Library

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date 28/2/84

Principal Investigator [redacted] Trainee Investigator (if any)

Application No. 84-008

Supporting Agency (if Non-ICDDR,B)

Title of Study Infant Mortality in a declining Fertility Population

Project status:
(✓) New Study
( ) Continuation with change
( ) No change (do not fill out rest of form)

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

1. Source of Population:
   (a) Ill subjects — Yes ~~No~~
   (b) Non-ill subjects — ~~Yes~~ ~~No~~
   (c) Minors or persons under guardianship — Yes No

2. Does the study involve:
   (a) Physical risks to the subjects — Yes No
   (b) Social Risks — Yes No
   (c) Psychological risks to subjects — Yes No
   (d) Discomfort to subjects — Yes No
   (e) Invasion of privacy — Yes No
   (f) Disclosure of information damaging to subject or others — Yes No

3. Does the study involve:
   (a) Use of records, (hospital, medical, death, birth or other) — Yes No
   (b) Use of fetal tissue or abortus — Yes No
   (c) Use of organs or body fluids — Yes No

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

5. Will signed consent form be required:
   (a) From subjects — Yes No
   (b) From parent or guardian (if subjects are minors) — Yes No

6. Will precautions be taken to protect anonymity of subjects — Yes No

7. Check documents being submitted herewith to Committee:
   — 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.

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

Principal Investigator

Trainee

SECTION I: RESEARCH PROTOCOL

1. Title : Infant Mortality in a Declining Fertility Population

2. Principal Investigator : A.K.M. Alauddin Chowdhury

   Co-investigator : James F. Phillips

3. Starting Date : As soon as the protocol is approved

4. Completion Date : Two years from date of starting

5. Total Direct Cost : US$ 25,884

6. Scientific Program Head

This protocol has been approved by the Community Services Research Working Group

*Signature of Associate Director, CSR _____

Date 27/2/1984

*This signature implies that the Associate Director for CSR takes responsibility for the planning, execution and budget for this particular protocol.

7. Abstract Summary

This study will explore two incremental components of infant deaths, may happen when the fertility control programs are implemented. The program in general decreases disproportionately the number of births of low maternal risk. Moreover, such program may increase the number of unwanted children in the population. Both the components are expected to raise the infant deaths. A study will be done to compare infant mortality rates of experimental area with MCH-FP intervention in terms of maternal risk factor and by unwanted children with an area where no such interventions are in existence.

8. Reviews

a) Ethical Review Committee _____

b) Research Review Committee _____

c) Director _____

SECTION II: RESEARCH PLAN

A. INTRODUCTION

The Matlab Demographic Surveillance System area consists of two areas: one is called Maternal Child Health and Family Planning (MCH-FP) area and the other has been termed as Comparison area. In MCH-FP area of Matlab, Bangladesh, a package of MCH care with family planning services have been given for the last five years with an expectation of immediate decline in infant mortality and fertility. This package has included maternal and child health services, where tetanus immunization and oral therapy for diarrhoeal disease components have been fully implemented. Aslo adequate advice are given to pregnant women on delivery practices and nutritional, hygienic and sanitary education. Since the health work is mainly oriented to the treatment and care of contraceptive users, the approach is more of comprehensive family planning service delivery than an integrated health service one. In the comparison area no such input is provided.

So far the result showed that in this area the decline in fertility rate were to the expected level (declined from 45 to 35). However, the infant death rate did not shown any significant changes. Although it was expected that infant deaths of the whole MCH-FP intervention area will decrease (Rahman, 1980), however, it did not happen yet. Apart from health care package the fertility control program itself, was expected to increase infant survival because of spacing of births too, failed to show any improvement on the overal infant mortality (Chowdhury, 1982). In Philippines, the recent Bohal Project providing midwifery services, family planning, rudimentary preventive and child care to

a population of 420,000 was unable to demonstrate any significant decline in infant mortality rate from the base level of about 70/1000 livebirths (Williamson, 1979) although the prevalence of contraceptive increased from 20 percent to 43 percent. In Nepal experiment with 714 full time village worker which was in most part was a health intervention and of some family planning. The result showed a significant decline in infant mortality however the improvement in contraceptive use was only 2% (JHU, 1982). The apparent static condition in infant mortality in Matlab MCH area may be a resultant of several reverse directional components which may arise out of the health and family planning interventions and may be associated with infant deaths: (1) the decremental components are direct health care services and child spacing; and (2) two incremental components are (a) proportionately more births are occurring from high risk maternal group because FP program may selectively postpone births of the lower risk maternal groups; and (b) with family planning program, motivation for small family size norms get stronger which may lead proportionately more high order births of undesired. Under such a condition, neglect to newborns may increase. One study in Thailand, showed that unwanted childred had 33% more infant deaths than the wanted children even when demographic and socio-economic factors were controlled. This was statistically significant (Frenzen, 1982). This kind of neglect will be more prominent when births occur from contraceptive failure. In this study, only the incremental components described above effecting the infant deaths will be looked at separately.

B. SPECIFIC AIMS

1. To compare the infant mortality rate of MCH-FP area with comparison by maternal risk of two areas.

2. To compare the proportion of unwanted children in the MCH-FP area with the comparison area.

3. To compare the infant mortality rate of the wanted with unwanted children of both MCH-FP and comparison areas.

C. METHODS AND PROCEDURE

"Maternal risk" for child mortality will be defined by child death experiences of the women. This will be done by taking ratio of observed deaths and expected deaths. Expected number of deaths are calculated on the basis of age, parity and date of births of the children of the women and by the use of current life table (Trussel, 1981).

Whether a child is wanted or unwanted will be known by interviewing the parents from a corss sectional survey. Wanted child will be categorised into three ways, such as wanted by both the parents, or by one parent, or by neither the parents.

This study will be based on a sample survey of 2500 pregnant women to know whether the babies were wanted or unwanted and then these pregnancies are to be matched with subsequent birth and death data from demographic surveillance system for evaluation of differentials of infant mortality. This study is possible because there have a continuous registration of births and deaths in the study area since 1966 which will give maternal risk factor accurately.

This survey data will contain information about number of children born alive to a mother and number of surviving children are to utilized for calculation of maternal risk. As date of birth of previous children born within last 17 years are accurately known, the estimated maternal risk factor will be reliable.

Using Trussell method in each record, the new variable called "maternal risk" will be added. Distribution of maternal risk of MCH-FP area will be compared with distribution of maternal risk of comparison area. If there is a difference in maternal risk because of contraceptive selectivity, infant mortality rates are to be calculated for both the areas separately by controlling maternal risk variables for their comparison. Logistic model can be used for controlling more variables which are associated with infant deaths and when they are different for two areas.

To find out unwanted births, mothers will be interviewed at pregnancy. Response bias under Bengali culture, will be less when asked about unwanted pregnancy than about unwanted births. Births have more cultural and emotional associations than the pregnancy itself and probably have more response bias.

Surveillance of pregnancies is already in existence in the MCH-FP area, where each community worker has a list of pregnant women in her area and this is being updated in each month. Out of that list a random sample of 1250 pregnant women will be selected for interview. Similarly, for comparison area, as no list of pregnant women is available, a list of all pregnant women is to be prepared and a random sample of another 1250 pregnant women will be

selected for interview. To minimize further response bias only the pregnant women who are in 1st and 2nd trimester are to be selected. Questionnaire is given in Appendix I. After the interview is over, these are to be computerised and a comparison of the two areas by unwanted pregnancies will be done. This pregnancies file will then to be updated with incoming birth and infant death reports from the demographic surveillance system. This updating will be continued till one year exposure of last birth is experienced. Altogether the study will take 24 months to be completed.

D. SIGNIFICANCE

In a high mortality society, study may show that a initial decline in fertility could shift births toward high maternal risk categories, thus, increasing overall infant mortality. Hence the effect of primary health care on infant mortality may not be apparent. Moreover, the number of unwanted children may increase with small family size norms and these unwanted births are attributable to deliberate neglect with increased risk of mortality. This may raise some policy issues about health care, more effective family planning services as well as the abortions.

REFERENCES

1. Frenzen P.D. and Hogan D.P. The impact of education and health care on infant mortality in a developing society: the case of rural Thailand. Demography; 19(3), 1982.

2. Rahman M and D'Souza. A review of findings in two rural areas of Bangladesh. ICDDR,B Special Publication No. 11, 1980.

3. Chowdhury M.K. et al. Demographic surveillance system. Volume 10. ICDDR,B Scientific Report No. 58, 1982.

4. Williamson N. The Bohol project and its impact. Studies in Family Planning; 10(6-7), 1979.

5. Trussell J and Preston S. Estimating the co-variates of childhood mortality from retrospective reports of mother. Health Policy and Education, 2, 1982.

6. The John Hopkins University. Population reports series L No. 3, Hampton House, 624 North Broadway, Baltimore MD 21205, 1982.

SECTION III: DETAILED BUDGET

1. Personnel Services

Name	Position	Level/Step	% Effort	Annual Salary	Cost in Tk for 1984
Dr. A.K.M. Alauddin Chowdhury	Scientist	-	25	US$ 67,600	425,000
Dr. James F. Phillips	Scientist	Expatriat	.	-	-
	Computer Programmer	VI	10	-	7,200
To be assigned from Branch	Data Entry Technician		10	-	3,600
"	Data Processing Asstt.		100	49,400	49,400
"	Field Supervisor (Female)		5	-	4,000
"	Community Health Worker (80)		2	-	14,400
To be hired	Female Interviewer (12)		50	-	54,000*
				Sub total:	557,600

2. Travel and Transportation

Speedboat hours 200 @ Tk.350/- per hour	70,000*
Land transport at Matlab, @ Tk.4/- x 300 miles	12,000*
Sub total:	82,000

3. Transportation of Materials - None

4. Rent, Communication and Utilities - None

5. Printing and Reproduction

Mimeography, xeroxing, stencil and special reproduction	2,000*

6. Other Contractual Services

Computer time, 100 hours	-
Computer stationeries	500*

	Cost in Taka for 1984
7. Supplies and Materials	
Office stationeries	5,000*
8. Equipment - None	
9. ICDDR,B Transport - None	
10. Patient Hospitalization - None	
11. Outpatient Care - None	
12. Information Services (Library & Publication) - None	
13. Construction, Renovation, Alterations - None	

*Incremental part.

B. SUMMARY BUDGET

		Cost in Taka for 1984
1.	Personnel Services	557,600
2.	Travel and Transportation	82,000
3.	Transportation of Materials	-
4.	Rent, Communication and Utilities	-
5.	Printing and Reproduction	2,000
6.	Other Contractual Services	500
7.	Supplies and Materials	5,000
8.	Equipment	-
9.	ICDDR,B Transport	-
10.	Patient Hospitalization	-
11.	Outpatient Care	-
12.	Information Services	-
13.	Construction, Renovation, Alterations	-
	Total:	647,100*

*Equivalent US$25,884 @ US$1.00 = Tk.25/=

Appendix I

PREGNANCY SURVEY

1. Name of women _____ VTS No. _____

   Area _____

2. Are you pregnant now? Yes ☐ No ☐

   → Month of gestation _____

3. Did you want to have this conception further delay? Yes ☐ No ☐

4. Did you try any contraceptive method to delay this conception? Yes ☐ No ☐

   → Name the method(s) _____

   Was this contraception failure Yes ☐ No ☐

5. Did your husband want this conception now? Yes ☐ No ☐

   ☐ Did he want earlier
   ☐ " " " later
   ☐ " " " never

6. Age _____ Parity _____ Living children _____

   Complimentary data to be added:

7. Date of 1st birth _____

   Date of 2nd birth _____

   . .
   . .
   . .
   . .

   Maternal risk factor _____ Residence status of mother MCH Comp

8. Was the pregnancy terminated to livebirth? Yes ☐ No ☐ → Induced / Spontaneous

   ☐ Single
   ☐ Twin

9. Sex of birth Male ☐ Female ☐

10. Date of termination _____

11. Is the newborn surviving at the end of one year? Yes ☐ No ☐

    Date of death _____

INTERVIEWEE CONSENT FORM

I know that the ICDDR,B (former Cholera Research Laboratory) Female Field Workers are collecting information about infant death desire for children and family planning practice. They have included me as one of their respondnets. I understand that I have the right to refuse to respond and I can withdraw from the study whenever I like.

I am assured that confidentiality will be maintained about all information obtained. Under these conditions I do hereby give my consent for interview.

_____

Signature/Left Thumb impression of
Woman/Birth Attendant

Date: _____

সাক্ষাৎদানের সম্মতি পত্র

আমি অবগত আছি যে, আই, সি, ডি, ডি, আর, বি-র (ভূতপূর্ব কলেরা রিসার্চ ল্যাবরেটরী) মহিলা কর্মীগণ পরিবার পরিকল্পনা, মায়ের স্বাস্থ্য এবং শিশু স্বাস্থ্য সম্পর্কে তথ্য সংগ্রহ করিতেছেন। অতএব অনেক মহিলার সঙ্গে তাহারা আমাকে সাক্ষাৎদাতা নির্বাচন করিয়াছেন। আমি জানি যে আমার সাক্ষাৎদান না করার অধিকার আছে এবং যে কোন সময়ে এ কার্যক্রম হইতে বিরত থাকিতে পারি।

আমাকে সেইসব বিষয় তথ্যাবলী সম্বন্ধে প্রশ্নাবলীর বিষয়বস্তু ব্যাখ্যা করা হইলে এ নিশ্চয়তার সহিত সাক্ষাৎদান করিতে সম্মতি দিলাম।

সাক্ষাৎদাতার স্বাক্ষর বা টিপসই
বৃদ্ধাঙ্গুলির ছাপ

তারিখ ______________

PROCEDURE TO MAINTAIN CONFINDENTIALITY

All the respondents will be identified by numeric codes which will be only used all the times instead of personal names used only in the homes for convenience of conversation and interview. The supervisor and investigators of the protocol will carefully handle the completed questionnaires. All the workers who will be dealing with the data will be trained, responsible and will be aware of the confidentiality of information.