THE AETIOLOGY OF REPRODUCTIVE TRACT INFECTIONS AMONG WOMEN ATTENDING THE BANGLADESH WOMENS HEALTH COALITION AND THE MARIE STOPES CLINIC SOCIETY CLINICS IN TAAN BAZAR AND DHAKA, BANGLADESH

BOGAERTS JOZEF
AND OTHERS

1998-039

Attachment 1

Date: 31 December 1998

(FACE SHEET) **ETHICAL REVIEW COMMITTEE, ICDDR,B**

Principal Investigator: J. BOGAERTS

Application No. 98-039

Title of Study: The aetiology of reproductive tract infections among women attending the Bangladesh Women's Health Coalition and the Marie Stopes clinic facility clinic in Tejgaon Dhaka and Dhaka, Bangladesh

Trainee Investigator (if any): _____

Supporting Agency (if Non-ICDDR,B) _____

Project Status: _____

[X] New Study

[ ] Continuation with change

[ ] No change (do not fill out rest of the 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) Minor or persons under guardianship — Yes (No)

2. Does the Study Involve:
   (a) Physical risk to the subjects — Yes (No)
   (b) Social risk — Yes (No)
   (c) Psychological risks to subjects — Yes (No)
   (d) Discomfort to subjects — (Yes)
   (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 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 the study — (Yes) No
   (b) Procedures to be followed including alternatives used — (Yes) No
   (c) Physical risk — (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 parents or guardian (if subjects are minor) — 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 with 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. Example 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 Committee 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.

J BOGAERTS

Principal Investigator

Trainee

Principal Investigator: Last, first, middle _____

International Centre for Diarrhoeal Disease Research, Bangladesh

RESEARCH PROTOCOL

FOR OFFICE USE ONLY
Protocol No: 98-039 Date: 15-12-98
RRC Approval: Yes/ No Date:
ERC Approval: Yes/ No Date:

1. Title of Project (Do not exceed 60 characters including spaces and punctuations)
The aetiology of reproductive tract infections among women attending the Bangladesh Women's Health Coalition and the Marie Stopes Clinic Society clinics in Taan Bazar and Dhaka, Bangladesh.

2a. Name of the Principal Investigator(s) (Last, Middle, First).	**2b. Position / Title**	**2c. Qualifications**
Bogaerts Jozef	Senior Scientist	MD, PhD, DPH

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

4. **Contact Address of the Principal Investigator**
4a. Office Location:
Laboratory Sciences Division
GPO BOX 128
Dhaka 1000 Bangladesh

4 b. Fax No: 880-2-872529
4 c. E-mail: bogaerts@cis.icddrb.org
4 d. Phone/Ext: 880-2-871751-60 Ext 2410

5. **Use of Human Subjects**	**5a. Use of Live Animal**	**5 b. If Yes, Specify Animal Species**
Yes [x]	Yes [ ]	
No [ ]	No [x]	

6. **Dates of Proposed Period of Support** ***(Day, Month, Year - DD/MM/YY)***

7. **Cost Required for the Budget Period**
7a. 1st Year **($):** 204,469 ***2nd Year*** **($):** 158,996 ***3rd Year($):*** 89,246

7b. **Direct Cost ($):** 452,711 **Total Cost ($):** 452,711

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.

Name of the Division Director — Signature — Date of Approval: 14/12/98

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 administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

10. Signature of PI J BOGAERTS

Date:

Principal Investigator: Last, first, middle _____

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☐ Check here if appendix is included

Principal Investigator: Last, first, middle _____

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
Bogaerts Jozef

Project Name
The aetiology of reproductive tract infections among women attending the Bangladesh Women's Health Coalition and the Marie Stopes Clinic Society clinics in Taan Bazar and Dhaka, Bangladesh.

Total Budget : 452,711 USD Beginning Date: as soon as funds are available Ending Date: after two years
4

HYPOTHESIS

According to currently available evidence, reproductive tract infections (RTI), including sexually transmitted infections (STI), are highly prevalent among female sex workers (SW) in Bangladesh. RTI are highly prevalent among women from the general population but STI are rare. Although infection with the human immunodeficiency virus (HIV) has been spreading at a high rate among SW in neighbouring countries such as India and Myanmar, the prevalence of HIV infection is tought to be less than 1% among SW in Bangladesh.

OBJECTIVES

1. To determine the aetiology of RTI/STI among female SW and women from the general population attending the Bangladesh Women's Health Coalition (BWHC) clinic in Taan Bazar, Narayanganj, and the Marie Stopes Clinic Society (MSCS) clinics in Dhaka, Bangladesh.
2. To identify risk factors associated with RTI/STI.
3. To validate the syndromic treatment of RTI.
4. To test for HIV infection.

BACKGROUND

Evidence from previous reports suggests that RTI/STI are common among SW in Bangladesh but very little attention has been paid to appropriate diagnosis and treatment of the diseases. Condom use remains very low despite the numerous health education programmes. The prevalence of HIV infection among SW has been estimated at less than 1%. Offering an accessible and non-prejudicial medical service to SW, together with health education, has proven to be effective in reducing the incidence of STI and HIV infection in other countries.
Population and clinic-based studies, both in rural and urban Bangladesh, demonstrated recently a high prevalence of RTI but a low prevalence of STI among women from the general population. This resulted in overtreatment for STI, stressing the need for improving the syndromic approach.

DESIGN AND METHODS

A cross-sectional sample of SW and women from the general population attending the BWHC clinic in Taan Bazar, Narayanganj, and the MSCS clinics in Dhaka, will be included in the study. All women will be interviewed for symptoms and risk factors associated with RTI/STI. A clinical examination will be performed and symptoms of RTI/STI will be noted. Laboratory tests for the diagnosis of bacterial vaginosis and infection with *Treponema pallidum, Neisseria gonorrhoeae, Trichomonas vaginalis, Chlamydia trachomatis, Haemophilus ducreyi,* herpes simplex virus, human papillomavirus and yeasts will be performed. Women presenting with clinical symptoms of RTI will receive a syndromic treatment. If necessary, treatment will be adapted to laboratory findings. HIV testing will be unlinked and anonymous. Unlinking will be done by removing all personal identifying features from the sample and testing will be performed at the end of the study. The presence of hepatitis B and C infections will also be detected.

Principal Investigator: Last, first, middle _____

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

Name	Professional Discipline/ Specialty	Role in the Project
1.Bogaerts Jozef	MBBS, Microbiologist	Principal Investigator, ICDDR,B
2.Tasnim Azim	MBBS, Immunologist	Co-Investigator, ICDDR,B
3.Ahmed Julia	MBBS	Executive Director, Medical BWHC
4.Nazneen Akhter	MBBS	Director , Medical BWHC
5.Yasmin Ahmed	MBBS	Country Director, MSCS
6.Najmul Hussein	MBBS	Programme Manager, MSCS

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.

1. The prevalence of RTI/STI is high among female SW attending the BWHC clinic in Taan Bazar, Narayanganj, and the MSCS clinics in Dhaka. RTI are highly prevalent among women from the general population visiting the same clinics but STI are rare.

2. RTI/STI are significantly related to the presence of risk factors.

3. The syndromic management of vaginal discharge has a low sensitivity and specificity, even among SW.

4. The prevalence of HIV infection is low among female SW in Bangladesh.

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).

The study aims to document the prevalence and aetiology of RTI/STI as well as the prevalence of HIV, hepatitis B and C infections among SW and women from the general population attending the above mentioned clinics. Clinical and laboratory parameters will be used for the diagnosis of RTI/STI. HIV infection will be assessed by detection of specific antibodies to HIV.

Specific parameters: symptoms of vaginal discharge, cervicitis, genital ulcers, genital warts, suprapubic parasites, and inguinal lymphadenopathy

Laboratory methods: see Research Design and Methods

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).

In developing countries, SW and their clients are responsible for sustaining and spreading STI in the community. Targeting these groups will have a greater impact on the prevalence of STI in the community than programmes that focus on the general population. If STI can be controlled in these groups can be kept free of STI, these diseases should decline in the entire population (1-2).
It has been demonstrated that clinic-based interventions, consisting of health education, condom promotion and free medical care, can result in a decline of HIV infection and STI among SW (3). Such interventions are highly cost-effective since they will identify a high number of infections and will prevent the spread of the diseases through early treatment. However, the success of such programmes will be determined by the availability of effective drugs or condoms and the assurance of privacy and confidentiality.
Very little data exist on the prevalence and aetiology of STI among SW in Bangladesh (4). SW are highly stigmatized and have no access to primary health care facilities, which serve almost exclusively married women and their children. Therefore, SW seek treatment outside the formal sector. As a consequence, STI infections are treated by health care providers who have received little or no training in STI management.

The city of Narayanganj (pop, 300,000) is a river port situated at 35 km from Dhaka and houses a large number of SW. The SW live in the brothel of Taan Bazar, the commercial area of the city. The number of SW permanently residing in the brothel is estimated at 3,500 -7,000. The BWHC started working with SW in 1994. The purpose of the programme was to improve the health status of the SW. The specific objectives were to give comprehensive reproductive health care, to promote condom use and to increase awareness about early care seeking for RTI. The programme incorporates SW as peer educators and involves the whole community of SW. In January 1995 the BWHC opened a clinic in front of the central market and the brothel. The clinic became fully operational in May 1996 and provides care to both the general population of Taan Bazar and the SW.

MSCS Bangladesh is affiliated with Marie Stopes International in London. The mission of MSCS is to improve the reproductive health and well being of both women and men. MSCS provides services primarily to female factory workers, sex workers and their clients as well as women of the lower income group. MSCS operates two clinics in Dhaka. After having conducted a survey in early 1996, MSCS started working with floating female sex workers through the two clinics. In collaboration with CARE-Bangladesh, a comprehensive programme for the prevention of HIV infection among floating SW in Dhaka was carried out during December 1996-March 1997. CARE-Shakti provides education and counselling to the floating SW with peer educators whereas clinical services are provided by MSCS at the two clinics and four satellite clinics.

Since laboratory facilities are not available in the BWHC or MSCS clinics, RTI/STI are diagnosed and managed according to the WHO syndromic management, which depends on patient's history and physical examination (5).

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).

DESIGN

Study sites
The BWHC clinic in Taan Bazar, Narayanganj, and the MSCS clinics in Dhaka, Bangladesh.

Recruitment of women
Women attending the respective clinics for medical care will be included in the study . Recruitment will be done by selecting women after registration, in order of arrival at the clinic and before any interview or physical examination has been performed. A maximum number of 10 women will be included in the study per day at each setting. Information will be given on the purpose of the study. The number of women refusing participation as well as the reason for refusal will be noted. Written consent will be required by signing a preprinted consent form (see further). Illiterate clients will be requested to give a finger-print.

METHODS

Interview
During the behaviour surveillance of the National HIV Surveillance Programme, conducted in 1998, it was demonstrated that SW in Taan Bazar are over-surveyed which had led to a "fatigue" towards interviewing. The interviews showed that condom use is very low among SW (C. Jenkins, personnal communication). Therefore, SW will only be interviewed on their clinical history and the interview will be conducted by the doctor. Women from the general population will be extensively interviewed in the clinic by a social worker. All interviews will be done before the performance of any physical or laboratory examination. Besides general questions on age, religion, educational status, income etc... specific questions will be asked on risk factors for RTI/STI **(Appendix 1 and 2)**.

Clinical diagnosis
After the interview a general clinical examination and an examination of the genitals, including a bimanual pelvic examination with speculum, will be performed by the doctor. Speculum examination will be performed before the bimanual pelvic examination. During speculum examination the presence of vaginal discharge and the condition of the cervix will be noted. The external cervix will be cleaned with a sterile gauze before taking samples from the endocervix. Only the presence of yellow pus on the endocervical swab will be considered as indicating cervicitis. During the general clinical examination special attention will be paid to the presence of lymphnodes and signs of secondary syphilis. Clinical findings will be noted onto a standard examination form **(Appendix 3)**.

Laboratory diagnosis

The laboratory methodology is summarized below. Swabs for the culture of *N.gonorrhoeae* and *H.ducreyi* will be directly plated onto selective media. Fresh examination for yeasts and *T.vaginalis* will be done in the respective clinics. Laboratory features will be recorded on a special form **(Appendix 4).**

Disease/pathogen	Parameters
Bacterial vaginosis	Gram-staining on vaginal fluid *
N.gonorrhoeae	Culture of *N.gonorrhoeae* from endocervix, urethra, rectum and pharynx**
T.pallidum	Serum antibody (RPR and TPHA), fluorescence microscopy on ulcers
T.vaginalis	Direct microscopic examination of vaginal fluid
C. trachomatis	Antigen detection in endocervix (PCR)
Yeast infection	Direct examination/Gram-staining of vaginal fluid
HIV	Serum antibody (latex or ELISA, Western Blot)
Hepatitis B	HBsAg, anti-HBc, HBe in serum (ELISA)
Hepatitis C	anti-HCV (ELISA), Line immuno assay, PCR
H.ducreyi	Culture /PCR on ulcer
Herpes simplex virus	PCR on vesicle/ulcer
Human papillomavirus	DNA hybridization test on cervical cells

* The Nugent criteria will be used for the diagnosis of bacterial vaginosis (6)
** culture of rectum and pharynx will only be performed for SW

In vitro susceptibility testing of *N.gonorrhoeae* will be performed routinely using the disk diffusion method. Typing and minimum inhibitory concentrations will be determined at regular intervals, depending on the number of isolates obtained over time. HIV testing will be unlinked and anonymous. Unlinking will be done by removing all identifying features from the sample after blood drawing. Testing will be done at the end of the study.

Treatment

Women presenting with clinical symptoms of RTI/STI will receive a syndromic treatment according to the flowcharts described in **Appendix 5**. Only women with yellow mucopus on the endocervical swab will receive treatment for cervicitis. Women with a positive microscopic examination for *T.vaginalis* will receive appropriate treatment on the first day. Women with a positive examination for yeast cells will receive specific treatment only when they are symptomatic. Partners of women from the general population are requested to attend the clinic for treatment. Treatment will be free of cost to the clinics.

Follow-up

All women will be invited to return to the clinic on the 7th day after the first visit. The women will be informed of the results of the syphilis tests, culture of *N.gonorrhoeae* or *H.ducreyi* and PCR test for *C.trachomatis*. If needed, treatment will be modified according to laboratory findings.

Women with a reactive RPR test on the first day, irrespective of the result of the TPHA test, will be requested to return after 3, 6, 9 and 12 months for assessment of the RPR titre. If any discordance is observed between the results of the RPR and TPHA tests on the first day, a second blood sample will be taken on day 7.

Women with genital ulcers will be requested to return on days 14, 21 and 28 for assessment of ulcer healing. Additional blood sampling will be performed on day 14 and 28.

Home visits or visits to the brothel will be organized to trace women not returning for follow-up.

SAMPLE SIZE

Sex Workers

According to available information, at least 40% of the SW will have a gonococcal/chlamydial infection and 5% will have a genital ulcer. For assessment of the prevalence of a gonococcal/chlamydial infection the minimum number of women to be included in the study will be **369** (5% precision, 95% confidence level). For validation of the syndromic management of vaginal discharge (70% sensitivity, 10% precision) 81 proven gonococcal/chlamydial infections are required (7). So, the minimum number of SW to be included for validation of the syndromic management will be 81/0.40=**203**.

Women from the general population
According to the results of a recently performed clinic-based study (unpublished data), approximately 3% of the women will have a gonococcal/chlamydial cervicitis. For assessment of the prevalence of gonococcal/chlamydial cervicitis the minimum number of women to be included will be **456** (2% precision, 95% confidence level). For validation of the syndromic management of vaginal discharge (70% sensitivity, 10% precision) the minimum number to be included will be 81/0.03=**2,700**.

LIMITATIONS AND DIFFICULTIES OF THE PROPOSED PROCEDURES

1. The study will only estimate the prevalence and aetiology of RTI/STI among SW attending the BWHC and MSCS clinics for medical care, not among SW living in the brothel or floating SW in Dhaka. Similarly, the prevalence of RTI/STI among women from the general population attending the clinics does not reflect the prevalence of the diseases among the population.

2. The questionnaire considers strictly private matters. The interviewers must be able to create a faithful relationship with the women.

3. Frequent load shedding may reduce the yield of *N.gonorrhoeae* and *H.ducreyi* and prevents microscopic examination for *T.vaginalis* and yeast infections

4. Problems with landlords and pimps may hamper clinic visits and follow-up of SW.

5. Political strikes (hartals) may delay the implementation of the study.

6. Since screening for HIV antibodies will be unlinked and anonymous, no correlation between risk factors and results of laboratory tests can be made a posteriori.

7. Basic health care facilities are almost exclusively attended by married women and their children. Unmarried women which are possibly more exposed to STI rarely visit these clinics and cannot undergo speculum examination.

ETHICAL ISSUES

No special diagnostic procedures or any hazardous materials will be used. Treatment of RTI/STI conforms to international guidelines (8). A single dose of 1 g azithromycin has proven to be highly effective in the treatment of chancroid, uncomplicated gonorrhoea and *C.trachomatis* infections (9-11). Data obtained during the interview are strictly confidential. Since unlinked anonymous testing for HIV infection will be carried out on blood samples drawn for other purposes such as syphilis serology, it is not necessary to inform each individual that blood may be tested for HIV. This is an internationally used method, conform with existing guidelines on human rights in biomedical research (12).

SAFETY PROCEDURES

Only sterile and disposable needles and syringes will be used. Disposable vaginal specula will be used. A workshop on universal precautions for blood-borne pathogens will be held for all staff members of the NGO clinics.

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 study will be carried out in the BWHC clinic in Taan Bazar, Narayanganj, and the MSCS clinics in Dhaka. In addition to a small room for microscopic examination, the support required in these clinics will be: an incubator and refrigerator, a microscope, microscopic slides and cover slips, a dropper with fysiologic water, immersion oil, cotton swabs, dacron tipped swabs, transport medium for *C.trachomatis* , disposable gloves, needles, syringes, toilet paper, tongue depressors, selective culture media for *N.gonorrhoeae* and *H.ducreyi*, jars for storage and transport of culture media, refrigerator, pens and waterproof markers, sparadrap, registers, questionnaires, clinical examination forms, laboratory forms, vaginal speculums, medicines. Interview will be performed in a separate room and total privacy.
The following facilities will be required in ICDDR,B: sufficient laboratory and office space, the medium preparation room, store room for equipment and reagents, incubators, candles and candle jars, microscope, Gram staining solutions, catalase and oxidase reagent, microscopic slides and cover slips, ingredients for the preparation of Thayer Martin agar, PCR kits for the diagnosis of *C.trachomatis*, Perkin Elmer PCR cycler, glucidisks and monoclonal antibodies for the identification of *N.gonorrhoeae*, nitrocefin disks for screening of the in vitro susceptibility, skim milk, refrigerator, deepfreezer at -80 C, sterile vials for the preservation of strains, warm water bath, RPR and TPHA kits, micropipettes with tips, multichannel pipettes with tips, serological pipettes, ELISA washer or aspiration pump, ELISA reader, UPS, computer with data base software and statistical programmes for data analysis, printer.

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).

Data will be analyzed using the statistical packages Epi-Info, Version 6, Centers for Disease Control and Prevention, Atlanta, Ga, USA or any other suitable statistical programme.
The advice of a specialist in biomedical statistics will be requested before starting the study and, if necessary, for helping in data analysis.

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.

After explanation of the aim of the study (see below), written consent will be obtained from all women included in the study. Since diagnosis will be performed according to standard methods and since recommended treatment regimens will be used, women attending the study have no higher risk for adverse reactions than other women. Unlinked and anonymous testing for HIV is an internationally used method, conform with existing guidelines on human rights in biomedical research. Clinical and laboratory data will be strictly confidential. Medical officers and any other medical personnel not directly involved in the study will have no access to the patient files which will be kept separately in the respective clinics. Named information will not be available to the health authorities.

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.

Animals will not be used.

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.

1. Brunham R. The concept of core and its relevance to the epidemiology and control of sexually transmitted diseases. Sex Tansm Dis 1991; 18: 67-68.

2. Over M, Piot P. HIV infection and sexually transmitted diseases. In: Jamison DT, Mosley WH, Measham AR, Bobadilla JL, eds. Disease control priorities in developing countries. New York: Oxford University Press, 1993: 445-529.

3. Laga M, Alary M, Nzila N, Manoka AT, *et al.* Condom promotion, sexually transmitted diseases treatment, and declining incidence of HIV-1 infection in female Zairian sex workers. Lancet 1994; 344: 246-248.

4. Sarkar S, Durandin F, Mandal D, Corbitt G, Islam N. High STD and low HIV prevalence among commercial sex workers (CSWs) in a brothel in Bangladesh: scope for prevention. *In*: Sixth Annual Scientific Conference. Programme and Abstracts, ICDDR,B, Mohakhali, Dhaka 1997, p. 37.

5. World Health Organization. Report of a study group : management of patients with sexually transmitted diseases. WHO Technical Report Series 810, Geneva 1991.

6. Nugent RP, Krohn MA, Hillier SL. Reliability of diagnosing bacterial vaginosis is improved by a standardized method of Gram stain interpretation. J Clin Microb 1991; 29: 297-301.

7. Vuylsteke B, Meheus A. In: Gina Dallabetta, Marie Laga, Peter Lamptey, Eds. Control of Sexually Transmitted Diseases. A handbook for the design and management of programs. Chapter 8. STD Syndrome Management. AIDSCAP/Family Health International 1996; p. 149-168.

8. 1993 Sexually transmitted diseases treatment guidelines. MMWR 1993; vol. 42.

9. Ridgway GL. Azithromycin in the management of *Chlamydia trachomatis* infections. Int J STD AIDS 1996; 7 (Suppl.1): 5-8.

10. Ballard RC, Ye H, Matta A, Dangor Y, Radebe F. Treatment of chancroid with azithromycin. Int J STD AIDS 1996; (Suppl.1): 9-12.

11. Waugh MA. Azithromycin in gonorrhoea. Int J STD AIDS 1996; 7 (Suppl.1): 2-4.

12. Council for International Organisations of Medical Sciences. Proposed international guidelines for biomedical research involving human subjects. CIOMS and WHO 1982; p.35-50.

Principal Investigator: Last, first, middle _____

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.

It is planned to present the results of this research in both internal an international conferences and to publish the data in an international journal.

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)

This study involves programmatic arrangements with the Bangladesh Women's Health Coalition and the Marie Stopes Clinic Society, which are non-governmental organizations based in Dhaka, Bangladesh.

Principal Investigator: Last, first, middle _____

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
Bogaerts Jozef	Senior Scientist	22 March 1949

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

Institution and Location	Degree	Year	Field of Study
Katholieke Universiteit Leuven, Leuven, Belgium	MBBS	1975	Medicine
Katholieke Universiteit Leuven, Leuven, Belgium	Clinical Biologist	1979	Clinical chemistry Microbiology
Institute of Tropical Medicine, Antwerp, Belgium	Diploma in Medical and Veterinary Mycology	1978	Mycology
Université Pierre et Marie Curie, Paris, France	Diploma in Statistics for Medicine and Biology	1991	Statistics
Katholieke Universiteit Leuven, Leuven, Belgium	Doctor in Medical Sciences	1995	Microbiology
Université Henri Poincaré, Nancy, France	Diploma in Public Health	1996	Public Health

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).**

Microbiologist at the Laboratoire Universitaire de Butare, Rwanda, Université Nationale du Rwanda, 1979-1980

Microbiologist at the Public Health Laboratory of Groningen and Drenthe, Groningen, the Netherlands, 1980-1981

Microbiologist and Head of the Laboratory of the Centre Hospitalier de Kigali, Kigali, Rwanda, 1981-1994

Desk officer at the Belgian Administration for Development Cooperation, Brussels, Belgium, 1994-1995

Senior Scientist, Laboratory Sciences Division, ICDDR,B, 1996-

Membership of scientific Societies

American Society for Microbiology.

Belgian Society for Tropical Medicine.

Principal Investigator: Last, first, middle _____

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
Tasnim Azim	Associate Scientist	22 September 1956

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

Institution and Location	Degree	Year	Field of Study
University of Dhaka, Bangladesh	MBBS	1983	Medicine
University of London, UK	PhD	1988	Immunology

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).**

Associate Scientist, Virology, Laboratory Sciences Division, ICDDR,B

Membership of scientific Societies

British Society for Immunology

Society for Mucosal Immunology

Bangladesh Society for Immunology

Principal Investigator: Last, first, middle _____

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
Ahmed Julia	Deputy Director, Medical Bangladesh Women's Health Coalition	11 November 1962

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

Institution and Location	Degree	Year	Field of Study
Sofia Higher Medical Academy, Sofia, Bulgaria	MBBS	1989	Medicine

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).**

In service training from Mymensing Medical College Hospital, 1990-1991

Medical Officer, BAPSA (Bangladesh Association for Prevention of Septic Abortion), 1991-1993

Medical Officer, Proshika, Urban Poor Development Programme Section,1993-1994

Deputy Director, Coalition Special Reproductive and Sexual Health Project, Bangladesh Women's Health Coalition (BWHC), 1994-1996

Executive Director, Medical BWHC, 1996-

Principal Investigator: Last, first, middle _____

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
Nazneen Akhter	Director, Medical Bangladesh Women's Health Coalition	1 March 1964

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

Institution and Location	Degree	Year	Field of Study
Chittagong University	MBBS	1988	Medicine
Dhaka University, National Institute of Prevention and Social Medicine	Diploma in Maternal and Child Health and Family Planning	1992	

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).

General practitioner

Medical Officer, Unity Through Population Services

Community Development Officer, Health Programme Manager, Terre des Hommes, the Netherlands

Director, Medical Bangladesh Women's Health Coalition

Principal Investigator: Last, first, middle _____

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
Yasmin Ahmed	Country Director Marie Stopes Clinic Society Bangladesh	23 July 1958

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

Institution and Location	Degree	Year	Field of Study
Dhaka University, Bangladesh	MBBS	1983	Medicine

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).**

In service training from Dhaka Medical College, 1983-1984

Medical Officer, Dhaka Medical College ,1984-1986

Medical Officer, Rehabilitation Institute and Hospital for the Disabled ,1986-1987

Consultant and Research Co-ordinator, Bangladesh fertility Research Programme , 1987-1990

Assistant Director, Bangladesh Institute of Research for Promotion of Essential and Reproductive Health and Technologies, 1990-1994

Country Director, Marie Stopes Clinic Society, 1994-

Principal Investigator: Last, first, middle _____

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
Najmul Hussein	Programme manager Marie Stopes Clinic Society Bangladesh	28 September 1955

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

Institution and Location	Degree	Year	Field of Study
Dhaka University, Bangladesh	MBBS	1982	Medicine

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).**

Medical Officer, Government of the Islamic republic of Iran, 1983-1988

Assistant Co-ordinator, Bangladesh Institute of Research for Promotion of essential and Reproductive Health and Technologies, 1989-1992

Medical Officer, Training Immunizers in the Community Approach Project, 1992

Urban Operations Officer, Expanded Programme on Immunization of USAID, 1992-1994

Programme Manager, Marie Stopes Clinic Society, 1994 -

Principal Investigator: Last, first, middle _____

International Centre for Diarrhoeal Disease Research, Bangladesh
Voluntary Consent Form

Title of the Research Project: The aetiology of reproductive tract infections among women attending the Bangladesh Women's Health Coalition and the Marie Stopes Clinic Society clinics in Taan Bazar and Dhaka, Bangladesh.

Principal Investigator: Bogaerts Jozef

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.

ENGLISH VERSION:

We are going to perform a study on reproductive tract infections among women attending this clinic. This study will help us to obtain information about the prevalence of different types of infections and their causes. The results of this study will improve the quality of our health care. When you will attend the study we will ask you some questions concerning your health. Some questions are very personal. You are free to answer these questions. All information will be strictly confidential . After obtaining information from you, a physical examination will be performed including a vaginal examination. A sample will be taken from your genital tract but your uterus will remain clean. In addition 10 ml blood will be drawn today from the vene of your arm for the diagnosis of syphilis. Samples obtained from you will be sent to the laboratory for examination. The results of these tests will be communicated next week. If there is any discordance in the test results we'll request you to give an additional sample on the seventh day after the first visit for confirmation of the first result. Even if you don't want to participate in this study, or if you want to leave the study during follow-up, you can continue to use the services of this clinic.

BANGLA VERSION: will follow

Signature of Investigator/ or agents
Date:

Signature of Participant
Date:

আন্তর্জাতিক উদারাময় গবেষণা কেন্দ্র, বাংলাদেশ
সম্মতি পত্র

এই ক্লিনিকে যেসব মহিলারা চিকিৎসা নিচ্ছে আমরা তাদের প্রজনন তন্ত্রে রোগের উপর একটি বৈজ্ঞানিক জরীপ শুরু করতে যাচ্ছি। এই গবেষণা মহিলাদের প্রজনন তন্ত্রের বিভিন্ন রকম রোগের প্রাদূর্ভাব ও তার কারণ সমূহ সম্পর্কে তথ্য উদ্‌ঘাটন করতে সাহায্য করবে। এই গবেষণার ফলাফল আগামীতে উন্নতর স্বাস্থ্য সেবা প্রদানে বিশেষ অবদান রাখবে বলে আমরা আশা করি। আপনাকে এই গবেষণায় অন্তর্ভূক্তির জন্য অনুমতি চাচ্ছি।

যদি আপনি এই গবেষণার অন্তর্ভুক্ত হতে সম্মত হন, তা হলে আপনাকে স্বাস্থ্য সম্পর্কিত কিছু প্রশ্ন করা হবে। কিছু কিছু প্রশ্ন থাকবে খুবই ব্যক্তিগত, এক্ষেত্রে আপনি চাইলে উত্তর নাও দিতে পারেন। আপনার দেওয়া সব তথ্যই গোপন রাখা হবে। আপনার থেকে তথ্য গ্রহনের পর জরীপের কাজ হিসাবে আপনার যোণীপথসহ শারিরীক পরীক্ষা করা হবে এবং যোনীপথ থেকে নমুনা সংগ্রহ করা হবে কিন্তু জরায়ু স্পর্শ করা হবে না। এ ছাড়া সিফিলিস সনাক্ত করার জন্য আপনার হাতের শিরা থেকে ১০ মিঃলিঃ (দুই চামুচ পরিমান) রক্ত সংগ্রহ করা হবে। আপনার থেকে যেসব নমুনা সংগ্রহ করা হবে সেগুলো পরীক্ষার জন্য গবেষণাগারে পাঠানো হবে। পরীক্ষার ফলাফল পরবর্তী সপ্তাহে আপনাদের জানানো হবে। যদি পরীক্ষার ফলাফল ত্রুটিপূর্ণ হয় তাহলে ফলাফল ত্রুটিমুক্ত করার জন্য আপানাকে প্রথম রক্ত গ্রহণের সাত দিন পরে আবার নমুনা দিতে হবে। আপনি যদি এই গবেষণায় অংশগ্রহণ নাও করতে চান অথবা গবেষণার মাঝে ফলো আপ কালীন সময় অংশগ্রহণ থেকে বিরত থাকেন, তবুও এই ক্লিনিকের সেবা আপনাকে যথারীতি প্রদান করা হবে।

আপনি যদি এই গবেষণায় অংশগ্রহণে সম্মত থাকেন, তা হলে আপনাকে নীম্নে নির্দ্দিষ্ট স্থানে আপনার স্বাক্ষর প্রদান বা বাম হাতের বৃদ্ধাঙ্গুলির টিপ সহি প্রদান করার জন্য অনুরোধ করছি।

আপনার সহযোগিতার জন্য ধন্যবাদ।

গবেষকের স্বাক্ষর
তারিখঃ

অংশগ্রহণকারীর স্বাক্ষর
তারিখঃ

সাক্ষীর স্বাক্ষর
তারিখঃ

Principal Investigator: Last, first, middle _____

Detailed Budget for New Proposal

Project Title: The aetiology of reproductive tract infections among women attending the Bangladesh Women's Health Coalition and Marie Stopes Clinic Society clinics in Taan Bazaar and Dhaka, Bangladesh.

Name of PI: Bogaerts Jozef **Budget Code**

Protocol Number: **Name of Division**: LSD

Funding Source: BADC **Amount Funded** (direct): **Total**: USD **Overhead** (%)

Starting Date: as soon as funds are available **Closing Date**: after 36 months

Strategic Plan Priority Code(s) :

Sl. No	Account Description	Salary Support			US $ Amount Requested		
	Personnel	**Position**	**Effort%**	**Salary (month)**	**1st Yr (6 mths)**	**2nd Yr (12 mths)**	**3rd Yr (6 mths)**
	Interviewer (2x)	GS-3	100	162	1,944	3,888	1,944
	Senior research officer (1x)	GS-6	100	470	2,820	5,640	2,820
	Medical officer/trainer (3 x)	NOA	100	657	11,826	23,652	11,826
	Research officer (1x)	GS-5	100	361	2,166	4,332	2,166
	Research officer (2 x)	GS-4	100	220	2,640	5,280	2,640
	Laboratory attendant (1 x)	GS-1	100	177	1,062	2,124	1,062
	SUBTOTAL				**22,458**	**44,916**	**22,458**
	International costs						
	Consultants (all costs)						5,000
	Investigations overseas					5,000	5,000
	SUBTOTAL					**5,000**	**10,000**
	Local travel						
	Staff				2,000	4,000	2,000
	Transport specimens				3,000	6,000	3,000
	SUBTOTAL				**5,000**	**10,000**	**5,000**
	International travel						
	Investigators						5,000
	Transport specimens abroad					1,000	1,000
	SUBTOTAL					**1,000**	**6,000**
	Supplies and Materials						
	Drugs				1,900	3,802	1,900
	Office supplies				2,000	4,000	2,000
	Laboratory supplies				17,506	35,013	17,506
	SUBTOTAL				**21,406**	**42,815**	**21,406**

Principal Investigator: Last, first, middle _____

	Other contractual services			
	Repair and maintenance	3,500	7,500	3,500
	Renovation ICDDR,B	10,000		
	Rent/Renovation BWHC	1,000	2,000	1,000
	Rent/Renovation MSCS	1,000	2,000	1,000
	SUBTOTAL	**15,500**	**11,500**	**5,500**
	Interdepartmental services			
	Computer charges/communications	1,000	3,000	1,875
	Lab charges/utilities (lyophilisation, incineration)	4,890	9,780	4,890
	Office supplies/medical illustration	2,000	4,000	2,000
	Maintenance	3,500	7,000	3,500
	Training and workshops	2,000	2,000	2,000
	SUBTOTAL	**13,390**	**28,780**	**16,390**
	Capital expenditures			
	ICDDR,B	107,000		
	SUBTOTAL	**107,700**		

	Transport costs on supplies, materials and capital expenditures (35%)	44,942	14,985	7,492
	SUBTOTAL	**44,942**	**14,985**	**7,492**
	TOTAL OPERATING COST	**204,469**	**158,996**	**89,246**
	Overhead %			
	TOTAL PROJECT COST			**452,711**

Principal Investigator: Last, first, middle _____

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.

The estimated budget represents the following costs:

1. Consumables, equipment and infrastructure: the space of a new laboratory will be used for this study. All reagents and equipment will be purchased on the budgetcode assigned to the study protocol.

2. Office supplies (computer, printer, UPS) are available but not in sufficient number.

ABSTRACT SUMMARY

The aetiology of reproductive tract infections among women attending the Bangladesh Women's Health Coalition and the Marie Stopes Clinic Society clinics in Taan Bazar and Dhaka, Bangladesh.

1. Study population

The study population will consist of female sex workers and women from the general population attending the Bangladesh Women's Health Coalition and the Marie Stopes Clinic Society clinics in Taan Bazar and Dhaka.
It will not consider any special group not being able to give voluntary informed consent.

2. The study methodology does not include any special diagnostic procedure. Treatment will be done according to international guidelines. Potential physical, psychological, social, legal or other risks will be comparable to routine clinical medicine.

3. Risks related to physical examination will be reduced by using sterile and/or single use equipment such as syringes, needles, vaginal specula, cotton swabs etc. The aim of the study will be clearly explained to the clients to avoid or reduce psychological risks. There are no procedures to assess the effectiveness of the procedures.

4. Safeguarding confidentiality and protecting anonimity.

Medical officers and any other medical personnel not directly involved in the study will have no access to the patient files which will be kept separately in the respective clinics. Named information will not be made available to the health authorities. HIV testing will be unlinked and anonymous. Unlinking will be done by removing all personal identifying features from the sample and testing will be performed at the end of the study.

5. Informed consent

Written informed consent will be obtained before the interview and after having explained the aim of the study.

6.Interview

Sex workers will only have a medical history. Women from the general population will undergo a more extensive interview of about 15-20 minutes. Interview will be done in a private room.

7. Benefits to the individual subject and to the society

The syndromic approach for the management of sexually transmitted infections (STI) will benefit to the sex workers since the prevalence of STI is expected to be very high among this group. This approach is probably less usefull for women of the general population where the prevalence of STI is very low. The aim of the study is just to find out the best approach for women of the latter group.

8. The activity requires the use of records and body fluids such as blood, cervical secretions and vaginal discharge specimens.

Principal Investigator: Last, first, middle _____

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)

Appendix 1 **QUESTIONNAIRE**

SW

1.Clinic regist no.....

2.Client serial no.....

3.Name client.....

4.Address.....

5.Age (years).....

6.Main complaints .....
.....
.....
.....

7.Have you suffered from spontaneous abortions? yes/no/unknown

if yes: number of abortions.....

8.Have you ever had an induced abortion? yes/no

if yes: number of abortions.....

9.Do you wash inside your vagina after sexual contact? yes/no/sometimes

if yes or sometimes, what is the product you use: water
soap
water with antiseptic
others (specify).....

10.Do you use any vaginal medication before or after sexual contact?

yes/no/sometimes

if yes, what kind of medicines? .....

11.Do you currently use medicines by mouth? yes/no

if yes, what kind of medicines?.....

12.Have you got a blood transfusion in the past? yes/no

if yes, when.....

13.Have you received injections in the last week? yes/no
in the last month? yes/no
in the last year? yes/no

14.Where do you usually go for your medical problems? village doctor
kobiraj
pharmacist
pir
MBBS doctor
others (specify).....

15.Are you currently using a family planning method? yes/no

if yes, specify: 1) pill 2)condom 3)norplant 4)injection 5)IUD 6)others

16.Have you pain or a burning sensation when passing urine? yes/no

17.Have you an itching sensation in the genital region? yes/no

18.Have you lower abdominal pain? yes/no

19.Have you diarrhoea at the moment? yes/no

20.Are you currently suffering from a vaginal discharge? yes/no

if yes, since when: 1)<8 days 2)≥8-14 days 3)≥14d-4 weeks 4)>4 weeks

what is the color today:

1)white 2)yellow 3)brown 4)green 5)colorless 6)unknown

21.Have you suffered from a sexually transmitted infection in the past?

yes/no/unknown

if yes, what kind of infection:.....

সংযুক্তি - ১

প্রশ্নাবলী

যৌনকর্মী

১. ক্লিনিক নিবন্ধিকরণ নংঃ -------
২. রোগীর ক্রমিক নংঃ ----------
৩. রোগীর নামঃ ----------
৪. ঠিকানাঃ ----------
৫. বয়স (বছরে)ঃ ----------
৬. প্রধান সমস্যাঃ ----------

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৭. আপনার কি কখনো গর্ভপাত হয়েছে? হ্যাঁ/না/জানা নাই
যদি হ্যাঁ হয়, কতবারঃ ----------
৮. আপনি কি কখনো স্বেচ্ছায় গর্ভপাত করিয়েছেন? হ্যাঁ/না
যদি হ্যাঁ হয়, কতবার ----------
৯. যৌন সঙ্গমের পর আপনি কি যোনিপথের ভিতর পরিস্কার করেন? হ্যাঁ/না/কখনো কখনো
যদি হ্যাঁ বা কখনো কখনো পরিস্কার করেন, তবে কি ব্যবহার করেন?
শুধু পানি
সাবান
পানির সাথে জীবানু নাষক মিশিয়ে
অন্যান্য (উল্লেখ করুন) ----------
১০. আপনি কি যৌন সঙ্গমের আগে অথবা পরে যোনিপথে কোন ঔষধ ব্যবহার করেন?
হ্যাঁ/না/কখনো কখনো
যদি হ্যাঁ বা কখনো কখনো ব্যবহার করেন, তবে কি ব্যবহার করেন? ----------
১১. আপনি কি বর্তমানে কোন ঔষধ খাচ্ছেন? হ্যাঁ/না
যদি হ্যাঁ হয় কি ধরণের ঔষধ খাচ্ছেন? ----------
১২. আপনার কি কখনো শরিরে রক্ত ভরতে হয়েছিল? হ্যাঁ/না
যদি হ্যাঁ হয়, কবে ----------
১৩. আপনি কখনো কোন ইঞ্জেকশন নিয়েছেন?
গত সপ্তাহে? হ্যাঁ/না
গত এক মাসে? হ্যাঁ/না
গত এক বছরে? হ্যাঁ/না

১৪. আপনার অসুখ হলে সাধারণত কোথায় যান?

গ্রাম্য চিকিৎসক
কবিরাজ
ফার্মাসিস্ট
পীর
এমবিবিএস ডাক্তার
অন্যান্য (উল্লেখ করুন) ----------

১৫. আপনি কি বর্তমানে কোন ধরণের পরিবার পরিকল্পনা পদ্ধতি ব্যবহার করছেন? হ্যাঁ/না

যদি হ্যাঁ হয়, কি ধরণের? ---- ১) বড়ি, ২) কনডম, ৩) ইঞ্জেকশন, ৪) বন্ধাকরণ, ৫) আই ইউ ডি, ৬) অন্যান্য

১৬. প্রসাব করার সময় আপনার কি কোন রকম ব্যাথ্যা বা জ্বালা পোড়া করে? হ্যাঁ/না

১৭. আপনার কি যোনিপথে কোন চুলকানি আছে? হ্যাঁ/না

১৮. আপনার তল পেটে কি কোন ব্যাথ্যা আছে? হ্যাঁ/না

১৯. আপনি কি বর্তমানে ডাইরিয়ায় ভুগছেন? হ্যাঁ/না

২০. আপনার কি বর্তমানে কোন যোনিপথে স্রাব হচ্ছে? হ্যাঁ/না

যদি হ্যাঁ হয়, কখন থেকে ---------- ১) < ৮দিন, ২) >৮-১৪ দিন, ৩) ≥১৪দিন থেকে ৪ সপ্তাহ, ৪) > ৪ সপ্তাহ

যদি হ্যাঁ হয়, আজকে রং কি ---------- ১) সাদা, ২) হলুদ, ৩) বাদামী, ৪) সবুজ, ৫) রং বিহীন, ৬) অন্যান্য

২১. আপনি কি পূর্বে কখনো কোন যৌনরোগে ভুগেছেন? হ্যাঁ/না/জানা নাই

যদি হ্যাঁ হয়, কি ধরণের যৌনরোগে ভুগেছিলেন? ----------

Appendix 2 **QUESTIONNAIRE**

GENERAL POPULATION

CENTRE.....

1. Clinic regist no .....

2. Client serial no .....

3. Date of first visit ../../..

4. Clients group: specify before starting questionnaire

AC, FP, MR, VD, EPI

5. Time of interview Start..... Closing time.....

6. Name of interviewer: .....Signature.....

7. Name Client.....

8. Address.....

9. Age (years) ....

10. Religion 1)Islam 2)Hindu 3)Christian 4)Buddhist 5)Other

11. Current civil status 1)married 2)widow 3)divorced/separated 4)single

12. Do you have any children yes/no
If yes, number of children ....

13. Have you ever been at school? yes/no

If yes, number of completed years in school

1.primary (1-5)
2.secondary (6-10)
3.high secondary (11-12)
4.graduate (>12) or postgraduate

14. Can you read: yes/no
Can you write: yes/no

15. What is your occupation? .....

16. What is your husbands occupation? .....

17. Monthly income (both partners together) .....

18. Have you had a stillbirth? yes/no

19. Have you had premature deliveries? yes/no/unknown

20. Have you suffered from spontaneous abortions? yes/no/unknown
if yes, number:...

21. Have you ever had an induced abortion? yes/no
if yes, number:...

22. Date/month of last menstruation .....

Now we are going to ask you some personal questions. If you answer explicitely it will help us in our research.

1.Where does husband currently work? 1)town 2)village 3)abroad

if abroad, specify where:.....

2.Does husband live at home? yes/no

3.Does his job take him away from home at night? yes/no/sometimes

4.Does your husband have married before you or after you? yes/no

5.If yes, number of current wifes: .....

6.Does your husband have relationships with other women? yes/no/unknown

7.Have you been married before? yes/no

8.Do you wash inside your vagina during menstruation? yes/no/sometimes

9.Do you wash inside your vagina after sexual contact? yes/no/sometimes

10.Do you have any general health problem? .....

11.Have you suffered from an abnormal vaginal discharge in the past? yes/no

12.Have you taken any medicines within 7 days before present visit?

yes/no/unknown

if yes, what kind of medicines?.....

from where did you bought the medicine? .....

who told you to take the medicine?.....

13.Are you using any family planning method at present? yes/no

if yes, what? 1)pill 2)condom 3)injection 4)sterilization 5)IUD 6)others
since when? months.....years .....

14.Have you pain or a burning sensation when passing urine? yes/no

15.Are you suffering from frequency of micturation? yes/no

16.Have you an itching sensation in the genital region? yes/no

17.Have you fever? yes/no

18.Have you lower abdominal pain? yes/no

19.Have you diarrhaea at the moment? yes/no

20.Have you lower back pain? yes/no

21.Are you menstruating for the moment? yes/no

22.Are you suffering now from a vaginal discharge? yes/no

if yes, since when:

1)<8days 2)>8- 14 days 3)>14d-4 weeks 4)>4 weeks

if yes, what is the color:

1)white 2)yellow 3)brown 4)green 5)colorless 6)unknown

23.Have you recently observed any change in your vaginal discharge? yes/no

সংযুক্তি - ২

প্রশ্নাবলী

সাধারণ রোগী

কেন্দ্র .....

১. ক্লিনিক নিবন্ধিকরণ নংঃ -------

২. রোগীর ক্রমিক নংঃ ----------

৩. প্রথম পরিদর্শনের তারিখঃ ----/----/ ----

৪. রোগীর শ্রেণী বিভাগঃ প্রশ্নাবলী শুরুর প্রথমেই ঠিক করে নিন

AC, FP, MR, VD, EPI

৫. সাক্ষাৎকারের সময়ঃ শুরু ---------- শেষ ----------

৬. সাক্ষাৎকার গ্রহণকারীর নামঃ ---------- স্বাক্ষরঃ ----------

৭. রোগীর নামঃ ----------

৮. ঠিকানাঃ ----------

৯. বয়স (বছরে)ঃ ----------

১০. ধর্মঃ ---------- ১) মুসলমান, ২) হিন্দু, ৩) খ্রীষ্টাণ, ৪) বৌদ্ধ, ৫) অন্যান্য

১১. বর্তমান বৈবাহিক অবস্থাঃ -----১) বিবাহিত, ২) বিধবা, ৩) তালাক প্রাপ্তা/আলাদা, ৪) অবিবাহিত

১২. আপনার কোন সন্তান আছে? হ্যাঁ/না

যদি হ্যাঁ হয়, সন্তান সংখ্যাঃ ----------

১৩. আপনি কি কখনো স্কুলে পড়েছেন? হ্যাঁ/না

যদি হ্যাঁ হয়, কত বছর স্কুলে পড়েছেন?

১. প্রাথমিক (১ - ৫)

২. মাধ্যমিক (৬ - ১০)

৩. উচ্চ-মাধ্যমিক (১১ - ১২)

৪. স্নাতক বা স্নাতকোত্তর (> ১২)

১৪. আপনি কি পড়তে পারেন? হ্যাঁ/না

আপনি কি লিখতে পারেন? হ্যাঁ/না

১৫. আপনার পেশা কি? ----------

১৬. আপনার স্বামীর পেশা কি? ----------

১৭. আপনাদের দুইজনার এরসাথে মাসিক উপার্জন কত? ----------

১৮. আপনার কি কখনো মৃত সন্তান হয়েছে? হ্যাঁ/না

১৯. আপনার কি কখনো নির্ধারিত সময়ের আগে সন্তান হয়েছে? হ্যাঁ/না

২০. আপনার কি কখনো নিজে থেকে গর্ভপাত হয়েছে? হ্যাঁ/না

যদি হ্যাঁ হয়, কতবার ----------

২১. আপনি কি কখনো স্বেচ্ছায় গর্ভপাত করিয়েছেন? হ্যাঁ/না

যদি হ্যাঁ হয়, কতবার ----------

২২. শেষ মাসিকের তারিখ/মাসঃ ----------

এখন আমরা আপনাকে কিছু ব্যক্তিগত প্রশ্ন করবো, আপনার যথাযথ উত্তর আমাদের গবেষণাকে সাহায্য করবে।

১. আপনার স্বামী বর্তমানে কোথায় কাজ করেন? --------- ১) শহর, ২) গ্রাম, ৩) বিদেশ
বিদেশ হলেঃ কোথায় উল্লেখ করুন? ----------
২. আপনার স্বামী কি বাসায় থাকেন? হ্যাঁ/না
৩. তাঁকে কি কাজের জন্য রাতে বাসার বাইরে থাকতে হয়? হ্যাঁ/না/কখনো কখনো
৪. আপার স্বামী কি আপানকে বিবাহের পূর্বে বা পরে কোন বিয়ে করেছেন? হ্যাঁ/না
৫. যদি হ্যাঁ হয়, বর্তমানে তার স্ত্রী সংখ্যা কত? ----------
৬. আপনার স্বামীর কি অন্য কোন মহিলার সাথে সম্পর্ক আছে? হ্যাঁ/না/জানি না
৭. আপনার কি আগে কোন বিবাহ হয়েছিল? হ্যাঁ/না
৮. মাসিকের সময় আপনি কি যোনিপথের ভিতর পরিস্কার করেন? হ্যাঁ/না/কখনো কখনো
৯. যৌন সঙ্গমের পর আপনি কি যোনিপথের ভিতর পরিস্কার করেন? হ্যাঁ/না/কখনো কখনো
১০. আপনার কি কোন শারীরিক সমস্যা আছে? হ্যাঁ/না
১১. আপনি অতীতে কি কখনো অস্বাভাবিক যোনিপথের স্রাবে ভুগেছেন? হ্যাঁ/না
১২. আপনি কি গত সাত দিনের মধ্যে কোন ঔষধ খেয়েছেন? হ্যাঁ/না/জানি না
যদি হ্যাঁ হয়, কি ধরণের ঔষধ? ----------
কোথা থেকে ঔষধ কিনেছিলেন? ----------
আপনাকে ঔষধ খেতে কে বলেছিল? ----------
১৩. আপনি কি বর্তমানে কোন ধরণের পরিবার পরিকল্পনা পদ্ধতি ব্যবহার করছেন? হ্যাঁ/না
যদি হ্যাঁ হয়, কি ধরণের? ---- ১) বড়ি, ২) কনডম, ৩) ইঞ্জেকশন, ৪) বন্ধাকরণ,
৫) আই ইউ ডি, ৬) অন্যান্য
কতদিন থেকে? মাস---------- বছর ----------
১৪. প্রসাব করার সময় আপনার কি কোন রকম ব্যাথ্যা বা জ্বালা পোড়া হয়? হ্যাঁ/না
১৫. আপনি কি ঘন ঘন প্রসাব করেন? হ্যাঁ/না
১৬. আপনার কি যোনিপথে কোন চুলকানি আছে? হ্যাঁ/না
১৭. আপনার কি জ্বর আছে? হ্যাঁ/না
১৮. আপনার তল পেটে কি কোন ব্যাথ্যা আছে? হ্যাঁ/না
১৯. আপনি কি বর্তমানে ডাইরিয়ায় ভুগছেন? হ্যাঁ/না
২০. আপনার পিঠের নিচের দিকে কি কোন ব্যাথ্যা হয়? হ্যাঁ/না
২১. আপনার কি বর্তমানে মাসিক হচ্ছে? হ্যাঁ/না
২২. আপনার কি বর্তমানে কোন যোনিপথে স্রাব হচ্ছে? হ্যাঁ/না
যদি হ্যাঁ হয়, কখন থেকে ---------- ১) < ৮দিন, ২) >৮-১৪ দিন,
৩) >১৪দিন থেকে ৪ সপ্তাহ, ৪) > ৪ সপ্তাহ

যদি হ্যাঁ হয়, রং কি ---------- ১) সাদা, ২) হলুদ, ৩) বাদামী, ৪) সবুজ,
৫) রং বিহীন, ৬) অন্যান্য
২৩. আপনি কি ইদানিং যোনিপথের স্রাবের কোন পরিবর্তন লক্ষ করেছেন? হ্যাঁ/না

Appendix 3 **CLINICAL EXAMINATION**

(all women)

Patient regist no
Client serial no

Diagnosis

Date
Name

Treatment

Indicate: first visit
follow-up

Date next visit

Group: SW
AC, FP, MR, VD, EPI

CLINICAL EXAMINATION

1. Height (cm) .....
2. Body weight (kgs) ...
3. Temp (°C).....
4. Lymphadenopathy (extra inguinal) (>0.5 cm) yes/no
   if yes, site:
5. Signs of secondary syphilis: yes/no

   if yes, describe localization and appearance
   .....

6. Vulva
   - genital warts yes/no
     - if yes, specify 1)condylomata acuminata
       2)condylomata lata
   - Bartholin's cyst/abscess yes/no
   - vulvar candidosis yes/no
   - urethral discharge yes/no
   - vesicles yes/no
   - ulcer yes/no
     - if yes, number of ulcers ...
       - painful ulcers?
       - dirty ulcers?
       - invasive ulcers?
       - since when? 1) < 8 days
         2)≥ 8- 14 days
         3)≥ 14d - 4 weeks
         4)> 4 weeks
   - vulvo/vaginal discharge yes/no
   - other abnormalities yes/no
     - if yes, specify.....

7. Peri-vulvar region, perineum and peri-anal region

warts 1)condylomata acuminata yes/no
2)condylomata lata yes/no

vesicles yes/no
ulcers yes/no
if yes, number of ulcers ...
painful ulcers? yes/no
dirty ulcers? yes/no
invasive ulcers? yes/no

since when? 1) <8 days
2)≥8- 14 days
3)≥14d-4 weeks
4)>4 weeks

pubic lice yes/no
tinea cruris yes/no
other abnormalities yes/no
if yes, specify .....

8.Speculum examination

condition of cervix ectopion yes/no friability yes/no ulcer yes/no endocervical mucopus present yes/no if present, specify: 1)yellow pus 2)blood 3)watery 4)white amount: 1)scanty 2)moderate 3)profuse cervical prolaps yes/no	*vaginal discharge* yes/no if yes, colour: 1)white 2)watery 3)bloody 4)greenish 5)yellowish 6)other amount: 1)scanty 2)moderate 3)profuse consistency: 1)clumpy/curd like 2)thin/watery 3)thick smell: 1)no smell 2)putrid

9.Examination of the inguinal regions

lymphnodes yes/no
if yes, bilateral yes/no

buboes yes/no
if yes, bilateral yes/no

fistulated yes/no

FOLLOW-UP

First follow-up visit DATE ../../..

1.Have your symptoms improved since last visit?

cured improved unchanged worse

2.Did you take the treatment as prescribed? yes/no

3.Clinical examination

4.Treatment

5.Laboratory examination

Second follow-up visit DATE ../../..

1.Have your symptoms improved since last visit?

cured improved unchanged worse

2.Did you take the treatment as prescribed? yes/no

3.Clinical examination

4.Treatment

5.Laboratory examination

Appendix 4 **LABORATORY DIAGNOSIS**

VAGINAL DISCHARGE 1.fresh examination: T.vaginalis yes/no

yeasts yes/no

filaments yes/no

2. Gram staining: BV score:

clue cells: yes/no

CERVIX

N.gonorrhoeae pos/neg

ß-lactamase pos/neg

C.trachomatis ELISA pos/neg

PCR pos/neg

SERUM

RPR1 TPHA2

RPR2 TPHA2

Appendix 5 **SYNDROMIC MANAGEMENT**

(with speculum examination)

A. Vaginal discharge:

- ***profuse, running, or malodorous***: Bacterial vaginosis/*T.vaginalis* infection

metronidazole, 4x500 mg orally in a single dose

- ***clumpy, curd-like, thick***: yeast infection

clotrimazole 500 mg, vaginal tablet in a single application

Remark

If microscopic examination of vaginal secretions is positive for *T.vaginalis* a specific treatment will be given **irrespective of the aspect or consistency of the discharge (see above)**. In the absence of symptoms the finding of yeasts will not lead to treatment.

B. Endocervical mucopus:

- yellow: treatment for gonorrhoea and chlamydia infection: 1 g azithromycin, orally in a single dose

- blood, watery, white: no treatment

C. Genital ulcers

Genital ulcers will be treated simultaniously for syphilis and chancroid:

- single oral dose of 1 g azithromycin
  +
- benzathine penicillin, 2.4 million units in IM injection.
  (in case of penicillin allergy, doxycycline 100 mg orally, 2 times a day for 14 days)

D. Pelvic inflammatory disease: outpatient treatment

Minimum criteria: - lower abdominal tenderness
- adnexal tenderness
- cervical motion tenderness

Additional criteria: - temp >38.3°C or 101.3 °F
- abnormal cervical or vaginal discharge

ciprofloxacin, 250 mg orally, 2 times a day for 14 days
+
metronidazole, 500 mg orally, 2 times a day for 14 days

E. Vulvar candidosis clotrimazole 500 mg, vaginal tablet in a single application
+
topical 1% clotrimazole cream