ETHICAL REVIEW COMMITTEE, ICDDR,B. 15 May 1984

17/5/84

Principal Investigator AKMA Chowdhury — Trainee Investigator (if any)

Protocol No. 84-021(P)

Supporting Agency (if Non-ICDDR,B)

Title of Study: Infant mortality dynamics 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).

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)

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)

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.

akhowdhury 21 MAY 1984

Principal Investigator — Date

SECTION I: RESEARCH PROTOCOL

Title	: Infant Mortality Dynamics in a Declining Fertility Population (Pilot Study)
Principal Investigator	: A.K.M. Alauddin Chowdhury
Co-Investigator	: James F. Phillips
Starting Date	: 1st July 1984
Completion Date	: 31st December 1984
Total Direct Cost	: US $2,972

Scientific Program Head:

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

Signature of Acting Associate Director, CSRWG W.D.

Date 16.05.84

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 infant mortality rates of experimental areas with MCH-FP intervention in terms of maternal risk factors and risks by unplanned children with a comparison area where no such interventions are in existence.

Review:

a) Ethical Review Committee _____

b) Research Review Committee _____

c) Director _____

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 that has been shown to have had pronounced fertility effects (Phillips et al., 1982) and modest, but notable, 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 interventions 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. However, such high risk pregnancies are unaffected by family planning. Only if there occurs the development of alternative opportunities for young women--especially education--will marriage be postponed; and will the risks of first births thus be reduced. (2) Conversely, births that are averted by family planning to women of high parity and experienced most children survived. Thus, women with

many living children--women of relatively high health standards--are averting births which otherwise would have survived. Hence the left over births of such population occur to women with high maternal risks and will spuriously increase the infant mortality. Such spuriously high rates nevertheless, emerge, 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 further complicate 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 when remain unaverted by a family planning program are at higher risk than 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. Thus emerges the paradox: family planning probably averts most of the unplanned births, but the death rate among the remainder of unplanned births is higher than the births in natural situation.

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 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 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 maternal-child health services, with fully implemented tetanus immunization and oral rehydration therapy for diarrhoeal diseases; advice for pregnant women on delivery practices and nutrition; and hygiene and sanitary education. Since the health program mainly is oriented toward treatment and care of contraceptive users, the approach is more of comprehensive family planning service delivery than of integrated health service. The comparison area receives no such inputs.

So far, in the 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 was expected that tetanus-related infant deaths for the whole MCH-FP intervention area would decrease due to vaccine use (Rahman, 1980). Still, child mortality among 1-4 year olds declined significantly after the intervention. Apart from the health care

package and the fertility control program, itself was expected to increase infant survival due to the spacing of births. However, there 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 largely consisted of health intervention with limited family planning. While these resulted a significant decline in infant mortality, contraceptive use increased only by 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 services and concommitant child spacing leading to a reduction of unplanned fertility; and (2) the incremental components may consist of the proportionately more births occurring from 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 and 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) and the health care system;

2. To compare infant mortality of births resulting from contraceptive failure and births among non-contraceptive using women.

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 census of 1982; and (5) health service data in Community Health Workers' record books.

Socio-economic and previous birth intervals will be analyzed, by matching birth data with 1982 updated 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 their child-births. This will be calculated at micro level by taking a ratio of observed number of child-deaths over expected number of child-deaths. Expected number of child-deaths is estimated by adding the probability of dying of all children to the age at these births. The mathemathical expression will be $= \sum_{i}^{n} (1-\ell x)$. n is the number of children previously born and ℓx is survival probability of the birth to age x (Trussell, 1982). In Matlab as the date of birth is known accurately from the vital registration system and have life-tables made every year, the estimate of maternal risk will be accurate.

This will provide a data file where each record will contain information for a cohort of children born in 1981 and 1982 on their survival during infancy, socio-demographic characteristics, immunization and other health support information, and contraceptive failure. 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 at 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 three major sets of predictors thought to be influence infant survival: (1) maternal risks; (2) fertility intentions; and (3) health interventions. These predictors also may interact to produce an additional effect.

The logistic hazard function under such circumstances would be:

$$\text{Logit } q = \ln\left(q/(1-q)\right) = \alpha + \sum_{i=1}^{I} \beta_i W_i + \sum_{j=1}^{J} \gamma_j X_j + \sum_{k=1}^{K} \zeta_k Y_k + \sum_{i=1}^{I} \sum_{k=1}^{K} \delta_{ik} W_i Y_k$$

where q is the probability of dying during infancy, W_i, X_j and Y_k are the factors of the three set of predictors, and β_i, γ_j and ζ_k are the factors of the estimated parameter of the predictors. The last term is designed to examine any additional effects of two-way interactions.

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 effeictive family planning services, as well as about abortions.

REFERENCES

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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).

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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.

SECTION III: DETAILED BUDGET

1. Personnel Services

Name	Position	Level/Step	% Effort	Annual salary	Project Requirement for 1984 in Taka
AKM Alauddin Chowdhury	Scientist	-	-	-	-
James F. Phillips	Scientist	Expatriat	-	-	-
To be assigned from branch	Computer Programmer	VI	20	-	14,400
" " " "	Data Entry Tech.		20	-	7,200
" " " "	Data Processing Asst.		50	50,000	25,000
				Sub-total	46,600

2. Travel and Transportation

Speedboat person hours 8 @ Tk.100/- per person hour	800
Land transport at Matlab, @Tk.4/- x 100 person miles	400
Sub-total	1,200

3. Transportation of Materials - None

4. Rent, Communication and Utilities - None

5. Printing and Reproduction

Mimeography, xeroxing, stencil and special reproduction	1,000

6. Other Contractual Services

Computer time, 60 hours	24,000
Computer stationeries	500
Sub-total	24,500

		Cost in Taka for 1984
7.	Supplies and Materials	
	Office stationeries	1,000

8. Equipment - None

9. ICDDR,B Transport - None

10. Patient Hospitalization - None

11. Out-patient Care - None

12. Information Services (Library & Publication) - None

13. Construction, Renovation, Alterations - None

B. SUMMARY BUDGET

		Cost in Taka for 1984
1.	Personnel Services	46,600
2.	Travel and Transportation	1,200
3.	Transportation of Materials	-
4.	Rent, Communication and Utilities	-
5.	Printing and Reproduction	1,000
6.	Other Contructual Services	24,500
7.	Supplies and Materials	1,000
8.	Equipment	-
9.	ICDDR,B Transport	-
10.	Patient Hospitalization	-
11.	Out-patient Care	-
12.	Information Services	-
13.	Construction, Renovation, Alterations	-
	Total Taka:	74,300

Equivalent US $ 2,972.00

Exchange Rate: Tk.25/- = 1 US $