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chment I.

E SHEET) ETHICAL REVIEW COMMITTEE, ICDDR,B. Date 8/7/95

cipal Investigator (1) Ms V. Hosegood (2) Dr A. Vanneste Trainee Investigator (if any) _____

ication No. 95-012 Supporting Agency (if Non-ICDDR,B) BADC

e of Study PILOT STUDY: A FOLLOW-UP OF A HISTORICAL ORT OF WOMEN IN MATLAB - TO MINE NUTRIONAL STATUS, FERTILITY ND MORTALITY. Project status:

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

le 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)

re 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 N/A
(d) Sensitive questions — (Yes) No N/A
(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 N/A

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

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

Victoria Hosegood
Principal Investigator

Trainee

15 JUN 1998

TITLE OF THE STUDY:

PILOT STUDY: A FOLLOW-UP OF A HISTORICAL COHORT OF WOMEN IN MATLAB-TO EXAMINE NUTRITIONAL STATUS, FERTILITY AND MORTALITY.

PRINCIPAL INVESTIGATORS:

V. HOSEGOOD (MCEU LSHTM)
A.VANNESTE (PI Maternity Care Program Matlab, ICDDR,B)

CO-INVESTIGATORS: M. STRONG (Divisional Director PFPD)

CONSULTANT: O.Campbell(MCEU LSHTM)

SITE OF THE STUDY: BANGLADESH, Comparison Area, MATLAB

EXPECTED STARTING DATE: September 1995

EXPECTED DATE OF COMPLETION: December 1995

DURATION OF PROJECT: 4 months

TOTAL BUDGET: 8,000 US$

FUNDING SOURCES: BADC

HEAD OF PROGRAMME: Dr. M.Strong

This protocol has been approved by PFPD:

Signature of Divisional Director: _____

Date of Signature: 8 May 1995

PHASE I PILOT STUDY: A FOLLOW-UP OF A HISTORICAL COHORT OF WOMEN IN MATLAB- TO EXAMINE NUTRITIONAL STATUS, FERTILITY AND MORTALITY.

BACKGROUND

The role of women's adult nutritional status as a determinant of health and mortality has been of interest to both researchers and service providers for several decades Krasovec,1991). Recently, the importance of *in utero,* and early life nutritional experiences in determining adult morbidity and mortality has been emphasized as an explanation for adult differentials in morbidity and mortality (Barker,1992;Leon et al.,1995).

In addition, there is continuing interest in the impact of childbearing on women's nutritional status in situations of poor dietary intake. Since the 1980's several researchers have suggested that maternal nutritional depletion occurs during adulthood where women have frequent births, close birth spacing, extended lactational periods, and poor dietary intake (Merchant and Martorell,1988; Winkvist et al.,1992). However, other researchers argue that there is insufficient data available to support this hypothesis (Winikoff,1983;Costello,1986).

For developing countries, in discussing women's adult nutritional status, there is little data detailing whether changes in nutritional status occur during adulthood, and which determinants of changes in nutritional status are important (Merchant and Kurz,1993;Baqui et al.,1993). This is mainly due to the absence of longitudinal studies of nutritional status.

This study uses several unique data sources and opportunities available within the ICDDR,B Demographic Surveillance System in Matlab, Bangladesh. Historical nutritional data for a large cohort of women can be compared with current nutritional status. Consequently, changes in nutritional status over the 20 year period can be observed, and analysed with relation to the demographic and socio-economic profiles for each woman.

RESEARCH OBJECTIVES

Researchers at ICDDR,B, in collaboration with the London School of Hygiene and Tropical Medicine (LSHTM),

1.- will examine the changes in nutritional status in a cohort of approximately 1,925 Matlab women by comparing nutritional indicators from 1975-1978, and current indicators measured in 1995.

2.- will relate any changes in women's nutritional status to a range of socio-economic and demographic characteristics e.g. age, socio-economic status, parity, birth intervals, marital status. In addition, secular changes can be investigated by comparing the nutritional status of similarly aged women from the different assessments.

3.- will identify 10 outlier women who have had large or unexpected changes in their nutritional status over the last 20 years. These extreme cases can be used to pilot a qualitative/quantitative questionnaire, which aims to describe changes in energy intake or output which may contribute to her improving or deteriorating nutritional status.

4.- will test the validity and ease of use, of a few new anthropometric indicator measurement techniques, e.g. arm span. These measurement techniques have been designed to measure more accurately nutritional status in older women, however, they have seldom been tested in developing countries.

SIGNIFICANCE OF THE STUDY

Numerous studies and conceptual frameworks consider the relationship between adult nutritional status and mortality to be important (Leslie,1991;Koblinsky et al.,1993). Both through a direct causal relationship with specific causes of death, e.g. short stature and obstructed labor; and indirectly, through increasing the susceptibility of an individual to morbidity or life-threatening conditions, e.g. anaemia and helminthic infections.

The Determinants of Natural Fertility Study is a unique source of data for developing countries, where there are few detailed longitudinal nutritional studies. For the Matlab area the data presents a historical profile of nutritional status in adult women, with a level of accuracy and detail that is exceptional. The ability to follow-up this cohort is a special feature of the DSS, where the routine surveillance allows us to identify outmigrants, deaths and survivors. By comparing nutritional status at specific ages, and over time, in individual women, we are able to look at secular and age effects

In the light of the hypotheses linking adult nutritional status and mortality, we feel it is important to begin to explore the changes in women's nutritional status in relation to the recent declines in women's mortality in Matlab. In addition, to start to answer questions about the impact of child bearing on nutritional status. It is also important to distinguish between nutritional changes which result from secular changes in food availability, tastes and costs; and those resulting from ageing. Therefore, intra-individual studies need to be conducted.

In the MCH-FP area of Matlab, data are collected on many women's health indicators, either routinely, i.e. nutritional indicators during antenatal visits; or during the many intervention studies. By contrast data for the Comparison area are much more limited. By obtaining data on current nutritional status and, changes in women's nutritional status will go some way to address the deficit of data on trends in nutritionally related morbidity and mortality in the Comparison area. Such data could help interpret some of the trends in adult women's health. For example, data on current nutritional status from this study will be comparable with current nutritional status as measured in the MCH-FP area. The significance of this study is summarized in Box 2.

BOX 2.

Study objectives	Outcomes of the study
1995 nutritional status data for adult women in the Matlab area.	Contributes to the data available to rural development schemes in evaluating health indicators.
A comparison of nutritional status in women in 1975-1978 and 1995	Provides historical data on economic and health indicators over a 20 year period.
Evaluate the association of changing nutritional status with indicators of women's health.	Allows a re-evaluation of the potential success of women's caloric supplementation programmes. Allows the identification of nutritionally vulnerable women.
Examine intra-individual changes in nutritional status over time	Contributes information to the discussion of maternal depletion syndrome. Allows future surveys to adjust more precisely for cohort and period effects.
Use anthropometric measures designed specifically for older women	Could suggest alternative and practical measurements to improve the validity of surveys which include older women.

FUTURE STUDIES POTENTIALLY ARISING FROM THIS STUDY.

This proposal describes Phase I of an ongoing plan of research in this area.

Results from Phase I will determine the order and feasibility of carrying on this line of research at ICDDR,B. The in depth qualitative work on energy intake and expenditure in Phase I will determine the feasibility of capturing such information over a 20 year history for the entire sample of women. If retrospective questioning about dietary histories, economic access, marital and familial influences does illicit useful information about nutritional changes these questionnaires will be administered to the entire cohort of women in Phase II. Also if it proves possible to locate and re-interview a large proportion of surviving women from the original cohort, consideration will be given to further nutritional and biophysical measures. For example, there is considerable interest in diabetes and insulin resistance in south Asians living in the UK. This would require blood samples two hours after food ingestion (but could be done on capillary blood). Equally, nutritional status could also be measured using newer measures such as bio-impedance. Planning Phase II would involve a larger number of researchers (and provided funds could be identified, could for example involve PhD, Masters students, or researchers from the ICDDR,B visiting the London School to develop the research).

ETHICAL IMPLICATIONS

This study has no major ethical constraints:

1. It will be explained to study women that they are free to refuse to participate in the measurements or questionnaires. A consent form must be signed by the subject, though it will be emphasized that they are free to withdraw from the process at any point.

2. Participation or non-participation by study women, has no influence on their involvement in the routine DSS activities, or access and utilization of health services.

3. The few anthropometric measures to be taken are non-invasive and identical to those the subject women underwent during the DNFS study.

4. The interview is very short, and requests only validating information on demographic and socio-economic data which is already available from the DSS.

5. The participation time required from the study population is limited to a single, approximately half an hour interview. Much of the data used in this study is secondary data already available from the DSS archives.

BUDGET

FUNDER: BADC

a)PERSONNEL COSTS

NAME	PERIOD Field work 3 months from starting date	
Translator	(1 x $200/month for 3 months)	600
Interviewers	(8 x $105/month for 3 months)	2,520
TOTAL PERSONNEL		3,120

b)OTHER CHARGES

1. SUPPLIES & MATERIALS,	
i. stationary and computing supplies	370
ii weighing scales, rulers & calipers	1,075
2. OTHER	
i. office rental	900
3. LOCAL TRAVEL	
i. transport Matlab	1,560
ii. water transport Matlab	975
TOTAL OTHER CHARGES	4,880
GRAND TOTAL BANGLADESH:	US $ 8,000

ICDDR,B will not receive overheads according to the BADC-ICDDR,B agreement.

7/5/95

FLOW CHART OF STUDY ACTIVITIES

The study is expected to have a 3 month field data collection phase and 3 month analysis and data dissemination phase. The component activities are described in the following flow chart.

START

Setting up of field operation ¦

Training of interviewers ¦

3 WEEKS

Field work starts ¦

3 MONTHS

Field work finishes ¦

Data analysis ¦

Data dissemination in ICDDR,B and LSHTM ¦

6 MONTHS

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APPENDIX 1.

QUESTIONNAIRE

The current addresses of DNFS participants living within the DSS area in 1995 will be obtained from the DSS office in Matlab. Interviewers will locate the women in the villages. If consent is obtained, they will conduct anthropometric measurements, and a short questionnaire.

****

FOR INTERVIEWER ONLY

Have you explained the study to the subject ? <y>
Have you obtained her consent on the consent form <y>

****

IDENTIFYING INFORMATION

RID. Number ##########
CID. Number ########
Date of Interview <mm/dd/yy> Interview number #####
Woman's first name _____
Husband's name _____
Father's name _____
Bari name _____
Village _____
Area <C/MCH>

IF DIFFERENT ON DAY OF INTERVIEW:

Why? _____
How long will she remain here? days <y/n> weeks <y/n>

Fill in details if not the same as above:
RID. Number
CID. Number
Date of Interview <mm/dd/yy>
Interview number _____
Woman's first name _____
Husband's name _____
Father's name _____
Bari name _____
Village _____
Area <c/>

GENERAL INFORMATION

Age ### years (DSS stated age ##)
Marital status <m/d/w) (DSS stated status m/d/y)

OTHER INFORMATION

Have you explained to the subject what we would like to do? <y/n>
Height #### mm
Weight ##.# kg
Arm circumference ### mm
Skinfold thickness ### mm
Arm span ###

DEMOGRAPHIC AND SOCIOECONOMIC INFORMATION

If currently married What is husband's occupation?_____
If divorced or widowed Who supports you ? _____
What is their occupation? _____
Do you have salaried occupation? <y>
What is it? _____

How many living children do you have? ##
How many live births did you have ? ##
How many live born children who died ? ##
How many stillbirths have you had? ##
How many spontaneous abortions have you had? ##

**********This Section For Investigator's Use Only **********

Has this been checked by supervisor <y>
Has this been checked by investigator <y>

Was this sent back to be re-checked <y>
Why _____
Was the rechecking completed <y>
What is the sheet number of re-checked form ######

Is this a case for following-up in phase 2 <y>
Why _____