



INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH

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15 July 1999

Memorandum

To : Dr. Motiur Rahman
Laboratory Sciences Division

From : Professor Mahmudur Rahman
Chairman, Ethical Review Committee

Mahmudur Rahman
15/7/99

Sub : Protocol # 99-012

This has reference to your memo of 15th July 1999 along with the modified copy of your protocol no. 99-012 entitled "Field evaluation of multiplex PCR based diagnosis for control and prevention of sexually transmitted infection/ reproductive tract infection among female sex workers".

I am pleased to inform you that the protocol is hereby approved upon your appropriate addressing of the issues raised by the Committee in its meeting held on 7th July 1999.

Thank you and wishing your success in running the protocol.

Copy:-Division Director
Laboratory Sciences Division



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15 July 1999

Memorandum

To : Dr. Motiur Rahman
Laboratory Sciences Division

From : Professor Mahmudur Rahman
Chairman, Ethical Review Committee

M Rahman
15/7/99

Sub : Protocol # 99-012

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12 July 1999

Memorandum

To : Dr. Motiur Rahman
Laboratory Sciences Division

From : Professor Mahmudur Rahman
Chairman, Ethical Review Committee

Signature
12/7/99

Sub : Protocol # 99-012

The Committee met on 7th July 1999 and considered your protocol # 99-012 entitled "Field evaluation of multiplex PCR based diagnosis for control and prevention of sexually transmitted infection/ reproductive tract infection among female sex workers". After a thorough review and discussion, the Committee made the following observations to be addressed in your protocol:

- a) on the face sheet, 2(b) through 2(f) should be marked as 'Yes' instead of 'No'.
- b) there are a number of typos in the English version of the consent form. In addition, some words have not been appropriately translated in the Bengali version of the consent form to convey the actual meaning of those words.
- c) patients with positive result should be provided counseling
- d) at page 10, the word 'patients' should be replaced by 'subjects'
- e) at page 3 (un-numbered), the words 'there is potential risk for the patients' should be deleted.
- f) although it is mentioned that multiplex PCR technique will be rapid and less expensive, it has not been mentioned how much time will it take to get the results and cost per test. In the methodology section, the PI should also mention that the Multiplex PCR will be used in the field in Bangladesh for the first time.

The Committee, therefore, requests you to revise the protocol incorporating the above observations in consultation with Dr. AKM Iqbal Kabir and resubmit it to the Chair for consideration.

Thank you.

copy:- Division Director
Laboratory Sciences Division



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Date: 15/7/99

To: Chairman
Ethical Review Committee

From: Dr. Motiur Rahman
LSD, ICDDR,B

Motiur Rahman.

Sub: Resubmission of protocol for ERC approval

ok
Kabir

Dear Sir,

Enclosed please find the revised version of the protocol entitled "Field evaluation of multiplex PCR based diagnosis for control and prevention of sexually transmitted infection/reproductive tract infection among female sex workers" for your approval. The proposal was modified as advised by chairman, ERC and in consultation with Dr. A. K. M. Iqbal Kabir.

Encl: Revised proposal

(FACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator: MOTIUR RAHMAN

Trainee Investigator (if any): Nil

Application No.

Supporting Agency (if Non-ICDDR,B) Government of

Title of Study: Field evaluation of multiplex PCR based diagnosis for control and prevention of sexually transmitted infection/reproductive tract infection among female sex workers.

Project Status: Bangladesh

☐ 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

5. Will Signed Consent Form be Required:

- (a) From subjects ☒ Yes ☐ No
 (b) From parents or guardian ☐ Yes ☒ No
 (if subjects are minor)

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 ☐ No
 (e) Invasion of privacy ☒ Yes ☐ No
 (f) Disclosure of information damaging to subject or others ☒ Yes ☐ No

6. Will precautions be taken to protect anonymity of subjects ☐ 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

7. Check documents being submitted herewith to Committee:

- ☐ Umbrella proposal - Initially submit an with overview (all other requirements will be submitted with individual studies
~~X~~ Protocol (Required)
~~X~~ Abstract Summary (Required)
~~X~~ 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)
~~X~~ Informed consent form for subjects
~~X~~ Informed consent form for parent or guardian
~~X~~ Procedure for maintaining confidentiality
~~X~~ Questionnaire or interview schedule*

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

* 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.

Motior Rahman 15/7/99

Principal Investigator

Trainee

Abstract

Sexually transmitted infections (STIs) represent a major public health problem in the developing countries. The burden of disease represented by STIs including HIV is not known; however, it is estimated that there are 333 million new cases (Trichomoniasis 170 million, Genital Chlamydia 89 million, Gonorrhea 62 million, and Syphilis 12 million) of STIs per annum and 10 to 15 million people are infected world wide with HIV every year. The estimated magnitude of new cases of human papillomavirus (HPV), herpes simplex virus (HSV) and chancroid are 30, 20 and 7 million respectively per annum. The major focus for STIs is South East Asia with an estimated 150 million new cases in 1995(WHO report 1995).

Commercial sex workers are the major reservoir of STIs including AIDS and remains as the potential source of infection for the society. It has recently been shown that co-infection of HIV with bacterial and parasitic agents of STIs/RTIs, increases the release of virion particles in the semen and ulcers in the genital region and thus increases the risk of both transmission and acquisition of HIV by patients with STIs.

In Bangladesh the prevalence and etiology of RTIs and STIs among general and high-risk population are not well documented. Lack of adequate laboratory infrastructure, trained health workers and motivation hamper the proper diagnosis and management. We have conducted a point prevalent study among FSWs in Dhaka city during summer '97 and have examined 224 FSWs for gonorrhea and syphilis. 94 (40%) of FSWs were found to be culture positive for gonorrhea and 76 (34%) were found to be positive for syphilis. We have recently conducted a study among FSWs in Dhaka city and have examined them for gonorrhea, syphilis, trichomoniasis and chlamydia infection. Of the one hundred fifty FSWs 28% had gonorrhea, 30% had syphilis, 42% had trichomoniasis and 26% had chlamydia infection.

Early and correct diagnosis and proper treatment of STD/RTI are essential not only to prevent complications associated with the infection, but also to control the spread of HIV infection. Conventional microbiological methods for diagnosis of etiology of STIs are widely used but have a number of limitations. Optimum methods of specimen collection and transport are paramount to accuracy in conventional microbiological diagnosis. Lack of specimen adequacy, the requirement of proper transportation of specimen, requirement for high level technical expertise and time required to obtain the results are the obvious limitations. Besides this it requires culture of the organism, serology, microscopy, fluorescence antibody test and/or cell culture. Considering the diagnosis of the whole panel of STI causing microorganisms it is expensive, time consuming and requires several different methods for each microorganism. The sensitivity and specificity range between 30% to 90%.

Recent advances in molecular biology have allowed for the development of sensitive diagnostic assays based on the detection of specific nucleic acid sequences in clinical specimens. Furthermore the high degree of sensitivity of such tests allow the use of alternative specimen types in which the abundance of microorganism is below the limit of detection of most traditional assays. Nucleic acid amplification based methods, PCR and LCR, were found

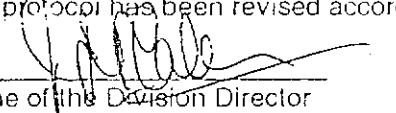
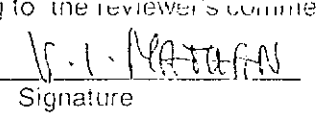
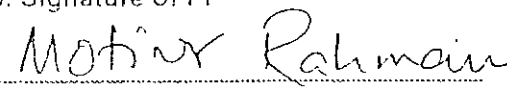
to have 95% to 100% sensitivity and specificity. Molecular diagnostic methods have selective advantages in simultaneous detection of a number of microorganisms by multiplex PCR. It is comparatively less expensive for large-scale screening and does not require special precaution for sample transport and a few microorganisms are enough for detection.

Multiplex PCR based diagnostic methods has selective advantage over conventional microbiological methods (i) it does not require special conditions for sample collection and transport, (ii) one single technique is sufficient to diagnose all the etiological agent, (iii) more than one etiological agents can be diagnosed simultaneously, (iv) rapid and cost effective, (v) applicable for field using a central reference laboratory in country like Bangladesh where laboratory infrastructure is not well developed and (vi) have 95% sensitivity and 100 specificity. As the incidence of HIV is still low in Bangladesh diagnosis and effective treatment and care of STIs/RTIs will be the first step in the control of HIV infection.

Clarification of other points (as requested in attachment 1a)

1. This study aims at development and evaluation of multiplex PCR based diagnosis of STI/RTI among female sex workers therefore sex worker will be enrolled in the study.
2. There is no potential risk for the patients as we will collect specimen for routine diagnosis and will use it for multiplex PCR.
3. Autoclaved vaginal speculum will be used, sterile and disposable needles and syringes and sterile swabs will be used. Only standard clinical examination will be performed.
4. All data obtained during the interview, clinical examination as well as laboratory finding are strictly confidential.
5. a. Signed consent form will be obtained.
b. Patient will be informed about the results.
6. Not applicable
7. Patient will get free diagnosis of their disease and will get free treatment. If multiplex PCR is found to be suitable and cost effective it can be applied for large scale surveillance. This study will provide us data regarding the prevalence of different STI/RTI among FSWs will help us in designing intervention strategies.
8. This study will require endocervical swab and blood.

Principal Investigator: Last, first, middle Rahman Motiur

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 punctuation's) Field evaluation of multiplex PCR based diagnosis for control and prevention of sexually transmitted infection/reproductive tract infection among female sex workers.			
2a. Name of the Principal Investigator(s) (Last, Middle, First) Motiur Rahman		2b. Position / Title Asstt. Scientist	2c. Qualifications MBBS, Ph. D
3. Name of the Division/ Branch / Programme of ICDDR, B under which the study will be carried out. LSD			
4. Contact Address of the Principal Investigator		4b. Fax No: 872529	
4a. Office Location: Laboratory Science Division		4c. E-mail: motiur@cis.icddr.org	
		4d. Phone / Ext: 2405, 2408	
5. Use of Human Subjects Yes ☒ No ☐		5a. Use of Live Animal Yes ☐ No ☐	
		5b. If Yes, Specify Animal Species	
6. Dates of Proposed Period of Support (Day, Month, Year - DD/MM/YY) 01 / 07 / 99 to 30 / 06 / 2001		7. Cost Required for the Budget Period 7a. 1 st Year (\$): 4,200 US\$ 2 nd Year (\$): 7,000 US\$ 3 rd Year: _____ 7b. Direct Cost (\$) Total Cost (\$) 11,200 US\$	
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 8/7/99	
9. Certification by the Principal Investigator		10. Signature of PI	
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.			
		Date: 26/5/99	

Principal Investigator: Last, first, middle ____ Rhaman Motiur ____

Table of Contents

	Page Numbers
Face Page.....	1
Project Summary.....	3
Description of the Research Project.....	4
Hypothesis to be tested.....	4
Specific Aims	4
Background of the Project Including Preliminary Observations.....	5
Research Design and Methods.....	7
Facilities Available.....	10
Data Analysis.....	10
Ethical Assurance for Protection of Human Rights.....	10
Use of Animals.....	10
Literature Cited.....	11
Dissemination and Use of Findings.....	13
Collaborative Arrangements.....	13
Biography of the Investigators.....	13
Detailed Budget.....	17
Budget Justifications.....	19
Other Support.....	19
Ethical Assurance : Protection of Human Rights	
Appendix.....	
Consent Forms in English	16
Consent Forms in Bangla	Annex 1

☐ Check here if appendix is included

Principal Investigator: Last, first, middle Rhaman Motiur

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: **Motiur Rahman**

Project Name: **Field evaluation of multiplex PCR based diagnosis for control and prevention of sexually transmitted infection/reproductive tract infection among female sex workers.**

Total Budget
11,200 US\$

Beginning Date
July 1999

Ending Date
July 2001

Hypothesis:

1. For therapeutic intervention of sexually transmitted infections/reproductive tract infections (STIs/RTIs) the use of polymerase chain reaction (PCR) is a suitable and cost effective method for rapid and reliable diagnosis.
2. The prevalence of STIs among female sex workers (FSWs) in Bangladesh is high and early diagnosis, proper treatment will reduce the spread of STIs.

Objectives:

1. To apply and evaluate a multiplex PCR base diagnosis of STIs/RTIs among FSWs.
2. To compare conventional diagnostic methods with multiplex PCR based method in respect to sensitivity, specificity and cost effectiveness.
3. To document the prevalence and etiology of STIs/RTIs among FSWs.

Background:

Sexually transmitted infections (STIs) including human immunodeficiency virus (HIV) represent a major public health problem in the developing countries. There has been growing evidence during recent years of the epidemiological synergism between HIV infection and STIs. Commercial sex workers are the major reservoir of STIs including AIDS and remains as the potential source of infection for the society. Early diagnosis and proper treatment of STIs/RTIs among the FSWs are essential not only to combat infection, but also to control the spread of infection. Conventional microbiological methods for diagnosis of STIs is widely used but has a number of limitations e.g., specimen collection and transport, lack of specimen adequacy, requirement for high level technical expertise, time required to obtain the results and high cost. Besides, these require culture of the organism, serology, microscopy, fluorescence antibody test and/or cell culture. Multiplex PCR based diagnostic methods has selective advantage over conventional microbiological methods (i) it does not require special conditions for sample collection and transport, (ii) one single technique is sufficient to diagnose all the etiological agent, (iii) more than one etiological agents can be diagnosed simultaneously, (iv) rapid and cost effective, (v) applicable for field using a central reference laboratory in country like Bangladesh where laboratory infrastructure is not well developed and (vi) have 95% sensitivity and 100 specificity.

Materials and methods: A cross sectional study will be conducted among female sex workers attending Health care clinic of Concern at Mirpur. Patients will be informed about the study and those who give written consent will be enrolled. Endocervical swab and blood will be collected from enrolled patients. Specimens will be analyzed etiological agents of STIs by conventional microbiological method. A multiplex PCR will be developed for simultaneous detection of STI pathogens and the sensitivity and specificity of multiplex PCR will be compared with conventional microbiological method. Women presenting clinical signs of STI/RTI will be treated according to WHO flow chart.

Principal Investigator: Last, first, middle Rhaman Motiur

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

Name	Professional Discipline/ Specialty	Role in the Project
1. Motiur Rahman	MBBS, Ph D. Microbiologist & Molecular biologist	Principle investigator
2. John Albert	Ph D. MRCP Microbiologist	Coinvestigator
3. Anowar Hossain	MBBS, MCPS Clinical Pathologist	Coinvestigator
4. Shamsun Nahar	MSc	Coinvestigator
5. Shahnewaz Alam khan	MBBS, MPH	Head, Health and Nutrition programme, Concern

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:

1. For therapeutic intervention of sexually transmitted infections/reproductive tract infections (STIs/RTIs) the use of polymerase chain reaction (PCR) is a suitable and cost effective method for rapid and reliable diagnosis.
2. The prevalence of STIs among female sex workers (FSWs) in Bangladesh is high and early diagnosis, proper treatment will reduce the spread of STIs.

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).

Objectives:

1. To apply and evaluate a multiplex PCR base diagnosis of STIs/RTIs among FSWs.
2. To compare conventional diagnostic methods with multiplex PCR based method in respect to sensitivity, specificity and cost effectiveness.
3. To document the prevalence and etiology of STIs/RTIs among FSWs.

Principal Investigator: Last, first, middle Rhman Motiur

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 infections (STIs) represent a major public health problem in the developing countries. The advent and increase of human immunodeficiency virus (HIV) infection during the last decade has highlighted the importance of infections spread by sexual route (Michael *et al.*, 1996). The burden of disease represented by STIs including HIV is not known; however, it is estimated that there are 333 million new cases (Trichomoniasis 170 million, Genital Chlamydia 89 million, Gonorrhea 62 million, and Syphilis 12 million) of STIs per annum and 10 to 15 million people are infected world wide with HIV every year. The estimated magnitude of new cases of human papillomavirus (HPV), herpes simplex virus (HSV) and chancroid are 30, 20 and 7 million respectively per annum. The major focus for STIs is South East Asia with an estimated 150 million new cases in 1995 (WHO report 1995).

There has been growing evidence during recent years of the epidemiological synergism between HIV infection and STIs. A recent study has demonstrated that control of STIs in a high prevalence rural area of Tanzania reduced seroconversion to HIV by 40% (Grosskurth *et al.*, 1995). In a number of recent studies it has been shown that co-infection of HIV with bacterial and parasitic agents of STIs/RTIs, increases the release of virion particles in the semen and ulcers in the genital region and thus increases the risk of both transmission and acquisition of HIV by patients with STIs (Hoffman *et al.*, 1996; Wasserheit *et al.*, 1992). Gonococcal infection is also considered to act as an independent cofactor in the transmission of HIV infection (Anaya *et al.*, 1994).

In developing countries bacterial pathogens are the most reported causes of genital ulcers and other STIs. In genital ulcer diseases mixed bacterial pathogens frequently occur. Syndromic approach to patient management as recommended by WHO is widely used but has obvious limitations. This approach has proven to have lesser predictive values in the diagnosis of chlamydial and gonococcal infections in high prevalence populations especially in women where asymptomatic carriage of the organism can be as high as 70% (Laga *et al.*, 1996). In rural Tanzania 2.2% of 5876 randomly selected males aged 15-54 year were found to have urethral gonorrhea, of them only 15% complained of urethral discharge (Grosskurth *et al.*, 1995). In antenatal clinics attendees from the same population in whom 39% of women harbor at least one STD pathogen. The recommended syndromic approach based on the presence of genital symptoms had a sensitivity of 43% and specificity of 55% for cervical gonococcal and chlamydial infection and discriminated poorly between infected and non infected women (Mayaud *et al.*, 1995). A study by Ndinya-Achola *et al.*, (1995) in Kenya confirmed the limitation of clinical diagnosis where in a clinical setting a trained medical officer was unable consistently or accurately to differentiate chancroid from syphilis or herpes and as many as 20% of the patients were found to have dual infections with two or more pathogens.

Principal Investigator: Last, first, middle _____ Rhaman Motiur

Female sex workers (FSWs) serve as the largest reservoir of sexually transmitted disease in the society (Arya *et al.*, 1988). In most parts of Asia and Africa, 80% to 90% of the venereal infections, including gonorrhea originate from FSWs (WHO 1963). FSWs were found to be the source of 60% of the gonococcal urethritis in men in Kenya (Adler *et al.*, 1996). There are approximately 100,000 FSWs in Bangladesh. They are almost ubiquitous in distribution, urban, semi-urban and rural. They are either organized in brothels or work as floating sex workers (Choudhury *et al.*, 1996).

In Bangladesh the prevalence and etiology of RTIs and STIs among general and high-risk population are not well documented. Lack of adequate laboratory infrastructure, trained health workers and motivation hamper the proper diagnosis and management. In a well documented study with adequate laboratory methodology Wasserheit *et al.* (1985) have shown that 22% of 1929 women reported symptoms of RTI and of them 68% had clinical and laboratory evidence of RTIs. In a similar study among patients attending a women clinic the prevalence of bacterial vaginosis was 44%, *C. trachomatis* and *N. gonorrhoeae* was 2% and syphilis was 2% (J. Bogaerts, personal communication). A cross sectional study among the slum dwellers in Dhaka city has shown that the prevalence of *N. gonorrhoeae* was 5% and syphilis was 11.5%. (Sabin *et al.*, 1997). We have conducted a point prevalent study among FSWs in Dhaka city during summer '97 and have examined 224 FSWs for gonorrhea and syphilis. 94 (40%) of FSWs were found to be culture positive for gonorrhea and 76 (34%) were found to be positive for syphilis (Bhuiya *et al.*, 1998). In a subsequent study the antimicrobial susceptibility of the isolates were studied. Among the gonococcal isolates 66%, 60% and 10% were resistant to penicillin, tetracycline and ciprofloxacin respectively (Bhuiya *et al.*, 1999).

We have recently conducted a study among FSWs in Dhaka city and have examined them for gonorrhea, syphilis, trichomoniasis and chlamydia infection. Of the one hundred fifty FSWs 28% had gonorrhea, 30% had syphilis, 42% had trichomoniasis and 26% had chlamydia infection (Rahman *et al.*, Unpublished results).

Early and correct diagnosis and proper treatment of STD/RTI are essential not only to prevent complications associated with the infection, but also to control the spread of HIV infection. Conventional microbiological methods for diagnosis of etiology of STIs are widely used but have a number of limitations. Optimum methods of specimen collection and transport are paramount to accuracy in conventional microbiological diagnosis. Lack of specimen adequacy, the requirement of proper transportation of specimen, requirement for high level technical expertise and time required to obtain the results are the obvious limitations. Besides this it requires culture of the organism, serology, microscopy, fluorescence antibody test and/or cell culture. Considering the diagnosis of the whole panel of STI causing microorganisms it is expensive, time consuming and requires several different methods for each microorganism. The sensitivity and specificity range between 30% to 90%.

Recent advances in molecular biology have allowed for the development of sensitive diagnostic assays based on the detection of specific nucleic acid sequences in clinical specimens. Furthermore the high degree of sensitivity of such tests allow the use of alternative specimen types in which the abundance of microorganism is below the limit of detection of most traditional assays (Carolyn *et al.*, 1997). Nucleic acid amplification based methods, PCR and LCR, were found to have 95% to 100% sensitivity and specificity (Brustain *et al.*, 1991). Molecular diagnostic methods have selective advantages in simultaneous detection of a number of microorganisms by multiplex PCR (Oriel *et al.*, 1996). It is comparatively less expensive for large-scale screening and does not require special precaution for sample transport and a few microorganisms are enough for detection. PCR and LCR based diagnostic methods have been described for *N. gonorrhoeae*, *Chlamydia trachomatis*, *T. pallidum*, *H. ducreyi*, *T. vaginalis*, human immunodeficiency virus, human papilloma virus and Herpes simplex virus (Class *et al.*, 1990; Hardy *et al.*, 1990; Reley *et al.*, 1992). Multiplex PCR for simultaneous detection of *N. gonorrhoeae* and *C. trachomatis*

Principal Investigator: Last, first, middle Rhaman Motiur

from urine, urethral and endocervical swab have been described. It has recently been shown that *T. pallidum*, *H. ducreyi* and Herpes simplex virus I and II can be detected simultaneously by the same system (Orle *et al.*, 1996). Using conventional microbiological methods the approximate direct cost for diagnosis of all the etiological agents of STI/RTI is US \$ 35 (*N. gonorrhoeae* \$ 0.5, *C. trachomatis* \$ 5.0, *T. pallidum* \$ 0.95, *H. ducreyi* \$ 0.6, *T. vaginalis* \$ 3.0, herpes simplex virus \$ 5.0 and human papillomavirus \$ 20.0) and it usually takes 5 to 7 days. In multiplex PCR method the direct cost for diagnosis of whole panel of STI pathogens will be approximately US \$ 9 and it will take 48 to 72 hours. Although multiplex PCR based diagnostic methods have been described their application for large scale screening has not been well documented and has not been tested in the field. Considering the advantages of this method we are applying multiplex PCR based diagnosis to study the prevalence of STI among female sex workers and to study the sensitivity and specificity of the method.

Rationale: Commercial sex workers are the major reservoir of STIs including AIDS and remains as the potential source of infection for the society. Early diagnosis and proper treatment of STIs/RTIs among the FSWs are essential not only to combat infection, but also to control the spread of infection. Conventional microbiological methods for diagnosis of STIs is widely used but has a number of limitations e.g., specimen collection and transport, lack of specimen adequacy, requirement for high level technical expertise, time required to obtain the results and high cost. Besides, these require culture of the organism, serology, microscopy, fluorescence antibody test and/or cell culture. Multiplex PCR based diagnostic methods has selective advantage over conventional microbiological methods (i) it does not require special conditions for sample collection and transport, (ii) one single technique is sufficient to diagnose all the etiological agent, (iii) more than one etiological agents can be diagnosed simultaneously, (iv) rapid and cost effective, (v) applicable for field using a central reference laboratory in country like Bangladesh where laboratory infrastructure is not well developed and (vi) have 95% sensitivity and 100 specificity. As the incidence of HIV is still low in Bangladesh diagnosis and effective treatment and care of STIs/RTIs will be the first step in the control of HIV infection. The project proposed here is mainly aimed at utilization of currently available molecular biology techniques and their utilization in a cost-effective manner. If multiplex PCR is proven to suitable and cost effective for diagnosis of STIs/RTIs it can be used for large scale screening of STIs/RTIs in different field conditions. An effective method for early diagnosis and treatment of STIs/RTIs will be a timely step to prevent the spread of the deadly disease.

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).

Materials and methods

Study site and design: This study will be conducted in Health care clinic of Concern Bangladesh, at Mirpur Vagrant Home. FSWs in this vagrant home includes floating sex workers and sex workers form residential hotels. All FSWs attending the clinic will be eligible for enrollment in the study.

Principal Investigator: Last, first, middle Rhaman Motiur

Inclusion criteria for enrollment includes:

- a. Age between 18 to 50 years.
- b. Non pregnant.
- c. Not treated with antibiotic in the preceding two weeks.
- d. With or without symptoms of STIs.

Exclusion criteria

- a. Age below 18 and above 50 years.
- b. Pregnancy.
- c. Antibiotic treatment in the preceding two weeks.
- d. Chronic or acute intercurrent infection which would compromise treatment evaluation.

Sample collection and diagnosis: FSWs will be informed about the objective of the study and those who give written consent will be included in the study. A clinical examination of the external genitalia as well as bimanual pelvic examination with a vaginal speculum will be performed and specimen will be collected.

Treatment: Women presenting clinical signs of STI/RTI will be treated according to WHO flow chart. Asymptomatic infection will be treated during follow up visit according to the PCR results.

Follow up: All women will be invited to come back on the 7th day after the first visit. Patient will be informed on the results of the test and if needed treatment will be adapted according to laboratory finding. Patient with STIs will be provided counseling

Sample size: Assuming a 95% sensitivity of PCR diagnosis and 75% sensitivity of conventional diagnosis the minimum number of patients required for this study will be 116 (confidence level of 95% with 80% power). According to our previous study, the prevalence of gonococcal infection among the FSWs is 40%. Considering a 40% prevalence a total of 290 FSWs will be included in the study.

METHODS

Specimen includes endocervical swab for culture and multiplex PCR, high vaginal swab for wet mount preparation; swab from genital ulcer will be taken from patients with genital ulcers. Blood samples will be collected to analyze the antibody to *T. pallidum* and HSV infection.

PCR diagnosis:

After collection, the swab will be vigorously agitated in 1 ml of transport medium (Roche AMPLICOR specimen transport medium). All specimens for PCR will be frozen and stored at -20 ° C after collection, until they were thawed and divided into 50 µl aliquots for use.

The aliquot will be incubated at 100° C for 10 min and then diluted 10-fold with Roche AMPLICOR specimen diluant containing Tween-20 and 6 mM magnesium chloride. Diluted specimen will be incubated at room temperature for 15 min. 50µl of processed swab specimen and 50 µl of reaction mixture (containing 20 mM tris buffer, 6.0 mM MgCl₂, 100 mM KCl, 24% glycerol 400 µM (each) dNTPs, 2U taq polymerase, 1U uracil-N-glycosylase and 50 pMol of each primer) will be used for PCR. Amplification will be performed in a thermal cycler (Perkin-Elmer PCR System 4800) with the following

Principal Investigator: Last, first, middle Rhaman Motiur

parameter: 50° C for 2 min to allow uracil-N-glycosylase inactivation of any carryover product; 95° C for 5 min to inactivate the uracil-N-glycosylase; and 35 cycles of denaturation (95° C), annealing (52° C), and extension (72° C) and a final extension of 72° C for 10 minutes.

Multiplex PCR system will be run by using combination of known primers for bacterial, parasitic and viral pathogens. For *N. gonorrhoeae* and *C. trachomatis* oligonucleotide primers designed from *cpbB* gene of endogenic cryptic plasmid which will amplify a 390 bp product and primers specific to common endogenous plasmid which amplifies a 517 bp product respectively will be used (Claas *et al.*, 1990; Hagbloom *et al.*, 1986). For *T. pallidum* and *H. ducreyi* oligonucleotide primers amplifying 239 bp fragment of the gene encoding the 47 kDa lipoprotein and primers amplifying 430 bp fragment of the *groEL* gene will be used respectively (Burstain *et al.*, 1991; Grimpel *et al.*, 1991; Noordhoek *et al.*, 1991; Weigel *et al.*, 1992). For *T. vaginalis* oligonucleotide primers amplifying 650 bp unique DNA repeats that is conserved in all strain will be used (Reley *et al.*, 1992). Herpes simplex virus I and II will be detected by using primers specific to glycoprotein B gene which will amplify a 325 bp fragment (Bzik *et al.*, 1986; Dewhirst *et al.*, 1992; Greisen *et al.*, 1994; Hardy *et al.*, 1990; Kimura *et al.*, 1990). Primers for *N. gonorrhoeae*, *C. trachomatis* and *T. pallidum* will be included in one set of multiplex PCR which will amplify 435, 517 and 239 bp fragments respectively. Primers for *H. ducreyi*, *T. vaginalis* and herpes simplex virus will be included in another set of multiplex PCR which will amplify 430, 650 and 325 bp fragments respectively. All amplification will be performed in duplicate for each sample. With each set of reaction a set of positive and negative control will be included. The amplified product will be analyzed in 1.2% agarose gel.

Conventional diagnosis:

Isolation of *N. gonorrhoeae*: Endocervical swab will be immediately inoculated onto pre-warmed Modified Thayer –Martin medium (MTM) and will be incubated at 37 c in candle extinction jars for 24 to 48 hours. The plates will be examined after 24 hours and a presumptive identification of *N. gonorrhoeae* will be made on the basis of colony morphology, Gram staining, oxidase and superoxol test of suspected gonococcal colonies. The isolates will be confirmed as gonococci by PCR using primers from the conserved region of *cpbB* gene, which will amplify a 390bp fragment of the gene (Ho *et al.*, 1992).

Diagnosis of *T. pallidum*: Serum samples will be analyzed for antibodies to *T. pallidum* by RPR (Becton-Dickinson, Cockeysville, MD) and Treponema pallidum haemagglutination test (TPHA) (Fujirrbio, Tokyo, Japan).

Diagnosis of *T. vaginalis*: *T. vaginalis* will be confirmed by direct examination of high vaginal swab by wet mount preparation and culture of *T. vaginalis* in TV pouch (Bio Med Diagnostics, San Jose, CA).

Diagnosis of *C. trachomatis*: *C. trachomatis* will be diagnosed by *C. trachomatis* enzyme immunoassay (EIA) (Chlamydia EIA test, Syva Company, Palo Alto, CA).

Diagnosis of *H. ducreyi*: *H. ducreyi* will be diagnosed by culturing genital ulcer swab in GC agar plate containing 2% hemoglobin, 5% fetal bovine serum, 10% CVA enrichment (GIBCO) and will be confirmed by Gram staining and biochemical tests. Confirmatory diagnosis will be made by PCR (Hawkes *et al.*, 1995)

Diagnosis of bacterial vaginosis: A whiff test will be carried out using a 10% solution of KOH and pH of the vaginal fluid will be measured during speculum examination. Presence of clue cells will be determined by gram staining of vaginal swab. Bacterial vaginosis will be defined as the presence of any three of the following four signs in the absence of trichomonas vaginitis: i. White homogeneous

Principal Investigator: Last, first, middle Rhaman Motiur
discharge; ii. Clue cells (>20% of epithelial cell) on vaginal wet mount; iii. Vaginal pH >4.5; or iv. Positive whiff test (amine odor using 10% potassium hydroxide on vaginal secretions).

Diagnosis of HSV2: Antibody to Herpes Simplex Virus 2 (HSV2) in serum will be detected by bioelisa HSV-2 IgG enzyme immunoassay (Biokit, Barcelona, Spain).

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 equipment's 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).

This study will be carried out in health clinic of Concern in Mirpur and LSD, ICDDR, B. The clinic has sufficient infrastructure for interviewing, examination and sample collection. The support required for the clinic is one simple microscope, refrigerator, slides, cover slip, cotton swab, transport medium, needle, syringe, stationary and medicine.

LSD of ICDDR, B has sufficient laboratory space and necessary equipment to conduct the research.

Data Analysis

Describe plans for data analysis. Indicate whether data will be analyzed by the investigators themselves or by other professionals. Specify what statistical software's 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 generated by the project will be analyzed by suitable statistical program. Primary data will be analyzed by SPSS or Epi-Info program.

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.

Social worker will explain the aim of the study to the subject and written consent will be taken from all the subjects. All data obtained during the interview, clinical examination as well as laboratory finding are strictly confidential. Autoclaved vaginal speculum will be used, sterile and disposable needles and syringes will be needed and sterile swabs will be used. Only standard clinical examination will be performed. Diagnosis will be done according to WHO syndromic management flow chart and the patient with positive results will be provided standard treatment. Patient with STIs will be provided counseling

Principal Investigator: Last, first, middle Rhaman Motiur

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.

No laboratory animal will be used in this study.

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.

Reference :

1. Adler, M, W 1996 Sexually transmitted diseases control in developing countries. Genitourin Med 72: 83-88.
2. Anaya JM, Joseph J, Scopelitis E, Espinoza LR. Disseminated gonococcal infection and human immunodeficiency virus. Clin Exp Rheumatol 1994; 12(6):668.
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Principal Investigator: Last, first, middle Rhaman Motiur

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Principal Investigator: Last, first, middle Rhaman Motiur

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 hoped that the project will generate data that will have national and international impact. The data generated by this project will be presented in national and international conferences and will be published in international journals.

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 project is collaborative one between Concern Bangladesh and ICDDR, B. The investigators from each institute will interact closely. Concern clinic will take the responsibility for patient enrollment. Investigator's in ICDDR, B will be responsible for collection of swab and serum, carrying out the diagnostic tests, providing treatment, data analysis and dissemination of the results. All investigators will meet monthly and will discuss the progress of the project.

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
Motiur Rahman	Asstt. Scientist	21st Dec 1961

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

Institution and Location	Degree	Year	Field of Study
Rangpur medical college, Rangpur Bangladesh.	MBBS	1985	Medicine Surgery
Microbiology & tumorbiology Centre Karolinska Institute, Stockholm, Sweden.	Ph. D	1977	Microbiology & Molecular biology

Principal Investigator: Last, first, middle Rhaman Motiur
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).

Professional experience

Sept'85 to Sept'86 : Assistant surgeon, Rangpur Medical college Hospital. Rangpur Bangladesh.
March'95 to March'97: Research Assistant, Microbiology & tumorbiology Centre, Karolinska Institute, Stockholm, Sweden.
April'97 to update : Assistant Scientist, LSD, ICDDR'B, Bangladesh.

Publications:

1. Bhuiya, B., **Rahman, M.**, Miah, R.A., Rahman, M. and Albert, M.J. (1998) High prevalence of Ciprofloxacin resistant *Neisseria gonorrhoeae* among the Commercial Sex Workers in Bangladesh. J Antimicrob Chemother. 48(5):675-76.
2. Bhuiya, B., **Rahman, M.**, Miah, R.A., Nahar, S., Islam, N., Ahmed, M., Rahman, K.M., Albert, M.J. (1998) Antimicrobial susceptibility, and plasmid content of *Neisseria gonorrhoeae* isolated from commercial sex workers in Dhaka, Bangladesh: Emergence of high level ciprofloxacin resistance. Accepted for publication in J. clin Microbiol.
3. **Rahman, M.**, Bhuiya, B., Miah, R.A., Islam, N., Rahman, K.M., J., Albert, M.J. (1997) Molecular epidemiology and plasmid profile of *Neisseria gonorrhoeae* isolated from commercial sex workers in Dhaka city. ASCON 1998, ICDDR'B, Dhaka, Bangladesh.
4. **Rahman, M.**, Jonsson, A.-B., and Holme, T. (1998) Monoclonal antibodies to the $\square$ -Gal-(1-4)- $\square$ -Gal-(1- epitope of *Moraxella catarrhalis* lipopolysaccharide react with the type IV pili of *N. meningitidis*. *Microbial pathogenesis*. 24(5):299-300.
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6. Ann-Beth Jonsson, **Motiur Rahman** and Staffan Normark. (1995) Pilus biogenesis gene, *pilC*, of *Neisseria gonorrhoeae*: *pilC1* and *pilC2* are each part of a larger duplication the gonococcal genome and share upstream and down stream homologous sequences with *opa* and *pil* loci. *Microbiol.* 141:2367-2377.
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Principal Investigator: Last, first, middle Rhman Motiur

9. **Rahman, M.**, Källström, H., Notmark, S., and Jonsson, A.-B. (1996) Characterization and surface translocation of pilus associated protein PilC of *Neisseria gonorrhoeae* and *Neisseria meningitidis*. *Proceedings of the 10th International Pathogenic Neisseria Conference*. 304-305.
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11. Jönsson, I., Holme, T., Krook, A., **Rahman, M.**, and Thorén, M. (1992) Variability of surface-exposed antigens of different strains of *Moraxella catarrhalis*. *Eur. J. Clin. Microbiol. Infect. Dis.* 11: 919-922.
12. **Rahman, M.** and T. Holme, (1996) Antibody response in rabbits to serotype-specific determinant in lipopolysaccharides from *Moraxella catarrhalis*. *J. Med. Microbiol.* 44: 1-7.
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18. **Motiur Rahman** (1997) Characterization of surface components of *Moraxella catarrhalis* and pathogenic *Neisseria*. ISBN- 91-628-2314-0.

Manuscripts submitted

1. Borelli, S., **Rahman, M.**, Holme, T., Alf, A, Lindberg, and P, -E, Jansson. (1996) *Moraxella (Branhamella) catarrhalis* and *Haemophilus influenzae* lipopolysaccharides express distinct Gal α 1-4Gal α epitopes as determined by the binding of specific *H. influenzae* anti-Gal α 1-4Gal α monoclonal antibodies. Submitted to Microbial pathogenesis.
2. Holme, T., **Rahman, M.**, Jansson P.E., and Vidmalm, G. (1998) The lipopolysaccharides of *Moraxella Catarrhalis*: structural relationship and antigenic properties. Submitted to Infection and Immunity.

Principal Investigator: Last, first, middle Rhaman Motiur

International Centre for Diarrhoeal Disease Research, Bangladesh Voluntary Consent Form

Title of the Research Project: Field evaluation of multiplex PCR based diagnosis for control and prevention of sexually transmitted infection/reproductive tract infection among female sex workers.

Principal Investigator: Motiur Rahman

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 presently performing a study entitled “**Field evaluation of multiplex PCR based diagnosis for control and prevention of sexually transmitted infection/reproductive tract infection among female sex workers.**” This study aims at evaluation of PCR based diagnosis of STIs and its comparison with conventional diagnostic methods. This study will help us to set up diagnostic tests where microbiological facilities are not available. After proper diagnosis we will offer you free treatment and follow up. The results of this study will help us to improve the quality of health care.

If you participate in our study a trained female doctor will perform your physical examination including a vaginal examination. Using a cotton-tipped stick, we will collect swab from your vagina for diagnosing the cause of your problem and also for other special tests for the research. The procedure is painless, and will not cause any harm to you. We will also collect 2.5 ml of venous blood from your forearm. You will be directly benefited from participation in this study since we will diagnose your problem and provide you free treatment. This will also prevent transmission of the disease to others. Additionally, the results of this study will benefit the society. There is no physical risks involved in this study. If you do not participate in this study, you will receive the standard treatment of this clinic. You would also be able to withdraw your participation at any time during the study without causing any penalty to you and without affecting your further treatment at this clinic. All of your medical information including the results of the laboratory tests will be kept confidential, and no body other than the investigators of this study and the Ethical Review Committee that oversee protection of human rights would be able to see them. We will be obliged to answer to your questions, now or a later time.

If you agree to participate in this study, please indicate that by putting your signature or left thumb impression on the specified space below.

Thank you for your cooperation.

Signature of Investigator
Date:

Signature of Subject
Date:

Continuation Sheet (Number each sheet consecutively)

Principal Investigator: Last, first, middle ___ Rhaman Motiur _____

Detailed Budget for New Proposal

Project Title: Field evaluation of multiplex PCR based diagnosis for control and prevention of sexually transmitted infection/reproductive tract infection among female sex workers.

Name of PI: Motiur Rahman

Protocol Number: _____ Name of Division: Laboratory Sciences Division

Funding Source: Govt. of Bangladesh. Amount Funded (direct): _____ Total: _____ Overhead (%) _____

Starting Date: 01/07/999 Closing Date: 30/06/2001

Strategic Plan Priority Code(s) : _____

Sl. No	Account Description	Salary Support			US \$ Amount Requested		
		Position	Effort %	Salary	1st Yr	2 nd Yr	3 rd Yr
	Personnel						
	Motiur Rahman	Asstt.Scientist	10%				
	Shamsun Nahar	Sr.Res.Officer	20%				
	Sub Total						
	Consultants						
	Local Travel				500	500	
	International Travel						
	Sub Total				500	500	
	Supplies and Materials (Description of Items)						
	1. Primer's Reagents, tubes plastic, gloves, Microscope, chemicals,				1,000	2,500	
	2. Pipettes, aerosol protective tips sticker				700	500	
	3. Reagents and kits for serology				1,000	2,500	
	4. Drugs				500	500	
	5. Books and stationary				500		
	Sub Totals				3,700	6,000	

Principal Investigator: Last, first, middle Rhaman Motiur

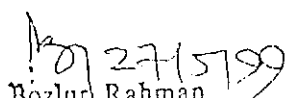
	Other Contractual Services			
	Repair and Maintenance			
	Rent, Communications, Utilities			
	Training Workshop, Seminars			
	Printing and Publication		,500	
	Staff Development			
	Sub Total		,500	

	Interdepartmental Services	1 st Yr	2 nd Yr	3 rd Yr
	Computer Charges			
	Pathological Tests			
	Microbiological tests			
	Biochemistry Tests			
	X-Rays			
	Patients Study			
	Research Animals			
	Biochemistry and Nutrition			
	Transport			
	Xerox, Mimeographs etc.			
	Other Operating Costs			

TOTAL DIRECT COST

4,200

7,000


 Md. Bozluur Rahman
 Senior Budget & Cost Officer
 ICDDR, B, Mohakhali
 Dhaka-1212, Bangladesh

Principal Investigator: Last, first, middle ____ Rhaman Motiur _____

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 budget presented here represents a minimum estimation of the costs.

1. One part time female physician will be employed for collection of samples.
2. Equipment and instruments: All equipment and reagents mentioned in the budget will be purchased from the budget code assigned to the study protocol.

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)

USAID – 1800 \$ for a pilot study entitled “Prevalence of sexually transmitted infections among female sex workers in Dhaka city”.

Principal Investigator: Last, first, middle Rhaman Motiur

Check List

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

1. Face Sheet Included ☒
2. 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 ☒

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র
মহাখালী, ঢাকা-১২১২

স্বৈচ্ছা সম্মতি পত্র

আমরা বর্তমানে "যৌন কর্মীদের যৌনরোগ নিরূপণ ও নিয়ন্ত্রণ এর লক্ষ্যে মাল্টিপ্রেস্ক্র পি, সি, আর এর মাঠ পর্যায়ে কার্যকারিতা সম্পর্কে" একটি জরিপ পরিচালনা করছি। এই গবেষণা আমাদেরকে সহজ ও সঠিকভাবে যৌনরোগ নির্ণয়ে সহায়তা করবে। উপরন্তু এই রোগ নির্ণয় পদ্ধতিতে যে সকল স্থানে প্রচলিত রোগ নির্ণয়ের সুবিধা নেই, সেই সকল স্থানের রোগীদেরও রোগ নির্ণয় সম্ভব হবে। আপনি এই গবেষণায় অংশ গ্রহণ করে আমাদের সাহায্য করতে পারেন।

আপনি যদি আমাদের এই গবেষণায় অংশ গ্রহণ করতে চান তাহলে:-

- ১। একজন ট্রেনিংপ্রাপ্ত মহিলা চিকিৎসক আপনার শারীরিক পরীক্ষা করবেন যার মধ্যে আপনার যৌনাস্র পরীক্ষাও অন্তর্ভুক্ত থাকবে।
- ২। একটি সোয়াব কাঠির সাহায্যে আমরা আপনার যৌনাস্র থেকে সোয়াব সংগ্রহ করা হবে। আপনার যৌনাস্রে যদি কোন ধরণের ঘা থাকে তবে সেখান থেকেও সোয়াব সংগ্রহ করা হবে। তাছাড়া আমরা আপনার হাতের ধমনী/শিরা থেকে তিন সিসি রক্ত সংগ্রহ করবো। এতে আপনি সামান্য ব্যথা অনুভব করবেন তবে আপনার কোন ক্ষতির সম্ভাবনা নেই।
- ৩। আপনাকে আপনার রোগ লক্ষণ অনুযায়ী প্রচলিত চিকিৎসা বিধান অনুযায়ী চিকিৎসা প্রদান করা হবে এবং সাতদিন পর আপনাকে পুনরায় আমাদের স্বাস্থ্য কেন্দ্রে আসার জন্য অনুরোধ করা হবে।
- ৪। ইতিমধ্যে আপনার স্পেসিমেন সমূহ পি সি আর রোগ নির্ণয় ও প্রচলিত রোগ নির্ণয় পদ্ধতিতে পরীক্ষা করা হবে।
- ৫। উপরোক্ত পরীক্ষাসমূহে যদি আপনার কোন রোগ নির্ণয় হয় তবে আপনাকে সে রোগের চিকিৎসা প্রদান করা হবে।
- ৬। আমাদের এই গবেষণা হতে আপনি সরাসরি উপকৃত হবেন, কারণ আমরা আপনার রোগের কারণ নির্ণয় করে আপনাকে বিনামূল্যে চিকিৎসা প্রদান করছি। এই ব্যবস্থা আপনার রোগটি অন্যদের মধ্যে ছড়াতে প্রতিরোধ করবে। উপরন্তু, এই গবেষণার ফল সমাজকে ভীষণভাবে উপকৃত করবে।
- ৭। এই গবেষণায় অংশগ্রহণ করলে কোনরূপ শারীরিক ঝুঁকির সম্ভাবনা নেই।
- ৮। আপনি যদি এই গবেষণায় অংশগ্রহণ নাও করেন তাহলেও এই ক্লিনিকের প্রচলিত ব্যবস্থা অনুযায়ী আপনি চিকিৎসা পাবেন। অন্যদিকে অংশগ্রহণ করেও যে কোন সময় কোনরূপ ক্ষতিপূরণ ছাড়াই আপনি আপনার সম্মতি প্রত্যাহার করতে পারবেন। এমনকি এই ক্লিনিক হতে প্রাপ্ত আপনার পরবর্তী চিকিৎসা ব্যবস্থারও কোনরূপ পরিবর্তন হবে না।
- ৯। ল্যাবরেটরী পরীক্ষার ফলাফল ও আপনার যাবতীয় তথ্য সম্পর্কে গোপনীয়তা রক্ষা করা হবে। এই গবেষণায় অংশগ্রহণকারী, গবেষকগণ এবং মানবিক অধিকার রক্ষার ইথিক্যাল কমিটি ছাড়া সেসব তথ্য অন্য কেউ জানতে পারবে না।
- ১০। আমরা যে কোন সময় আপনার যে কোন প্রশ্নের উত্তর দিতে বাধ্য থাকবো।

আপনি যদি এই গবেষণায় অংশগ্রহণে ইচ্ছুক হন, তাহলে অনুগ্রহ করে নিচে প্রদত্ত নির্দিষ্ট স্থানে স্বাক্ষর অথবা টিপসহি দিন।

আপনার সহযোগিতার জন্য ধন্যবাদ।

গবেষণায় অংশগ্রহণকারীর স্বাক্ষর/টিপসহি
তারিখঃ

পরীক্ষকের স্বাক্ষর
তারিখঃ