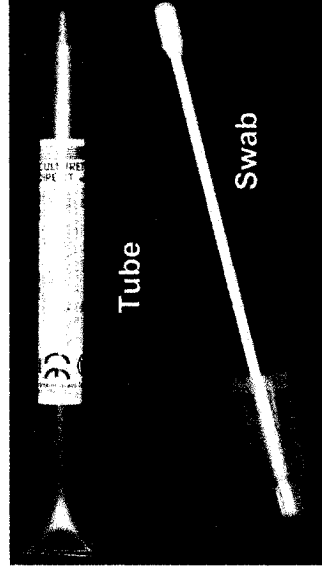
The Chlamydia and Gonorrhea Self-Test

Testing for Chlamydia and Gonorrhea

Now you can find out if you have Chlamydia or Gonorrhea by doing your own test that does not require an invasive exam from a doctor.

You can do two of these tests. One test is a swab test, the other is a urine test. For the first test, you will insert a type of Q-tip into your vagina to get secretions from your vagina. For the second test you will pee in a cup.

The samples will be tested in a lab to find out whether or not you have either Chlamydia or Gonorrhea.



The Swab and Urine Self-Test

Test 1: The Swab Self-Test

To perform the swab self-test, you will need to be undressed from the waist down. You will need to be in a position where you can comfortably insert a cotton swab into your vagina. (Sitting on the toilet seat, or standing with one foot on a chair are good positions.)

You can safely perform both of these tests if you are pregnant or if you are having your period.

To obtain the vaginal specimen:

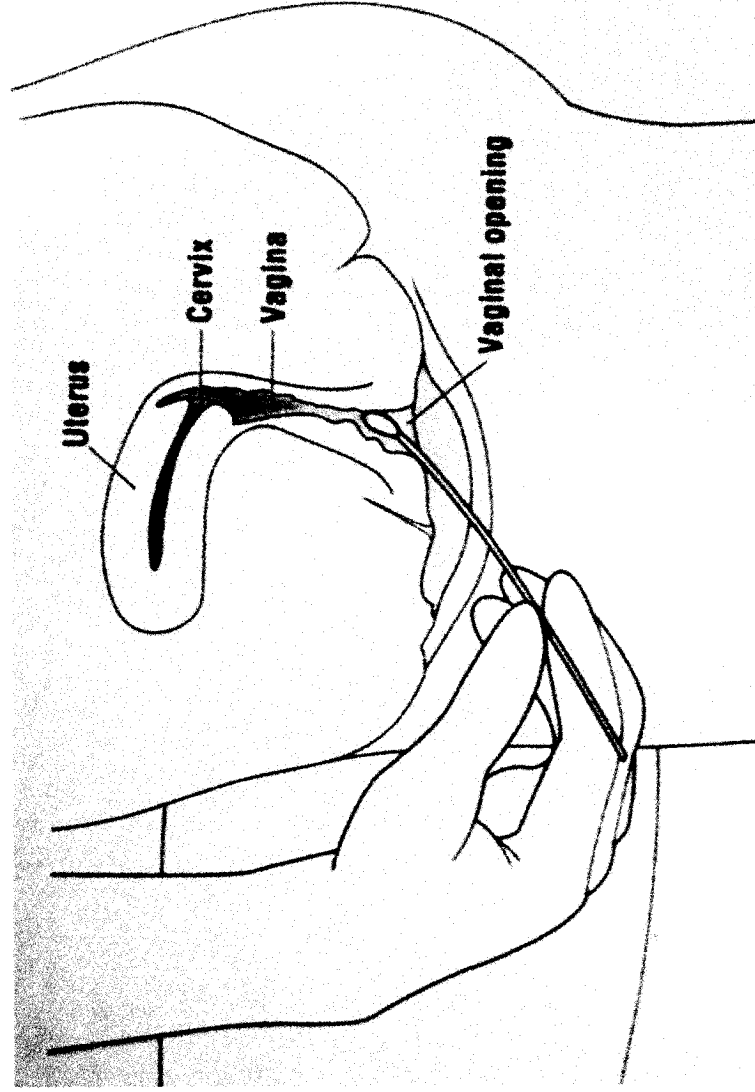
1. Take the swab out from inside the plastic tube.

2. Insert the cotton tip of the swab about one inch inside the opening of your vagina and rotate it around. Make sure you touch the wall of the vagina, so that moisture from the vagina is absorbed onto the swab.

3. Remove the swab from your vagina and place it back into the test tube closing it tightly.

4. Hand the test tube to the nurse or health care provider.

5. Now you can do the urine self-test.



Prueba 2: Auto-Examen de Orina

Nota: Por favor hacer la prueba vaginal con isopo de algodón antes de que usted orine.

Para obtener la muestra de orina:

1. Coloque el vasito bajo su vagina para que pueda recoger el primer orina.
2. Llene el vaso hasta la línea donde esta marcado.
3. Cuidadosamente entregue el vaso al encargado de salud para que no se vaya a derramar.

Este folleto, preparado por Sara B. Newman USUHS, Bethesda, MD 301-295-0305 es adaptado de un libro de instrucción en Polaneczky et al 1998 Use of self-collected vaginal specimens for detection of Chlamydia. *Obstetrics and Gynecology* 91:3;1998 375-378.

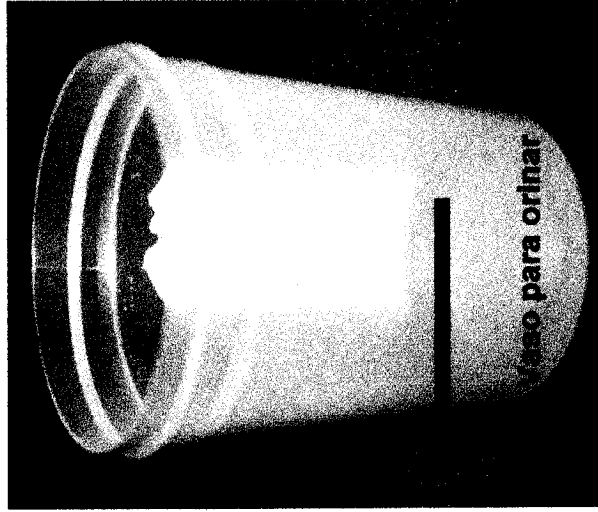
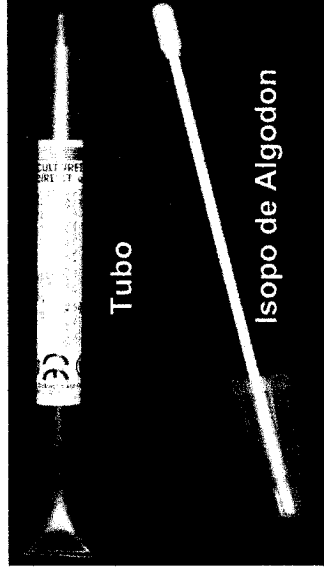
El Auto-Examen de Clamidia y Gonorrea

Examen de Clamidia y Gonorrea

Ahora Ud. puede descubrir si tiene clamidia o gonorrea haciendose su propio examen, sin requerir un examen medico.

Usted puede hacer dos de estas pruebas-- una con un isopo de algodón y la otra con una prueba de orina. Para la primera prueba, usted introducirá un isopo dentro de su vagina para sacar la humedad. Para la segunda prueba usted orinara en un vaso.

Las muestras serán examinadas en un laboratorio para averiguar si usted tiene gonorrea o clamidia.



El Auto-Examen de Orina y Isopo

Prueba 1: El auto-examen de isopo

Para hacerse esta prueba por si misma, usted tiene que desvestirse de la cintura para abajo. Necesita Ud. estar en una posición comoda para introducir el isopo en su vagina. (sentada en el inodoro o parada con un pie en una silla son buenas posiciones.)

Ud. puede hacer estos exámenes seguramente aunque usted esté embarazada o si usted esté con la regla.

Para obtener la muestra vaginal:

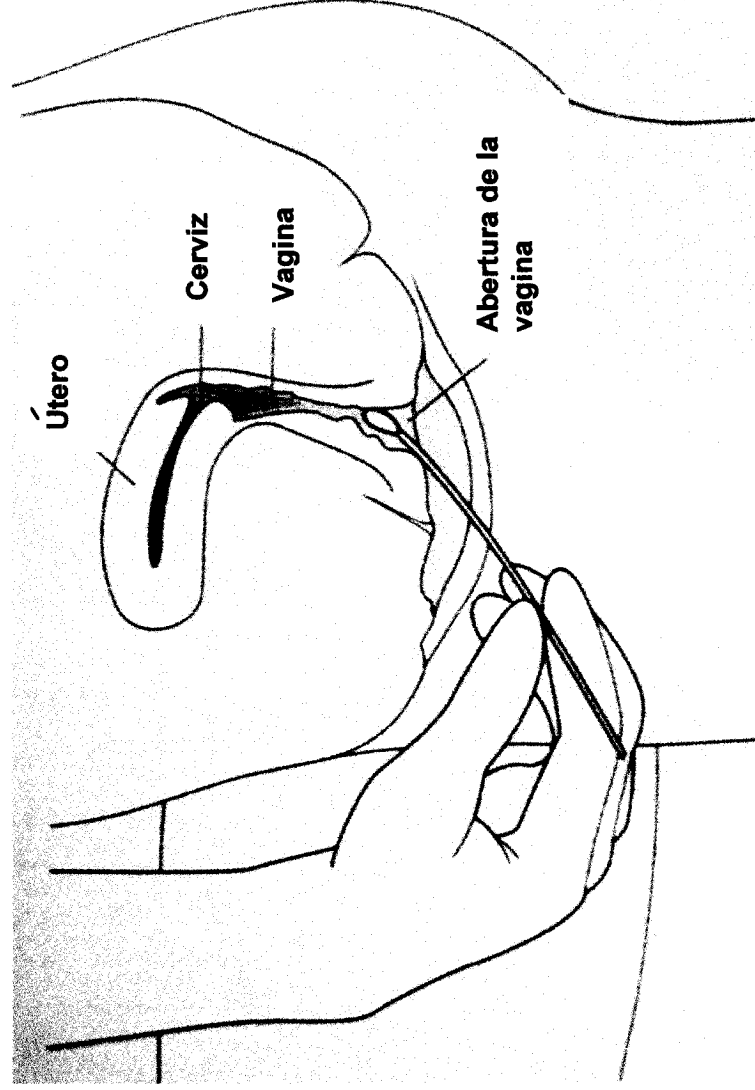
1. Saque el tubo con el isopo de algodón.

2. Inserte el isopo de algodón más o menos una pulgada dentro de su vagina y rotelo alrededor. Asegurese de tocar las paredes de la vagina para que la humedad sea absorbida en el isopo de algodón.

3. Saque el isopo de su vagina y póngalo de regreso dentro del tubo de la prueba y cierrelo hasta que quede bien tallado.

4. Dele el tubo de la prueba a la enfermera o al encargado de salud.

5. Ahora usted puede hacerse la auto-examen de orina.



Appendix E

Laboratory Sheet With Preferences Questionnaire

Chlamydia Laboratory
 Johns Hopkins University
 Division of Infectious Diseases
 School of Medicine
 720 Rutland Ave
 Baltimore, MD 21205-2196

PRISON SITE

FCI Danbury, Rt. 37 CT 06810
Phone 203 743 6471 (422)

COLLECTION DATE

M	M	D	D	Y	Y

PATIENT DATA

Last Name	First name	MI
Registration #		
Study ID#		

SPECIMEN SOURCE

Urine
 Vaginal

STUDY CONSENT

Urine Consent Yes No
 SAS Consent Yes No

QUESTIONS (Ask following questions after specimen is collected)

- When was the first day of your LMP? _____ Are you currently menstruating? Yes No (circle one)
- Did you find it easier to give the swab or urine sample? Swab Urine (circle one)
- Why did you choose to provide the urine/swab and not the urine/swab? _____
- In the future, would you prefer to give a swab or urine sample? Urine Swab No preference (circle one)
 Why? _____
- In the future would you prefer to get a pelvic exam or do your own swab to detect CT/GC? Pelvic Swab

For lab use only:

LABORATORY

Date received:

M	M	D	D	Y	Y

Date tested:

M	M	D	D	Y	Y

Conditions if unable to process:

<input type="checkbox"/>	Broken/Leaked in Transit
<input type="checkbox"/>	Inadequate ID/Ship Label
<input type="checkbox"/>	Inappropriate Specimen
<input type="checkbox"/>	Inadequate Specimen
<input type="checkbox"/>	Other

Test Results:

SAS Results	Pos	Neg
Chlamydia		
Gonorrhea		
Urine Results	Pos	Neg
Chlamydia		
Gonorrhea		

Technician: _____
 Comments: _____