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Principal Investigator Keith Sabin Trainee Investigator (if any) _____
Application No. 96-001 Supporting Agency (if Non-ICDDR,B) _____
Title of Study A Prevalence Study of Project status:
Selected Sexually Transmitted Diseases and (X) New Study
Associated in Risk Factors in Urban Slum Dwellers () Continuation with change
() No change (do not fill out rest of form)

Circle the appropriate answer to each of the following (If Not Applicable write NA).

1. Source of Population:
(a) Ill subjects ☒ Yes ☐ No
(b) Non-ill subjects ☒ Yes ☐ No
(c) Minors or persons under guardianship Yes ☒ No
2. Does the study involve:
(a) Physical risks to the subjects Yes ☒ No
(b) Social Risks ☒ Yes ☐ No
(c) Psychological risks to subjects ☒ Yes ☐ No
(d) Discomfort to subjects ☒ Yes ☐ No
(e) Invasion of privacy ☒ Yes ☐ No
(f) Disclosure of information damaging to subject or others Yes ☒ No
3. Does the study involve:
(a) Use of records, (hospital, medical, death, birth or other) Yes ☒ No
(b) Use of fetal tissue or abortus Yes ☒ No
(c) Use of organs or body fluids ☒ Yes ☐ No
4. Are subjects clearly informed about:
(a) Nature and purposes of study ☒ Yes ☐ No
(b) Procedures to be followed including alternatives used ☒ Yes ☐ No
(c) Physical risks ☒ Yes ☐ No
(d) Sensitive questions ☒ Yes ☐ No
(e) Benefits to be derived ☒ Yes ☐ No
(f) Right to refuse to participate or to withdraw from study ☒ Yes ☐ No
(g) Confidential handling of data ☒ Yes ☐ No
(h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure ☒ Yes ☐ No
5. Will signed consent form be required:
(a) From subjects ☒ Yes ☐ No
(b) From parent or guardian (if subjects are minors) Yes ☒ No
6. Will precautions be taken to protect anonymity of subjects ☒ Yes ☐ No
7. Check documents being submitted herewith to Committee:
☒ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
☒ Protocol (Required)
☒ Abstract Summary (Required)
☒ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
☒ Informed consent form for subjects
☐ Informed consent form for parent or guardian
☒ Procedure for maintaining confidentiality
☒ Questionnaire or interview schedule *
* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:
 1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
 2. Examples of the type of specific questions to be asked in the sensitive areas.
 3. An indication as to when the questionnaire will be presented to the Cttee. for review.

We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

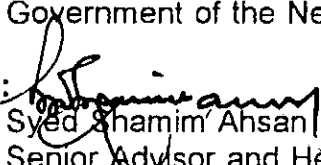
Keith Sabin
Principal Investigator

Trainee

SECTION I: RESEARCH PROTOCOL

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3. **Title of Project:** A Prevalence Study Of Selected Sexually Transmitted Diseases And Associated Factors In An Urban Slum Dwelling Population In Dhaka, Bangladesh
4. **Starting Date:** 1 March 1996
5. **Date of Completion:** November 1996
6. **Total Budget Requested:** US \$127,000 (one hundred twenty-seven thousand US dollars)
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8. **Head of Programme:** 
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Abstract

This cross-sectional study will measure the prevalence of selected sexually transmitted diseases (STD) in women and men in an urban slum dwelling population of Dhaka, Bangladesh. The information will be used to determine the extent of need for STD screening and treatment in a community maternal and child health and family planning project.

Diagnoses will

be made with state-of-the-art, less invasive diagnostic tests.

Abstract -- Summary

This cross-sectional study will measure the prevalence of selected sexually transmitted diseases (STD) in women and men in an urban slum dwelling population of Dhaka, Bangladesh. The information will be used to determine the extent of need for STD screening and treatment in a community maternal and child health and family planning project. Diagnoses will be made with state-of-the-art, less invasive diagnostic tests.

Introduction

The Urban Maternal and Child Health/Family Planning (MCH/FP) Extension Project (hereafter "the Project") of the International Center for Diarrheal Disease Research, Bangladesh (ICDDR,B) studies the delivery and use of MCH and FP services in an urban setting. The primary areas of interest have been immunization, diarrhea treatment, nutrition, maternal morbidity and family planning. The current focus of the Project is operations research into the delivery of the above services. Reproductive health has been receiving increased attention recently but little is known about the prevalence of STDs in Bangladesh. This study proposes to determine the prevalence of STDs in men and women. The information collected will be useful to design detection and treatment approaches for STDs. It may also provide family planners with information to improve contraceptive method continuation by addressing problems of STDs and related symptoms.

Goals and Objectives

This study will determine the prevalence rates and public health importance of STDs in slums of Dhaka. If STDs are important then relevant operations research can be undertaken by the Project, contributing to reduced morbidity and mortality and perhaps greater contraceptive continuation rates.

Background

Bangladesh is the most densely populated country on the planet. It is also among the poorest countries in terms of per capita GNP. The government has a tremendous interest in maintaining and improving its maternal and child health and family planning programs. STDs are the leading cause of morbidity in women aged 15-49. A reduction in STD prevalence can avert serious illness in women and potentially fatal outcomes for children. This study will determine the prevalence of STDs and the extent to which screening and treatment for STDs need to be incorporated into the Urban MCH/FP extension project.

Health of mothers and their children is intricately bound up in the success of family planning programs, which require the acceptance and continued use of modern contraceptive methods. Women who believe that a modern method causes illness or has some adverse side effect will not accept the method or will discontinue the method shortly after acceptance. High prevalence of STDs can serve to decrease acceptance and continuation of family planning methods. Wasserheit *et al.* found that trends in OC use decreased when adverse publicity about its alleged risk circulated in the community.

The study of STD prevalence rates in developing countries has been hindered by a number of obstacles. Primary among the obstacles was inadequate methods to determine infection. Women living in many developing countries do not readily submit to pelvic exams and other invasive methods of diagnosis. Clinical differential diagnosis lacks specificity and sensitivity for exact etiologies. In many traditional societies men receive diagnosis and treatment in STD clinics but women often do not use the clinics for cultural reasons or because the infections are more often asymptomatic in women. Newly developed assays for the detection of STDs with non-invasive methods obviate the need for pelvic exams and swabs to determine etiology.



STD prevalence in high-risk men will provide some insight to the distribution of STDs in the population. They may prove to be a core group of transmitters with public health importance. Further, there may be substantial morbidity among the men.

Good population-based data on STDs is lacking in the developing world and, in particular, Asia. Wasserheit *et al.* studied the association of reproductive tract infections (RTI) and contraceptive behavior in women of Matlab, Bangladesh.³ They found pelvic inflammatory disease (PID) to be associated with discontinuation of contraceptive method. The study was performed under rural field conditions and employed differential diagnosis to ascertain PID cases. Only symptomatic women were enrolled.

A population-based study of prevalence of syphilis and STD symptoms was performed in rural Tanzania.¹⁵ Serology for syphilis was performed on men and women. Other STDs were evaluated by self-reported ulcers or urethral discharge. The lack of specific etiology is a major limitation of this study.

A study in rural Rakai district, Uganda is presently under way to diagnose and treat all STDs in the district using modern non-invasive methods to identify the etiologies of infections (Wawer, Gray *et al.* unpublished). This study has had very good participation despite the fact that there was no prior contact with the study population. Another study will begin soon in Kenya to diagnose and treat STDs in a town and rural population.

A study of STDs in rural Matlab, Bangladesh is currently being done. However, no systematic study of STDs has been performed in urban areas where rates are likely to be different from rural regions. Urban dwellers are often at higher risk for STDs because of greater population density, increased size of sexual contact circles and the breakdown of families and social norms.

Definitions

Reproductive tract infection is broadly defined as any infection of the reproductive tract, i.e., the vagina, cervix, fallopian tubes or ovaries. There are three types of reproductive tract infection: 1) bacterial, viral or protozoan STDs, 2) endogenous infections caused by overgrowth of organisms normally present in the genital tract of healthy women, and 3) iatrogenic infections, which are associated with medical procedures.¹ STDs include all infections transmitted by sexual contact (See Table 1). Pelvic inflammatory disease (PID) is a clinical syndrome of inflammation of the female genital tract (uterus, fallopian tubes and ovaries) caused by any of several microorganisms characterized by severe abdominal pain, high fever, vaginal discharge and in some cases destruction of tissue that can result in sterility. Salpingitis is infection of the fallopian tubes.

Contraception in this study refers to the consistent use of a modern contraceptive method including intrauterine devices (IUD), oral hormone pills, injectable hormones, barrier methods and surgical sterilization, either tubal ligation or vasectomy. Contraceptive use will be self-reported as a frequency and confirmed by MCH/FP workers where on-going contact with the couple exists. Some effort to determine whether the method is used properly will also be extended.



Table 1

Infections that will be studied

Sexually Transmitted Diseases	Diagnostic test	Mode
<i>Treponema pallidum</i>	Toluidine Red Unheated Serum Test (TRUST)/TPHA	Serum
<i>Neisseria gonorrhea</i>	Polymerase chain reaction (PCR)	Urine
<i>Chlamydia trachomatis</i>	PCR	Urine
<i>Trichomonas vaginalis</i>	PCR?/In-Pouch	Urine?/Self-administered swab
<i>Hemophilus ducreyi</i>	PCR	Urine?/Swab
Hepatitis B virus	Enzyme Linked Immunosorbent Assay (ELISA) for HBsAg	Serum

Note: Bacterial vaginitis (BV) and *Candida albicans*, important reproductive tract infections, are not included for two reasons: 1) they are not typically STDs, 2) they require vaginal swabs, which may be exceedingly difficult to obtain from this population. Hepatitis B is a STD although the primary route of transmission in Bangladesh is probably not sexual. It is preventable by immunization and therefore measuring the prevalence of HBV exposure has important public health implications.

Prevalence

The primary factors contributing to high STD prevalence rates include demographic explosion and urbanization, economic and sociocultural factors, limited education, insufficient health services and shortage of drugs and condoms.⁵ Nearly all of these factors are present in the Dhaka slums. The low status of women and inappropriate use of antibiotics leading to drug-resistant strains of bacteria also contribute to high STD prevalence in Bangladesh.⁵

Bangladesh

A population-based study by Wasserheit *et al.* found 21% of the enrolled women in rural Matlab, Bangladesh had a reproductive tract infection.² Pelvic infection was diagnosed by tenderness during pelvic exam or by positive culture for an etiologic agent. Cervical and vaginal infections were diagnosed by culture of an etiologic agent. Exposure status was ascertained by interview with the women. They found the highest unadjusted prevalence rates in women using tubectomy (44%) and IUD (38%). Women using hormonal methods (9%) or not using any methods (6%) had lower prevalence rates of infection. The differential infection rates for contraceptive methods are explained by the authors as possibly reflecting the difference in women who accept modern invasive methods (tubectomy, IUD) versus women who choose non-invasive methods. At the same time, the authors write that they do not believe this to be the underlying cause for different reported infection rates. Acute STD infection was reported as rare. Major limitations of this study include that most initial diagnoses were made without lab confirmation and that the study population was not representative of the general population. The women were already enrolled in a MCH/FP program and potentially were receiving treatment for any ailments. Only symptomatic women were referred to clinic; asymptomatic women were assumed to be uninfected.

Recent urban clinic-based studies by Chowdhury⁷ and Bhatta⁸ were performed in Dhaka and Chittagong respectively. Chowdhury's study took place in a predominantly poor community of Dhaka. Women seeking health or family planning services in the MCH/FP clinic of the Bangladesh Women's Health Coalition were screened for STDs. Nearly 99% of respondents were diagnosed with some type of RTI, primarily BV. STDs found were syphilis (0.5%) and gonorrhea (3.8%). Bhatta's study in Chittagong examined women who attended a mobile STD clinic during a four day period. Four percent of women presented with genital warts (HPV) including five with anal warts. Twenty-six percent of women with a suspected history of syphilis



were Venereal Disease Research Laboratories (VDRL) positive. Confirmatory testing is not reported. Positive gonorrhea swabs were returned from 13.4% of women tested. Bhatta concluded that the symptomatic STD point prevalence was 2.6% (513/20,000) in women of child-bearing age. If target group attendance at this clinic was below 100%, the actual point prevalence is higher. These studies relied on case series, limiting the ability to draw inferences about the population. The representativeness of the cases is unknown.

Jesuthasan cites several unpublished studies of STD prevalence in Bangladesh.⁹ An outpatient department and a MCH clinic reported STD prevalence of 58% among males and 45% among females aged 15-29. Another study showed gonorrhea prevalence in a vagrant group home doubling from 10% to 20% in a six month period (October 1992-April 1993). Commercial sex workers (CSW) in Jessore and Mongla had a STD prevalence of 40-50% and HIV sero-prevalence of 0.5%. CSWs in a brothel in Goaland had a syphilis prevalence rate of 19% and a gonorrhea prevalence rate of 24%.

Table 2 Previous STD Studies In Bangladesh

PLACE	TYPE	RESULTS	LIMITATIONS
Dhaka slum n = unreported	MCH/FP Clinic Case Series	RTIs 99.0% (mostly BV) Syphilis 0.5% Gonorrhea* 3.8%	Not representative Married Women Aged 18-40 yrs
Chittagong n = 980	Mobile STD Clinic Case Series	STD Prev (est) 2.6% HPV 4.0% Syphilis Hx 26.0% Gonorrhea 13.4%	Not representative Women only
Matlab n = 2929	Population-based Sample	RTIs 21.0% PID 0.9% Cervicitis 3.6% (N.g., C.t.) Vaginitis 10.4% (BV, T.v., C.a.) Lower RTI 6.4% (BV, N.g., C.t.)	Many Dx without lab test Poor follow-up for test Only symptomatics Women only
Jessore & Mongla n = unreported	CSWs	STD Prev 40-50% HIV+ 0.5%	Not representative Women only
Goaland n = unreported	CSW brothel	Syphilis 19.0% Gonorrhea 24.0% HIV+ 0.3%	Not representative Women only
Dhaka n = unreported	Outpatients and MCH clinic	STD Prev Male 58.0% Female (15-29) 45.0%	Not representative
Unknown n = unreported	Vagrant Group Home	Gonorrhea 20.0%	Not representative Men only

South Asia

Dixon-Mueller and Wasserheit assert that gonorrhea has been found in 12% of Asian women tested.¹⁰ Bang *et al.* found 10.5% of 650 rural women in India over 13 years old had confirmed syphilis serology.¹¹ In this community-based study, *T. vaginalis* was found in 14% of women and gonorrhea in only 0.3% of women. However, gonorrhea was not confirmed by endocervical swab culture, only gram stain, so this may be underreported. Reported syphilis prevalence rates in women in India range from 1% in two antenatal clinics in Delhi hospitals to 23% VDRL positivity in pregnant women in Nagpur.¹² These clinic based studies do not use samples representative of the general population. Jha *et al.* found gonorrhea in 10% of Indian women studied.¹³

Laga in a review of the proportion of penicillinase producing *Neisseria gonorrhoea* (PPNG) cites a rate of 17% of isolates in India from 1990 data.¹⁴ Penicillin resistant strains will make control more difficult and expensive for developing countries. Since self-medication and use of inadequate doses of antibiotics are common practices in Bangladesh, there is a strong possibility that PPNG will be found in Dhaka. This will not be tested in this study.

Developing World

Dixon-Mueller and Wasserheit cite African studies of PID that found prevalence to be about 20%.¹⁰ Modeling by Over and Piot suggests that urban dwellers in developing countries may have prevalence rates of STDs in adults ranging from 1.2% for chancroid to 4% for chlamydia.¹⁵ Laga reviews chlamydia infection rates among urban pregnant women around the world.¹⁰ Baltimore had the highest reported infection rates (38%) but it also had the best diagnostic capabilities and surveillance system. Rwanda had the next highest rates at 16%. Saudi Arabia had a prevalence of 9%. Laga also describes the situation in Zimbabwe where there is a good health information system. In a population of 10 million, about 1 million cases of STDs were reported in one year of which 40% had urethritis, 25% genital ulceration and 20% vaginal discharge/PID. A population-based study in rural Tanzania found high rates of history of genital discharge syndrome among men (GDS; 28%) and genital ulcerative syndrome (GUS; 14%). Annual incidence for men was 6.8% for GDS and 3.6% for GUS. Prevalence of active syphilis was 8.1% for men and 9.4% for women.¹⁶ Active syphilis was associated with proximity to a major road and increased age.¹⁷

A major limitation to using STD prevalence rates from other countries relates to differences in cultures. Bangladesh is a predominantly conservative Muslim society in which women have low social status. Sexual networking and sexual practices are likely to be very different in different countries as in different population groups within one country. There are reportedly 22,000 registered CSWs in Bangladesh so some cautious inference may be drawn from comparisons between Bangladesh and its neighbors. Bangladeshi men who frequent CSWs may serve as core transmitters of STDs along with the CSWs. Thailand and India have thriving sex industries and soaring STD incidence and prevalence rates in their urban centers.¹⁵ India and Thailand are also confronting large epidemics of HIV/AIDS.¹⁸

Contraceptive Prevalence in Bangladesh

The use of contraceptive methods is well characterized in the study population. Jamil *et al.* found 31.3% of currently married slum dwelling women under age 50 followed by the Urban Surveillance System (USS) were using modern methods of contraception in 1990.¹⁹ Other studies of urban Dhaka contraceptive methods found higher rates of contraceptive prevalence. These studies were not performed exclusively with slum dwelling women. One can expect that contraceptive prevalence might be somewhat lower among slum dwelling women than the general urban population. The Contraceptive Prevalence Survey (CPS) of 1990 found 39.8% and the Bangladesh Fertility Survey (BFS) of 1989 found 38.5% of currently married women under age 50 using modern methods. The same demographic block of women who ever used modern contraceptive methods was 57% in the USS, 67.2% in the CPS and 59.1% in the BFS. The most recent study is the ICDDR,B Baseline Survey of Zone 3 in Dhaka in 1994.²⁰ The pill was used by 19.8% of women surveyed in Zone 3 slums. Injectable hormones were the next most popular method (7.0%) followed by sterilization (6.4%), traditional methods (5.4%), condoms (3.0%) and IUD (2.6%). Male sterilization was reported by 0.6% of those surveyed. The drop out rate for couples quitting their method was 38% in the slums compared to 31% in the non-slum neighborhoods. Adverse side effects from the contraceptive method was reported as the reason for discontinuation by 31% of drop-outs.

Morbidity

Reproductive tract infections are the greatest cause of morbidity in women aged 15-49.²⁰ STDs are the second leading cause of healthy life lost in women aged 15-49 after maternal mortality.¹



PID is the end result of untreated gonococcal or chlamydial infection. Long term consequences of PID include infertility, potentially fatal tubal pregnancy, chronic pelvic pain, and recurrent bouts of upper tract infection.¹⁰ PID can also result in miscarriage, stillbirth, low birth weight and premature birth. Lower tract infections can lead to adverse outcomes also. Fetal death, low birth weight and congenital infection of infants result from most STDs. Congenital eye infections and blindness are caused by gonococci and chlamydia. Adverse effects of STD infections are listed in Table 2.

The WHO estimates that 60 to 80 million couples worldwide experience infertility, mostly caused by *N. gonorrhea* and *C. trachomatis*.⁵ Reproductive tract infection causes approximately 15-39% of sterility in Asia.²¹ Strong evidence for the role of STDs in female infertility exists. Westrom found a single episode of PID was associated with a seven fold rise in the likelihood of tubal and nontubal factor infertility.²² Two and three episodes of STD infection had relative risks for infertility of 16.2 and 28.3 respectively.

The indirect consequences of infertility can be great in many societies. Women who do not have children are considered to be of low worth. Domestic violence that can escalate to murder is not unheard of in some developing countries.

Ectopic pregnancy is seven times more likely following one or more episodes of PID. In developing countries there is a higher risk of morbidity and mortality from this condition due to the lack of diagnostic and treatment modalities. Risk of premature delivery is three times greater for mothers with gonococcal infection and 4.4 times greater for endometritis. Half of the cases of ophthalmia neonatorum are STD-related.⁷

Mechanisms

STDs are transmitted during intimate sexual contact either penile-vaginal, penile-anal or penile-oral. HBV and HIV are transmitted more efficiently when the female's mucosal membranes are ruptured and the virus can enter the woman's blood system. Microabrasions occur in the vagina during normal sexual activities permitting ingress of pathogens. Mucosal ruptures often result from insertion of objects into the vagina or the use of drying agents to enhance male pleasure during intercourse. Ruptures in the form of lesions may also be the result of genital ulcerative STDs such as syphilis, chancroid or herpes. These ulcerative lesions not only enhance the contraction of infection but the transmission as well. Ulcers generally shed virus or bacteria. Herpes can also be transmitted by saliva during oral sex or mouth to mouth contact.

Each infection has its own natural history. Gonorrhea invades the columnar epithelium of the urethra, cervix and other genital tissues after introduction to the reproductive tract. It may be transported to the upper reproductive tract by sperm or trichomonads.²³ *T. pallidum* enters the body through small breaks in the host skin. It soon forms a chancre from which exudate may continue to spread the bacteria.²¹ Chlamydia are obligate intracellular bacteria that are introduced to the host in a cyst-like form and then enter the host's columnar epithelial cells of the conjunctivae, urethra, endocervix, endometrium and fallopian tubes.²³ Trichomonas is very efficiently transmitted from men to women and women to men. Men may spontaneously eradicate the infection in the urinary tract. Women rarely do so. *T. vaginalis* thrives best under any conditions that raise the vaginal pH to 5.5-5.8 (normal = 3.5-4.5).²⁵ *H. ducreyi* requires a break in the skin or mucous membrane to establish infection.²⁷ HBV enters the blood of the host through abrasions or lesions.also.²⁸



Table 3 Major STD Microbial Agents and Conditions They Produce

Agent	Acute disease	Pregnancy-associated condition	Chronic condition
<i>Neisseria gonorrhea</i>	Urethritis Cervicitis Salpingitis	Prematurity Septic abortion Ophthalmia Postpartum endometritis	Infertility Ectopic pregnancy
<i>Chlamydia trachomatis</i>	Urethritis Cervicitis Salpingitis	Ophthalmia Pneumonia Postpartum endometritis	Infertility Ectopic pregnancy
<i>Treponema pallidum</i>	Primary and secondary syphilis	Spontaneous abortion Stillbirth Congenital syphilis	Neurosyphilis Cardiovascular syphilis Gumma
<i>Hemophilus ducreyi</i>	Genital ulcer	None known	?Impotence
<i>Trichomonas vaginalis</i>	Urethritis	Infants may be infected at birth	None known
Hepatitis B Virus	Acute hepatitis	Perinatal HBV	Chronic hepatitis Cirrhosis Hepatoma Vasculitis
Not considered in this study			
HPV	Genital warts	Laryngeal papillomatosis	Genital cancer
HSV-2	Genital ulcer	Neonatal HSV Prematurity	?Genital cancer
HIV	Mononucleosis syndrome	Prematurity Still birth Perinatal HIV	AIDS

Source:

PID caused by certain STDs such as chlamydia and gonorrhea cause tubal infertility in women by scarring the fallopian tubes. Scarring can also lead to ectopic pregnancies which may put the mother's life in danger. Chlamydia infections during pregnancy can adversely affect the fetus causing stillbirth, premature death or lead to congenital infection. Other STDs are strongly linked to cancers. HBV is believed to cause hepatocellular carcinoma

Some contraceptives are associated with increased likelihood of contracting a STD while others lower it.¹⁹ Oral contraceptives (OC) may slightly increase the risk of chlamydia and genital warts. The risk from OC is strongly associated with increased ectopy of the endocervix.²⁰ Cervical ectopy increases the area of susceptible columnar epithelial cells on the ectocervix. Oral and injectable hormones may prevent PID but little data are available. IUDs increase the risk of bacterial vaginosis by upsetting the balance of the microenvironment within the vagina. IUD users have increased risk of PID also. This may be from improper insertion of the IUD or it may be that the tail of the IUD facilitates the ascent of cervical and vaginal microorganisms into the uterus.²¹ Condoms provide the greatest protection from STDs by inhibiting any contact between the partners' mucosal surfaces and bodily fluids. Diaphragms and cervical caps protect the cervix from contact with STDs.



Specific Aims

The main objectives of this study are to determine the prevalence of selected STDs in the study population and to assess selected factors associated with these STDs.

Primary Objectives:

1. Determine the prevalence of symptomatic and non-symptomatic STDs in a random population-based sample of urban slum women and men.
2. Determine factors associated with STDs in poor urban women and men.

Secondary Objective:

1. Evaluate, based on data collected, the desirability of STD screening and treatment at family planning clinics.

Methods

Study Populations

The sampling frame will consist of married women aged 15-35 living in fifteen *thanas* (districts) of a slum area of Dhaka, Bangladesh. The Project has performed a baseline survey of demographic and contraceptive data in a representative purposive sample of five *thanas*. We will draw a representative sample from a population that was originally selected by a new purposive sample. The population is largely Muslim with some Hindus. Residents range from poor to middle class. Some women work.

The population-based survey of men will be drawn from the same slum areas of Dhaka as the women. The sampling frame of men will consist of all males over the age of 15 years. As the women, these men are generally of low SES and mostly Muslim.

The study population includes poor urban slum dwelling women of child bearing age (15-35) in Dhaka, Bangladesh for whom the project has collected data through the Urban Surveillance System (USS) of five *thanas* in 1993. The population of the fifteen *thanas* to be surveyed is likely to be very similar to the USS sample. The age structure of the slums in the USS is very young (46% below 15 years; 3.6% above 60 years). Women are less educated than men; 13% of women have had any formal education compared to 33% of men. One-fifth of the population moved to their present home within the previous year. Sewerage, drainage, electricity and gas services are poor or non-existent in many of the slums. The slums are prone to great changes in a short time. They may disappear over night. A replacement rule in this event will be in effect.

Studies of male residents of the slums could be complicated by the difficulties inherent in finding men at home during the day. Initially, households will be chosen from the USS clusters. Appointments to meet with the men of the households will be made if the men are not found at home. Two attempts will be made to contact the men of a selected household. After two attempts the household will be replaced in the sample according to replacement rules. If data collection does not proceed apace, men will be recruited by a proportional purposive sample by profession. The three leading occupations of slum dwelling men are street vendor, rickshaw puller and construction laborer. Vendors, rickshaw pullers and construction laborers will be approached at their respective work sites and asked to participate in the study. The work sites will be enumerated as clusters. Individuals will be selected by the appearance of a randomly selected digit in their reported birth dates. Vendor patrons may also be selected to fill out the sample.



Inclusion Criteria

- All married couples where the woman is aged 15-35. All women fitting these criteria in a selected residence will be included.
- Men aged greater than 15 years residing in Dhaka slums for at least one year.

Exclusion Criteria

The exclusion criteria flow from the inclusion criteria. Single women and women younger than 15 and older than 35 will be excluded from the couples sample. Men who have not lived for at least one year in Dhaka will be excluded from the men's sample.

Sampling Methods

A probability sample of the study population will be drawn. Multi-stage areal sampling of clusters with defined boundaries will be performed.

The mapped slums will be divided into clusters or primary sampling units (PSU). Each PSU will consist of a slum or a proportion thereof. The size of the clusters will be about 20-100 households. Within each cluster, a subsample of 10 eligible women (elementary units) will be randomly selected to participate in the survey.³³ The sample size is calculated based on these elementary units, i.e., the household. Multi-stage sampling is required due to the lack of information on household composition. The primary advantage to this method is the ease with which one can add clusters to the sample while retaining representativeness and avoid the need to resample if sample size is not achieved initially. The method is also more feasible given the large target population and the transient nature of some slums. It is also the most economic form of sampling.³⁴ Levy and Lemeshow describe methods for obtaining population means and variances with cluster sampling.³⁵

Sampling Frame The clusters will be mapped in detail and eligible households will be listed. Eligibility is determined by residence in the boundaries of the cluster. Clusters will have defined boundaries with appropriate landmarks mapped.

Demographic and family planning information was collected using similar methods in the Dhaka slums in a relatively short period.³⁶

Study Design

1. The study is a cross sectional prevalence survey.
2. Households in the designated slum *thanas* will be sampled. Participants will be asked for informed consent. Most men and women will be questioned and have specimens taken at home. A subsample of men and women will be accompanied to a health facility where they will receive a physical exam. They will be compensated for their time.
3. Ask about symptoms of RTIs, demographic data, risk factors for STDs in general and for specific etiologic agents, and collect urine and blood specimens from each woman and man. Women will be asked to give two self-administered vaginal swabs. Men will be asked for a single swab only if a genital ulcer is reported.
4. Test blood for syphilis and HBV. Test urine for gonorrhea and chlamydia and swabs for *Trichomonas* and *Hemophilus ducreyi*. Test men's swabs for *Hemophilus ducreyi*.
5. Treat couple or individual male for any demonstrated STDs

Variables and Data Collection Definition and Measurement

The operational definitions of the variables are tabulated in the Appendix. Most outcome variables are categorical binary (e.g., absence or presence of infection; use or non-use of contraception), some are continuous (e.g., age at menarche) and others are ordinal (e.g., SES).



The dependent variables are the presence of STDs of any etiology and secondarily, the etiologic agent of the STDs.

The independent variables are listed in the appendix.

Interaction with other factors

We will attempt to measure all possible confounders associated with STDs without disturbing the social sensibilities of the women. The most important factors are related to sexual behaviors but we will not be questioning the women about this directly. The men will be questioned about the number and type of partners they have and if they use condoms. High frequency of sexual contacts increases risk of STDs especially if the partner is a commercial sex worker. Low socio-economic class may be associated with increased risk of STDs because women may not have a steady water source. Hygienic practices during menses may be too costly for low SES women. Disposable sanitary napkins or tampons and fuel to boil water to clean rags are too expensive for the poor.

Marital status of the men is important in determining the number of partners an individual may have. Single and widowed men may have more partners than married men. Religion is related to marital status in that Islam permits polygyny. Religion may also impact on behaviors surrounding the sex act. Islam prohibits sex during menses, for instance. Menses raises the pH of the vagina making it more hospitable to exogenous infectious agents.

Time residing in Dhaka is a potential confounder. If STDs are more prevalent in densely populated Dhaka than in the place from whence they came, the opportunity for exposure is greater for people residing in Dhaka for longer periods.

Procedures for Collection

For the sample of women, all data will be collected during one scheduled visit to the woman's home. Female nurse/paramedics (NP) will interview the women and collect urine and blood from participants at home or in clinic. The woman will be asked to give 5cc of blood by venipuncture. If she refuses to submit to venipuncture, she will be asked for finger stick blood. Two 0.5cc microtainers of blood will be collected from one finger stick at home. The women will then be instructed in self-administration of a vaginal swab. Men and women will be asked if they are aware of any open sores in their genital areas. If they are, they will be asked to swab the sore also. Universal precautions for work with bodily fluids will be followed. One lancet and one pair of rubber gloves per interviewee will be provided to the NP. The questionnaire will be close-ended. Compensation will be offered. Treatment will be provided if the women describe symptoms indicative of a STD though syndromic treatment will not be possible without a pelvic exam.

For men the data and samples will be collected by trained male NP from sampled men in the home. Treatment will be made according to syndromic management algorithms. This would reduce the likelihood of someone going untreated due to failure to return for test results. Appointments to give results and any further indicated treatment will be made during the initial meeting.

Logistics

Samples will be returned to the ICDDR,B laboratory for processing. Urine will be collected in labeled plastic containers. Blood will be collected by 5cc vacutainer or a single finger stick in two plastic 0.5cc microtainers (Becton-Dickenson). Urine and blood samples do not require refrigeration unless testing becomes backed up. Data will be reviewed and entered in a



computer database as it is collected. It will be reviewed again after data entry. Data management is discussed in greater detail below.

Sample Size and Power

The sampling method is proportional cluster sampling. Sample size for cluster sampling is derived in a manner similar to sampling for population surveys. The sample size derived for a population survey is multiplied by a factor, the design effect, usually between 1.0 and 2.5. The design effect is determined by taking the ratio of within-cluster variability to the group variability of a simple random sample of equal size.³⁷ Clusters of 10 households will be compared to 10 randomly chosen households within the study zone. The design effect ratio approaches one as the within-cluster correlation decreases. If the ratio is one, then the sample of 10 people in the cluster is equivalent to a simple random sample of 10 individuals. The advantage to this method is efficiency and cost. A NP can visit a cluster of 10 households more easily than 10 randomly chosen households in a sprawling slum. The cluster design has a potential limitation by controlling for SES since clusters will most likely contain individuals of similar SES. Nonetheless, all SES that are represented in the slums will have an equal opportunity for selection.

The sample size formula for a population-based prevalence study is: $n = \frac{Z_{\alpha}^2 pq}{d^2}$ where Z_{α} is the critical value of the normal distribution (1.96 for 95% CI), p is the proportion with disease and q is the proportion without disease (1- p), and d is the difference around the mean to be detected (the confidence interval).

Table 4 Sample Size Calculations

<i>P</i> - Population Prevalence (%)	<i>d</i> - Precision (%)	<i>n</i> - Sample Size
0.50	0.50	764
0.50	0.25	3057
3.00	3.00	124
3.00	1.50	497
3.00	1.00	1118
5.00	2.50	292
5.00	5.00	73

Total population size of Dhaka slums is estimated at 2 million

The best estimate of STD prevalence in the population is probably somewhat greater than the 2.6% found in symptomatic women in Chittagong district. This study should identify both symptomatic and asymptomatic women. If a conservative precision of 1.5% (resulting in a confidence interval of 1.5-4.5% assuming 3% prevalence) is chosen then the baseline sample size is 497 individuals. If the design effect is taken to be 1.5 and the potential refusal rate is taken to be 10% then the final sample size to detect a true mean prevalence of 3% is 825. Therefore 83 clusters will be selected. The men's group to be sampled will be smaller because they are at higher risk and STD prevalence is expected to be higher (~5.0%) than in married women. Five hundred men will be sampled.

Data Management and Analysis Plan

Interviews and test results will be recorded on a pre-coded form. All data collection will be standardized and described in an operations manual. Data from the surveys will be entered by professional data entry staff at regular intervals following collection. Identifying information will be stored separately, under lock and key, from the study variables. The data will be reviewed and checked before entry into the computerized database. Questionable data will be reviewed with the data collector. Return visits will be made where deemed necessary. Urine and blood



specimens will be analyzed in the ICDDR,B laboratory. A polymerase chain reaction thermal cycler will be dedicated to the study for urinalysis. All reagents and two lab technicians will also be dedicated exclusively for the Project. Samples will be tested within a reasonable period following collection. Results will be recorded on pre-coded forms stored in the lab. The data from the lab will be entered in separate computer files (blinding the lab technicians) and merged with the survey data files. Ten percent of samples will be randomly selected and shipped to The Johns Hopkins School of Hygiene and Public Health for confirmatory testing in the lab of Dr. J. Zenilman. Other quality control measures will be taken as indicated by the manufacturer of each diagnostic test.

Data Collection Plan

Visits will begin when training is completed and other logistical issues are resolved. Visits will continue until the targeted sample size is achieved. Universal precautions will be observed. Disposable gloves will be supplied in sufficient quantity for blood collection. Logistics for the safe disposal of used sharps will be developed.

Interviewers can conduct an average of 6 household interviews each day. Field Research Officer (FRO) will supervise the NP activities. The FRO will be supervised in the field by the PI based in the field offices. An FRO based at the Centre will perform data editing and supervise scheduling for the interviewer/paramedics.

- * A field visitation schedule will be developed for a 90 day visitation period. Interviewers will visit the households within two days of the schedule. Data collection forms will be bound in books by cluster (roughly 30 per book). Sera will be transported by the NP or other Project staff to ICDDR,B each evening along with collected urine samples and swabs from households. The data collection forms will also be returned to ICDDR,B each evening. The sera and urine do not require special refrigeration over the short term. A carrying case for the samples will be devised for each interviewer. Venipuncture samples will be stored under appropriate conditions, -70 °C for blood and standard refrigeration for urine. Data collection forms will be reviewed by the FRO each day. The FRO edits the forms and resolves any extreme values with the NP. The edited data is then entered into the computer database. Errors detected during data entry and verification will be reviewed with the FRO. Errors found will be recorded on error check forms. These forms and subsequent decisions regarding the errors found will be reviewed for reliability.

The field monitoring and data quality control will exist on two levels. The FRO will be responsible for all field operations and will supervise collections. A Research Investigator will be the liaison between the ICDDR,B and the FRO. The Investigator will assure that field collections are being appropriately supervised. The FRO will perform spot checks on NP and re-interview a 5-10% subsample. Initial checking of data forms is performed by the interviewers immediately following data collection before she leaves the household. The FRO will do final editing before data entry.

Detailed Data Collection of Each Visit

The NP will explain the general nature of the study and seek informed consent. The NP will: 1) administer the survey instrument to the woman; 2) obtain a urine sample from the woman; 3) draw a single 5cc vacutainer or two 0.5cc microtainers of blood from the man or woman; 4) collect self-administered swabs for TV and chancroid. If any treatable infection is found, the NP will return to the couple with a standard one dose treatment regimen for both partners. Probable cases of PID will be referred to clinic.

The analysis will determine the prevalence of specific causes of STDs, the prevalence of symptoms of STDs and RTIs and seek other factors contributing to prevalence of STDs and RTIs. The prevalence will be calculated as number of cases as determined by positive tests.

over the population tested. The 95% confidence interval will be calculated with standard error corrected for cluster sampling.

$$x_{clu} = \left[\frac{M}{m} \right] \sum_{i=1}^n \left(\frac{N}{n} \right) \sum_{j=1}^n x_{ij}$$
 where M = # of clusters, m = # of PSU, N = total population, n = chosen population and x = the number of events. The standard error can be calculated by

$$(SE)x_{clu} = \left[\frac{M}{\sqrt{m f}} \right] \left[\frac{\sum (x - \bar{x})^2}{m-1} \right]^{1/2} \cdot \left(\frac{N-n}{N} \right)^{1/2}$$
 where f is the proportion sampled from a cluster.

Exploratory data analyses will be used to check for extreme values and outliers before final analyses. These analyses will also check assumptions for later analyses. The data will be analyzed on a 486/25 notebook computer using SPSS for Windows 6.1 and Epiinfo 6.02 statistical packages and electronic databases. The data entry screens will be built with Foxpro and will include range checks to limit data entry errors. All variables will be examined using descriptive statistics. The appropriate measure for significance for categorical data is the χ^2 .

statistic. The degree of association may be estimated by the ϕ coefficient ($\phi = \frac{\sqrt{\chi^2}}{n}$) or the

odds ratio (OR = $p_{11} \cdot p_{22} / p_{12} \cdot p_{21}$).³⁹ Means of continuous variables will be compared using the Student t test where appropriate. Independent variables will be fitted to a multiple logistic regression model to determine measures of association while controlling for other variables.

Table 5 Dummy Table of Joint Proportions of Sample for Factors A & B

Characteristic A	Characteristic B		
	Present	Absent	Total
Present	p ₁₁	p ₁₂	p ₁
Absent	p ₂₁	p ₂₂	p ₂
Total	p ₁	p ₂	p

Reliability, Validity and Limitations

Reliability Testing

The data collection instrument will be pilot tested in the field prior to the study. An anthropologist will be consulted on the construction of the survey instrument. Supervisors will randomly re-interview a 10% subsample of participants to test the accuracy of the interviewers.

Validity

Validity will be high given the high sensitivity and specificity of the proposed diagnostic tests. The method of contraception will be ascertained with a high degree of certainty because of health program records. Randomly chosen samples will be split and shipped to a reference laboratory in Baltimore, MD for quality control.

The survey instrument may be used in conjunction with another study in Matlab, Bangladesh. This will improve external validity and allow for comparisons with a rural population.

Sources of Bias



Interviewers will be unaware of infection status. Therefore, the interview will be performed under masked conditions. The underlying purpose of the study will be masked to some degree by the broad nature of questions asked.

The questions in the survey are personal in nature. It is possible that people will not answer them honestly or directly. In particular, accurate data for the spouse may be difficult to obtain using non-specific proxy questions for spousal behavior. The direction of this information bias will be toward a null finding for associations between risk factors and infections.

The random selection process for women should limit potential biases. We will attempt to compare individuals who refuse to participate with those who do participate to define any differential refusal rates. This process will be repeated for individual questions' refusal rates.

The men's study will not be a truly random sample. Selection bias is very likely especially if we must offer financial incentives to participate. The nature of the study, a serosurvey, is conducive to great selection bias. The bias should be non-differential unless people who feel ill are more likely to agree to give a blood or urine sample. In this case, the bias would be away from the null. The sample prevalence of disease will be known from the data collected though some risk factors may not be as reliable. The population prevalence is not as important to know as whether this group of men has the potential to be core transmitters in the population.

The specificity and sensitivity of the PCR are very high when used properly. There is the potential for reduced specificity due to contamination of the thermal cycler. The thermal cycler will be dedicated to tests for the Project only. All measures to maintain the purity of the cycler and the quality of the testing will be taken. High false positive rates will bias the study away from the null leading to mistaken inferences regarding associations between risk factors and infection.

Other Limitations

The main limitation is that we will not be performing clinical examinations with complete pelvic exams. This would require better trained health workers, more time and money. Furthermore, we do not believe that consent would be forthcoming from the very traditional families living in the Dhaka slums. An adequate representative sample would probably be very difficult to obtain if pelvic exams were included in the protocol. A major limitation is the inability to collect larger quantities of blood via venipuncture. This would probably lead to many refusals to participate in the study and jeopardize the ability to achieve an adequate sample size. Collecting small amounts of blood (2 cc if we fill four 0.5cc microtainers) also limits our ability to archive samples, perform a larger number of quality assurance tests and test for other STDs such as human papilloma virus (HPV). Women in Bangladesh may be at risk for HPV⁴⁰ though the expense of treating large numbers of women for warts or cervical cancer is probably beyond the financial capability of the Bangladesh government. An important limitation is our inability to do antimicrobial resistance testing for gonorrhea because we will be taking few cultures.

Ethical Implications, Consent and Confidentiality

Signed informed consent will be obtained from each participating woman. Individuals unable to sign their names will be asked for a thumb print. The nature of the study will be fully explained with all inherent risks and benefits. All individuals with infections uncovered by the study will be offered one dose treatment for both members of the couple. The woman will be given her spouse's medication and she will have the option to inform him herself or allow the Project staff to inform him. The men will also be treated. Treatment will be the standard indication for each infection. Confidentiality will be maintained by coding all blood and urine samples and safeguarding the code under lock and key. All interviews will be conducted in private in a health facility unless the participant insists otherwise. Contraceptive services and any other health care



services provided locally will be unaffected by an individual's refusal to participate in the study. A consent form is attached.

Significance

STDs are a major cause of morbidity in women aged 15-49 in the developing world. It seems obvious that STD screening and control for women can be achieved through maternal and child health and family planning programs. Yet, most MCH/FP programs do not perform screening or offer treatment for RTIs. Complaints might often be referred to STD clinics that typically cater to male clients. The stigma attached to attendance at a STD clinic prevents many women from seeking care. It is essential to know the prevalence of RTIs in a population using family planning and the degree to which the contraceptive using population differs from the non contracepting population, especially with respect to STD status. This study will provide the basis for operations research to include STD screening and treatment in the MCH/FP Project. Additionally, the WHO algorithm will be field tested for use by community health workers in an urban setting and compared to state of the art assays. The assays represent important technology transfers to Bangladesh. If the STD problem is as prevalent as we believe then the sampling system, data collection and testing system will provide a model to evaluate the effectiveness of any future STD control program.

Cates and Stone discuss the need to connect prevention and treatment of STDs with prevention of unplanned pregnancy.⁴⁰ They enumerate four similarities in prevention of STDs and pregnancy. One, they both require sexual contact, thus making behavioral changes common to both prevention methodologies. Two, both discriminate against women in terms of transmission, diagnosis and long-term complications. Three, the imbalance of power between men and women confronts planners in both RTIs and unplanned pregnancy prevention. Finally, both RTIs and unplanned pregnancy occur in people under 25 years of age and of low socioeconomic status. They also discuss eight differences between RTIs and unplanned pregnancy prevention. Most salient to the rationale of this study are: one, STD clinics focus on treating males while family planning clinics focus on females, and two, STD clinics emphasize crisis management (symptomatic infections) while FP clinics emphasize preventive measures. Bertrand, in a review of service delivery mechanisms, found that community based distribution (CBD) programs for FP services works well in many countries.⁴¹ One of the main obstacles to CBD is opposition by biomedical professionals who see lay people usurping their roles. Diagnosing infection and prescribing medication for STDs may increase these tensions. Bertrand cited the need for increased operations research for community-based distribution of STD services to assess needs and determine the potential impact of a program.

The need to introduce state of the art diagnostic tests are verified by Roseberry et al. who tested a variety of potential indicators for rapid assessment of STDs in Uganda and Senegal.⁴² All individual symptoms and leukocyte exams had poor sensitivity and specificity. Only RPR for syphilis had high sensitivity and specificity.

Finally, seroprevalence data for HBV can be used to evaluate current vaccination schemes or to determine if greater effort need be placed on a HBV vaccination program.⁴³

Facilities Required

The laboratory of the ICDDR,B will be sufficient for all proposed diagnostic tests following the purchase of some materials. Administrative and computing facilities associated with the Project will be adequate for the study with the provision of specific equipment and supplies.



Appendices

Appendix I

Operational Definitions of Some Variables

See attached survey instruments.

Appendix II

Job Descriptions

Principal investigator - Ph.D. candidate, will supervise the all aspects of the project

Co-investigator - Laboratory Director

Field Supervisor - will supervise the collection of data and samples

Interviewers/NP - will collect the data and samples

Lab technicians - will perform the laboratory analyses

Data entry - will create data entry screens and enter data into database

Appendix III

Diagnostic Tests to be Employed

The TRUST (New Horizons Diagnostics Co., Columbia, MD) is a faster, cheaper version of the VDRL assay for syphilis (5000 determinations = \$750). It can be read in 24 hours with high sensitivity and specificity (reactive agreement with FTA-ABS = 100%; non-reactive agreement = 94.7%). TRUST can also be read quantitatively. It requires a serological rotator with a humidifying cover. TRUST also requires that blood is collected in a tube containing EDTA anticoagulant.

Polymerase chain reaction (PCR) will be used to test urine samples for chlamydia and gonorrhea and maybe trichomonas and chancroid. Lee *et al.* report sensitivity of 93.8% and specificity of 99.9% for chlamydia in first void urine samples using LCR.¹¹ PCR DNA primer sequences for urine samples of gonorrhea and chlamydia have been developed. Mahoney and colleagues reported sensitivity and specificity of 100% for multiplex PCR testing for chlamydia in first void urine. They reported 92.3 and 100% respectively for gonorrhea testing.¹² Trichomonas and chancroid primers should be ready by early next year. The primers are selected to complement DNA from the organism. Pieces of the organism present in the urine are placed in thermal cycler where the DNA from the organism is melted and then annealed to the primers. The DNA is then reproduced until as many as one million strands would be present. A simple test tells whether the DNA is present.

The study will purchase a PCR thermal cycler that will be dedicated for STD use only. It will be donated to ICDDR,B at the termination of the study.

The InPouch TV culture system (Biomed Diagnostics) will be used to test for the presence of *Trichomonas vaginalis*. Sensitivity and specificity are greater than 90%. It requires no special storage equipment and can be read with a standard microscope after 4-8 hours.

HBV will be tested by ELISA. The enzyme linked immunosorbent assay is a well filled with antibody to which an antigen of interest is attached. If a sample from an infected person is introduced to the well, antibody to the antigen will attach to the fixed antigen on the bottom of the well. The fluid in the well will change color and can be read with a spectrophotometer. ELISA for hepatitis B identifies anti-HBsAg, the antibody to the hepatitis B surface antigen.

Appendix IV

Drugs for Treatment



Azithromycin is a highly effective, single dose (1gm) treatment for chlamydial urethritis and cervicitis, *H. ducreyi* and *N. gonorrhea*. Adverse side effects are reported to be mild intestinal disturbance in less than 10% of recipients. A second drug may be desirable to maximize treatment effectiveness and reduce selection of azithromycin resistant strains. The drug is not contraindicated for pregnant women. Curative efficacy for gonococcal cervicitis (GC) is 92-100%, for chancroid 97% and for chlamydia it is 96-100%.

Ciprofloxacin can be used effectively in a single 250mg dose against *H. ducreyi* and *N. gonorrhea*. It has 99%+ efficacy in curing GC. It is well tolerated in conjunction with azithromycin. Pregnant women should receive cefixime instead of ciprofloxacin.

Cefixime will only be used for pregnant women as the second drug with azithromycin. It has a high degree of intestinal disturbance when used with azithromycin (30-60% of patients). Efficacy is 96%.

Benzathine penicillin is effective against *T. pallidum* in a single dose (2.4 million units IM). It is effective against incubating, early and latent syphilis and it is cheaper than ceftriaxone. Epinephrine will be available in the event of anaphylactic reaction to penicillin.

Metronidazole is curative for *T. vaginalis* and may reduce the prevalence or intensity of bacterial vaginosis in 2 gm doses. Metronidazole is not contraindicated in pregnancy. It will be administered a day after azithromycin and ciprofloxacin (where indicated) to reduce potential gastrointestinal upset.

Appendix V

STD Prevalence Survey Consent Form

To be read to all potential study participants prior to data collection.

See attached consent forms.

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I am visiting you to ask you to participate in a prevalence study of selected sexually transmitted diseases (*meho and promeho*) in Dhaka city slums. The study is a collaboration between the ICDDR,B and Johns Hopkins School of Public Health. The study aims to better your health and the health of your neighbors by helping to improve reproductive health care in your community.

To help meet our objectives, I would like to ask you some questions about your views on health including your situation and activities and symptoms of illness you may have had. The whole interview will take 30-45 minutes.

All information and test results you give will be secret; I will not talk about what you said with anyone, including your spouse. Your name will not be used and I will not let anyone in this community see the completed questionnaire. The completed questionnaire and samples will be kept locked in the project office. The data and samples collected may be used for further studies following the removal of all names and addresses.

I will also ask you to provide some specimens. I will draw 5 cc (one teaspoon) of blood from a vein in your arm; I will only do this one time. I will ask you to fill a plastic container, which we will provide, with urine. I will also ask you to wipe your genitals with a clean piece of cotton, in private, and give me the cotton.

If you agree to participate in this study please sign or give your left thumb imprint below.

Interviewer

Date

Participant

Witness



STD

15. BUDGET FOR ARI STUDY

SALARY: LOCAL

Position	Grade	#	Rate	Month	Subtotal	Total
Field Research Officer	GS-5	1	385	6	2,310	
Nurse/Paramedic	GS-5	12	385	4	18,480	
Lab. Officer	GS-5	1	385	6	2,310	
DMA Gr-I	GS-4	1	295	4	1,180	
Lab Technician	GS-3	1	244	6	1,464	
DMA Gr-II	GS-3	1	244	3	732	
						\$26,476

SALARY: INTERNATIONAL

International Fellow	Fellow	1	1500	12	18,000	\$18,000
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TRAVEL: LOCAL

Conveyance costs					2,640	\$2,640
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TRAVEL: INTERNATIONAL

Travel Costs		1	2000		2,000	
Perdiem		1	185	4	740	
						\$2,740

SUPPLIES & MATERIALS

Drugs & laboratory supplies					12,025	
Miscellaneous (office & etc.)					8,000	
						\$20,025

CAPITAL EQUIPMENT

Refrigerators		1	300		300	
Cold chain box		12	50		600	
Computer & accessories		1	3000		3,000	
Thermal cycler (PCR)		1	9000		9,000	
Other capital items					4,915	
						\$17,815

STD

OTHER DIRECT COSTS

Compensation to participants	2.5	1500	3,750	
Miscellaneous			3,500	
				\$7,250

INTER-DEPARTMENTAL

Xerox/mimeo			2,000	
				\$2,000

TOTAL DIRECT COST				96,946
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OVERHEAD (@ 31%)				30,053
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TOTAL				127,000
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5/2/96
Abdul Ahad
Budget & Cost Officer
ICDDR, B, Mohakhali
Dhaka-1212, Bangladesh

Abstract Summary for Ethical Review Committee

This cross-sectional study will measure the prevalence of selected sexually transmitted diseases (STD) in women and men in an urban slum dwelling population of Dhaka, Bangladesh. The information will be used to determine the extent of need for STD screening and treatment in a community maternal and child health and family planning project. Diagnoses will be made with state-of-the-art, less invasive diagnostic tests.

1. The study is a random sample of slum dwellers. Married women between the ages of 15 and 35 will be surveyed. Men older than 15 years will be surveyed regardless of marital status. The rationale is to provide information on a representative sample of slum dwelling adults in Dhaka. Single women are not sampled because the mores of the community make it difficult for them to acknowledge premarital sexual relations.
2. Physical risks of participation are very minor. There may be some soreness from the needle prick when blood is drawn. Very rarely, people get an infection at the site. Sometimes husbands may not understand how their wives got an infection. Violent behavior may ensue. For this reason husbands will not be informed without a request from the woman to do so. There are psychological risks inherent in informing an individual of his/her infection. Successful treatment of infections should mitigate these risks.
3. All sharps will be new and universal precautions will be followed. Treatment will be offered following the interview if symptoms clearly indicate a treatable infection. Treatment will also be offered for spouses and children if indicated. Follow-up treatment will be provided after the test results are known if these results differ from the initial diagnosis. Husbands will not be informed of the nature of a wife's infection without the expressed request of the wife. She can choose to provide the treatment to her husband with any story she likes. She can also avail herself of the services of the nurse/interviewer to explain the infection and treatment to her husband.
4. Confidentiality will be maintained by coding all blood, urine and swab samples and safeguarding the code under lock and key. Only the PI's will have access to the code. Survey instruments will also be stored in a locked file cabinet in the Project office. The data files will be protected by password. The interviews will be conducted in the home under whatever conditions of privacy the man or woman can engineer. Test results will be supplied only to the survey participant.
5. Informed consent will be sought. Nurse/Interviewers will be trained to read the consent form verbatim before asking an individual to participate in the study. Signed consent will be sought. Illiterate individuals will be asked for a thumb print. No information will be withheld from the study participants. The treatment is outlined in the consent form.
6. The interview will take place in the home of the participant. Some men working as vendors may prefer to be interviewed at their street stall. The interview and specimen collection should take approximately 45 minutes.
7. The participant benefits primarily if he or she is infected because they and their family will be treated. They will also learn to identify symptoms of sexually transmitted diseases and when and where to seek treatment for STD. They will also learn the benefits of practicing safer sex in future. Society benefits when individuals with STD are treated thus reducing the potential for further transmission of the infection. Society also benefits from treatment of ill individuals because they can become more productive members of society. Finally, if prevalence rates of STD are found to be high, services for the detection and treatment of STD may be improved for this population. Since risks to individuals are few and minor, these benefits



clearly outweigh them. Indirect benefits include compensation and free condoms.

8. The study requires the collection of blood, urine and self-administered swabs. The blood specimen will be collected by first asking for 5 cc by venipuncture. If the individual balks, s/he will be asked for 1 cc by finger prick. Urine will be collected in a plastic container provided the participant. The swabs will be vaginal wipes for testing for presence of *Trichomonas vaginalis* in all women. Men and women will be asked for swabs if they report presence of genital ulcers.



Survey Number

**International Centre for Diarrhoeal Disease Research,
Bangladesh**

Maternal Child Health And Family Planning Project

Urban Extension Project

Women's Questionnaire for the STD Study in Dhaka Slums

Date of Interview
DD MM YY

Interviewer:

1. Cluster Number
2. Household Number
3. Study Number
4. What is your Date of Birth (dd.mm.yy)
5. What is your Religion

Muslim = 1
Hindu = 2
Christian = 3
Other = 4

6. How many years of schooling have you completed
7. What is your occupation
8. How long have you resided in Dhaka (mm.yy)
9. What was your age at first marriage
10. How many marriages have you had in your lifetime
11. What is your current marital status

Single = 1
Married = 2
Divorced/separated = 3
Widowed = 4

12. How many wives does your husband currently have
13. How long is your current marriage (years)
14. What is your husband's Occupation
15. Where does your husband currently work?

Dhaka = 1
Village/Rural Area = 2
Town/city (not Dhaka) = 3
Out of Bangladesh = 4

Where?

Other = 5

16. In the past one month, how many nights has your husband spent away from home?

Most / all nights = 1 ☐
Spent occasional nights away from home = 2
He was always home at night = 3

17. How many times have you been pregnant?



18. How many children do you have who are currently living? ☐

Health Questions

19. Have you had any fever in the past one week? ☐

20. Have you taken any medication in the past one week? ☐

21. If you have taken any medication list here the type if you know ☐

22. Have you ever had a blood transfusion? ☐

If yes, what year was the last one? ☐

23. Current method of contraception: ☐

None = 1

Oral Pill = 2

Injectable = 3

IUD = 4

Condoms = 5

Sterilization/tubectomy = 6

Vasectomy = 7

Other barrier methods = 8

Other method (specify) = 9

24. What was your age at first menstruation ☐

25. Are you menstruating regularly ☐

26. If yes, how many days ago was the first day of your last period ☐

If you are is menstruating regularly ask the following:

27. Length of menstrual cycle (days) ☐

28. Number of days you bleed for ☐

29. Was your last menstrual period ☐

Same amount of bleeding as usual = 1

Heavier bleeding than usual = 2

Less bleeding than usual = 3

30. Was your last menstrual period ☐

Same amount of pain as usual = 1

More painful than usual = 2

Less painful than usual = 3

No pain = 4

31. Do you ever spend time in bed because of pain when bleeding ☐

If yes, how many days each period do you spend in bed ☐

32. Do you ever pass any clots? ☐

Ask these questions whether or not you are is currently menstruating regularly.

33. What do you use as sanitary protection? ☐

Nothing = 1

Towels bought from shop = 2

Tampons bought from shop = 3

Cloth/towel/rag made at home = 4

Tampons made at home = 5

Petticoat = 6



34. When you menstruate, how many times in one day do you change your protection? ☐ ☐

35. Do you ever wash INSIDE your vagina during menstruation? ☐

If yes, what do you wash inside yourself with? ☐

Water only = 1

Soap and water = 2

Savlon and water = 3

Salt and water = 4

Dry rags / cloth = 5

Other (specify) = 6

36. Do you currently have any symptoms relating to your reproductive health ☐

LIST ALL SYMPTOMS SHE COMPLAINS OF _____

NOW EXPLAIN THAT YOU ARE GOING TO ASK HER ABOUT SOME SYMPTOMS WOMEN OFTEN SUFFER FROM. YOU WILL NEED TO KNOW WHETHER SHE CURRENTLY HAS THESE SYMPTOMS OR WHETHER SHE HAS EVER SUFFERED FROM THEM IN THE PAST.

37. VAGINAL DISCHARGE:

Do you have an abnormal vaginal discharge at the present time? ☐

38. If yes, how long has it been abnormal? ☐

< 7 days = 1

> 7 days ≤ 1 month = 2

> 1 month = 3

> 1 year = 4

39. Have you suffered with an abnormal vaginal discharge in the past? ☐

40. If you have a vaginal discharge, what color is it today? ☐

White = 1

Yellow = 2

Brown = 3

Other Color = 4

Watery = 5

No discharge = 6

41. Does your vaginal discharge smell offensive? ☐

42. If yes for how long has it smelt offensive? ☐

≤ 7 days = 1

> 7 days ≤ 1 month = 2

> 1 month = 3

> 1 year = 4

43. If you have discharge now or have had it in the past, have you ever stopped meeting with your husband because of it? ☐

44. Have you ever sought treatment/advice for abnormal vaginal discharge (either now or in the past)? ☐

45. GENITAL ITCHING

Do you suffer with any genital itching at the present time?

46. If yes, for how long has this been present?

≤ 7 days = 1

> 7 days ≤ 1 month = 2

> 1 month = 3

> 1 year = 4

47. Have you suffered with genital itching in the past?

48. Have you ever sought treatment/advice for genital itching (either now or in the past)?

49. LOWER ABDOMINAL PAIN

(n.b. Make sure that she is not referring to menstrual pain)

Do you have any lower abdominal pain at the present time?

50. If yes, for how long has this been present?

≤ 7 days = 1

> 7 days ≤ 1 month = 2

> 1 month = 3

> 1 year = 4

51. Have you suffered with lower abdominal pain in the past?

52. Have you ever sought treatment/advice for lower abdominal pain (either now or in the past)?

53. DYSAREUNIA (Pain during sex)

How long ago did you last meet with your husband?

1 day = 1

≤ 7 days = 2

> 7 days ≤ 1 month = 3

> 1 month = 4

> 1 year = 5

54. The last time you met with your husband, was it painful?

If yes, was the pain on the outside = 1

or on the inside in the abdomen = 2

55. Have you ever had pain in the past while meeting with your husband?

56. Have you ever sought treatment/advice for pain during sexual intercourse?

57. DYSURIA (pain passing urine)

In the past one week have you suffered with pain while passing urine?

58. In the past one week, have you been passing urine

The same frequency as usual = 1

More often than usual = 2

Less often than usual = 3

59. Have you ever suffered pain while passing urine?

60. Have you ever sought treatment/advice for pain while passing urine?



61. GENTAL PROLAPSE

Do you suffer with any genital prolapse?

62. If yes, for how long has this been present?

≤ 1 month = 1

> 1 month ≤ 1 year = 2

> 1 year = 3

63. Have you ever sought treatment/advice for genital prolapse?

64. When you cough, sneeze or laugh, do you leak urine?

65. GENTAL ULCER

Do you suffer with any genital ulcer at the present time?

66. If yes, is it painful

67. If yes, for how long has this been present?

≤ 7 days = 1

> 7 days ≤ 1 month = 2

> 1 month = 3

> 1 year = 4

68. Have you suffered with genital ulcer in the past?

69. Have you ever sought treatment/advice for genital ulcer (either now or in the past)?

If you have ever sought treatment for any reproductive health problems,
please answer these questions:

70. Where did you go first for treatment or advice?

71. Did the treatment help you?

72. If no, where did you go next?

73. Did the treatment help you?

74. If you have or had a reproductive health problem but never sought treatment or help
for it, is it because:

No time to go for advice or treatment

Treatment is too expensive

Symptoms not severe enough

You treat yourself at home

Did not know where to go for treatment

Too shy to seek treatment

Other reasons

75. Which symptoms did you not seek treatment for?(specify)

76. In the past one month, has your husband suffered from.

Pain on passing urine

Abnormal discharge from the penis

Genital ulcer

77. If your husband had these symptoms, did he stop meeting with you because of them?

78. Did he seek treatment for them?

79. Did you have any treatment?

80. Would you be willing to answer more questions in the future? ☐

THE FOLLOWING QUESTIONS ARE RATHER PERSONAL. REMIND THE WOMAN THAT EVERYTHING SHE TELLS YOU IS IN COMPLETE CONFIDENCE. SHE MAY WANT TO CLEAR THE ROOM.

81. How old were you when you first met with your husband ☐

82. Do you ever wash INSIDE your vagina after sexual intercourse ☐

Water only = 1

Soap and water = 2

Savlon and water = 3

Salt and water = 4

Dry rags cloth = 5

Other (specify) = 6

LABEL THE URINE CUP, IN-POUCH, SWABS AND THE VACUTAINER WITH THE SURVEY ID NUMBER. MAKE SURE THE NUMBERS ARE IDENTICAL. IF THE WOMAN COMPLAINS OF LOWER ABDOMINAL PAIN OR ULCERS, REFER HER TO CLINIC. TELL HER YOU WILL RETURN WITH THE RESULTS AND TREATMENT IF ANY IS NECESSARY. GIVE HER CONDOMS AND 100 TAKA.

THANK YOU VERY MUCH FOR PARTICIPATING IN THIS STUDY.

DDMMYY

[illegible]

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| | | | | | |
| | | | | | |

6. How many years of schooling have you completed
7. What is your occupation
8. How long have you resided in Dhaka (mm.yy)
9. What was your age at first marriage
10. How many marriages have you had in your life
11. What is your current marital status

-

Where?

16. In the past one month, how many* nights have you spent away from home?

1

- 10

Health Questions

19. Have you had any fever in the past one week? ☐
20. Have you taken any medication in the past one week? ☐
21. If he has taken any medication list here the type if he knows _____

22. Have you ever had a blood transfusion? ☐
If yes, what year was the last one?
23. Current method of contraception: ☐
- | | |
|-------------------------|-----|
| None | = 1 |
| Oral Pill | = 2 |
| Injectable | = 3 |
| IUD | = 4 |
| Condoms | = 5 |
| Sterilization/tubectomy | = 6 |
| Vasectomy | = 7 |
| Other barrier methods | = 8 |
| Other method (specify) | = 9 |

24. Have you ever used condoms? ☐
- IF NO, ASK:* *IF YES, ASK:*
25. If you are not using condoms, why not? *OR* If you are using condoms, why?
- _____
- _____

26. Do you have any problems relating to your genital area? ☐
27. Do you currently have any problems relating to your sexual health ☐
LIST ALL SYMPTOMS HE COMPLAINS OF _____
- _____
- NOW EXPLAIN THAT YOU ARE GOING TO ASK HIM ABOUT SOME SYMPTOMS MEN OFTEN SUFFER FROM. YOU WILL NEED TO KNOW WHETHER HE CURRENTLY HAS THESE SYMPTOMS OR WHETHER HE HAS EVER SUFFERED FROM THEM IN THE PAST.

28. DYSURIA (pain passing urine)
In the past one week have you suffered with pain while passing urine? ☐
29. If yes, how long has this been present? ☐
- | | |
|--------------------|-----|
| ≤ 7 days | = 1 |
| > 7 days ≤ 1 month | = 2 |
| > 1 month | = 3 |
| > 1 year | = 4 |

30. Have you ever suffered pain while passing urine in the past? ☐
IF HE HAS PAIN PASSING URINE NOW, OR HAS SUFFERED FROM IT IN THE PAST, ASK THE FOLLOWING QUESTIONS, OTHERWISE GO TO QUESTION # 46

31. Have you ever sought treatment/advice for pain while passing urine? ☐
32. If yes, where did you go for treatment/advice? _____ ☐
33. Did the treatment help you? ☐



34. If no, where did you go next for treatment or help? ☐
35. Did the treatment help you? ☐
36. If you have a problem with painful urination but have never sought treatment/help, is it because:

No time to go for advice or treatment ☐

Treatment is too expensive ☐

Symptoms not severe enough ☐

He treats herself at home ☐

Did not know where to go for treatment ☐

Too shy to seek treatment ☐

Other reasons ☐

37. Do you have any urethral discharge at present? ☐

38. If yes, for how long has this been present? ☐

≤ 7 days = 1

> 7 days ≤ 1 month = 2

> 1 month = 3

> 1 year = 4

39. Have you suffered from urethral discharge in the past? ☐

40. Have you ever sought treatment/advice for urethral discharge (either now or in the past)? ☐

41. If yes, where did you go for treatment/advice? ☐

42. Did the treatment help you? ☐

43. If no, where did you go next for treatment or help? ☐

44. Did the treatment help you? ☐

45. If you have a problem with urethral discharge but have never sought treatment/help, is it because:

No time to go for advice or treatment ☐

Treatment is too expensive ☐

Symptoms not severe enough ☐

He treats herself at home ☐

Did not know where to go for treatment ☐

Too shy to seek treatment ☐

Other reasons ☐

46. GENITAL ULCER

Do you suffer with any genital ulcer at the present? ☐

47. If yes, is it painful? ☐

48. If yes, for how long has this been present? ☐

≤ 7 days = 1

> 7 days ≤ 1 month = 2

> 1 month = 3

> 1 year = 4

49. Have you suffered with genital ulcer in the past? ☐

50. Have you ever sought treatment/advice for genital ulcer (either now or in the past)? ☐

51. If yes, where did you go for treatment/advice? ☐

52. Did the treatment help you? ☐



SURVEY NUMBER ☐☐☐☐☐☐

53. If no, where did you go next for treatment or help? ☐

54. Did the treatment help you? ☐

55. If you have a problem with genital ulcer but have never sought treatment/help, is it because:

No time to go for advice or treatment ☐

Treatment is too expensive ☐

Symptoms not severe enough ☐

He treats herself at home ☐

Did not know where to go for treatment ☐

Too shy to seek treatment ☐

Other reasons ☐

56. Does your wife/partner have any problems of the genital tract? ☐

57. Do you know what symptoms your wife/partner has? ☐

58. If you have received treatment for current symptoms, was your wife/partner also treated? ☐

59. If your wife/partner has recently received treatment for a problem of the genital tract, were you treated also? ☐

60. THE FOLLOWING QUESTIONS ARE PERSONAL. I ASSURE YOU THAT EVERYTHING YOU TELL ME WILL REMAIN CONFIDENTIAL. I WILL TELL NO ONE ELSE WHAT YOU SAY TO ME NOW OR HAVE SAID BEFORE.

How old were you the first time you had sexual intercourse? ☐☐

61. During your lifetime, how many women have you had sexual intercourse with (including your wife)? ☐☐

62. Have you ever given gifts/money/food in exchange for sex? ☐

63. How many women have you had sexual intercourse with during the past one year (including your wife/wives)? ☐☐

64. After sexual intercourse, do you usually wash yourself in the genital area? ☐

65. If yes, what do you wash yourself with? ☐

Water only = 1

Soap and water = 2

Savlon and water = 3

Salt and water = 4

Dry rags / cloth = 5

Other (specify) = 6

LABEL THE URINE CUP AND THE VACUTAINERS WITH THE SURVEY ID NUMBER. LABEL ANY SWABS TAKEN WITH ID NUMBERS. MAKE SURE THE NUMBERS ARE IDENTICAL. TELL HIM YOU WILL RETURN WITH THE RESULTS AND TREATMENT IF ANY IS NECESSARY. GIVE HIM CONDOMS AND 100 TAKA.

THANK YOU VERY MUCH FOR PARTICIPATING IN THIS STUDY.



CONSENT FORMS

I am visiting you to ask you to participate in a prevalence study of selected sexually transmitted diseases (*meho and promeho*) in Dhaka city slums. The study is a collaboration between the Cholera Hospital and Johns Hopkins University. The study aims to better your health and the health of your neighbors by helping to improve reproductive health care in your community.

To help meet our objectives, I would like to ask you some questions about your views on health including your situation and behaviors and symptoms of illness you may have had. The whole interview will take 30-45 minutes.

I will also ask you to provide some specimens which we will test for disease. I will draw 5 cc (one teaspoon) of blood from a vein in your arm. I will only do this one time. I will ask you to fill a plastic container, which we will provide, with urine. I will also ask you to wipe your genitals with a clean piece of cotton, in private, and give me the cotton.

All information you give will be secret; I will not talk about what you said with anyone, including your spouse. Your name will not be used and I will not let anyone in this community see the completed questionnaire. The completed questionnaire and samples will be kept locked in the project office. The data and samples collected may be used for further studies following the removal of all names and addresses.

If you agree to participate in this study please sign or give your left thumb imprint below.

Interviewer

Date

Participant

Witness



ঢাকা শহরের বস্তিগুলিতে বাছাই করা কয়েকটি যৌন রোগের (মেহ ও প্রমেহ) উপর একটি গবেষণায় অংশ নেওয়ার জন্য আমরা আপনাকে অনুরোধ করছি। কলেরা হাসপাতাল ও আমেরিকার জনস হপকিনস ইউনিভার্সিটির যৌন উদ্যোগে এই গবেষণাটি পরিচালিত হবে। এই এলাকায় প্রজনন স্বাস্থ্য সেবার উন্নতি করে আপনার ও আপনার প্রতিবেশীদের স্বাস্থ্যের উন্নতি করাই আমাদের গবেষণার উদ্দেশ্য।

আপনার স্বাস্থ্য, বিভিন্ন অভ্যাস ও যদি কোন রোগের লক্ষণ আপনার থেকে থাকে - এই সমস্ত বিষয় সম্পর্কে আপনার মতামতের উপর ভিত্তি করে আমরা আপনাকে কিছু প্রশ্ন জিজ্ঞাসা করতে চাই। আমাদের সাথে এসব বিষয় নিয়ে আলোচনা করতে আপনার ত্রিশ-চল্লিশ মিনিট সময় লাগবে।

রোগ নির্ণয় করতে পরীক্ষার জন্য আমরা আপনাকে কিছু নমুনা দিতে অনুরোধ করবো। আপনার হাত থেকে এক চা চামচ পরিমাণ অর্থাৎ ৫ সি, সি, রক্ত নেওয়া হবে। শুধু একবারই এই রক্ত নেওয়া হবে। আপনাকে একটি প্লাষ্টিক ফোটা দেওয়া হবে। ফোটাটিতে আপনার প্রস্রাব দেওয়ার জন্য আমরা অনুরোধ করবো। একটি পরিষ্কার তুলা দিয়ে আড়ালে যেয়ে আপনার গোপন অঙ্গটি আপনি মুছবেন এবং সেই তুলাটি আমাদের দেওয়ার অনুরোধ করবো।

আপনি আমাদের যা যা বলবেন, তা গোপন রাখা হবে। যেসব কথা আপনি আমাদের বলেছেন তা আমরা কাউকেই বলবো না, এমনকি আপনার স্বামী/স্ত্রীকেও না। আপনার নাম এখানে ব্যবহার করা হবে না, এলাকার কাউকেই আপনার দেওয়া তথ্য নিয়ে পূরণ করা প্রশ্নমালাটি দেখাবো না। পূরণ করা প্রশ্নমালাটি এবং নমুনাগুলি তালাবদ্ধ করে রাখা হবে। আপনার নাম ও ঠিকানা সরিয়ে দিয়ে আপনার দেওয়া তথ্যগুলি এবং সংগ্রহ করা নমুনাগুলি পরবর্তী অন্য কোন গবেষণাতে ও ব্যবহার করা হতে পারে।

যদি এই গবেষণায় অংশ নিতে আপনি রাজী থাকেন, তাহলে নীচে আপনার স্বাক্ষর বা টিপসই দিন।

ইন্টারভিউয়ার

তারিখ

অংশগ্রহণকারী

সাক্ষীঃ