



INTERNATIONAL CENTRE FOR
DIARRHOEAL DISEASE
RESEARCH, BANGLADESH

85-008

26

Memorandum

TO : Members of the Research Review Committee
and the Ethical Review Committee of the ICDDR,B DATE: Feb. 6, 1985

FROM : Judith Wasserheit, M.D.

SUBJECT : FAMILY PLANNING-RELATED INFECTIOUS MORBIDITY PROTOCOL

The ICDDR,B, particularly within the scope of the CSRWG, has long accepted as one of its mandates research in the field of population dynamics and family planning. In its Matlab field station and extension areas it currently conducts a massive project which offers both MCH-FP services and a unique testing ground for MCH-FP approaches which might have broader applicability in the national program. Because population control is, along with diarrhoeal disease control, one of Bangladesh's most pressing medical problems, the Centre's work in this area has been both well accepted and productive.

The enclosed proposal examines the infectious complications of our family planning interventions. It is the belief of the co-investigators that this study is a logical and necessary part of our longstanding commitment to MCH-FP services and research because it will both improve the quality of care delivered to our patients and provide data which will help the national program develop simple screening, follow-up, and treatment recommendations for infections in contracepting women throughout Bangladesh. It would be both unethical and scientifically unsound for the ICDDR,B or any organization to offer hundreds of thousands of people a set of health interventions without examining the possible complications of those interventions. Particularly in the context of a growing clinical impression that infections constitute a significant problem among our contracepting women, the co-investigators submit the enclosed protocol for evaluating family planning related infections.

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator J.N. Wasserheit, M.D. Trainee Investigator (if any) _____Application No. 85-008Supporting Agency (if Non-ICDDR,B) FORD FOUNDATION & ICDDR,BTitle of Study Evaluation of Family

Project status:

Planning-Related Infectious Morbidity☒ New Studyin Bangladesh - Matlab Arm (ERC Sheet-1)☐ Continuation with change☐ No change (do not fill out rest of form)

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

1. Source of Population:

(a) Ill subjects ☒ Yes ☐ No(b) Non-ill subjects ☒ Yes ☐ No(c) Minors or persons under guardianship ☒ Yes ☐ No NOT IN MATLAB ARM OF STUDY

2. Does the study involve:

(a) Physical risks to the subjects ☒ Yes ☐ No(b) Social Risks ☒ Yes ☐ No(c) Psychological risks to subjects ☒ Yes ☐ No(d) Discomfort to subjects ☒ Yes ☐ No(e) Invasion of privacy ☒ Yes ☐ No(f) Disclosure of information damaging to subject or others ☒ Yes ☐ No

3. Does the study involve:

(a) Use of records, (hospital, medical, death, birth or other) ☒ Yes ☐ No(b) Use of fetal tissue or abortus ☒ Yes ☐ No(c) Use of organs or body fluids ☒ Yes ☐ No

4. Are subjects clearly informed about:

(a) Nature and purposes of study ☒ Yes ☐ No(b) Procedures to be followed including alternatives used ☒ Yes ☐ No(c) Physical risks ☒ Yes ☐ No(d) Sensitive questions ☒ Yes ☐ No(e) Benefits to be derived ☒ Yes ☐ No(f) Right to refuse to participate or to withdraw from study ☒ Yes ☐ No(g) Confidential handling of data ☒ Yes ☐ No(h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure ☒ Yes ☐ No

5. Will signed consent form be required:

(a) From subjects ☒ Yes ☐ No(b) From parent or guardian (if subjects are minors) ☒ Yes ☐ No ☒ NA6. Will precautions be taken to protect anonymity of subjects ☒ Yes ☐ No

7. Check documents being submitted herewith to Committee:

☐ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).☒ Protocol (Required)☒ Abstract Summary (Required)☒ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)☐ Informed consent form for subjects☐ Informed consent form for parent or guardian☒ Procedure for maintaining confidentiality☒ Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

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

Judith A. Wasserheit/MS
Principal Investigator_____
Trainee

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator J. N. Wasserheit, M.D. Trainee Investigator (if any) _____Application No. 85-008Supporting Agency (if Non-ICDDR,B) FORD FOUNDATION & ICDDR,BTitle of Study Evaluation of Family Planning-Related Infectious Morbidity in Bangladesh - Mohammadpur Arm (ERC Sheet-2)

Project status:

☒ New Study☐ Continuation with change☐ No change (do not fill out rest of form)

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

1. Source of Population:

(a) Ill subjects ☒ Yes ☐ No(b) Non-ill subjects ☒ Yes ☐ No(c) Minors or persons under guardianship Yes ☒ No

2. Does the study involve:

(a) Physical risks to the subjects Yes ☐ No(b) Social Risks Yes ☒ No(c) Psychological risks to subjects Yes ☒ No(d) Discomfort to subjects ☒ Yes ☐ No(e) Invasion of privacy ☒ Yes ☐ No(f) Disclosure of information damaging to subject or others Yes ☒ No

3. Does the study involve:

(a) Use of records, (hospital, medical, death, birth or other) Yes ☒ No(b) Use of fetal tissue or abortus Yes ☒ No(c) Use of organs or body fluids ☒ Yes ☐ No

4. Are subjects clearly informed about:

(a) Nature and purposes of study ☒ Yes ☐ No(b) Procedures to be followed including alternatives used ☒ Yes ☐ No(c) Physical risks ☒ Yes ☐ No(d) Sensitive questions ☒ Yes ☐ No(e) Benefits to be derived ☒ Yes ☐ No(f) Right to refuse to participate or to withdraw from study ☒ Yes ☐ No(g) Confidential handling of data ☒ Yes ☐ No(h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure ☒ Yes ☐ No

5. Will signed consent form be required:

(a) From subjects ☒ Yes ☐ No(b) From parent or guardian (if subjects are minors) Yes ☐ No ☒ NA6. Will precautions be taken to protect anonymity of subjects ☒ Yes ☐ No

7. Check documents being submitted herewith to Committee:

☐ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
☒ Protocol (Required)☒ Abstract Summary (Required)☒ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)☒ Informed consent form for subjects☐ Informed consent form for parent or guardian☒ Procedure for maintaining confidentiality☒ Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

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

Judith L. Wasserheit, M.D.
Principal Investigator_____
Trainee

SECTION I - RESEARCH PROTOCOL

85-008
24.2.85
ICDDR,B LIBRARY
DHAKA 1218

1. Title: Evaluation of Family Planning-Related Infectious Morbidity in Bangladesh.

2. Principal Investigator: Judith N. Wasserheit, M.D.

Co-Investigators: J. Chakraborty, S.I.
Jeffrey R. Harris, M.D.
James F. Phillips, Ph. D.
Sabera Rahman, M.B.B.S.
Md. Yunus, M.B.B.S.

Consultants: Donald Avoy, M.D.
Michael Bennish, M.D.
Bradford Kay, Dr.P.H.
King K. Holmes, M.D., Ph.D.

3. Starting Date: March 15, 1985

4. Completion Date: September 15, 1986

5. Total Direct Cost: \$189,356.00

6. Scientific Program Head: This protocol has been approved by the
Community Services Working Group.

Signature of Scientific Program Head: _____

Date: _____

22.2.85

7. Abstract Summary: Because of the magnitude of the over-population problem in Bangladesh, family planning is one of the foremost national priorities. In order to address methods for maximizing user compliance and continuation, this study will examine one of the most easily modifiable determinants of contraceptive acceptance: infectious morbidity.

Using standardized histories, physical examinations, and laboratory studies, both a rural and an urban population will be evaluated to define the incidence and prevalence of family planning-related infectious complications, their microbiologic spectrum, and the risk factors predisposing to them. The point prevalence of pelvic infections in the family planning population in

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Matlab will be established by surveying 3,000 contracepting women for symptoms suggestive of infection and by performing detailed physical examinations and comprehensive microbiologic studies on the subset of symptomatic women. This information will also define the microbiologic organisms responsible for family planning-related pelvic infection in rural Bangladesh.

In Matlab passive surveillance of pelvic infections will also be established at the health center level by instructing Community Health Workers (CHW's) to refer to the Lady Family Planning Visitors (LFPV's) any woman suspected of having upper genital tract infection. The LFPV's will examine these women and perform only three on-site laboratory tests (a swab test, a whiff test, and an assessment of vaginal pH). Not only will the incidence of pelvic infection in this population be generated from these data, but also, an ongoing system for evaluating family planning-related infection in Matlab will have been developed.

An urban family planning population will be sampled at the Mohammedpur Model Clinic in Dhaka. The same standardized histories, physical examinations, and laboratory studies employed in the prospective study arm in Matlab will be administered to 500 women prior to initiation of a new method of contraception and two weeks, three months, and six months later. Incidence figures and microbiologic spectrum data for pelvic infections in an urban setting will be developed in this arm of the study.

Together, by identifying risk factors for family planning-related

infections, the two study arms will enable us to develop recommendations both for simple screening procedures and for follow-up care to minimize family planning-related infectious morbidity. By defining the etiologic agents responsible for infectious complications in Bangladesh, we will be able to develop more rational empiric antibiotic recommendations. Our data will also provide estimates of the current impact of infection on compliance with and a cost of family planning.

8. Reviews: i) Ethical Review Committee: _____

ii) Research Review Committee: _____

iii) Director: _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objectives: Overpopulation is, undeniably, one of the most pressing problems confronting not only Bangladesh, but many other developing nations. Family planning programs have, therefore, become a major focus of national and international attention. Acceptance and continued compliance with family planning interventions is, however, low throughout most of Bangladesh with use-prevalence of modern methods averaging 13.8% of eligible women in 1983 (1). Even in high use-prevalence areas such as the Matlab field-station of the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B), where user rates run as high as 40% (2), many women terminate use soon after accepting. The two most common reasons given for termination are "side effects" and "inconvenience" depending on the method involved (3-6). In an attempt both to maximize the acceptance of family planning and to achieve better compliance with the sustained practice of contraception, investigation of infectious morbidity related to family planning interventions is necessary. This protocol addresses the need to understand more fully the nature of contraceptive-related infectious morbidity and the measures that may be taken in service programs to control the problem through paramedical care.

2. Background: It is currently the clinical impression in the Matlab station of ICDDR,B that pelvic infection is a significant problem among women participating in the family planning program (7). Data from 1977 through 1980 indicate that symptoms consistent with infection (lower abdominal pain or abnormal vaginal discharge in any contracepting woman; increased bleeding or spotting in any woman not using injectables) were reported by approximately 12.5% of women using intrauterine devices (IUD's), tubectomy, or hormonal methods and by almost 53% of women using only IUD's (3). Now, almost five years later, with sharp increases in the use of IUD's (8), we would expect even higher figures. Yet the Matlab women, like women throughout Bangladesh, receive limited screening for cardiovascular risk factors and no screening for infection prior to beginning contraception. While patients are checked for hypertension, anemia, and diabetes prior to administration of depot medroxyprogesterone acetate (DMPA) or tubectomy, not even a cervical gram stain, a swab test, or a vaginal wet prep is done to evaluate the lower genital tract milieu. Although the absence of such procedures may be justified in the national program on the basis of cost and logistics, no such rationale exists in Matlab where carefully controlled field conditions permit high standards of care. Moreover, by providing such care, Matlab can contribute to our understanding of the magnitude of and approaches to contraceptive-related morbidity in Bangladesh.

If a contracepting woman does develop signs and symptoms consistent with upper (i.e. endometritis or salpingitis) or lower (i.e. vaginitis or cervicitis) genital tract infection, she is usually treated empirically with antibiotics, again without the benefit of even basic laboratory confirmation

of the diagnosis. In Bangladesh this is problematic for two reasons:

a) The clinical diagnosis of upper tract infection is notoriously unreliable. In developed countries, only 65% of women who undergo laparoscopy for clinically suspected pelvic infection have confirmation of the diagnosis (9-10). Since the cornerstone of the clinical diagnosis is the complaint of lower abdominal pain with tenderness on bimanual examination, one would expect that the specificity of a clinical diagnosis would be even lower in a setting in which gastroenteritis is very common.

b) Appropriate empiric antibiotic therapy depends upon knowledge of the relative frequencies with which various organisms are likely to be responsible for a syndrome in a given population. For genital tract pathogens, these patterns usually differ in different countries, in rural and in urban areas within each country, and in different socioeconomic groups. While these patterns are fairly well established in developed countries (11-13), at the present time there are no studies from Bangladesh or the Indian subcontinent which provide comprehensive microbiologic data. Those studies that have been published come from India and present prevalence figures for tuberculous genital tract disease which vary from 6% (14) to 47% (15) of cases, report cervical isolation rates for Neisseria gonorrhoeae of 1.4%, and do not comment on recovery rates of Chlamydia trachomatis, facultative enteric flora, or anaerobes. A recent Bangladeshi survey of antibody to C. trachomatis performed in diarrhea patients without pneumonia or conjunctivitis revealed sero-prevalence totalling 27% of the 93 patients studied (16). This prevalence increased with age. Does this

represent the presence of C. trachomatis as a genital tract pathogen? Should we be using tetracyclines in the therapy of pelvic infections in Bangladesh? Are resistant Neisseria spp. present as in much of Southeast Asia? Or is the majority of infection caused by facultative and anaerobic flora because of poor perineal hygiene and frequent diarrheal episodes? Obviously a thorough microbiologic evaluation of every symptomatic woman in Bangladesh is impractical. We are proposing only that such an evaluation is necessary on a research basis to establish recommendations for empiric antibiotic therapy of pelvic infections in rural and in urban Bangladesh analogous to those published by the Centers for Disease Control (CDC) for the United States (17).

Several method-specific issues about family planning-related infections must also be considered:

a) IUD-related: IUD-related upper genital tract infection is believed to result from ascent of bacteria present in the vagina and/or cervix along the tail "conduit" of the IUD. As a foreign body, an IUD may also impair the normal ability of the endometrium to kill the bacteria that do ascend. In developed countries, the relative risk of upper tract infection in a parous IUD-user is 4 to 5 times that of a woman who is not contracepting (18). Although such infections may be caused by organisms such as N. gonorrhoeae and C. trachomatis, the woman's own facultative and anaerobic fecal flora are often responsible in Western countries. Non-specific vaginitis (NSV) is also more common among IUD-users than among non-users (19) although the pathophysiology is not yet well understood.

Analogous data are not available for Bangladesh, but a recent study of IUD-associated hospitalizations in developing countries (including Bangladesh) (20) reported that while approximately one-quarter of IUD-associated hospitalizations in developed countries are for pelvic infection, approximately one-third of those in less developed countries are for this diagnosis. Because of the greater availability of health care resources in the former setting, hospital based data may, in fact, mask an even greater difference in infection rates between developed and developing nations.

In Bangladesh, rates of IUD-associated infection may be influenced not only by problems with adherence to aseptic insertion techniques, but also by the location of the insertion procedure. As more home insertions are performed, it is mandatory that we examine whether adequate sterile technique can be practiced in a village house. The relationship among recurrent diarrheal episodes, poor perineal hygiene, and the vaginal milieu is also of particular concern in IUD-users. In light of the association between fecal or abnormal vaginal flora and pelvic infection in developed countries where aggressive perineal hygiene is easier to maintain and where diarrheal episodes are less common, it is logical that these factors may play a far greater role in a country like Bangladesh. These questions can be addressed with simple pre- and post-insertion screening (see methods, below). If an association is demonstrated, consideration might be given to the use of inverted-tailed or tailless IUD's (which do not offer bacteria a mechanical conduit from the vagina to the endometrium (21)) or to single dose antibiotic therapy for

diarrheal episodes among IUD-users.

b) Hormonal method-related: Oral contraceptive pill (OCP) use has, in developed countries, been associated not only with a slight protective effect against upper genital tract infection (relative risk compared to non-contracepting women of 0.3 to 0.9 (18)), but also with milder disease if infection does occur (22). A protective effect has similarly been suggested for DMPA (23). Although OCP use has repeatedly been linked to vaginal candida infections, the incidence of this side effect of hormonal therapy is less with DMPA (23). No clinically significant effects on systemic immunity have been demonstrated for DMPA (23) and in Matlab only four injection site abscesses occurred during 14,000 injections (24). In light of these data, infectious morbidity would not be expected to be a major problem among users of hormonal birth control methods. Instead, the goal of assessing them in the context of Bangladesh would be to determine whether they are slightly protective against infection in a developing country where people are at high risk for infectious morbidity.

c) Tubectomy-related: Although tubal ligation by a vaginal approach has been associated with a significant risk of pelvic infection, tubectomy via suprapubic "minilaparotomy" incision, particularly when performed as an interval procedure (rather than following termination of pregnancy), rarely results in infection (25). Wound infections occur more frequently in developing countries than in developed countries, possibly due to a combination of poor nutrition and poor hygiene. Re-evaluation of post-operative wound care techniques might result in fewer infections.

3. Rationale: Compliance with family planning interventions is, in any society, multifactorial. In Bangladesh, as in many developing countries, it is determined by social and religious traditions, by level of education and acquisition of an active rather than a passive world view, by convenience, by cost, and by morbidity. In light of the urgency of the population problem, approaches which impact on rapidly modifiable factors are those which should be pursued first and most aggressively. Of all the determinants of compliance with family planning programs, morbidity is one of the easiest to change. Its control is also crucial to the success of any family planning program because of the tendency of many contraceptors to attribute any health problem to the contraceptive method regardless of whether it is, in fact, related. Termination of contraception is often the first recourse unless the woman believes that true contraceptive-related side-effects are being anticipated and treated attentively. While side-effects which are due to inherent properties of the method (e.g.: abnormal vaginal bleeding with hormonal methods) are difficult to alter, infectious morbidity related to family planning interventions could be evaluated and, one would predict, dramatically decreased using simple, inexpensive approaches.

This problem can not, however, be dealt with effectively until its magnitude and risk factors are defined. Currently in Bangladesh, an information vacuum surrounds questions about family planning-related infectious morbidity. By collecting the data described below, we can not only improve the quality of family planning-related care in Matlab and at the Mohammedpur Clinic, but also supply the national program with the scientific tools with which to

control the problem. Permitting infectious complications to go unmonitored and unaddressed at the programmatic level is not only irresponsible, but also secondarily impairs the efficacy of family planning programs by resulting in otherwise unnecessary use-termination. Moreover, many hospitalizations and health center visits now focus on management of problems that could readily be averted with better screening and follow-up care aimed at contraceptive-related infectious morbidity.

The execution of this proposal is also designed to incorporate the development of several new Bangladeshi resources. Conceptually we feel that the building of local scientific expertise and facilities for ongoing work in the field of family planning-related infectious morbidity is as fundamental to the success of this project as is the collection of the above-mentioned data. With this in mind, a multidisciplinary team of technical experts consisting of Bangladeshi family planning physicians, aerobic and anaerobic microbiologists, and data managers will receive specialty training in this area. In addition, a self-sufficient aerobic clinical microbiology laboratory equipped to evaluate family planning-related infections will be established at the Mohammedpur Model Clinic as part of this project.

Finally, this proposal will strengthen the Matlab family planning program. It will require intensive training and supervision of the CHW and LFPV corps in family planning-related infectious morbidity. These efforts will be reinforced by the establishment of an ongoing passive surveillance system through which such infections can be monitored.

B. SPECIFIC AIMS

1. To evaluate the prevalence and incidence of family planning-related infection in both a rural and an urban setting in Bangladesh.
2. To assess the impact of these infections on compliance and on cost.
3. To determine the microbiologic spectrum of these infections.
4. To identify risk factors for these infections in order to develop simple, replicable screening procedures.
5. To develop screening and follow-up recommendations for decreasing infectious morbidity related to family planning interventions.
6. To train a multidisciplinary team of technical experts for national institutions as a surveillance and advisory resource for ongoing evaluation of family planning-related infectious complications so that the technical achievements of the project can be widely disseminated and integrated into national policy.
7. To establish at the Mohammedpur Model Clinic a self-sufficient aerobic clinical microbiology laboratory capable of evaluating family planning-related infections.
8. To initiate in Matlab an ongoing passive surveillance system to monitor

family planning-related infection.

C. MATERIALS AND METHODS

1. Study Design:

a) Matlab: The Matlab MCH-FP Project was designed to examine the determinants of demographic dynamics and the inter-relationships between maternal-child health and family planning. It functions in both a clinical service and a research role using a cadre of paramedical personnel. Utilizing the existing Community Health Worker (CHW) and Lady Family Planning Visitor (LFPV) network, the extensive demographic surveillance system (DSS) and record keeping system (RKS), and the laboratory capabilities of both the Matlab and the Dhaka stations of ICDDR,B, women living in the Matlab area will be evaluated as described below. This research and training proposal will not displace any of the current activities of the MCH-FP program, but rather, through its focus on evaluating and reducing family planning-related complications, will broaden and upgrade the clinical service.

i-Rural Point Prevalence Arm: Over a six-month period during fortnightly rounds of visits, 3,000 or approximately half of the women currently using IUD's, hormonal methods, or tubectomy will have administered to them by the CHW's a standardized questionnaire (Appendix A) focusing on symptoms of contraceptive-related infection. Ten CHW's will be selected randomly from each of the four research blocks for this survey. Women whose responses are suggestive of infection will be referred to the LFPV or to the

MCH-FP physician for a standardized physical examination (Appendix B) and laboratory evaluation (Appendix C). These forms, which will also be used in the "Prospective Arm" of the study at the Mohammedpur Clinic in Dhaka (see below), include questions about therapy, ultimate disposition (eg: hospitalization), and whether method use was terminated. This information will allow us to determine the impact of infection on both cost and compliance.

On the basis of prior data we estimate that approximately 600 of these 3,000 women will require referral for examination and laboratory studies. From Western figures, of these, at least 50 women can be expected to have pelvic infection. This number will be sufficient to establish prevalence by method and to describe the microbiologic spectrum of disease. It should also be noted in Appendix C that the laboratory evaluation is designed to provide thorough microbiologic information including a diagnosis of NSV, trichomoniasis, and candidiasis from vaginal specimens; chlamydial and gonococcal infection from cervical specimens; and chlamydial, gonococcal, facultative enteric, ^{and} anaerobic infection from endometrial specimens. Risk factors for infection will be assessed not only using data from Appendix A, but also using data from the DSS and RKS (eg: prior contraceptive methods, age at marriage - presumably generally in Bangladesh a surrogate for age of first intercourse, ^{and} religion).

ii-Rural Passive Surveillance Arm: All CHW's will also be instructed to refer to their LFPV's any woman with spontaneous complaints

suggestive of pelvic infection. The referred women will be examined and only a swab test, a whiff test, and an assessment of vaginal pH will be performed. Instead of the forms in Appendices A-C, only a registry (Appendix D) of these patients will be maintained by the LFPV's. The data will be analyzed at the end of one year to assess incidence rates for pelvic infection and to examine the utility and the format of the system.

b) Mohammedpur Model Clinic - Urban Prospective Arm: The procedures summarized in Appendices A-C will be used to evaluate 500 women who request IUD's, hormonal birth control methods, or tubectomy and who, during the six months prior to enrollment, have not used any family planning method or have used only methods which do not alter the cervico-vaginal environment (eg: condoms, rhythm, withdrawal). These women will undergo this evaluation (except for endometrial brushing) prior to initiation of contraception, and two weeks, three months, and six months later whether or not they are symptomatic. In the event that any of these women present for interval clinic visits with spontaneous complaints consistent with infection, they will also be offered this evaluation. Endometrial brush specimens will be obtained only at the initial visit and at any visit during which the patient complains of symptoms. A field-worker will be responsible for motivating patients to attend their follow-up visits.

This part of the study will not only provide baseline information about signs, symptoms, and genital tract flora in non-contracepting women, but will also enable us to follow new contraceptors prospectively, observing changes in lower genital tract flora particularly in relation to diarrheal

episodes. We will be able to define risk factors and incidence rates for pelvic infections in an urban family planning clinic population. Finally, we will have data with which to compare the microbiologic spectrum of pelvic disease in Dhaka and in Matlab.

2. Clinical Methods:

a) Physical Examination: After obtaining informed consent, a routine physical examination will be performed as outlined in Appendix B. In addition to assessment of blood pressure, conjunctivae (for anemia), injection and tubectomy sites, and extremities (for varicosities), special attention will be focused on a detailed bimanual and speculum pelvic examination. The LFPV's and FP physicians will be trained extensively in grading of cervical motion, uterine and adnexal tenderness; assessment of adnexal masses and cervical ectopy or friability; and distinguishing among cervicitis and various types of vaginitis.

b) Specimen Collection: As indicated in Appendix C, vaginal swab, cervical swab, endometrial brush, and rectal swab specimens will be obtained during the study. The LFPV's and FP physicians will be carefully trained in the methods for obtaining and interpreting these specimens. While these techniques are simple and reliable when performed correctly, the results of both the cultures and gram stains are uninterpretable if cervical specimens are contaminated with vaginal secretions or if endometrial specimens are contaminated with cervico-vaginal secretions. With this in mind, particular attention will be given during training to clearing the cervix of vaginal

secretions prior to obtaining the cervical swabs and to washing the cervical os with antiseptic solution (as if for IUD insertion) prior to brushing the endometrium.

3. Laboratory Methods:

a) Enteric Cultures: Specimens obtained in Matlab will be processed in the Matlab Microbiology Laboratory. Specimens obtained at the Mohammedpur Clinic will be processed at ICDDR,B, Dhaka. Work-up at both sites will be according to the routine methods currently in use.

b) Anaerobic Cultures: All anaerobic specimens from Matlab and from the Mohammedpur Clinic will be transported to ICDDR,B, Dhaka in Port-A-Cul tubes where they will be inoculated on Brucella and LKV agars. Identification will be performed by the methods of the Virginia Polytechnic Institute (VPI) manual (28), although no chromatographic speciation will be attempted.

c) Chlamydial Cultures and Monoclonal Antibody Studies: Because the ICDDR,B chlamydia laboratory can accommodate only a limited volume of specimens, cultures will be performed only on a 33% sample of the Matlab women referred in the point prevalence arm of the study (estimated to be approximately 200 women). These specimens will be transported in 0.2M sucrose-phosphate containing 2% fetal calf serum and antibiotics to ICDDR,B, Dhaka where they will be cultured in McCoy cells using 96-well microtiter plates.

All women except those in the passive surveillance arm of the study will have smears of cervical and endometrial specimens prepared for fluorescence-conjugated monoclonal antibody diagnosis of chlamydial infection. These reagents will be donated by the SYVA Corporation, Palo Alto, California. Smears will be read at ICDDP, B, Dhaka. The subset of women on whom both cultures and monoclonal antibody studies are performed will validate the exclusive use of monoclonal antibody studies in the remaining patients by providing sensitivity and specificity data.

d) Other Aerobic Cultures: All specimens to be cultured for aerobic organisms (eg: N. gonorrhoeae, G. vaginalis, etc.) will be plated on site and processed at the Mohammedpur Clinic Microbiology Laboratory. This will require transport of specimens from Matlab during six months of the study. Identification of these organisms will be done using standard methods (sugar utilization, oxidase, gram stain, etc.). *Gonococci* isolates will be tested for sensitivity to penicillin, tetracycline, and trimethoprim-sulfamethoxazole.

e) Gram Stains: All slides for gram staining will be processed and read at the Mohammedpur Clinic Microbiology Laboratory. The criteria for NSV, mucopurulent cervicitis, and endometritis established by Spiegel, et al (26), Brunham, et al (27), and Kiviat (10), respectively will be used.

f) Vaginal Wet Mounts, pH, and Whiff Tests: Assessment of vaginal fluid will be performed on site. NSV will be diagnosed by the criteria of Amsel, et al (19).

4. Therapeutic Considerations: All women felt to have infection requiring treatment will be offered free antibiotic therapy. The antibiotic regimen will be selected at the discretion of the clinician involved from a recommended drug list (Appendix E). All women to whom antibiotics are dispensed will be asked to return for follow-up evaluation. All women with positive cultures or monoclonal antibody studies for N. gonorrhoeae or C. trachomatis will be requested to return for test-of-cure studies after completion of antibiotics. Such women will also be given appropriate antibiotics for their husbands. Any IUD-user felt to have upper genital tract infection will have her IUD removed and be given another method of contraception. Women with infection will be asked to abstain from sexual intercourse until therapy is completed.

During the training period for the LFPV's and the FP physicians, emphasis will be placed on the above aspects of therapy of family planning-related infection and their rationale. In the event of questions or problems during the study period, consultation with Dr. Wasserheit will be recommended.

5. Data Entry and Analysis: Data entry will begin as soon as patient enrollment starts and will run concomitantly. Analysis will begin as soon as each study arm is completed. All data management will be based at ICDDR,B, Dhaka under the supervision of Dr. Phillips (or his replacement).

6. Resource and Technical Development:

a) Personnel: As an integral part of this project, both classroom and on-site training will be provided to the Matlab paramedical corps of MCH-FP workers. Training will also be given to develop a multidisciplinary team of technical experts in the field of family planning-related infections.

i-Matlab CHW and LFPV Corps: During the three months prior to patient enrollment, the CHW's will receive classroom instruction in the basic manifestations, epidemiology, and pathophysiology of family planning-related infections. Special emphasis will be placed on the importance of recognizing upper tract infections (endometritis and salpingitis) because of the potential seriousness of their sequelae (eg: ectopic pregnancy, chronic pain, recurrent infection, and infertility). During the latter part of the three-month training period, these concepts will be applied to development of history-taking skills by training the CHW's to use the history form (Appendix A) in the field setting.

Training for the LFPV's will run concurrently, but will be done together with that of the FP physicians (see below).

Together with the LFPV's,
ii-Multidisciplinary Team: The Matlab MCH-FP physician and the Mohammedpur Clinic physicians, all of whom have backgrounds in obstetrics and gynecology, will receive intensive training in upper and lower genital tract infections, their clinical characteristics, antibiotic therapy, and special examination and laboratory procedures (such as the clinical criteria for diagnosing NSV, attention to vaginal contamination in obtaining cervical gram stains, evaluation of swab tests, sterile endometrial brush techniques, etc -

see Clinical Methods, above). Attention will also be focused on wound and injection site infections and on criteria for evaluating sterile procedures. Training will be both didactic and clinical and will be supervised by Judith N. Wasserheit, M.D., infectious disease research scientist, ICDDR,B whose primary research interest has been female pelvic infections (CV attached). Dr. Wasserheit will provide clinical as well as research support for the Matlab program.

Two Bangladeshi microbiologists will study for three months with the research group of King K Holmes, M.D., Ph.D. in Seattle, Washington prior to the patient enrollment period. One of these microbiologists will be trained in isolation and identification techniques for aerobic pelvic pathogens (eg: Gardnerella vaginalis, Trichomonas vaginalis, Candida spp., N. gonorrhoeae, mycoplasmas, Gp B streptococci, and lactobacilli) and in criteria for evaluating vaginal, cervical, and endometrial gram stains (10,26,27). During the patient evaluation period, this person will work at the Mohammedpur Clinic Microbiology Laboratory.

The other microbiologist will study anaerobic isolation and identification techniques with particular emphasis on anaerobes which play a role in pelvic infections (eg: Bacteroides spp., peptococci, peptostreptococci, etc.). This person will also be trained in staining and reading of smears using fluorescein-conjugated monoclonal antibody reagents. He/she will be based at ICDDR,B, Dhaka during the study period. Both microbiologists will work under the joint supervision of Dr. Wasserheit and Dr. Bradford Kay, Acting Head Microbiology Branch, ICDDR,B (CV attached).

One Bangladeshi senior data manager will be trained at ICDDR,B, Dhaka by James F. Phillips, Ph.D., the demographer who has developed the computerized data management system for the Matlab MCH-FP program (CV attached). This person will become familiar with the special issues involved in family planning and infectious disease epidemiology and data analysis. He/she will be responsible for developing computer-generated forms which interface with the existing RKS.

b) Facilities: Under the auspices of the Ford Foundation, a self-sufficient aerobic clinical microbiology laboratory will be established at the Mohammedpur Model Clinic. This facility will be capable of evaluating family planning-related infections.

7. Project Schedule: Although formal laboratory, clinical, and data management training will start simultaneously and run concomitantly for three months, patient enrollment at the two study sites will be staggered by three months to maximize supervision in the initial phases both in Matlab and at the Mohammedpur Clinic. An approximate time-table is provided (Appendix F).

D. SIGNIFICANCE

Through a better understanding of family planning-related infectious morbidity we will be able not only to improve the quality of clinical care administered in Matlab and at the Mohammedpur Clinic, but also by developing screening, follow-up, and therapeutic recommendations to offer the national program an approach to greater contraceptive acceptance. If family planning

is truly a priority for Bangladesh and the developing world, then a better understanding of family planning-related infection must be sought.

E. FACILITIES REQUIRED

No new facilities will be required at ICDDR,B. As discussed above, a new Ford Foundation sponsored clinical microbiology laboratory will be established at the Mohammedpur Model Clinic.

F. COLLABORATIVE ARRANGEMENTS

Training and consultative support for this project will be provided by the research group of Dr. King K. Holmes in Seattle, Washington. Transportation and living costs for the training of the two microbiologists will be borne by the Ford Foundation. Training costs in Seattle will be borne by Dr. Holmes. To co-ordinate aspects of training, facilitate transportation of fragile study supplies, and obtain consultation on details of the project, Dr. Wasserheit will spend at least one week in Seattle during the training period.

As discussed above, clinical collaboration with the Mohammedpur Model Clinic will be required for nine months during the urban prospective arm of the study.

ABSTRACT SUMMARY #1
MATLAB ARM

1. SUBJECT POPULATION: In Matlab only symptomatic women will be eligible for examination and laboratory studies. These procedures are not only compatible with accepted standards of care, but, in fact, offer patients optimal evaluation for family planning related complaints. No children or persons incapable of giving voluntary informed consent will be eligible.
2. POTENTIAL RISKS: Pelvic examination and endometrial brushing may cause discomfort to the patient particularly if upper tract infection is present. This discomfort is, however, transient and the benefit to the patient of the information so obtained usually far out weighs the temporary pain. Endometrial brushing (like IUD insertion) performed without adequate cleansing of the cervix may, theoretically, result in inoculation of cervicovaginal flora into the endometrium. Although endometrial brushing-related pelvic infections have not been a problem clinically, particular attention will be given during training (see above) to correct preparation of the cervix before the procedure.
3. CONTROL OF POTENTIAL RISKS: See no. 2, above.
4. CONFIDENTIALITY: Patients will be identified by number in their records and during data manipulation.

5. INFORMED CONSENT: Because all procedures performed on ICDDR,B patients during this study will be done on symptomatic women and because these procedures should be performed for appropriate clinical care regardless of the study, verbal rather than signed consent will be obtained. Symptomatic women presenting to the LFPV's in the point prevalence arm

of the protocol will be read the attached statement, given a chance to ask questions, and requested to indicate verbally whether they understand and agree to the examination and specimen collection procedures. No information will be withheld from patients.

6. INTERVIEW: Standardized interviews will be performed only in the point prevalence arm of the Matlab part of the study. They will be done by the CHW's during one of their routine fortnightly visits in the subject's home. They will include a slightly more detailed written version of information that is currently collected verbally after initiation of a new contraceptive method and will require approximately 10 minutes.

7. POTENTIAL BENEFITS: The potential benefits of this study to individual patients include improved monitoring, care, and therapy of family planning-related infections. These will be provided free of charge to the patient. By defining the magnitude, risk factors, and microbiologic spectrum of family planning-related infections in Bangladesh, this work will provide the country with information with which it can control one of the road-blocks to more extensive use of contraception. Through the resources developed as part of this project, Bangladesh will gain new expertise and facilities for

ongoing work in this area. In the opinion of the investigators, these individual and societal benefits far outweigh the potential risks described above.

8. USE OF RECORDS AND SPECIMENS: In addition to the information solicited in the history form (Appendix A), information on prior contraceptive methods, gravidity and parity, religion, socioeconomic status, and education of the Matlab women will be taken from the DSS and/or RKS. No body tissues or fluids other than a vaginal swab, a cervical swab, an endometrial brush, and a rectal swab are required for this study.

VERBAL CONSENT FOR FAMILY PLANNING-RELATED INFECTIOUS MORBIDITY STUDY

POINT PREVALENCE ARM, MATLAB

(To be read to patient by LFPV)

You have been asked to come here to see me because you told the CHW that you are having some problems and from what you said she thought it might be an infection with which I could help you. I am going to check you for tenderness in your lower abdomen and then look to see if there is any evidence of infection in your female organs. At the same time I will take some specimens which will tell us whether you have an infection and, if so, what kind of infection it is. This information will make it possible to give you the best treatment.

When I examine you and take the specimens you may feel a little fleeting discomfort. Do not be frightened by this. It will pass quickly. For one of the specimens I will also wash the part of your womb where a baby would come out. This is so that the inside of your womb will remain clean. If any problem were to occur, however, I would give you medicine for it.

If you do not want to be examined or have these tests performed, I will still try to help you by giving you routine care. However, because I will not have as much information, I may not be able to care for you as well. If you have any questions about what I have said, please ask them now. If you understand what I have said and are ready now, please come inside and I will check you.

পরিবার পরিকল্পনা সম্পর্কিত রোগ জীবাণ দ্বারা সংক্রমিত
কার্যক্রমের মৌখিক সম্পত্তি পত্র

আপনি গ্রাম্য স্বাস্থ্য কর্মীকে আপনার অসুবিধার কথা বলেছিলেন তাই গ্রাম্য স্বাস্থ্য কর্মী অনুমান করি যাচ্ছেন ইহা আপনার কোন সংক্রমক অসুখ হতে পারে যাহার জন্য আমরা আপনাকে সাহায্য করিতে পারি, তাই আপনাকে আমাদের ক্লিনিকে আসার জন্য বলা হয়েছে। এখানে আমরা আপনার তল পেট চাপ দিলে ব্যথা আছে কিনা এবং মহিলা প্রজননতন্ত্রে কোন সংক্রমনের লক্ষণ আছে কিনা তাহা পরীক্ষা করিব। এবং সেই সময় আমরা কিছু নমুনা সংগ্রহ করিব যাহা হতে আমরা বলিতে পারিব আপনার কোন প্রকার সংক্রমিত অসুখ আছে কিনা এবং থাকিলে তাহা কি প্রকার। এই সকল তথ্য আপনাকে সূচিকিংসা করার সুযোগ দিবে।

যখন আমরা আপনাকে পরীক্ষা করিব এবং নমুনা নিব তখন আপনার একটু অসুবিধা হতে পারে। ইহাতে আপনার তল পাওয়ার কিছু নাই। এই কাজটি খুব তাড়াতাড়ি হবে। নমুনা সংগ্রহের এক পর্যায়ে আমরা আপনার বাচ্চাদানির এক অংশ পরিশ্কার করিব যে জামুগা দিয়ে বাচ্চা প্রসব হয়, যাহা দ্বারা আপনার বাচ্চা দানির ভিতরের দিক পরিশ্কার থাকিবে। ইহাতে যদি কোন অসুবিধা থাকে তাহা হলে আপনার জন্য আমরা চিকিৎসার ব্যবস্থা করিব।

আপনি যদি আমাদের দিয়া কোন পরীক্ষা নাও করান তবুও আপনাকে আমরা সাহায্য করিব ও নিয়মিত আপনার খোঁজ খবরাদি নিব। কিন্তু যেহেতু আপনাকে পরীক্ষা না করিলে আপনার রোগ সম্বন্ধে তথ্যাদি পাবো না তাই আপনার জন্য ভাল চিকিৎসার ব্যবস্থাও করিতে পারিব না। আমরা যাহা বলিলাম সেই সমস্তই যদি আপনার কোন প্রশ্ন থাকে তবে অনুগ্রহ করে তাহা জিজ্ঞাসা করুন। আমরা আপনার প্রশ্নের যথাযত উত্তর দিতে চেষ্টা করিব। আর যদি আমরা যাহা বলিলাম তাহা বুঝিয়া থাকেন এবং সন্তুষ্ট থাকেন তবে ভিতরের কামরায় যান আমরা আপনাকে পরীক্ষা করিয়া দেখিব।

ABSTRACT SUMMARY #2 - MOHAMMEDPUR ARM

1. SUBJECT POPULATION: At the Mohammedpur Clinic women who have not contracepted in the 6 months prior to enrollment or who have used methods that do not alter vaginal flora (e.g.: condoms, withdrawal, or abstinence) will be eligible for examination and laboratory studies. In order to evaluate prospectively the incidence of and risk factors for infections among users of various family planning methods, these women will ^{be} evaluated whether or not signs and symptoms of infection are present. Each woman will be evaluated prior to initiation of contraception to obtain baseline data. No children or persons incapable of giving voluntary informed consent will be eligible.

2. POTENTIAL RISKS; Same as for Matlab arm abstract summary. It should be noted, however, that in this arm of the study, endometrial brushing will be performed only prior to initiation of contraception (i.e.: at the enrollment visit) and if the patient presents with symptoms of upper tract infection. At the 2-week, 3-month, and 6-month follow-up visits only cervical, vaginal, and rectal specimens will be obtained. These procedures are potentially associated only with slight discomfort.

3. CONTROL OF POTENTIAL RISKS: As mentioned in the abstract summary for the Matlab arm, particular attention will be given during LFPV training to correct preparation of the cervix and to maintenance of sterile technique before endometrial brushing. In both arms of the study, should symptomatic pelvic infection occur, antibiotic and analgesic therapy will be given.

4. CONFIDENTIALITY: Patients will be identified by number in their records and during data manipulation.

5. INFORMED CONSENT: Because both symptomatic and asymptomatic patients will be evaluated and because follow-up visits will be required, a signed informed consent form will be used in the Mohammedpur arm of the study. The attached consent will be obtained by the interviewer at the Clinic after discussing the study with the patient. This will be done prior to filling out the form in appendix A. No information will be withheld from patients.
6. INTERVIEW: Standardized interviews (appendix A) will be conducted at the Clinic after informed consent is obtained. These will be performed by Clinic staff knowledgeable about family planning methods and will require approximately 10 minutes.
7. POTENTIAL BENEFITS: Same as discussed in the abstract summary for the Matlab arm of the study.
8. USE OF RECORDS AND SPECIMENS: Because no data-base comparable to the DSS or the RKS exists at the Mohammedpur Clinic, all information will be solicited directly from the patients. No records will, therefore, be used in this arm of the study. No body tissues or fluids other than a vaginal swab, a cervical swab, an endometrial brush, and a rectal swab are required for this study.

4 If you have any questions, please ask them now. !

If you agree to participate in the study, please sign the following
statement:

SIGNED CONSENT FOR FAMILY PLANNING-RELATED INFECTIOUS MORBIDITY STUDY
PROSPECTIVE ARM, MOHAMMEDPUR FERTILITY SERVICES & TRAINING CENTRE

Because of the huge over-population problem here in Bangladesh, family planning is, as you know, very important. Women sometimes, however, have problems with their family planning methods and decide to drop or change their methods because of these problems. One type of problem that is easy to treat is called infection. Unfortunately, we do not yet know how often this is a problem for Bangladeshi women who use various family planning methods or what things make a Bangladeshi woman more likely to get such an infection.

In order to find the answers to these questions and to make family planning easier for all women, the Mohammedpur Clinic is doing a study. Women like you who are just starting with a new family planning method will be checked very carefully before the method is started to make sure there is no evidence of infection. This check will include questions about symptoms of infection and about activities or other medical problems that might increase the risk of infection. Your answers to these questions will be confidential and you may, of course, refuse to answer any question. After the questions, you will have an examination which will include a few tests, again to look for infection. Although you may have a little bit of discomfort during the examination, it will pass quickly and you should not be afraid. You may also notice that the the part of your womb where a baby would come out will be washed before one of the test specimens is taken. This is so that the inside of your womb will remain clean. If any problem were to occur, however, you would be given medicine for it.

Two weeks, three months, and six months after you have started this new family planning method you will be checked again (though without some of the tests) to make sure no problems have developed. If, in between scheduled visits, you have any problems, you should come to the clinic and you will also be checked.

By participating in this study, you will receive more thorough and frequent care than is usually available. In addition, some of the tests that will be offered to you are available nowhere else in Bangladesh. If, however, you decide to leave the study, you may do so at any time and the Mohammedpur Clinic will continue to care for you in the routine manner.

If you do not want to participate in this study, the Clinic will provide you with routine contraceptive care.

MOHAMMADPUR FERTILITY SERVICES AND TRAINING CENTRE
AURANGZEEB ROAD, MOHAMMADPUR, DHAKA-7.

Volunteer's Consent for Participation in
Evaluation of family planning related
infectious Morbidity in Bangladesh Study

Name of Volunteer: _____ Age: _____

Clinic Number: _____

Volunteer's Statement

I, the undersigned, as a volunteer for this study, understand that its purpose is to evaluate Family Planning related infection associated with the following methods: _____ or _____ of _____. I understand that I am to use no other contraceptive while participating in the study and that I am to return to this institution for periodic follow-up visits. Throughout my participation in the study, I will receive contraceptive supplies at no cost to me. If I am overdue for a menstrual period or if I have an allergic reaction to the contraceptive, I understand that I must immediately report such an event to the clinic. I further understand that I withdraw from the study at any time or refuse to participate in the study. In either case, I can still receive the services of this institution. I have been informed in writing how to contact _____ in case of emergency. The study, and its benefits has been fully explained to me by Dr. _____ who will be responsible for safeguarding my welfare while I participate in this study. I understand that the study has been approved by the Ministry of Health and Population Control, Government of Bangladesh. I agree to participate in this study as a volunteer subject.

Date

Signature of Volunteer

Investigator's Statement

I, the undersigned, have defined and explained to the volunteer in her native language the benefits of the study, as well as the study procedures.

Date

Signature of Investigator

Date

Signature of Witness of above
signatures and explanation

रमाराधन १३३, काठेनिधि, जगदीश्वर १३ कोने हाटो ३

रमाशम १३३, काठमाण्डौ, नेपाल
३०६२२२२२२२२, रमाशम १३३, काठमाण्डौ, नेपाल

[illegible]

पुष्पगिरि - ५३३

[illegible]

॥ श्रीगणेश ॥

ਪ੍ਰਮਾਣਿਤ ਕਰਦੇ ਹਨ :

[illegible]

इसके उपरि लिखे जायेगा कि यह निम्नलिखित है ---

३०५७ - - - - - १०८६२४ - १०८६२४
 ३०५७ - - - - - १०८६२४ - १०८६२४

[illegible]

১৯৭০-৭১ অর্থবছর
 জাতিসংঘের উন্নয়ন কর্মসূচির অধীনে
 জাতিসংঘের উন্নয়ন কর্মসূচির অধীনে
 জাতিসংঘের উন্নয়ন কর্মসূচির অধীনে

[illegible]

ଅନ୍ୟତମ ସ୍ଥଳ । ଏହି ସ୍ଥାନରେ - ଡାକ୍ତର - ଅବଧାନ - ମଧ୍ୟ
 ମାଣ୍ଡଳରେ କିଛି କ୍ଷମାପଣ ଯାହା, କିଛି ଶୁଦ୍ଧ ଶାସ୍ତ୍ର ! ତାହା ଯାହା

১৬৭৭/৭৮-এ কলকাতা মহানগর কর, ১৬৭৭/৭৮-এ
 কলকাতা মহানগর কর, ১৬৭৭/৭৮-এ কলকাতা মহানগর কর, ১৬৭৭/৭৮-এ

ନିଜର ପ୍ରତିଭାକୁ ଏହିପରି ଭାବରେ ପ୍ରଦର୍ଶିତ କରିବାକୁ ଏହିପରି
 ଏକ ପ୍ରକାରର ପ୍ରତିଭାକୁ ଏହିପରି ଭାବରେ ପ୍ରଦର୍ଶିତ କରିବାକୁ ଏହିପରି

[illegible][illegible]

ଯେଉଁ ଗ୍ରନ୍ଥରେ ଉକ୍ତ ଶ୍ରୀମତୀଙ୍କ ନାମ ଉଲ୍ଲେଖ ଅଛି - ୧୫୦୦ (ପାଞ୍ଚ)
 ତଥ୍ୟାବଳୀରେ ଶ୍ରୀମତୀଙ୍କ ଉଲ୍ଲେଖ ଅଛି - ୧୫୦୦ (ପାଞ୍ଚ)

ନିମ୍ନ ଉପ ଶ୍ରମିକଙ୍କ ସହାୟତା ପ୍ରଦାନ କରିବା ପାଇଁ ଆବେଦନ କରାଯାଇଛି ।

[illegible]

എന്ന ഭാഗം - എന്തെങ്കിലും കാരണത്താൽ നിലനിൽക്കുന്ന അപര-
ഭാഗം - ഇത് പലപ്പോഴും ഒരു മൂല്യമുള്ള
വസ്തുവായിരിക്കാം.

[illegible]

॥ ॐ नमो भगवते वासुदेवाय ॥
 श्री गुरुदेव ! आपने जो आज्ञा दी है, मैं उसे
 आज ही मान लूँगा, और मैं आपकी आज्ञा का पालन
 करूँगा, और मैं आपकी आज्ञा का पालन
 करूँगा, और मैं आपकी आज्ञा का पालन

කිසිදු අවස්ථාවක, 1968 ට්‍රැන්ෂික්ට්ස් සමාගම මෙම පොතේ

କେନ୍ଦ୍ର

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ମୁଦ୍ରାବଳୀର ମୂଲ୍ୟ :-

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APPENDIX A

FAMILY PLANNING HISTORY FORM

- 1) Name : _____
- 2) Registration No. : ____/____/____
- 3) Current ID No. : ____/____/____
- 4) Serial No. : _____
- 5) Husband's Name : _____
- 6) Number of years married : ____
- 7) Of last 14 days, how many nights did
your husband spend in your house : ____
- 8) Religion : ____
- 9) Total Pregnancies : ____
- 10) Living Children : ____
- 11) Contraceptive method currently being used : ____
 - 1) None
 - 2) IUD (home insertion)
 - 3) IUD (health center insertion)
 - 4) Pill
 - 5) Injection
 - 6) Tubectomy
 - 7) Other (describe): _____
- 12) Date of starting method : ____/____/____
day month year
- 13) Ever used other FP method : ____
 - 1) No
 - 2) Yes
- 14) Ever used IUD : ____
 - 1) No
 - 2) Yes
- 15) Last prior FP method : ____
 - 1) None
 - 2) IUD
 - 3) Pill
 - 4) Injection
 - 5) Tubectomy
 - 6) Other (describe): _____
- 16) Date last prior FP method dropped: ____/____/____
day month year
- 17) Date : ____/____/____
day month year

9,99 = does not know
8,88 = not done or not applicable
- 18) First day of last menstrual period (LMP) : ____/____/____
day month year
- 19) Last (cleaning) day of last menstrual period
(LMP) : ____/____/____
day month year

- 20) Abnormal vaginal discharge present? ---
 1) No
 2) Yes
 3) Menstruating
- 21) If yes (2), for how many days? --- days

- 22) What color is it? ---
 1) clear
 2) white
 3) yellow or green
 4) red or bloody
 5) other (describe): _____
- 23) Is there an odor? ---
 1) No
 2) Yes
- 24) Abnormal vaginal bleeding present? ---
 1) No
 2) Yes
- 25) If yes (2), - what type? ---
 1) spotting, between periods
 2) prolonged bleeding during period
 3) heavier bleeding during period
 4) decreased bleeding during period
 5) other (describe): _____
- 26) Materials used during last period ---
 1) None
 2) Unwashed rags
 3) Freshly washed rags
 4) Store bought pads
 5) Other (describe): _____
- 27) Intercourse during last bleeding period? ---
 1) No
 2) Yes
- 28) Number of times patient had intercourse
 in the last 2 weeks. ---
- 29) During the past week, pain present inside
 abdomen (when not menstruating)? ---
 1) No
 2) mild (yes, but could continue
 normal activities)
 3) moderate (yes, but could only continue
 normal activities with medication
 or with difficulty)
 4) severe (yes, could not continue normal
 activities).

30) If yes (2 - 4), - for how many days?

days

For Questions ~~31-35~~: 1) No
2) Yes

- 31) In right upper abdomen?
- 32) In left upper abdomen?
- 33) In right lower abdomen?
- 34) In left lower abdomen?
- 35) In middle upper abdomen?

36) Type of pain?

- 1) cramping
- 2) biting or aching
- 3) stabbing
- 4) other (describe): _____

For questions ~~37-39~~: 1) No
2) Yes

- 37) Abdominal pain present during intercourse?
- 38) Abdominal pain present during menses?
- 39) Any diarrhoea in past two weeks

40) In which direction do you wipe after a bowel movement?

- 1) front to back
- 2) back to front

41) Number of baths per week?

FOR WOMEN WHO HAVE HAD TUBECTOMIES ONLY:

For questions ~~42-44~~: 1) No
2) Yes

- 42) Pain or discomfort present in area of operative site?
- 43) Redness present at operative site?
- 44) Pus present at operative site?

45) Date of onset of these symptoms

___/___/___
day month year

FOR WOMEN WHO ARE USING INJECTABLES ONLY:

46) Date of last injection

___/___/___
day month year

For questions ~~47-49~~: 1) No
2) Yes

- 47) Pain present at injection site?
- 48) Redness present at injection site?
- 49) Pus present at injection site?

50) Date of onset of these symptoms

___/___/___
day month year

51) Other complaints?

1) No

2) Yes (describe): _____

52) Diagnosis:

1) No acute problem,

2) Pelvic infection [pain present inside abdomen when not menstruating (#~~39~~³⁷) or during intercourse (#~~37~~³⁷)]

3) Lower genital tract infection [abnormal vaginal discharge present (#~~30~~³⁰)]

4) Wound infection [pain, redness, or pus at operative site (#~~42,43~~^{42,43}, or ~~44~~⁴⁴)]

5) Injection site infection [pain, redness, or pus at injection site (#~~47,48~~^{47,48}, or ~~49~~⁴⁹)]

6) Other (describe): _____

53) Disposition: (if diagnosis is 2,3,4 or 5 above, REFER)

1) No acute problem, home

2) Refer to LFPV

3) Other (describe): _____

STUDY NUMBER (To be filled in by Coder)

APPENDIX B

FAMILY PLANNING EXAMINATION FORM

- 1) Name : _____
- 2) Husband's Name : _____
- 3) Registration No.: _____/_____/_____/_____/_____/_____
- 4) Current ID No. : _____/_____/_____/_____/_____/_____
- 5) Serial No. : _____/_____/_____/_____/_____/_____
- 6) Date : _____/_____/_____
day month year

9,99 = does not know

8,88 = not done or not assessable

Vital signs:

- 7) Weight: _____ Kg.
- 8) BP: _____ / _____
mm Hg
- 9) Temperature: _____ F

HEENT

- 10) Conjunctivae: _____
 - 1) Pink (normal)
 - 2) Pale

SKIN

- 11) Injection site _____
 - 1) Normal
 - 2) Abnormal

For questions ~~12-16~~ 12-16: 1) No
2) Yes

- 12) If abnormal (2), is it swollen? _____
- 13) Is it red? _____
- 14) Is it tender? _____
- 15) Is pus present? _____
- 16) Other abnormalities (describe): _____

- 17) Tubectomy scar site _____
 - 1) Normal
 - 2) Abnormal

For questions ~~18-22~~ 18-22: 1) Yes
2) No

- 18) If abnormal (2), is it swollen? _____
- 19) Is it red? _____
- 20) Is it tender? _____
- 21) Is pus present? _____
- 22) Other abnormalities (describe): _____

For tenderness questions (23-34):

- 1 = Absent
- 2 = Mild (pain reported by patient, but no change in facial expression or muscle tone)
- 3 = Moderate (pain manifested by change in facial expression or muscle tone, but otherwise patient tolerates examination)
- 4 = Severe (patient cannot tolerate examination without body movement)

ABDOMEN

- | | | |
|-----|--|-----|
| 23) | Right upper quadrant direct tenderness? | --- |
| 24) | Right upper quadrant rebound tenderness? | --- |
| 25) | Left upper quadrant direct tenderness? | --- |
| 26) | Left upper quadrant rebound tenderness? | --- |
| 27) | Right lower quadrant direct tenderness? | --- |
| 28) | Right lower quadrant rebound tenderness? | --- |
| 29) | Left lower quadrant direct tenderness? | --- |
| 30) | Left lower quadrant rebound tenderness? | --- |

PELVIC: Bimanual examination

- | | | | | | |
|-----|---|---------|------|---------|-------|
| 31) | Cervical motion tenderness? | | | | -- |
| 32) | Uterine tenderness? | | | | -- |
| 33) | Right adnexal tenderness? | | | | -- |
| 34) | Left adnexal tenderness? | | | | --- |
| 35) | Uterine size? | | | | -- |
| | 1) normal | | | | |
| | 2) enlarged | | | | |
| 36) | If enlarged, number of weeks | | | | -- -- |
| 37) | Right adnexal fullness or mass? | | | | --- |
| | 1) No | | | | |
| | 2) Yes | | | | |
| 38) | If right adnexal fullness or mass present,size? | -- | -- x | -- | -- |
| | | cm long | | cm wide | |
| 39) | Left adnexal fullness or mass? | | | | -- |
| | 1) No | | | | |
| | 2) Yes | | | | |
| 40) | If left adnexal fullness or mass present,size? | -- | -- x | -- | -- |
| | | cm long | | cm wide | |

Speculum Examination

VAGINA:

- 41) Discharge
- 1) absent
 - 2) present in vagina, but cervical os clear
 - 3) present at cervical os and in vagina
 - 4) menstruating

42) If discharge present (2 or 3), - color?
1) clear
2) white
3) yellow or green
4) bloody
5) other (describe) _____

43) Consistency?
1) thick
2) thin or watery

44) Character?
1) homogeneous
2) inhomogeneous

45) pH

46) KOH odor
1) negative
2) positive

CERVIX:

47) Ectopy?
1) absent
2) present

48) If ectopy present (2), percent? _____ %

49) Cervical friability?
1) absent
2) present

Cervical erosion? 1) absent
2) present
50) Swab test
1) negative
2) positive (yellow or green)

EXTREMITIES:

51) Varicosities?
1) absent
2) present

OTHER IMPORTANT FINDINGS:

1) No
2) (Describe:)
52) Clinical Diagnosis:
1) No acute problem
2) Pelvic infection [endometritis or salpingitis:
tenderness on bimanual examination - (#24-25)]
3) Cervicitis [cervical discharge and positive swab
test (#44+51)]
4) Vaginitis [vaginal discharge (#44)]
5) Wound infection
6) Injection site infection
7) Other (describe): _____

53) Treatment

- 1) None
- 2) Metronidazole 1 gm BID for 14 days
plus
Doxycycline 100 mg BID for 14 days (pelvic infection)
- 3) Trimethoprim Sulfamethoxazole - 160/800 mg
(2 tablets) BID for 14 days
plus
Metronidazole 1 gm BID for 14 days (pelvic infection)
- 4) Trimethoprim sulfamethoxazole 160/600 mg
BID for 7 days (cervicitis)
- 5) Doxycycline 100 mg BID for 7 days (cervicitis)
- 6) Metronidazole 500 mg BID for 7 days
(NSV-PH>4.5, positive KOH odor)
- 7) Metronidazole 2 gm (trichomoniasis -
PH>5.0, negative KOH odor)
- 8) Nystatin (Yeast infection -
PH<4.5, negative KOH odor)
- 9) Cloxacillin 500 mg QID for 7 days
(Wound or injection site infection)
- 10) Other: (describe)_____

54) Method dropped? (IUD pulled or pill or injection stopped) _____

- 1) No
- 2) Yes

55) Disposition

- 1) home without follow-up visit
- ✓ 2) home with visit by CHW on _____/____/____
- 3) home with return visit to LFPV on _____/____/____
- 4) hospitalize
- 5) Other (describe):_____

STUDY NUMBER (To be filled in by Coder) _____

APPENDIX C

FAMILY PLANNING LABORATORY FORM

- 1) Name : _____
- 2) Husband's Name : _____
- 3) Registration No. : ____/____/____/____/____
- 4) Current ID No. : ____/____/____/____/____
- 5) Serial No. : _____
- 6) Date : ____/____/____
day month year

9,99 = does not know

8,88 = not done or not assessable

GRAM STAIN RESULTS

- 7) Epithelial cells at 50x, all others at 1000x
 - None = 1
 - < 1 per field = 2
 - 1-5 per field = 3
 - 5-30 per field = 4
 - >30 per field = 5

Vaginal:

- 8) Epithelial cells
- 9) WBC
- 10) RBC
- 11) Clue cells
- 12) Lactobacilli (large positive rods)
- 13) G.Vag. (small variable rods)
- 14) Positive cocci
- 15) Negative cocci
- 16) Bacteroides (small negative rods)
- 17) Mobiluncus (curved negative rods)
- 18) Fusobacteria (negative rods)
- 19) Yeast
- 20) Trichomonas
- 21) Other (describe) _____

Cervical:

- 22) Epithelial cells
- 23) WBC
- 24) RBC
- 25) Clue cells
- 26) Lactobacilli (large positive rods)
- 27) G.Vaginalis (small variable rods)
- 28) Positive cocci
- 29) Negative cocci
- 30) Yeast
- 31) Other (describe) _____

VAGINAL FLUID RESULTS

- 32) NaCl wet mount/KOH prep
 - 1) normal
 - 2) abnormal

For questions 32-37: 1) No
2) Yes

- 33) If wet mount is abnormal, are trichomonads present?
34) Clue cells?
35) Yeast?
36) WBC?
37) RBC?

CULTURE RESULTS

Vaginal:

- 1) absent
2) present
38) G.Vaginalis
39) Vibrionaceae.
40) Facultative enteric spp. (see code list)
41) Anaerobic spp. (see code list)
42) Other (describe)_____

Cervical:

- 1) absent
2) present
43) N.gonorrhoeae
44) C.trachomatis
45) Other (describe)_____

Endometrial:

- 1) absent
2) present
46) N. gonorrhoeae
47) C. trachomatis
48) G. vaginalis
49) Vibrionaceae
50) Facultative Enteric spp. (see code list)
51) Anaerobic spp. (see code list)
52) Other (describe)_____

Rectal Swab

- 1) absent
2) present
53) Vibrionaceae
54) Facultative enteric spp. (see code list)
55) Other (describe)_____

CHLAMYDIAL MONOCLONAL ANTIBODY RESULTS

- 1) negative
2) positive
56) Cervical
57) Endometrial

STUDY NUMBER (To be filled in by coder) .

PELVIC INFECTIONS SURVEILLANCE REGISTRY

[illegible]

APPENDIX E

FAMILY PLANNING-RELATED INFECTIONS STUDY

DRUG LIST

1) For upper tract infection (excluding pregnant women):

- a) Trimethoprim-Sulfamethoxazole, 160 mg/800 mg p.o. BID
plus
Metronidazole, 1 gm p.o. BID
together for 10-14 days.

OR

- b) Doxycycline, 100 mg p.o. BID
plus
Metronidazole, 1 gm p.o. BID

2) For cervicitis (excluding pregnant women):

- a) Trimethoprim-Sulfamethoxazole, 160 mg/800 mg p.o. BID
for 7 days

OR

- b) Doxycycline, 100 mg p.o. BID for 7 days.

3) For trichomoniasis (excluding pregnant women):

Metronidazole, 2 gm p.o. as a single dose.
(Husbands should also receive metronidazole in the same dose.)

4) For candidiasis:

Mycostatin vaginal tablets, 100,000u p.v. Qd for 14 days.

APPENDIX F

TIME-TABLE FOR FAMILY PLANNING-RELATED INFECTIOUS MORBIDITY STUDY PROPOSAL

SEATTLE U.of W	TECHNICIAN TRAINING
ICDDR,B MATLAB	CLINICAL POINT PREVALENCE ARM ----- TRAINING RURAL PELVIC INFECTION SURVEILLANCE ARM
MOHAMMADPUR CLINIC	ORDERING OF SUPPLIES & URBAN PROSPECTIVE ARM LABORATORY SET-UP ENROLLMENT FOLLOW-UP
ICDDR,B DHAKA	STATISTICAL CONTINUOUS DATA ENTRY & CLEANING WITH ANALYSIS & MSS TRAINING INITIAL DATA ANALYSIS PREPARATION
	0 3 6 9 12 15 18

SECTION-III: BUDGET

A. DETAILED BUDGET

1. Personnel Services:

<u>Name</u>	<u>Position</u>	<u>% Time</u>	<u>\$/18months</u>
J.N. Wasserheit	Principle Investigator	90	67,500.00*
J. Chakraborty	Co-Investigator	25	Centre Support
J.R. Harris	Co-Investigator	15	Centre Support
J.F. Phillips	Co-Investigator	15	Centre Support
S. Rahman	Co-Investigator	NA	MMC Support**
Md. Yunus	Co-Investigator	10	Centre Support
_____	Anaerobic Microbiologist (Research Officer) (Level 4)	100	3,380.00
_____	Statistical Officer(SO)/ Data Management Officer (DMO) (Level 6)	100	6,400.00
_____	Sr. Secretary (Level 5)	100	4,550.00
<u>Personnel Training Costs</u>			
Stipend and transportation for 3 months training of ICDDR,B and MMC Microbiologists at \$5000.00 each			10,000.00
SUB-TOTAL:			91,830.00

* \$37,500.00 of Dr. Wasserheit's salary and benefits will be paid by the Ford Foundation.

** MMC = Mohammedpur Model Clinic

CHW and LFPV costs incurred during training or execution of this project will be borne by the MCH-FP Program as agreed by Drs. James Phillips and Michael Rowland.

2. Supplies and Materials: **

<u>Item</u>	<u>Unit Price</u>	<u>Number</u>	<u>Total Cost</u>
<u>Enteric Cultures</u>			
W/Presumptive ID non-	2.80	ICDDR,B-1200	3,360.00
Shigella/Salmonella/E coli (Vagina & Endometrium)		MMC -3000	8,400.00
W/O presumptive ID (rectum)	1.80	ICDDR,B- 600	1,080.00
		MMC -2250	4,050.00
Cary-Blairmedium	0.05	ICDDR,B-1800	90.00
(all sites)		MMC -5250	265.00
Darkfield Examination	0.20	ICDDR,B-1800	360.00
(all sites)		MMC -5250	1,050.00
<u>Anaerobic Cultures</u>			
Brucella Plates	0.48	ICDDR,B-1200	580.00
(Vagina & Endometrium)		MMC -3000	1,440.00
LKV agar	0.50	ICDDR,B-1200	600.00
(Vagina & Endometrium)		MMC -3000	1,500.00
Port-a-Cul	10/12.55	ICDDR,B-1200	1,520.00
(Vagina & Endometrium)		MMC -3000	3,800.00
Chlamydia cultures	15.00	ICDDR,B- 400	6,000.00
(Cervix & Endometrium)		MMC -Monoclonals only -	
Gonococcal transp.med.	1.50	ICDDR,B-1200	1,800.00
(Cervix & Endometrium)		MMC-no transport nec.	-

***Supplies provide for samples from 4 sites in 600 women in the Matlab point prevalence arm, screening of 450 women in the Matlab Surveillance arm, and samples from 4 sites in 500 women at the initial MMC visit followed by samples from 3 sites (Endometrium excluded except in symptomatic patients) in 500 women at each of 3 follow-up visit. A margin is provided by assuming 250 women in this arm will require 4 site evaluation at each interval visit,

Thayer-Martin Plates	0.6z	ICDDR,B-None nec.	-
(Cervix & Endometrium)		MMC-3,000	1,860.00
<u>G.Vaginalis Plates</u>	0.50	ICDDR,B-None required	-
(Vagina & Endometrium)		MMC-3,000	1,500.00
<u>G.Vaginalis transp.med.</u>	100/60.00	ICDDR,B-1200	720.00
(Vagina & Endometrium)		MMC-None required	-
Endometrial brushes	10/12.00	ICDDR,B-600	720.00
		MMC-750	900.00
Calgi Swabs (III)	2000/128.25	ICDDR,B-5000	320.00
(6/patient-visit)		MMC-13,500	900.00
Glass slides	144/10.75	ICDDR,B-5,250	390.00
		MMC-13,500	1,000.00
Small test tubes (Dispos)	1000/25.00	ICDDR,B-600	25.00
		MMC-2,250	50.00
PH Paper	3 rolls/6.20	ICDDR,B-1,050	15.00
		MMC-2,250	25.00
Gram + AFB Stain		ICDDR,B-3,000	375.00
Reagents		MMC-8,250	1,125.00
Whift test + Wet		ICDDR,B-1650	90.00
Mount reagents		MMC-4500	160.00
(Nacl & KOH)			
Speciation reagents		-	1,500.00
(Sugars, Oxidase, etc.)			
Cover slips	10,000/45.00	ICDDR,B-1200	11.00
(2 Per Wet prep)		MMC-4500	34.00
Antiseptic solution		ICDDR,B-600	50.00
(for endometrial brushing)		MMC-750	60.00
Clerical & Office Supplies		ICDDR,B only	1,000.00
For MMC ONLY			
Pipets (disposable)			
1 ml	500/100.00	1000	200.00
5 ml	500/160.00	1000	320.00
Petri dishes (disp)	5cs/250.00	5cs	250.00
Testtubes 10x75 (disp)	1000/25.00	1000	25.00
Sensitivity discs	10 Pkg/25.00	30 pkg	75.00
(Penicillin, tetracycline, TMP/SMX)			

Buffer Pack	20.00	1	20.00
Para film	1 pkg/25.00	1	25.00
Autoclave bags	1000/165.00	1000	165.00
" " Holders	25.00	1	25.00
" Tape	16/35.00	16	35.00

Misc. (Soap/disinfectant, washing materials)
aluminium foil, brown wrapping paper,
record books, forms, etc.). 1,000.00

ICDDR,B	SUB-TOTAL:	19,106.00
MMC	SUB-TOTAL:	31,759.00
COMBINED	SUB-TOTAL:	50,865.00

3. Equipment:

<u>Item</u>	<u>Unit Price</u>	<u>Number</u>	<u>Total Cost - \$</u>
For ICDDR,B			
2-bladed specula	20.00	10	200.00
Word Processor	2,000.00	1	2,000.00
W/Printer			
		SUB-TOTAL:	2,200.00

For MMC

Incubator	2,050.00	1	2,050.00
Refrigerator	500.00	1	500.00
Self.taring scale	1,200.00	1	1,200.00
Auto dave mittens	pr./25.00	1 pr	25.00
Microscope w/ accessories	3,000.00	1	3,000.00
Distillation unit	1,895.00	1	1,895.00
pH Meter	495.00	1	495.00
pH Meter Electrode	55.00	1	55.00
Hot Plate/Magnistir	190.00	1	190.00
Stir Bars	set/47.00	1 set	47.00
Stirrer Retriever	pr/13.00	1 pr	13.00

Water Bath	710.00	1	710.00
Discard Containers	6/90.00	6	90.00
Tripods	9.00	3	27.00
Bunsen Burner	10.00	5	50.00
BB Lighter	12/15.00	12	15.00
BB Lighter Tips	6/1.00	12	2.00
Inoculating Wire	12pkg/8.00	12pkg	8.00
Inoculating holder	4.00	6	24.00
Cornwall Syringe w/ cannula	115.00	1	115.00
Extra Syringe Barrel	32.00	1	32.00
Pi-Pumps	2/30.00	2	30.00
Testtube rack	17.00	2	34.00
Testtube brush	12/10.00	12	10.00
Candle Jar	5.00	12	60.00
Timer	45.00	1	45.00
Staining Rack	20.00	1	20.00
Forceps (assorted)	6/20.00	6	20.00
Diamond Pencil	8.00	1	8.00
Felt Tip Marker	12/16.00	12	16.00
Grease Pencil	12/ 8.00	12	8.00
Glass Beads	1 lb/ 14.00	1 lb	14.00
Beaker - 50ml	12/16.00	12	16.00
150ml	12/30.00	12	30.00
600ml	6/25.00	6	25.00
1000ml	6/45.00	6	45.00
Graduated cylinder-100ml	4/40.00	4	40.00
500ml	1/20.00	2	40.00
1000ml	1/25.00	2	50.00
Erlenmeyer Flasks-1000ml	6/20.00	6	20.00
2000ml	8/50.00	8	50.00
Testtube w/ cap -13X100	288/125.00	288	125.00
16X100	288/170.00	288	170.00

SUB-TOTAL: 11,419.00

4.	<u>Patient Hospitalisation:</u> None required	-
5.	<u>Outpatient Care:</u> (based on \$8.00/patient treated with analgesics and antibiotics for 14 days) Assumes half of symptomatic patients will require therapy	4,000.00
6.	<u>ICDDR,B Transport:</u> Specimen transport from Matlab to Dhaka during 6 month point prevalence arm	2,000.00
7.	<u>Travel and Transport of Persons</u> 2 round trip air tickets between Dhaka and Seattle for Dr. Wasserheit to facilitate training coordination, supply transport, and data analysis.	3,000.00
8.	<u>Transportation of Things:</u> Specimen delivery from MMC to ICDDR,B daily for 9 months by bicycle messenger.	120.00
9.	<u>Rent, Communications & Utilities</u> Postal charges, ICDDR,B	100.00
10.	<u>Information Services:</u> None required:	-
11.	<u>Printing & Reproduction</u> Xeroxing of training materials at 4¢/copy x100 people (80CHW's, 7LFPV's, 13 M.D.'s) x 20 pages each. Printing of forms (3,000) Sundry Xeroxing costs	80.00 500.00 30.00
	SUB-TOTAL:	610.00
12.	Other Contractual Services: None required	-
13.	Construction, Renovations, Alterations: None required	-

B. BUDGET SUMMARY

	<u>\$/18months</u>
1. Personnel Services	91,830.00
2. Supplies and Materials	50,865.00
3. Equipment	13,619.00
4. Patient Hospitalisation	-
5. Outpatient Care	4,000.00
6. ICDDR,B Transport	2,000.00
7. Travel & Transport of Persons	3,000.00
8. Transport of Things*	
9. Rent, Communications & Utilities	100.00
10. Information Services	-
11. Printing & Reproduction	610.00
12. Other Contractual Services	-
13. Construction, Renovations, Alterations	-
Sub-Total:	\$ 166,144.00
ICDDR,B Overhead on Direct ICDDR,B items only (totalling \$92,846)	23,212.00
Grand Total:	\$ 189,356.00

Of the total \$189,356.00 cost of the project, The Ford Foundation has agreed to support \$ 159,356.00. The remaining \$30,000.00 constitute forty-five percent of Dr. Wasserheit's personnel costs and, as indicated in the detailed budget, will be supported by the ICDDR,B.

The Ford Foundation will also give a \$20,428.00 grant directly to the Mohammedpur Clinic for their Study-related Personnel, medication, transportation, communication and renovation costs.

*Up to \$120.00 from ICDDR,B overhead (see enclosed copy of memo from Ms. Charlene Dale).



INTERNATIONAL CENTRE FOR
DIARRHOEAL DISEASE
RESEARCH, BANGLADESH

Memorandum

TO : Dr. Judith Wasserheit, CSRWG

FROM : Charlene B. Dale *C.B. Dale*
Resources Development

SUBJECT : Budget for Family Planning related
Infectious Morbidity Study

DATE: 10 February 1985

To confirm our discussion today, there were two typographical errors in the budget submission of this proposal to the Ford Foundation : (1) The budget summary neglected to include \$ 120.00 for the purchase of a bicycle for the project which was correctly shown in the budget detail, and (2) the budget summary correctly included the \$ 4,000.00 for outpatient care, but this figure was inadvertently omitted in the detail.

Since the bicycle is a needed piece of equipment to transport specimens to our lab from MMC and the cost is very small, I recommend (and received agreement from Budget & Finance on this) that the cost be expended from the project overhead instead of reissuing the proposal request to Ford.

I certainly regret the mistake occurred; a corrected budget is attached.

cc: - Associate Director, Resources Development
- Budget & Finance Officer

CBD:sz