Attachment 1.
(FACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date 5/9/99

Principal Investigator NAZMUL ALAM Trainee Investigator (if any) _____

Application No. 99-026 Supporting Agency (if Non-ICDDR,B) SDC

Title of Study Prevalence and risk factors for STDs among residents at Tejgaon truck stand

Project status:
(✓) New Study
( ) 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:
   - NA 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
   - NA 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.

NAZMUL ALAM
Principal Investigator

_____
Trainee

Principal Investigator: Last, first, middle Alam Nazmul

International Centre for Diarrhoeal Disease Research, Bangladesh

FOR OFFICE USE ONLY

RESEARCH PROTOCOL

Protocol No: Date:

RRC Approval: Yes/ No Date:

ERC Approval: Yes/No Date:

1. Title of Project (Do not exceed 60 characters including spaces and punctuations)
"Prevalence and risk factors for STDs among residents at Tejgaon truck stand."

2a. Name of the Principal Investigator(s) (Last, Middle, First).	2b. Position / Title	2c. Qualifications
Alam Nazmul	Research Officer	MSc (Microbiology)

3. Name of the Division/ Branch / Programme of ICDDR,B under which the study will be carried out.

Public Health Sciences Division, Reproductive Health Programme

4. Contact Address of the Principal Investigator

4a. Office Location: Dhaka

4b. Fax No: 886050

4c. E-mail: nazmul@icddrb.org

4d. Phone / Ext: 871751-60 Ext. 2232

5. Use of Human Subjects	5a. Use of Live Animal	5b. If Yes, Specify Animal Species
Yes ☑	Yes ☐	
No ☐	No ☑	

6. Dates of Proposed Period of Support
(Day, Month, Year - DD/MM/YY)
Sixteen month from 15th September 1999

7. Cost Required for the Budget Period
7a. Ist Year ($): 46,357 2nd Year ($): 16,643 3rd Year:

7b. Direct Cost ($) 63000 Total Cost ($) 71820

8. Approval of the Project by the Division Director of the Applicant

The above-mentioned project has been discussed and reviewed at the Division level as well by the external reviewers. The protocol has been revised according to the reviewer's comments and is approved.

Prof. Lars Åke Persson — Name of the Division Director; Signature

31/8 99 — Date of Approval

9. Certification by the Principal Investigator

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administra tive penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the re-quired progress reports if a grant is awarded as a result of this application.

10. Signature of PI

Date: Aug. 31st 1999

Project title: Prevalence and risk factors for STDs among residents at Tejgaon truck stand.

Abstract summary for the Ethical Review Committee:

Sexually Transmitted Diseases including AIDS have created a major demographic, economic, social and political impact worldwide. The purpose of this project is to estimate the prevalence and risk factors for STDs among adult residents at Tejagon truck stand other than the truck drivers and their helpers. Population under the subgroups will be enlisted through a pilot survey and then 1000 respondents will be selected by systematic random sampling to participate in the project. Data will be collected in three steps: i. Qualitative approach ii. Quantitative survey and iii. Case-referent study.

1. Study subjects for this project will be adult population residing/working in Tejgaon truck stand like motor mechanics, labourers, shopkeepers, brokers, and floating CSWs excluding truck drivers and their helpers. It is important to intervene these subgroups of population because they share sociocultural activities including sexual behaviours and practices as with truck drivers and helpers.

2. The methods of research to be implemented in this project will not create any potential risk to the subjects. However, biological specimen (Urine, blood and vaginal swab) will be collected from the subjects that may cause physical discomfort.

3. Male physician will examine and collect specimen from male participants while female physician will examine and collect specimen from female participants. Physical examination and specimen collection will be done in secured place maintaining privacy and confidentiality.

4. Strict confidentiality will be maintained for the personal information to be collected through the interviews, clinical and laboratory investigations. Concerned project staff and principal investigator of the study will have access to the collected data. Report from the study findings will be prepared with out mentioning any personal identity of the participants.

5. During interviews privacy of the respondents may be invaded to some extend. Both verbal and written consent (Consent form attached) will be taken from the subjects prior to enrollment in the project. The project does not have any plan to withheld any information from the subjects. The respondents will have the right to withdraw their participation from the study any time and it will not create any barrier to seek health advice from the Paricharja clinic.

6. In case-referent part of the study, interviews will be carried out with structured questionnaire with 97 cases (positive for STIs either single or in combination) and 194 referents (negative for any STIs). In-depth interviews will also be carried out with 10 cases and 10 referents. Interview sessions will be conducted at the work place or residence of the respondents and duration for each interview will be approximately 20 minutes.

7. Clinical consultation, medicine for the treatment of STIs and laboratory investigations will be provided to the respondents free of cost. Project health workers will counsel to the subjects on safer sex and other necessary health advice will also be provided as appropriate. Information to be derived from study findings will be useful for the health planners to develop effective control strategies to combat STD/AIDS in the country.

8. Project will require body fluid like blood, urine and vaginal/ cervical swab as mentioned earlier. Collected specimen will be screened in laboratory to diagnose selected STIs namely syphilis, gonorrhea, chlamydial infection and trichomoniasis. Proper diagnosis and treatment of these infections will safe the concerned subjects from probable health complications.

Table of Contents

Check here if appendix is included

Principal Investigator: Last, first, middle Alam Nazmul

PROJECT SUMMARY: Describe in concise terms, the hypothesis, objectives, and the relevant background of the project. Describe concisely the experimental design and research methods for achieving the objectives. This description will serve as a succinct and precise and accurate description of the proposed research is required. This summary must be understandable and interpretable when removed from the main application. (TYPE TEXT WITHIN THE SPACE PROVIDED).

Principal Investigator **Alam Nazmul**

Project Name: **"Prevalence and risk factors for STDs among residents at Tejgaon truck stand."**

Total Budget **$ 63000** Beginning Date: 15th Sept. 1999 Ending Date:

ABSTRACT

Sexually transmitted diseases (STDs) including AIDS have created a major demographic, economical, social and political impact worldwide. The HIV/AIDS pandemic has raised awareness about RTIs with the recognition that many RTIs are linked to the transmission of HIV. In order to reduce the spread of sexually transmitted RTIs, it is essential that individuals at risk understand the modes of transmission, the signs and symptoms, and the fatality of untreated infections. In Bangladesh, several studies conducted and those indicated high STD prevalence in some subgroup population and still relatively low occurrence of HIV. This provides a unique opportunity to combat HIV/AIDS in the country.

Tejgaon truck stand is one of the busiest truck spots in Dhaka City occupied by three thousand drivers along with several thousand other associates like motor mechanics, labourers, shopkeepers, brokers, and floating CSWs. As truck drivers are considered to be a high-risk group for STDs, there is no reason to exclude their associates from this group since they share the same sociocultural activities including sexual behaviours and practices. This study will be conducted on the residents at Tejgaon truck stand excluding the truck drivers and their helpers.

This study will include three steps of data collection namely a qualitative approach, a quantitative survey, and a nested case – referent approach. The present study intends to estimate the prevalence of STDs such as gonorrhoea, syphilis, chlamydial infections and HIV in the study population. Perceptions of sexual risk behaviour and STDs will be explored and assessment will be made for risk factors for STDs in the population at the truck stand. Findings of the study will be useful to formulate recommendations for the national STD/AIDS control programme for further initiatives. Dissemination of the study will be achieved through seminars, recommendations for the policy makers and scientific publications.

Principal Investigator: Last, first, middle _____Alam Nazmul_____

KEY PERSONNEL (List names of all investigators including PI and their respective specialties)

	Name	Professional Discipline/ Specialty	Role in the Project
1.	Nazmul Alam	Microbiologist	Principal Investigator
2.	Josef Bogaerts	Senior Scientist	Consultation in Laboratory test
3.	Md. Yunus	Public Health Scientist	Consultation in field survey
4.	Rubina Shaheen	Epidemiologist	Sample design and data analysis
5.	Sharful Islam Khan	Social Scientist	Design/ monitor/analysis qualitative part
6.	Perwez Salman Chawdhudy	STD specialist/ Dermatologist	Clinical set-up and sample catch-up
7.	Andres de Francisco	Public Health Specialist	Consultation in data analysis and report writing.

DESCRIPTION OF THE RESEARCH PROJECT

Hypothesis to be tested:

Concisely list in order, in the space provided, the hypothesis to be tested and the Specific Aims of the proposed study. Provide the scientific basis of the hypothesis, critically examining the observations leading to the formulation of the hypothesis.

Hypothesis:

i. The prevalence of STDs in the adult population at the truck stand is as high as reported from previous studies on truck drivers.

ii. Risky sexual behaviour is over represented in the residents / working population of the truck stand, increasing the risk of STD transmission.

Specific Aims:

Describe the specific aims of the proposed study. State the specific parameters, biological functions/ rates/ processes that will be assessed by specific methods (TYPE WITHIN LIMITS).

Study Objectives:

a. To estimate the prevalence of selected STDs in an adult population in Tejgaon truck stand other than the drivers and their helpers.

b. To explore the sexual risk behaviour related to STDs in the study population.

c. To describe the health care seeking practices for STDs in the target group.

Background of the Project including Preliminary Observations

Describe the relevant background of the proposed study. Discuss the previous related works on the subject by citing specific references. Describe logically how the present hypothesis is supported by the relevant background observations including any preliminary results that may be available. Critically analyze available knowledge in the field of the proposed study and discuss the questions and gaps in the knowledge that need to be fulfilled to achieve the proposed goals. Provide scientific validity of the hypothesis on the basis of background information. If there is no sufficient information on the subject, indicate the need to develop new knowledge. Also include the **significance and rationale** of the proposed work by specifically discussing how these accomplishments will bring benefit to human health in relation to biomedical, social, and environmental perspectives. (DO NOT EXCEED 5 PAGES. USE CONTINUATION SHEETS).

BACKGROUND:

Sexually transmitted diseases (STDs) including AIDS have created a major demographic, economical, social and political impact worldwide. In 1993 World Bank estimated that STIs alone (excluding HIV) is the second major cause of healthy life loss after maternal morbidity and mortality in women aged 15-45 years. Among men in the same age group HIV ranges considerably higher than other STIs (Guideline for STI control and prevention, ODA, 1996).

Both long and short-term sequelae of untreated RTIs/STIs often cause profound biomedical, social and economic impact on individuals and society. At least two dozen microbial agents and parasites can be transmitted by sexual contact. The best-known sexually transmitted infection, HIV, strikes more than 2.5 million people a year (Islam Q.M, 1996). As evidence builds that infection with other STD pathogen may increase transmissibility of HIV as much as nine fold (Dadian M.J, 1996). Infection with *Neisseria gonorrhoeae* and *Chlamydia trachomatis* causes urethritis and upper reproductive tract infection leading to pelvic inflammatory disease (PID). Untreated gonococcal and chlamydial infection to the pregnant women may cause miscarriage and neonatal pneumonia and ophthalmia neonatorum. Syphilitic infection can cause serious birth defects and neurological disorders. Bacterial vaginosis, most prevalent RTI can cause premature delivery and low birth weight infants.

There is a need to determine not only the prevalence and risk factors of STDs but also the health care seeking behaviour related to these diseases in order to develop effective STD/AIDS control strategies. Nevertheless, in order to develop management guidelines and in order to implement en effective syndromic approach for the treatment and control of STDs information is needed about:

i. Health cares seeking behaviour of STD patients.
ii. Local prevalence/incidence of STIs.
iii. Antimicrobial susceptibility of bacterial pathogens.
iv. Drug availability and distribution system, (Mayaud, 1994).

Relatively little is known about the magnitudes of RTI/STIs in Bangladesh but there is a growing public health concern. Data from a recent study indicates a high prevalence of vaginal candidiasis and Bacterial vaginosis and lower prevalence of 1% of STDs in a rural population (Hawkes S, 1997). Study conducted on 1534 men and women in Dhaka slum indicated the prevalence of syphilis, chlamydial infection and gonorrhoea were 6%, 1.7% and 1% respectively but no infection of HIV were found (Sabin.K, 1998). Data from a brothel based study indicate that 28% of commercial sex workers (CSW) were infected either by *C. trachomatis* or *N. gonorrhoeae* and 57% of these women had past or present history of syphilitic infection (Sarker S, 1998).

A situation analysis of sexual behaviour in Dhaka city revealed a high prevalence of risky practices among various population groups (Hashmi, 1995). Though HIV/AIDS is not yet known to be widespread in Bangladesh, the high prevalence of STDs and identified risky sexual behaviour are factors, which could hasten its transmission.

Truckers are highly vulnerable to HIV/AIDS as a result of having unsafe and uncontrolled sex (S.Alam, 1996). It has been reported that the truck drivers in Bangladesh during over night inter district driving, stop over at different places with brothel and have sex with floating girls and run a great risk (Arco, 1997). One surveillance conducted on 145 truck drivers at Tejgaon and Mirpur Truck stand in Dhaka city has found 15% syphilis and no HIV positive (Barua, 1997)

Studies indicate that India's long-distance truck drivers average 200 sexual encounters per year; at any given time, 70% of them have STDs. Preliminary surveys estimate that almost 33% are infected with HIV. HIV seroprevalence among truckers in Madras requesting HIV testing because they have STDs increased from almost 60% in 1993 to 91% in 1995 (Shreedhar J. 1995). Certain groups in a population including long distance truck drivers and their sex partners have been reported to have a disproportionate effect on the transmission dynamics of STDs including HIV (Nyamuryekunge, 1997). A study in Tamil Nadu, India found three HIV positives among 302 long distance truck drivers in a rural settings (Singh, 1994).

Tejgaon truck stand is one of busiest truck stands in Bangladesh. This stand harbors three thousand trucks, which are being operated by more than three thousand drivers. Almost 70% of those trucks are involved in long distance transport covering the country. To operate such a big activity naturally truck stands are occupied by a group of associates other than truck drivers and their helpers, such as motor mechanics, day labourer (engaged in loading and unloading), machinery/stationary shopkeepers and brokers/office bearers of transport agencies. The presence of a number of permanent and floating CSW is not uncommon in the truck stand.

The study population for this proposed intervention will be the adult population (both male and female) residing and or working at the Tejgaon truck stand other than the truck drivers and their helpers. People residing/working in the truck stand may share similar risk factors for STDs as the long distance, since they live in the same socio-economic setting and share the same social background and life style. Thus the study is proposed to estimate the prevalence of STDs in the study population and to explore the sexual risk behaviour among them.

Research Design and Methods

Describe in detail the methods and procedures that will be used to accomplish the objectives and specific aims of the project. Discuss the alternative methods that are available and justify the use of the method proposed in the study. Justify the scientific validity of the methodological approach (biomedical, social, or environmental) as an investigation tool to achieve the specific aims. Discuss the limitations and difficulties of the proposed procedures and sufficiently justify the use of them. Discuss the ethical issues related to biomedical and social research for employing special procedures, such as invasive procedures in sick children, use of isotopes or any other hazardous materials, or social questionnaires relating to individual privacy. Point out safety procedures to be observed for protection of individuals during any situations or materials that may be injurious to human health. The methodology section should be sufficiently descriptive to allow the reviewers to make valid and unambiguous assessment of the project. (DO NOT EXCEED TEN PAGES, USE CONTINUATION SHEETS).

METHODOLOGY:

Study area:

The study will be carried out at the truck stand of Tejgaon area in Dhaka City. The advantages to conduct this intervention in this area are:

i) Tejgaon truck stand is one of the busiest truck spot in Dhaka city which provides work place for several thousand associated people like motor mechanics, loading unloading labourers, brokers, shopkeepers and a group of CSWs. Population under these subgroups will be included as the study population. Moreover, this truck stand may be a representative of the truck stands in the country.

ii) To use the set up of Paricharja clinic for physical examination and biological sample collection for laboratory investigations.

ii) Paricharja has a basic laboratory set-up that will provide an opportunity for on spot sample processing and to perform microscopic examination detecting endogenous infections.

Sampling frame:

As we did not have the access to background information of the target population needed to the study (eg. sex, age, etc). A pilot survey will be conducted to enlist adult male and female population living/ working in the truck stand prior to recruit for the study. We will use simple random sampling techniques from the list to recruit participants for the study. Men and women sample will be selected according to their percentage in total population. Age for the male sample will be 18 years to 60 years and for female sample 15 years to 49 years. The study area will be divided into four operational blocks based on the equal number of samples.

Sample size calculation:

An estimated prevalence of 10% STDs in residential people at the truck stand would lead to the identification of 100 STD positive cases in 1000 individuals. If exposure to risky sexual behaviour (eg. sex without condom, sex with CSWs) in the cases group is 30% and 15% in referent group then 97 cases and 194 referents are needed for a confidence level of 95% and a power of 80%. The truck stand population is considered to be a more or less mobile group. Given that consideration with 20% absentees and 5% refusal in the study population than speculated sample size will be 1250 individuals. From 1250 individual we expect

1000 respondents to be attended to the clinic that leads to the identification of 97 cases and from the STD negative pool 194 referents will be selected randomly. For case-referent study 97 cases and 194 referents will be interviewed through structured questionnaire.

STUDY DESIGN:

This study will provide an opportunity to estimate both prevalence of STIs and associated risk factors to acquire STDs in the study population. Data collection will be conducted from three stages of the study programme, a qualitative part, quantitative surveys and a case – referent approach. Data to be generated from the quantitative surveys will be used to estimate the prevalence of STDs in study population. Information gathered through the case – referent approach would be useful to define the high-risk behaviour for STDs in the study population.

i) QUALITATIVE APPROACH:

Qualitative component of the study will be completed in two steps with two different objectives. In the first step, two or three focus group discussions and informal verbal communication will be conducted with the representative of the study population in order to understand their perceptions and attitudes towards sexuality, sexual risk behaviour and sexually transmitted diseases. One expert from social and behavioral sciences division of ICDDR,B will organize the focus groups and he will write down the needed information. Information collected from these discussions and communications will be used to formulate the questionnaire for the case referent study. In the second step, ten cases (positive for STD by laboratory screening) and ten referents (negative for STD) will be selected randomly for in depth interviews to have detail idea on perception and attitude towards sexual risk behaviours of these two groups. Comparison will be made on perceived sexual behaviour between two groups in order to define high-risk behaviour for STDs in the study population. Findings of risk behaviour through in depth interviews will be compared with the finding of the case – referent study.

ii) QUANTITATIVE STUDIES:

a. Clinical Examination:

Interviewer employed in the study will invite the participants to attend the clinic for physical examination and treatment. After arrival at the clinic, medical officers will offer full general health screening and a more specifically sexual health screening to each respondent. During clinical check-up participants will be asked to present any symptoms for diseases or any discomfort they have and want to discuss with the physician. Male physician will examine male participants and female physician will examine the female participants. Advice and treatment will be given accordingly with standard medical guidelines. Clinicians will record information on physical condition observed on the participant and will ask a few more added questions defined previously. Clinicians will also collect biological samples (See Appendix-1) for laboratory investigations. Clinical diagnosis will be based on the syndromic approach adapted by WHO and later on modified by Ministry of Health and Family Welfare and National Integrated Population Health Programme (NIPHP) with the title "Technical standard and service delivery protocol for management of RTI/STD". Clinical diagnosis will be validated with etiologic findings in laboratory and patient's treatment regime will then be altered accordingly, if necessary. There will have some odds cases those are not clinically positive but found infected with any STI pathogen during laboratory diagnosis. In those cases effort will be made to provide full treatment according to the clinician's advice by locating them in their resident or work place.

b. Laboratory Investigations:

A 5-cc venous blood specimen will be collected by single-use syringe from all participants and separated serum will be used to perform laboratory test diagnosing syphilitic . . infection. 25 ml first void urine (FVU) from men and cervical swab from women will be collected to test for chlamydial infections and gonorrhoea. Culture and microscopy to diagnose *Trichomonas vaginalis* (TV) will be performed on vaginal swab from women. Laboratory investigations (See Appendix-1) will also include microscopy on vaginal swab from women to diagnose Bacterial vaginosis (BV) and candidiasis if advised by the physician but the findings of these endogenous infections will not be included as a study findings. All laboratory specimens will be stored immediately at -20^0C for further testing. Laboratory personnel engaged in the project will be trained on laboratory analysis of the test and on specimen handling and storage. All laboratory results will be recorded on a pre-structured form. Laboratory tests will be conducted in Laboratory Sciences Division of ICDDR, B except some serological test (RPR and TPHA) for syphilis and microscopy for Candida and Trichomonas to be conducted at Paricharja lab. Commercial kit for both PCR and RPR/ TPHA will be used in laboratory investigation. Quality control of a number of randomly selected samples will be carried out in any established laboratory in home or abroad after being discussed with the consultant.

iii) CASE – REFERENT APPROACH:

a. Case definition:

Cases will be the individuals positive for any of the STIs either single or in combination namely gonorrhoea, syphilis, chlamydial infections and trichomoniasis by laboratory screening. Referents will be the individuals negative for all of the STDs mentioned above. Matching for cases and referents will be done for age (+/- 2 years) and sex. Referent will be selected randomly from the negative STD listed population in each operational block.

b. Interviews:

The same questionnaire will be administered for both cases (n=97) and referent (n=194) selected in the study to collect information on socio-economic status, health care seeking practices, sexual behaviour and practices, use of condoms during sex and knowledge on STDs and HIV/AIDS. Interview will be carried out by male interviewer for the males and by female interviewer for the female. Training will be provided to the interviewers prior to the beginning of the study.

PARTNER NOTIFICATION:

One of the fundamental tools in STD control strategies is sexual partner/s to be treated concurrently. Any person diagnosed with a STD within the study will be advised that his/her partner will also require treatment. The method of partner notification will be one the following:

- The infected client will be asked to bring his/her partner to the clinic. or
- Interviewer/ health assistant will visit the partner in their home to provide medication advised by the clinician. or
- Infected person will be given treatment for him/herself and his/her partners to be taken concurrently.

Since partner notification may be a socially sensitive issue, some of the cases may be reluctant to notify their partner to the study staff in that situation the respondents will be counseled and advised by the physician to ensure treatment to their partner by himself/herself.

Facilities Available

Describe the availability of physical facilities at the place where the study will be carried out. For clinical and laboratory-based studies, indicate the provision of hospital and other types of patient's care facilities and adequate laboratory support. Point out the laboratory facilities and major equipments that will be required for the study. For field studies, describe the field area including its size, population, and means of communications. (TYPE WITHIN THE PROVIDED SPACE).

The advantages to conduct this intervention in this area are:

iii) Tejgaon truck stand is one of the busiest truck spot in Dhaka City. This truck spot provides work place for several thousand associated people like motor mechanic, loading unloading labourers, brokers, shopkeepers and a group of CSWs. Population under these subgroups will be included as the study population. Moreover, this truck stand may be a unique representative of the truck stands in the country.

iv) To use the set up of Paricharja clinic for physical examination and biological sample collection for laboratory investigations.

iii) Paricharja has a basic laboratory set-up that will provide an opportunity for on spot sample processing and to perform microscopic examination detecting endogenous infections.

Data Analysis

Describe plans for data analysis. Indicate whether data will be analyzed by the investigators themselves or by other professionals. Specify what statistical softwares packages will be used and if the study is blinded, when the code will be opened. For clinical trials, indicate if interim data analysis will be required to monitor further progress of the study. (TYPE WITHIN THE PROVIDED SPACE).

Analysis:

Quantitative data to be generated from the three components of this study will be coded and computerized using Fox-pro PC packages. Prevalence for STDs (Syphilis, Chlamydia, Gonorrhoea, Trichomonas) will be calculated for the total study population with EPI Info and SPSS statistical packages. Prevalence rate will be calculated for both male and female group separately. Odds ratios for STDs in relation to different factors (age, sex, marital status, use of condoms during sex and number of sex partners) will be assessed in bivariate and multivariate analyses. Qualitative data to be generated by in-depth interviews will be translated, coded and analysed using appropriate anthropological methods in order to define any possible trends for risk behaviour and STDs.

Ethical Assurance for Protection of Human Rights

Describe in the space provided the justifications for conducting this research in human subjects. If the study needs observations on sick individuals, provide sufficient reasons for using them. Indicate how subject's rights are protected and if there is any benefit or risk to each subject of the study.

Ethical issue:

All respondents will be explained about the purpose of the project prior to enrolment in the study and each participant will then be signed the informed consent paper. Samples collected from the subjects will only be used in the purpose of screening diseases or pathogens as described earlier. Treatment with free medicine will be provided to the respondents detected with any STIs or other infections. Confidentiality of the collected information will be ensured since most of the data are very much personal and sensitive.

Use of Animals

Describe in the space provided the type and species of animal that will be used in the study. Justify with reasons the use of particular animal species in the experiment and the compliance of the animal ethical guidelines for conducting the proposed procedures.

Not Applicable

Literature Cited

Identify all cited references to published literature in the text by number in parentheses. List all cited references sequentially as they appear in the text. For unpublished references, provide complete information in the text and do not include them in the list of Literature Cited. There is no page limit for this section, however exercise judgment in assessing the "standard" length.

References:

1. Adler M, Foster S, Richens J, Slavin H. Health and population occasional paper, Sexual Health and Care: Sexually transmitted infections, Guideline for prevention and control. 1996, p-70.

2. Alam S, Roy B,Islam T. Population assessment on truckers on STD/HIV/AIDS. XI th International conference on AIDS. Vancouver. July 1996.

3. Barua, P.C.A servey of seroprevalence and KAP about STD and AIDS on LDTD in Dhaka city. M.Med.Sc dessertation .1997. The University of Newcastle.Australia.

4. Dadian M.J. Public approaches to STD control. New challenges in the era of AIDS. AIDS Caption. July 1996. Vol.III, No 2 .24-28.

5. Hashmi,S.M., 1995, "Mapping of HIV/AIDS risk population in Dhaka", HIV/AIDS and Mobility; Bangladesh, p 88-94, CCDB, Dhaka, Bangladesh.

6. Islam Q.M. STD: The burden and the challenge. AIDS Captions. May,1996.Vo.3 No-1. 4-7.

7. Mayaund P, Ka-Gina G, Grosskurth H. STD case management in prevention and management of STD in Eastern and Southern Africa. Current approaches and future directions. NSRESA monograph 3, 1994.

8. Nyamuryekunge K, Lankamm U, Vuylsteke B, Mbuya C, Hamelmann C, Dallabetta G, STD services for women at truck stop in Tanjania: evaluation of acceptable approaches. East Afr Med J 1997, Jan 74:6 343-7.

9. Sarker S, Islam N, Durandin F, Siddiqui N, Panda S, Jana S, Corbitt G, Klapper P, Mandal D. Low HIV and high STD among CSWs in a brothel in Bangladesh: Scope for prevention of large epidemic. Int. J STD AIDS, 1998 Jan 9:145-7.

10. Sabin K, Rahman M, Hawkes S, Ahsan K, Begum L, Black R, Baqui A. Prevalence of selected sexually transmitted infections and associated factors in slum communities of Dhaka, Bangladesh. To be submitted to The Journal of Sexually Transmitted Infections.

11. Hawkes Sarah, Francisco A de, Mabey D, Chakraborty J. Reproductive Tract Infections in Rural Bangladesh. (Personal communication).

12. Shreedhar J. AIDS in India. Harvard AIDS Review. 1995. Fall.2-9.

13. Singh,Y.N and Malaviya, A.N. Long distance truck drivers in India: HIV infection and their possible role in disseminating HIV into rural area. Int. J.STD AIDS 1994. 5:2 137-8.

Dissemination and Use of Findings

Describe explicitly the plans for disseminating the accomplished results. Describe what type of publication is anticipated: working papers, internal (institutional) publication, international publications, international conferences and agencies, workshops etc. Mention if the project is linked to the Government of Bangladesh through a training programme.

Dissemination and Policy implications:

- Data to be obtained from this study will be disseminated in scientific forum through seminars and publications in scientific journals.
- Findings from this study will be useful to formulate recommendations for the National STD/AIDS control programme for further initiatives and actions.

Principal Investigator: Last, first, middle _____Alam Nazmul_____

Collaborative Arrangements

Describe briefly if this study involves any scientific, administrative, fiscal, or programmatic arrangements with other national or international organizations or individuals. Indicate the nature and extent of collaboration and include a letter of agreement between the applicant or his/her organization and the collaborating organization. (DO NOT EXCEED ONE PAGE)

The study involves co-investigators from Laboratory Sciences Division (LSD) of ICDDR,B, Social & Behavioral Sciences Programme (SBSP) of PHSD, ICDDR,B and 'Paricharja', a national level NGO. Paricharja will provide their Clinical and Laboratory based set-up to conduct the study. This organization has been in operation along with their clinical set-up at Tejgaon truck stand for more then two years, where the study population is located.

Principal Investigator: Last, first, middle Alam Nazmul

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

Name	Position	Date of Birth
Nazmul Alam	Research Officer, RHP, PHSD ICDDR, B,; Dhaka, Bangladesh	8th January, 1968

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location	Degree	Year	Field of Study
University of Dhaka	M.Sc	1994	Microbiology
LSHT&M and UCL	Certificate in Training	1997	Medical Microbiology

Research and Professional Experience

Concluding with the present position, list, in chronological order, previous positions held, experience, and honours. Indicate current membership on any professional societies or public committees. List, in, chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **(DO NOT EXCEED TWO PAGES. USE CONTINUATION SHEETS).**

Work experience :

a) Product Officer (June,1994 to August,1995) Burrough Wellcome & Co (BD) Ltd.

b) Research Officer (Sept. 1995 to August.1997) RTI Project at ICDDR,B.
   i. Screening and confirmation of serum samples for syphilis, detection of *Chlamydia trachomatis* and HSV antigens using ELISA, microscopy and culture for gonorrhea including confirmation and sensitivity testing and microscopy for the diagnosis of vaginal infections (Candidiasis, Trichomoniasis and Bacterial vaginosis).
   ii. Establishment of procedures for the long-term storage and preservation of clinical samples and isolates.

c) Research Officer (September, 1997 to date) Reproductive Health Program, PHSD,ICDDR,B
   i) Review, field test, translation and prepare guideline of questionnaire for 'Male involvement in reproductive health' project. Evaluation of sub-centre level male clinics at Matlab and develop recommendations to increase male flow to the clinic.
   ii) Assist Acting programme head in report writing (Annual work plan, Periodic progress report etc.) for the donors on 'Male Involvement in Reproductive Health project'.

Training :

a) "HIV/AIDS peer educator's" training programme from 31st August to 1st September, 1998.
b) "Introductory course on Epidemiology and Biostatistics" from 16th February to 12th March, 1998, at ICDDR,B.
c) "Laboratory diagnostics of RTIs and STIs including molecular aspects(PCR and LCR) and tissue culture techniques from 6th October, 1997 to 8th January, 1998 at University College London (UCL) Hospitals and London School Hygiene & Tropical Medicine (LSH&TM), UK.
d) "English language course for academic trainee" from 6th July to 4th September 1997 at British Council, Dhaka and band score 6.5 was obtained in IELTS.
e) "Bench methodologies on RTI/ STIs laboratory diagnosis" from September, 1995 to December, 1995 ,in ICDDR,B by Trevor Sykes, Consultant Microbiologist, University College London Hospitals.

Presentation:

- *Alam Nazmul*, Islam Shamim Sufia, Ahmed Farid, Gausia Kaniz, de Francisco Andres, Hawkes Sarah. "Comparison of laboratory and clinical diagnoses of Bacterial Vaginosis: Can simple clinical criteria be used in PHC level."(Abstract) Proceedings for 6th Annual Scientific conference on" Reproductive tract infections and Sexually transmitted infections" in ICDDR, B, held on 8th-9th March,1997.

- J. Chakroborty, *Alam Nazmul*, Shaha P, Ahmed Farid, de Francisco Andres "Role of male clinic to promote reproductive health issues: The Matlab experience." (Abstract). Proceedings for 8th Annual Scientific conference in ICDDR,B, held on 12-14th Feb,1999.

- de Francisco Andres, Hall Andy, *Alam Nazmul*, Azim Tasnim, "Perinatal transmission of Hepatitis-B virus in rural Bangladesh" (Abstract). Proceedings for 7th Annual Conference (ASCON- VII) in ICDDR, B, held on 14th and 15th February,1998.

Publications :

Alam Nazmul, Bengali writing on "AIDS: Concerns All": Shasta Shanglap, News letter of ICDDR,B. December 1996. 3; 1-2.

Paper accepted:

i. de Francisco Andres, Hall Andy, *Alam Nazmul*, Azim Tasnim "Hepatitis-B infection in rural Bangladeshi mothers and babies". Submitted to 'South East Asian Journal of Tropical medicine and Public Health'.

Membership :

Bangladesh Graduate Microbiologist Association (BGMA)

A brief introduction of the co-investigators involved in the projects.

-Josef Bogaerts*MD, PhD
Senior Scientist, LSD. ICDDR,B

-M. Yunus* MBBS, MPH.
Acting Head
Reproductive Health Programme, PHSD, ICDDR, B

-Rubina Shaheen*MBBS, M.Med.Sc
Senior Medical Officer, RHP, PHSD, ICDDR,B.

-Sharful Islam Khan* MBBS, MHSS
Research Fellow, SBSP, PHSD. ICDDR,B

-Parwez Salman Choudhury† MBBS, DD.
Executive Director, Paricharja

-Andres de Francisco* MD, MPH, PhD
Senior Public Health Specialist. Global Forum for Health Research, Geneva.

*International Centre for Diarrhoeal Disease Research, Bangladesh
†Paricharja, 12/C Asad Avenue, Mohammed Pur, Dhaka.

Principal Investigator: Last, first, middle _____Alam Nazmul_____

Detailed Budget for New Proposal

Project Title: **"Prevalence and risk factors for STDs among residents at Tejgaon truck stand."**

Name of PI: **Alam Nazmul**

Protocol Number: Name of Division: Public Health Sciences Division

Funding Source: **SDC** Amount Funded (direct): $ 63000 Total: $ 71820 Overhead (%) 12%

Starting Date: 15th September 1999 Closing Date:

Strategic Plan Priority Code(s):

Sl. No	Account Description	Salary Support			US $ Amount Requested		
	Personnel	Position	Effort%	Salary	1st Yr	2nd Yr	Total
01	Dr. Rubina Shaheen	Sr. Med. Officer (NOB)	8%	841	841		
02	New recruitment	Medical Officer (NOA)	50%X2	635	7620		
03	New recruitment	Research Investigator (NOA)	100%	635	7620	2540	
04	N/R	Sr. Lab. Technician (GS IV)	100%	267	3204	534	
05	N/R	Interviewer (GS III)	100%X2	224	5376		
06	Mr. Farid Ahmed	Sr. Programmer (NOA)	8%	635	320	320	
07	Shamim Sufia Islam	Coding Assistant (GSIII)	16%	283	283	283	
	Sub Total					**28941**	
	Consultants				1000		
	Local Travel				250	250	
	International Travel					3000	
	Sub Total					**4500**	
	Supplies and Materials (Description of Items)						
1.	Medicine				1000		
2.	Lab. Supplies: Reagents and Chemicals				9000	8366	
3.	Equipment: Microcentrifuge, Freezer, PC with Printer and UPS				5193	1000	
4.	Stationary Supplies				1000		
	Sub Totals					**27559**	

	Other Contractual Services			
	Repair and Maintenance			
	Rent, Communications, Utilities	**250**	**250**	
	Training Workshop, Seminars	**250**	**250**	
	Printing and Publication	**400**	**100**	
	Staff Development	**250**	**250**	
	Sub Total		**2000**	

	Interdepartmental Services	**1st Yr**	**2nd Yr**	**3rd Yr**
	Computer Charges			
	Pathological Tests			
	Microbiological tests			
	Biochemistry Tests			
	X-Rays			
	Patients Study			
	Research Animals			
	Biochemistry and Nutrition			
	Transport	**250**	**250**	
	Xerox, Mimeographs etc.	**250**	**250**	
	Other contractual	**500**	**500**	
	Sub Totals		**2000**	
	Other Operating Costs			
	Capital Expenditure			

TOTAL DIRECT COST **$63000 (Sixty three thousand dollars only)**

Principal Investigator: Last, first, middle _____Alam Nazmul_____

Budget Justifications

Please provide one page statement justifying the budgeted amount for each major item. Justify use of man power, major equipment, and laboratory services.

One epidemiologist will be recruited to help develop strategies for sample recruitment and on possible mode of data analysis.

Two medical officers (one male and one female) will be needed for medical data collection including physical examination, biological sample collection and for providing treatment for detected illnesses.

Research Investigator will be the over all in charge to the project and will specifically involved with the plan and implementation of the interventions for the project. He will design and supervise data collection tools in clinic, laboratory, and in case-referent interviews. He will organize data analysis, data interpretations and report writing for the project. Principal Investigator of the project may take over the position.

One Sr. Laboratory Technician will be recruited to conduct laboratory investigations. Two interviewers will be needed to conduct pilot survey, interviews for the case- referent study and partners notification for STD cases. Two man/months from Data entry technician and one man/month from a programmer will be required for data entry, management and analysis.

The study will provide free medicine to the respondents with STDs and other general illnesses diagnosed by physicians. Budget is allocated for laboratory reagents and chemicals needed for the screening STD pathogens. To process the biological specimens like blood and urine a centrifuge is required. To conduct microscopy and other laboratory investigations, equipment are needed like Microscope, however, while using
the set-up of LSD, ICDDR, B, it is possible to share some of the existing laboratory equipment to be used for PCR and Western blotting. One PC will be procured to provide backup for data entry, analysis and other secretarial activities of the project.

Fund is allocated for the clinic charge where clinical examination and specimen collection from respondents and for possible transport in home and abroad during data collection and dissemination of study findings. Fund is also allocated for miscellaneous activities including interdepartmental services, stationery supplies and printing job.

Principal Investigator: Last, first, middle _____Alam Nazmul_____

Other Support

Describe sources, amount, duration, and grant number of all other research funding currently granted to PI or under consideration. (DO NOT EXCEED ONE PAGE FOR EACH INVESTIGATOR)

N0t Applicable

Appendix 1:

LABORATORY INVESTIGATION TO BE UNDER TAKEN:

Organism	Sample site	Method
1. *N. gonorrhoeae*	Cervical swab (women) Urine (men)	Polymerase Chain Reaction (PCR)
2. *C. trachomatis*	Cervical swab (women) Urine (men)	PCR
3. *T. pallidum*	Blood	RPR & TPHA
4. *T. vaginalis*	vaginal swab	Microscopy/ Culture
5. *C. albicans*	v. swab	Microscopy
6. Bacterial vaginosis	v. swab	Microscopy*

* Nugent's scoring system will be used to diagnose BV during microscopic examination. Nugent's scoring method is shown in below:

Morphotype/points	0	1	2	3	4
Lactobacillus	4+	3+	2+	1+	0
Gardenella/Anaer rod	0	1+	2+	3+	4+
Mobiluncus	0	1+	2+	3+/4+	4+

1+ = <1Morphotype (Average in five field)
2+ = 1-5 Morphotypes
3+ = 6-30 Morphotypes
4+ = >30 Morphotypes

Score 1-3 is considered as normal, score 4-6 is considered as intermediate and score 7-10 is considered as BV.

Appendix 2.

TIME FRAME FOR THE STUDY:

Interventions	1st m	2 m	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Quantitative survey i. Pilot survey ii. Clinical Check-up iii. Laboratory Invest.	+	+	 + +	 + +	 + +	 + +	 + +	 + +	 + +	 + +	 + +	 + +	 + +	 + +		
Qualitative Interviews i. Focus group ii. In-depths					 +						 +	 +				
Case referent approach					+			+			+			+		
Data entry and analysis						+			+			+		+	+	
Report writing and dissemination															+	+

Principal Investigator: Last, first, middle _____Alam Nazmul_____

APPENDIX-3

International Centre for Diarrhoeal Disease Research, Bangladesh
Voluntary Consent Form

Title of the Research Project:

Principal Investigator:

Before recruiting into the study, the study subject must be informed about the objectives, procedures, and potential benefits and risks involved in the study. Details of all procedures must be provided including their risks, utility, duration, frequencies, and severity. All questions of the subject must be answered to his/ her satisfaction, indicating that the participation is purely voluntary. For children, consents must be obtained from their parents or legal guardians. The subject must indicate his/ her acceptance of participation by signing or thumb printing on this form.

We are informing you to participate in a study on reproductive health to be conducted by ICDDR,B. Problems in reproductive system can cause many health complications in both men and women especially lower abdominal pain, infertility and neonatal complications to females and infertility in males. Some of the infections of reproductive tract remain asymptomatic for at least a period of time, especially in women. So we are requesting to participate in the current study even you don't have any signs and symptoms of diseases.

If you are interested to join the study we would invite to give your consent on the following activities describe below.

1. One physician will ask you some questions on your reproductive health and he/she (male physician for male and female physician for female) will examine your general health especially your reproductive health. Physician will examine in and out side of your reproductive tract and he/she will also collect some specimen for testing in the laboratory to ensure whether you have any infections. Biological specimen will include blood, urine (for men) and cervical/ vaginal smear (for women). Physician will not do anything that can impair your fertility in no way as this is not the objective of the project.

2. One health worker may ask you some additional question on your reproductive health and will give you health advises if you need.

Results from all examinations will keep secret. The respective clinician and principal investigator for the study will only be informed the results of the examination. If you are detected with any diseases that need to be treated then the clinician will provide you the free of cost medicine.

We can affirm you that the involvement to the project is completely depend if your wish to and if you do not involve in the project then that will no way hamper your care seeking to the clinic later.

If you have any question on this project please do not hesitate ask to the physician and health workers. Thank you for your cooperation.

I agreed to join the project after knowing all explanations.

Signature of Investigator/ or agents
Date:

Signature of Subject/ Guardian
Date:

আর্ন্তজাতিক উদারাময় গবেষণা কেন্দ্র, বাংলাদেশ

Prevalence and Risk Factors for STDs Among Residents adult Population at Tejgaon Truck Stand

সম্মতি পত্র

আমরা আপনাকে আই সি ডি ডি আর বি পরিচালিত প্রজনন স্বাস্থ্যের উপর একটি গবেষনা কার্যে অংশ গ্রহণ করার জন্য অবগত করছি। প্রজনন তন্ত্রের কোন সমস্যা পুরুষ এবং মহিলার উভয়ের জন্য স্বাস্থ্য জটিলতার সৃষ্টি করতে পারে, তাদের মধ্যে মহিলাদের তলপেটে ব্যথা , সন্তান জন্মদানের অক্ষমতা ও নবজাতকের চোখের সমস্যা এবং পুরুষদের সন্তান উৎপাদনের অক্ষমতা অন্যতম । বিশেষত: মহিলাদের ক্ষেত্রে প্রজনন তন্ত্রের কোন কোন সংক্রমন দীর্ঘদিন পর্যনত কোন লক্ষন ছাড়াই থেকে যেতে পারে । কাজেই আপনার প্রজনন তন্ত্রের কোন লক্ষন না থাকলেও আমরা আপনাকে এই গবেষনা কার্যক্রমে অংশ গ্রহণ করতে অনুরোধ করছি। যদি আপনি এই কার্যক্রমে অংশ গ্রহণ করতে রাজি থাকেন তবে আমরা নিম্নে উল্লিখিত কার্যক্রমে আপনার সম্মতি কামনা করছি ।

১। একজন চিকিৎসক আপনার প্রজনন স্বাস্থ্যের উপর কিছু প্রশ্ন জিজ্ঞাসা করবেন এবং তিনি পুরুষ অংশ গ্রহণকারীর জন্য পুরুষ চিকিৎসক এবং মহিলা অংশ গ্রহণকারীর জন্য মহিলা চিকিৎসক) আপনার সাধারন স্বাস্থ্য বিশেষ করে প্রজনন তন্ত্র পরীক্ষা করবেন। চিকিৎসক আপনার প্রজনন তন্ত্রের ভিতর ও বাহির পরীক্ষা করবেন এবং ল্যাবরেটরীতে পরীক্ষা করে রোগ নির্ণয় করার জন্য আপনার কাছ থেকে কিছু নমুনা (specimen) সংগ্রহ করবেন । এই জৈব নমুনার মধ্যে থাকবে, পুরুষদের কাছ থেকে রক্ত এবং মুত্র এবং মহিলাদের কাছ থেকে রক্ত এবং সারভাইক্যাল / ভ্যাজাইনাল স্মেয়ার ।

২। একজন স্বাস্থ্যকর্মী আপনার প্রজনন স্বাস্থ্যের উপর কিছু প্রশ্ন জিজ্ঞাসা করবেন এবং আপনার দরকার হলে আপনাকে কিছু স্বাস্থ্য উপদেশ দিবেন।

আপনার কাছ থেকে সংগৃহীত তথ্য এবং নমুনার পরীক্ষাকৃত ফলাফল সম্পূর্ণ গোপন রাখা হবে । পরীক্ষার ফলাফল শুধুমাত্র নির্ধারিত চিকিৎসক এবং গবেষনার মুখ্য পর্যবেক্ষক শুধু অবগত থাকিবেন । যদি আপনার কোন রোগ নির্নীত হয় যার চিকিৎসা দরকার তখন চিকিৎসক আপনাকে ব্যবস্হাপত্র দিবেন এবং বিনামূল্যে ঔষধ প্রদান করিবেন।

আমরা আপনাকে আশ্বস্ত করছি যে , এই প্রকল্পে অংশ গ্রহণ সম্পূর্ণ আপনার ইচ্ছার উপরে নির্ভর করে এবং আপনি যদি এতে অংশ গ্রহণ না করেন তবে "**পরিচর্যা**" ক্লিনিকে পরবর্তীতে আপনার চিকিৎসা গ্রহন কোন ক্রমেই বাধাগ্রস্হ হবে না।

এই প্রকল্প সম্পর্কে আপনার যদি আরও কোনকিছু জানবার থাকে তা কোন সংকোচ ছাড়াই চিকিৎসক বা সংশিলষ্ট স্বাস্থ্যকর্মীকে জিজ্ঞাসা করতে পারেন ।আপনার সহযোগীতার জন্য আপনাকে ধন্যবাদ।

আমি সমস্ত বিবরন জানার পর সম্পূর্ণ স্বইচ্ছায় এই প্রকল্পে অংশ গ্রহণ করতে সম্মত হয়েছি ।

স্বাক্ষর ..... তারিখ ঃ.....

(অংশ গ্রহণ কারীর স্বাক্ষর /টিপসহি/নাম)

প্রত্যক্ষদর্শীর স্বাক্ষর ..... ১।

..... ২।

সাক্ষাতকার গ্রহণকারীর স্বাক্ষর..... তারিখ ঃ.....

Principal Investigator: Last, first, middle _____Alam Nazmul_____

APPENDIX-4

RTI study in Tejgaon truck stand.

Laboratory form

Study No: ----------
Lab ID : ----------

Date at test done: ----------

1. **Syphilis:**

RPR	:	Positive	☐
		Negative	☐
TPHA	:	Positive	☐
		Negative	☐

2. **Neisseria gonorrhoeae:**

Microscopy	:	Positive	☐
		Negative	☐
Culture	:	Positive	☐
		Negative	☐
PCR	:	Positive	☐
		Negative	☐

3. **Chlamydia trachomatis:**

PCR	:	Positive	☐
		Negative	☐

4. **Trichomonas vaginalis**

Microscopy	:	Positive	☐
		Negative	☐
Culture	:	Positive	☐
		Negative	☐

5. **Bacterial vaginosis:**

Microscopy	:	Normal	☐
		Intermediate	☐
		BV	☐

6. **Candida** :

Microscopy	:	Positive	☐
		Negative	☐

Signature

- Questionnaire for the Case- Referent study is not included because according to the protocol focus group discussions with the representative of the study population will provide useful information to pose appropriate questions in order to achieve the study objectives. However, the questions will cover general socioeconomic information, present and past reproductive health illnesses, health care seeking practice and sexual behaviours of respondents.

Principal Investigator: Last, first, middle _____Alam Nazmul_____

Check List

After completing the protocol, please check that the following selected items have been included.

Face Sheet Included	✓
1. Approval of the Division Director on Face Sheet	✓
3. Certification and Signature of PI on Face Sheet, #9 and #10	✓
4. Table on Contents	✓
5. Project Summary	✓
6. Literature Cited	✓
7. Biography of Investigators	✓
8. Ethical Assurance	✓
9. Consent Forms	✓
10. Detailed Budget	✓

R-1

I reviewed the study proposal entitled "Prevalence and risk factors for STDs among residents at Tejgaon truck stand." The proposal describes a multi-faceted study that will include a qualitative component, a quantitative survey and a case-referent study.

The subject of the study is important and scientifically obtained results will be useful in assisting the national STD/HIV program to develop programs to reach certain sectors of the population.

However, there are several issues that should be considered before funding this study.

- A study of a very similar nature was just completed in the Tejgaon truck stand by researchers associated with BRAC and the University of Alabama-Birmingham. There is no mention of this study in the protocol and it should be made clear that the present study will essentially be replicating a previous study in some degree, namely in estimating STD prevalence rates, estimating care seeking behaviors and evaluating syndromic management for this population.

- Assuming that repeating an earlier study is good science, and I believe it is, the fact that Paricharja has a clinic in this truck stand makes the site unusual compared to other truck stands in the city and the country. The presence of a clinic biases the study population to one that ostensibly has access to treatment and some health information by proximity to a clinic that aims to serve this population. I think that this bias should be addressed and that claims that this population is representative of other truck stands in the country or even the city should be dropped.

- A listing of residents of the truck stand was developed by the UAB researchers. Much time could be saved if the present group could obtain the list.

- Where did the estimated STD prevalence of 10% come from? This seems like a reasonable estimate but does it include RTIs such as candida and bacterial vaginosis?

- The qualitative component is described as the first part of the study and refers to interviews with cases and referents. How will these individuals be identified prior to collection of specimens and laboratory testing? It seems that a less systematic sampling system for respondents in this part of the study needs to be developed. The second step of the qualitative study mentions that it will be performed after the laboratory testing is completed. I think that the first step will necessarily not have cases and referents participating.

- Why will trichomonas not be included in the study findings? It is understandable to omit candida but trichomonas is a STD, not an endogenous infection.

- Would it be possible to retain age and gender of the cases after unlinking specimens for HIV testing? This would provide very useful information while retaining the anonymity of the respondent.

- I strongly urge the researchers to collect information about recent and distal percutaneous exposures of the respondents. HIV and syphilis are also blood borne pathogens and transmission by exposure to a needle stick, even within the health care system is very possible. (See Luby et al 1997 from Pakistan). Furthermore, since you are collecting blood specimens, it would be useful to test for hepatitis B chronic (HBsAg) infection and history of infection (anti-HBc). It remains unclear how much sexual transmission of hepatitis B there is in Bangladesh but that is a question that could possibly be addressed by this study.

- Informing a sexual partner of a partner's infection is important public health practice. However, it should be made clear to the infected individual that the partner will probably be able to find out who the reporting person was, should the participant choose to permit study staff to contact their partner.

- It would be very important to allow the respondents to report their symptoms prior to confirmation by physical examination. There is no survey instrument attached to the protocol so it is difficult to establish whether appropriate questions will be posed to meet the study objectives about health care seeking behavior or estimating high risk sexual behaviors.

- The sample size paragraph is confusing. It would seem that the researchers will interview 1250 individuals to obtain 97 cases and 194 controls (referents). Does this mean that they will interview 1250 individuals in the quantitative survey portion of the study and hope that they will derive 100 cases from that survey? If so, this is acceptable. If not, they should clarify why they will interview 1250 people for a case-referent study of 300 persons.

- The cases and referents are not stratified by gender in this protocol. That seems to me to be a big problem. In studies I have done and read, men have uniformly higher rates of infections than women in non-CSW populations. I understand that women will be sampled according to their proportion in the population. However, I believe that women should be over-sampled to achieve statistical power for the female population.

- The medical officers will have to examine about 4.5 patients per day to complete the study in 14 months. The interviewers will have to perform a similar number of interviews in this time period. This seems reasonable if the

interviewers are not waiting for the examinations to be completed before finding their next respondent.

- Is there any plan to obtain quality control testing for chlamydia and gonorrhea in another lab? Will the lab be using commercial kits or an in-house protocol? Commercial kits will obviate some of the need for external quality control.

- There are two problems with the time frame. One, it is unclear why the case-referent study is only performed every three months. Will cases and referents be re-interviewed and this is the rough time-frame foreseen for a critical number of cases to make interviewing worthwhile? Will all cases identified in the initial survey be enrolled as cases for the case-referent study? Will the referents be drawn from the uninfected individuals identified by the initial survey? If so, what infections will constitute the case definition? I think a clear case definition needs to be established *a priori*. Also, any matching criteria or selection process for obtaining the referents should be clearly laid out *a prior*. Otherwise, this is a cross-sectional survey with cases and controls obtained simultaneously and any associations uncovered will have to be couched in very careful language. For example, if the case definition includes RPR(-)/TPHA(+) persons, these people will be prevalent cases and the odds ratio becomes in appropriate as a measure of association. The correct measure is the prevalence ratio.

- Finally, I think it is dangerous to leave data entry and analysis until the 13th month of the study. Data entry and data cleaning should be on-going to catch mistakes as they happened, when they are still correctable. It would be preferable to have a part-time data entry person working for 11 months rather than a full-timer working for three.

Quality of the project	High/medium
Adequacy of project design	High
Suitability of methodology	High
Feasibility within time period	High
Appropriateness of the budget	High
Potential value of field of knowledge	High/medium

I think the quality of the project could be improved by addressing some of the issues raised in this review. I am unsure of potential value to the field because this appears to be a very similar study to one that was just completed in the same population.

I support the application with qualification on technical grounds that the case definition for the case-referent study be clearly defined and that other issues raised herein be adequately addressed.

R-2

Prevalence and risk factors for STDs among residents at Tejgaon truck stand

Main point:

This is a worthwhile study which is identifying an often overlooked group at possible high risk of STI/HIV transmission. The hypothesis, study objectives and rationale are all clearly stated, potentially achievable and appropriate. My main concern lies with the sample sizes and the size of the entire population. I would suggest that there is a little more clarity needed on how sample sizes were calculated for each part of the study, and what the exact numbers required for each of the 3 parts of the study will be.

Minor points:

1. How many people will be included in the quantitative studies? Is it the 1000 mentioned in the sample size calculation?
2. What is the purpose of the clinical exam? Why not collect serological samples, urine specimens (for diagnosis of chlamydia and gonorrhoea in both men and women) and self-administered vaginal swabs? The sample collection methodology used by Keith Sabin et al could be useful here. Clinical examination lowers the participation rate, and its expected outputs are not clear from this study. It cannot be used to 'validate' syndromic management as written in the proposal - the laboratory findings can only be used to confirm or refute the diagnosis, not the management strategy.
3. *Trichomonas vaginalis* is NOT an endogenous infection. Why are TV and candida not to be included in the morbidity survey? They can contribute a substantial fraction of the RTI burden in women especially.
4. Is it possible to test for HSV as well as HIV?
5. How many people will be interviewed using the case-referant approach?
6. How will follow-up be conducted? If clinical diagnosis is at odds with laboratory results, how will the infected and untreated participants in the study be located?
7. Budget:

- What are the roles of the research investigator and the research assistant?
- Why is there no funding for a laboratory post? Who will carry out the sample processing in the lab?
- What is the 'clinic charge'?

- What is 'miscellaneous'?

8. What diagnostic criteria will be used for BV?
9. Will TV be cultured? If not, why not?

Response to Reviewer-1:

I am grateful with the reviewers for realizing the importance of the protocol and providing with few quarries and suggestions. I will answer their concern point by point.

- It is true that researchers from BRAC and UAB recently conducted study at the Tejgaon truck stand. The study population for their intervention was primarily the women at reproductive age residing nearby slum (within ½ km) at the Tejgaon truck stand. Later on they included truck drivers as their study population for an added intervention. While the study population for our study will be the male and female residing/working in the truck stand (motor mechanics, loading unloading labour, brokers, shopkeeper and floating CSWs) excluding the truck drivers themselves. As because the hypothesis of our proposed study is to prove that the prevalence and risk factors for STDs in people residing/working at the truck stand is as high as found in truck drivers.

  Another distinctive feature for this proposed study is the cases-referent approach that will help us to define risk factors for STDs in the study population. Hence, the proposed study obviously will not be the repetition to the study conducted at the Tejgaon truck stand, rather, there will be an distinct advantage to compare the prevalence and risk of STDs in both truck drivers and their associates working in the same setting.

- Paricharja has been in operation with a clinic in the Tejgaon truck stand since December 1996. The study population selected for the study is considered as a high-risk group for STDs which need to be explored from public health point of view. Using the set-up of Paricharja would definitely make the process much more feasible outlying disadvantages. Behavioral change due to the presence of 'Paricharja' clinic would be marginal if any, as the clinic has been in operation for just over 2 years only.

- We will definitely use the listing of residents of the truck stand prepared by UAB scientist if it covers all our study population and I hope partially it will.

- Estimated prevalence of STDs (10%) in the truck stand population is quoted personal communication with Dr. Parwez Choudhury, Executive Director, Paricharja. He is a co-Investigator to the UAB study as well as ours one.

- First part of the qualitative study will be 'focus group discussions' and information gathered from this part will be used to formulate questionnaire for the case referent study. Cases and referents will not be used as respondents in this part of the study. Cases and referents will be selected when laboratory component is completed in each operational block.

- Changes have been stated to the proposal accordingly under 'Laboratory Investigation' heading.

- Thanks to the reviewer for this nice suggestion. I think it is possible to retain the age and gender while unlinking the specimen for HIV testing. The process might compromise a bit to the strength of the anonymity but it does not affect to the ultimate objectives of the technique. Changes have been made to the protocol under 'Unlinking for HIV testing' heading.

- Effort will be made to collect information about recent and distal percutaneous exposure by setting questions on case-referent questionnaire approach. As we will collect 5cc venous blood specimen from each respondent so could be considered screening for Hep-B markers if budget permits.

- Reviewer's concern about the partner's notification is well taken. However, I think it will not be a big problem to address the issue through proper counseling to the respondents and their partners. In this case, participants will be free to communicate their partners whether through study staff or of their own. Clarification has been stated in the protocol under heading 'Partner notification'.

- Clarification has been made under ' Qualitative survey' heading of methodology section. Questionnaire for case-referent survey will be finalized after conducting the focus group discussion part of qualitative components.

- Clarification has been made to the Sample size calculation and sample selection for interviewing in case-referent study under 'Sample size' heading.

- It is mentioned in the protocol that the men and women will be sampled according to their proportion in the study population. Analysis on both prevalence and case-referent study will be done stratifying gender. Men and women sample may be adjusted after getting list of study population from pilot survey to achieve adequate statistical power.

- Stated in the Laboratory Investigation section of the protocol under 'Laboratory Investigation' heading.

- The reviewer's concerned with interviewing the cases and referent in every three months is well taken. In fact, we shall select cases and referents after having laboratory results to be prepared so in every three months we will suppose to come up with a reasonable number of cases and referents in each operational block to conduct quantitative interviews. Definition for cases and referents are mentioned in the proposed proposal. Cases will be laboratory based positive for STDs (GC, Chlamydia, and Syphilis, either single or in combination). Syphilis positives will be selected as a case when both RPR & TPHA are positive.

- Thanks the respondent to alert about the late data entry. Data entry will be done continuously by a part time Data entry technician. Changes have shown under 'Time frame for the study' heading.

Response to the reviewers 2:

I am grateful to the reviewer for realising the importance of the study and raising some quarries. I will answer them point by point.

1. The concern about the sample size is well taken however, in the proposal we clearly mentioned that sample is calculated taking in an account with 10% expected prevalence (Personal communication with Dr. Pervez, Co PI to the study conducted at the truck stand by UAB scientist) in order to select 97 cases (definition provided in the protocol) for STDs with 90% confidence and 80% power. Given that assumption sample size should be 1000 and taking into account the 25% attrition the speculated sample will be 1250.

2. The quantitative study will involve 1000 participants for clinical and laboratory investigation with the aim to define 97 cases. Then interview for cases-referent study will be conducted with 97 cases and 194 referents (selected randomly from the STD negative pool).

3. The concern about the usefulness of the clinical check-up is important. The suggestion is good it might be cost effective and less time consuming. But I think in current perspective clinical checkup will somehow encourage the participants to attend the clinic since they will find opportunity to consult the physician with their perceived illnesses if any, with free of cost medication. Clinical check up will help to collect health information by physician and enhance the quality of specimen collection in the clinic.

4. *Trichomonas vaginalis* will be screened in women and analysis will be done accordingly but the pathogen will not screen in male as urethal swab will not be collected in men while detecting TV from urine is less sensitive.

5. Interview for cases-referent study will be conducted with 97 cases and 194 referents (selected randomly from the STD negative pool).

6. Sera to be collected initially for the HIV and Syphilis testing but effort will be made to perform screening for HSV and Hep-B virus markers if budget allows. However, there are few studies conducted quantifying the prevalence of Hep-B markers in both rural and urban setting but yet to be published (Sarah Hawkes and Kith Sabin's study)

7. Reviewers concern about the follow up for the laboratory positive odds cases with clinical diagnosis is well taken as they need to be treated. Our plan is to locate them at their residents by the health workers and they will be asked to take medication as prescribed by the physicians. This part is incorporated in the protocol under Clinical examination' heading.

8. ※ Research Investigator will be the over all in charge of the project and will specifically involved with the plan and implementation of the interventions for the project. He will design and supervise data collection tools in clinic, laboratory, and in case-referent interviews. He will organize data analysis, data interpretations and report writing for the project. Principal Investigator of the project may take over the position.

   Research Assistant will actually be involved in the laboratory based activities. He/she supposes to be a graduate Microbiologist. The designation for Research Assistant may be changed as Senior Laboratory Technician.

   ※Clinic Charge is the cost for utilizing the set up of the clinic that can be paid thorough sharing the personnel cost, updating clinic set-up etc.

   ※Title 'Miscellaneous' will be changed as interdepartmental cost and stationary supplies in the RRC protocol format.

9. Bacterial Vaginosis will be diagnosed in the laboratory using the Nugent's criteria established by Nugent's et al .(Describe in the Appendix-1)

10. TV will be screened in women by Microscopy and culture of vaginal swab clarification is stated in the protocol under 'Laboratory Investigation heading'.