ment 1. Date 22/1/86

ETHICAL REVIEW COMMITTEE, ICDDR,B.

28

ipal Investigator AKM Alauddin Chow Trainee Investigator (if any)

ication No. 86-002 Supporting Agency (if Non-ICDDR,B)

le of Study Infant Mortality Dynamics in a Declining Fertility Population.

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

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

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

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)

s 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)

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.

(PTO)

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

AKM Alauddin Chow
Principal Investigator

Trainee

87-002

22/1/86

Cop. 1

SPECIAL [illegible] PROTOCOL

1. Title : Infant Mortality Dynamics 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 externally funded

4. Completion Date : One year from starting date

5. Total Funding Sought : US $29,475

6. Scientific Program Head

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

Signature of ~~Acting~~ Associate Director, CSRWG _____

Date 27.11.85

7. Abstract Summary:

This study will explore two incremental causal determinants of infant deaths, which may arise when fertility control programs are implemented. An effective family planning program decreases disproportionately the number of births of low maternal risk. In turn, this leads to the spurious conclusion that elevated risks are associated with family planning. Moreover, such a program may increase the effect of unplanned children on mortality while reducing the overall infant mortality rate in the population. Thus, while family planning has direct benefits by averting births and the deaths associated with averted births, spurious and unexpected correlates of death can arise from the selectivity of fertility impact. The proposed study will compare, using a comparison area where no such interventions exist, infant mortality rates in experimental areas which have MCH-FP intervention, in terms of maternal risk factors and risk by unplanned children, health intervention components, and socioeconomic variables.

8. Review:

a) Ethical Review Committee _____

b) Research Review Committee _____

c) Director _____

RECEIVED 8 OCT 2001

## SECTION II: RESEARCH PLAN

### A. INTRODUCTION

Since 1977, the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) has been running a research project at its Matlab field station -- a project which has been shown to have had pronounced fertility effects (Phillips et al., 1982) and [illegible], but little, if any, mortality effects (Chen et al., 1983). This program, at least in its early years, had no apparent effect on the demand for contraception (Chowdhury et al., 1983), thus suggesting that the impacts seen arose from the delivery of services to a population already motivated to use contraceptives, but lacking effective means of doing so.

The modest mortality effects, despite concurrent direct intervention with tetanus and other MCH techniques, is surprising. The premise of this protocol is that births averted by a successful family planning program are selective for certain elements in the population and, therefore, that births occurring in the Matlab service area are not of comparable risk to births occurring in the natural fertility area where fertility has not declined. More specifically, we posit two outcomes due to the selectivity of averted births: (1) High risk pregnancies occur among nulliparous women, since their age at marriage is low; and such high risk pregnancies are unaffected by family planning. Only if there occurs the development of alternative opportunities for young women -- [illegible] education -- will marriage be postponed; and will the risks of first births thus be reduced. (2) Conversely, births that are averted by family planning will occur [illegible] in high parity [illegible] women. Thus, [illegible]

many living children--women of relatively high health standards--are averting births which otherwise would have survived. Hence the left over births of such a population occur to women with high risks, and will spuriously increase infant mortality. Such spuriously high rates emerge nevertheless, because in such a situation, women with high children mortality experience or those who are young and nulliparous become a greater proportion of total pregnancies. Understanding this dynamic is crucial to interpreting the health consequences of successful family planning in rural Bangladesh.

Moreover, selectivity of births averted can complicate further interpretation of the correlates of child survival in a declining fertility population. For example, several authors have shown that unplanned fertility poses elevated mortality risks to children born, particularly if the child is female in a society with a strong male preference. However, if unintended fertility is eliminated or reduced, as appears to be the case in Matlab, it is reasonable to suggest that fewer deaths will results, because planned pregnancies will entail lower risk. This tendency thus compensates for the selectivity of births among otherwise high risk infants. Still, it is reasonable to hypothesize that those few unplanned births, which are not prevented by a family planning program, are at higher risk than are births in a natural fertility population. For these selected mothers are likely to be uneducated, unreceptive to MCH care, confined to home and otherwise at relatively high risk.

In summary, our thesis is that simple mortality rate differentials or incautious analysis of correlates can produce misleading conclusions, owing to the selectivity of contraceptive use and the efficacy of the Family Planning Health Services Project at Matlab.

Analysis is facilitated by the Matlab Demographic Surveillance System area in rural Bangladesh, which is divided in two: a Maternal Child Health and Family Planning (MCH-FP) treatment area, and a comparison area. In the Matlab MCH-FP area, a package of MCH care plus comprehensive family planning services has been provided for the last six years--with an expectation of an immediate decline in infant mortality and fertility. Included are integrated maternal child health services, with fully implemented tetanus immunization and oral rehydration therapy (ORT) for diarrhoeal diseases; clinic care of children; measles immunization; advice for pregnant women on delivery practices and nutrition, and supply of birth delivery kits; and hygiene and sanitary education. The comparison area receives no such inputs.

So far, in the MCH-FP service area there has been a decline in fertility to anticipated levels (from 45 to 35 percent). However, the infant death rate did not change, although it had been expected that comprehensive vaccination in the entire MCH-FP intervention area would result in a significant decrease in tetanus-related infant deaths (Rahman, 1980). At the same time, child mortality among 1-4-year-olds did decline significantly after the comprehensive intervention was introduced. Apart from the health care

package, the fertility control program itself was expected to increase infant survival, due to the spacing of births. However, ther has not been any improvement in overall infant mortality (Chowdhury, MK, 1982). Similar findings have been reported from the Philippines for the recent Bohal Project, which provided midwifery services, family planning, and rudimentary preventive and child care to a 420,000 population. Analysis was unable to show any significant decline in the infant mortality rate from the base level of about 70/1,000 live births (Williamson, 1979), although contraceptive prevalence increased from 20 to 43 percent. In Nepal, among 714 full-time village workers, an experiment was done, which the result was of health intervention with limited family planning. While these resulted a significant decline in infant mortality, contraceptive use increased by only 2% (JHU, 1982).

The apparent static condition of infant mortality in the Matlab MCH-FP area may be due to at least two influencing components, which may arise from the MCH-FP interventions. Thus, (1) the decremental components may consist of direct health care components and concommitant child spacing leading to a reduction of unplanned fertility; and (2) the incremental components may consist of the proportionately more births occurring in high risk maternal groups (mothers with experience of child deaths), because the FP program may selectively postpone births among lower risk maternal groups.

Interestingly, one study in Thailand showed that there were 33% more infant deaths among unwanted than among wanted children, even when demographic and socio-economic factors were controlled. This was statistically significant (Frenzen, 1982).

Thus, one can posit that infant mortality will be greater when births occur after contraceptive failure. It is suggested that this study will examine separately each of the two components described above that affect infant deaths. Table 1 shows the fertility and mortality conditions of the two Matlab areas. When compared for the two areas, still-birth and neonatal data suggest that the above hypotheses may be correct.

Table 1

Still-birth ratios, neonatal, post-neonatal and child mortality rates in the MCH-FP versus the comparison areas

| Calendar Year | Still-birth | | Neonatal | | Post-neonatal | | 1-4 year old children | |
|---|---|---|---|---|---|---|---|---|
| | MCH-FP | Comp. | MCH-FP | Comp. | MCH-FP | Comp. | MCH-FP | Comp. |
| 1974 | | | 69 | 77 | 55 | 69 | 22 | 24 |
| 1975 (famine year) | | | 65 | 83 | 116 | 115 | 36 | 33 |
| 1976 | | | 54 | 65 | 43 | 34 | 31 | 33 |
| 1977 | | | 74 | 64 | 42 | 48 | 18 | 19 |
| 1978 (MCH-FP intervention begins) | 42 | 55 | 68 | 78 | 46 | 47 | 22 | 22 |
| 1979 continued | 41 | 43 | 71 | 74 | 44 | 44 | 17 | 26 |
| 1980 " | 46 | 36 | 59 | 72 | 34 | 44 | 18 | 25 |
| 1981 " | 40 | 36 | 65 | 68 | 37 | 46 | 19 | 24 |
| 1982 " | 35 | 35 | 58 | 67 | 48 | 51 | 19 | 28 |

B. SPECIFIC AIMS

1. To compare, for the MCH-FP versus comparison areas infant mortality rates, by maternal risk factors (parity and child survival experience) as well as by health care components.

2. To compare, in the two areas, infant mortality of births resulting from contraceptive failure and births among non-contraceptive using women along with health care components.

C. METHODS AND PROCEDURE

This study involves no further data collection. Data already collected at different sources are to be pooled, in order to test the hypothesis.

The analysis will be based on the birth cohorts of 1981 and 1982 of both the MCH-FP and comparison areas, and the children's survival status in the first year of life. The data sources to be used are: (1) birth registration data 1981 and 1982; (2) death registration data 1981, 1982 and 1983; (3) longitudinal contraceptive prevalence data; (4) updated 1982 census data; and (5) health service data in Community Health Workers' record books, where data on all the health components at the micro level are available.

Socio-economic and previous birth intervals will be analyzed, by matching birth data with updated 1982 census data. Moreover, all these 1981 and 1982 births will be divided into two groups: among contraceptive-using women who conceived due to contraceptive failures; and among non-contracepting women. The former group will be considered as women of unintended fertility. These data will be available in contraceptive prevalence data files.

Health data on such things as mothers' tetanus immunization, infants' measles immunization, child treatment at the Family Welfare Centre and Oral Rehydration Therapy distribution--data which will be available from Community Health Workers' records--will be fed into a computer, to match with birth registration data.

Maternal risk in this proposal will be defined by the child-deaths already experienced by the women at the time of a given birth. This will be calculated at the micro level, by taking a ration of the observed number of child-deaths over the expected number of child-deaths. The expected number of child deaths is estimated by adding the probability of dying of all children to the age at this birth. The mathemathical expression will be $= \sum_{i}^{n} ( 1-\ell x )$ -- where n is the number of children previously born and $\ell x$ is the survival probability of the birth to age x (Trussell, 1982). In Matlab, as each child's birth date is known accurately from the vital registration system and as life-tables exist for each subsequent year, the estimate of maternal risk will be accurate.

This will provide a data file, wherein each record will contain information for a cohort of children born in 1981 and 1982--information about their survival during infancy, socio-demographic characteristics, immunizations and other health support information, and mothers' contraceptive failures. The independent variables to be studied are: age, sex, birth order, education, previous birth interval, maternal risk factor, tetanus and measles immunizations, curative health services, and contraceptive failure births. Infant deaths will be treated as dependent variables.

Data Analysis

Maternal risk will be compared for the MCH-FP versus comparison areas. If a difference is seen due to contraceptive selectivity, then, in the first step, standardized infant mortality rates will be calculated and compared for the two areas. Secondly, a logistics model will be used to control simultaneously other variables, which are expected to be associated with infant deaths and may be different for the two areas.

This analysis will focus on four major sets of predictors thought influence infant survival: (1) maternal risks; (2) fertility intentions; (3) health interventions and (4) socio-demographic variables. These predictors also may interact to produce an additional effect.

The logistic hazard function under such circumstances would be:

$$\text{Logit } q = \ln\left(q/(1-q)\right)$$

$$= \alpha + \sum_{i=1}^{I} \beta_i W_i + \sum_{j=1}^{J} \gamma_j X_j + \sum_{k=1}^{K} \zeta_k Y_k + \sum_{\ell=1}^{L} \delta_\ell Z_\ell + \sum_{i=1}^{I} \sum_{k=1}^{K} \delta_{ik} W_i Y_k$$

where q is the probability of dying during infancy, $W_i$, $X_j$, $Y_k$ and $Z_\ell$ are the vectors of the four sets of predictors, and $\beta_i$, $\gamma_j$, $\zeta_k$ and $\delta_\ell$ are the vectors of the estimated parameter of the predictors. The last term is designed to examine any additional effects of two-way interactions.

Table 2 gives individual elements of the four sets of predictors to be considered in the model.

Table 2

Set of Predictors by Individual Elements

| Predictors | Individual Elements |
|---|---|
| A. Maternal Risk | (a) Children born alive |
| | (b) Children surviving |
| | (c) Ages of the children |
| B. Fertility Intentions | (a) No contraceptions |
| | (b) Contraceptive failure |
| | (c) Contraceptive discontinued for birth |
| C. Health Interventions | (a) Tetanus immunizations |
| | (b) Measles vaccine |
| | (c) ORT |
| | (d) Delivery kit |
| | (e) Clinic care |
| | (f) Nutrition education |
| D. Socio-demographic | (a) Maternal education |
| | (b) Age of mother |
| | (c) Previous birth interval |
| | (d) Religion |
| | (e) Occupation of husband |
| E. Community level variables | (a) Close to public institutions |
| | (b) Close to service personnel |
| | (c) Literacy level of the community |
| | (d) Religion of the community |
| | (e) Close to urbnisation |

D. SIGNIFICANCE

In a high mortality society, study may show that an 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, births occurring to mothers with low fertility intention may contribute to increased mortality risk. Such a finding may raise policy issues about health care and more effective family planning services, as well as about abortions.

## REFERENCES


1. Chen LC, Rahman M, D'Souza S, Chakraborty J, Sarder AM and Yunus M (1983). Mortality impact of an MCH-FP program in Matlab, Bangladesh. Studies in Family Planning, 14 (39): 199-209.

2. Chowdhury AI, Philips JF, Rahman M (1984). Predicting the adoption of contraception: A multivariate analysis of contraceptive intentions and subsequent use in Matlab thana, Bangladesh.(mimiograph) Accepted for for publication in the Studies in Family Planning.

3. Chowdhury MK, Razzaque A, Mostafa G, Sarder AM and D'Souza S (1982). Demographic surveillance system - Matlab. Volume Ten. Vital events and migration tables 1980. Dhaka, International Centre for Diarrhoeal Disease Research, Bangladesh. Scientific Report No. 58.

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

5. Philips JF, Stinson WS, Bhatia S, Rahman M and Chakraborty J (1982). The demographic impact of the Family Planning Health Services Project in Matlab, Bangladesh. Studies in Family Planning, 13(5): 131-148.

6. Rahman M, Chen LC, Chakraborty J, Yunus M, Chowdhury AI, Sarder AM, Bhatia S and Curlin GT (1982). Use of tetanus toxoid for the prevention of neonatal tetanus. 1. Reduction of neonatal mortality by immunization of non-pregnant and pregnant women in rural Bangladesh. Bull. WHO, 60(2): 261-267.

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

8. The Johns Hopkins University. Population Reports Series L No. 3, Hampton House, 624 North Broadway, Baltimore, MD 21205, USA (1982).

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

SECTION III: DETAILED BUDGET

| 1. PERSONNEL SERVICES<br>Name | Position | Level/ step | % effort | Annual salary and fringe benefits | Project requirement in US dollar |
|---|---|---|---|---|---|
| AKM Alauddin Chowdhury | Principal Investigator | P4-6 | 25 | 50,000 | 12,500* |
| ~~James F. Phillips~~ | ~~Co-Investigator~~ | - | ~~10~~ | ~~78,000~~ | ~~ICDDR,B support~~ |
| To be hired | Comuter Programmer | VI-6 | 50 | 5,250 | 2,625 |
| To be hired | Data Entry Tech. | III-6 | 50 | 2,500 | 1,250 |
| To be hired | Research Associate | STM-1 | 100 | 6,600 | 6,600 |
| To be hired | Secretary, Gr.I | VI-6 | 20 | 5,250 | 1,050 |
| | | | | Sub-total | 24,025 |

2. TRAVEL AND TRANSPORTATION

| | | |
|---|---|---|
| Local transport to visit Matlab | | 500 |
| | Sub-total | 5,000 |

3. TRANSPORTATION OF MATERIALS - None

4. RENT, COMMUNICATIONS AND UTILITIES - None

* 5. PRINTING AND REPRODUCTION — This should be requested ICDDR,B support from hence.

Mimeography, xeroxing, stencil and special publication

6. COMPUTER SERVICES

| | |
|---|---|
| Computer time, 100 hours | 2,000 |
| Computer stationery | 500 |

* This amount to be reimbursed to ICDDR,B. PI will get his usual salary from ICDDR,B and not a portion of this amount will go to his own account.

Note: 1 US $ = 26.0613 BD taka

* Financial support for this item will be sought from IDRC Cairo

| | Project Requirments in US dollar |
|---|---|
| 7. SUPPLIES & MATERIALS | |
| Office stationery | ICDDR,B support |
| 8. EQUIPMENT - None | |
| 9. TRANSPORT - None | |
| 10. PATIENT HOSPITALIZATION - None | |
| 11. OUT-PATIENT CARE - None | |
| 12. INFORMATION SERVICES (LIBRARY & PUBLICATION) - None | |
| 13. CONSTRUCTION - None | |
| 14. MANAGEMENT COST | |
| 30% overhead cost | ICDDR,B support |

## B. SUMMARY BUDGET

| | | Project Requirements in US dollar | ICDDDR,B support value US$ |
|---|---|---|---|
| 1. | Personnel Services | 24,025 | ~~7,800~~ |
| 2. | Travel and Transportation | 500 | - |
| 3. | Transportation of Materials | - | - |
| 4. | Rent, Communication & Utilities | - | - |
| 5. | Printing and Reproduction | - | 450 |
| 6. | Computer services | 2,500 | - |
| 7. | Supplies & Materials | - | 250 |
| 8. | Equipment | - | - |
| 9. | Transport | - | - |
| 10. | Patient Hospitalization | - | - |
| 11. | Out-Patient Care | - | - |
| 12. | Information Services (Library & Publication) | - | - |
| 13. | Construction | - | - |
| 14. | Management Cost | - | - |
| | | 27,025 | 700 |

(1 US$ = 26.0613 BD Taka)

*~~If outside fund will not available, IDRC will bear the travel cost and~~ tution fees.

## PROCEDURE TO MAINTAIN CONFIDENTIALITY

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