Attachment 1.6 4

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator: Capri Mara Fillmore Trainee Investigator (if any) _____

Application No. 83-020P   Supporting Agency (if Non-ICDDR,B) *FAO*

Title of Study __Analysis of Chan's data__   Project status:

and comparison with Sommer's data.   ( ) New Study

(Pilot protocol)   ( ) 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   N.A 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   N.A
       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 informa-
       tion damaging to sub-
       ject or others   Yes No

3. Does the study involve:
   (a) Use of records, (hosp-
       ital, 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   N.A
       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 with-
       draw from study   Yes No
   (g) Confidential handling
       of data   Yes No
   (h) Compensation &/or treat-
       ment where there are risks
       or privacy is involved in
       any particular procedure Yes No

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

6. Will precautions be taken to protect NA
   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)
   NA Statement given or read to subjects on
       nature of study, risks, types of quest-
       ions to be asked, and right to refuse
       to participate or withdraw (Required)
   NA Informed consent form for subjects
   NA Informed consent form for parent or
       guardian
   NA Procedure for maintaining confidential-
       ity
   NA 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 question-
      naire 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.

___Capri Mara Fillmore___ __Ablemm__   _____
Principal Investigator   Trainee
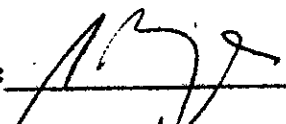
SECTION I: RESEARCH PROTOCOL

1. **Title** : Analysis of Chen's Data and Comparison with Sommer's Data.

2. **Principal Investigator** : Capri Mara Fillmore

3. **Co-Investigator** : Kashem Shaikh

    Supervisor : Dr. Stan D'Souza

4. **Starting Date** : 25 April 1983

5. **Completion Date** : 25 July 1983

6. **Total Direct Cost** : US$ 646

7. **Scientific Program Head:**

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

    *Signature of Scientific Program Head:_____

    Date:_____

    *This signature implies that the Scientific Program Head takes responsibility for the planning, execution and budget for this particular protocol.

7. **Abstract Summary:**

    Lincoln Chen collected data for 2 nutrition surveys between January 1978 and June 1980 in 8 villages. The anthropometric data from these studies will be put in a month-by-month data bank form of ID. No., sex, age, weight, height, and arm circumference. Percentiles, Z-scores, and distribution curves will be determined for height-for-age, weight-for-age, height-for-weight, arm circumference-for-height, and arm circumference-for-age. Taking into consideration the economic-agricultural contexts of the years in which the data were collected, this protocol attempts to prepare the way for future comparative analyses.

8. **Reviews:**

    i)   Ethical Review Committee:_____

    ii) Research Review Committee:_____

    iii) Director:_____

ABSTRACT SUMMARY

None of the questions for the Ethical Review Committee apply because this study involves only old data sets, and will not involve contact with any patient or population surveyed.

SECTION II: RESEARCH PLAN

A. INTRODUCTION

1. Objective

The Andre Mayer Research Fellowship requires the connecting and comparing of many data bases collected over the years. The process of putting the data into a workable form (to be called the "Anthropometric Data Bank Form"), which is necessary to facilitate comparison of different data bases, began with the Sommer/Lowenstein data and this protocol will add Chen's data to the data bank. These two data sets will then be compared, taking into consideration the economic-agricultural contexts of the years in which these data sets were collected.

2. Background

i) Establishment of a Matlab Anthropometric Data Bank

Although several anthropometric studies have been done in Matlab, so far there has been no attempt to link-up one data set with another. The focus of the Andre Mayer Research Fellowship is to look at changes in anthropometric measurements over time. In order to do this research it will be necessary to link up several anthropometric data sets by forming a Matlab Anthropometric Data Bank (MADB). The data bank will consist only of anthropometric data (all other information will be excluded from MADB). Its format is as follows:

Columns	1-4	Village code
Columns	5-8	Family code
Columns	9-10	Individual code
Columns	11-16	Date of data collection
Columns	17-20	Age of child at time data was collected (in months with one decimal point)
Column	21	Sex (male = 1, female = 2)
Columns	22-24	Weight (in kg, one decimal)
Columns	25-28	Height (in cm, one decimal)
Columns	29-31	Arm circumference (in cm, one decimal)
Columns	32-36	NCHS Z-score weight-for-height
Columns	37-41	NCHS Z-score height-for-age
Columns	42-46	NCHS Z-score weight-for-age
Columns	47-51	NCHS Z-score arm circumference-for-age
Columns	52-56	NCHS Z-score arm circumference-for-height
Columns	57-59	Tricepts skinfold measurement (one decimal)

The first usage of the MADB for the Andre Mayer Research will be to see if there are any trends in anthropometric measurements over the years, plotting the average measurements or the percentage below a certain cut-off point, as shown in the hypothetical case of Figure 1. The Sommer/Lowenstein data are now being put in the MADB format. The intention of this protocol is to put Chen's data in the same format, which would allow for a rough comparison of the two data sets.

ii) The History of Food Crises and Disasters in Bangladesh

The short history of Bangladesh has been one filled with more food
crises and disasters than probably any country in the world. Natural
disasters have been especially devastating to Bangladesh since its
economy is so dependent on agriculture and agriculture has always been
the main income source of most of its people. Anthropometric measurements
are no doubt affected by food crises situations, and as a result comparisons
of anthropometric data sets must take into consideration the economic/
agricultural contexts of the particular years in which the data was
collected.

Matlab anthropometric data spans the time from December 1970 to
July 1982, during which time Bangladesh underwent several food crises
situations. The first occurred on November 7, 1970 when a cyclone and
subsequently a tidal wave devastated crops and killed millions of people
in southern Bangladesh (then East Pakistan). Food relief to that area,
and the fact that the most sickly children were probably washed away in
the flood, caused this area   to have probably the best
nourished children in Bangladesh at that time (Sommer and Mosley, 1973).
Since food relief was relatively swift in coming the markets nation-wide
were not seriously affected. Comilla District food production was "normal"
that year.

The War of Independence lasted from March 25 to December 16, 1971
during which time crops were destroyed and agricultural productivity was
low due to war involvement. Crop yields during that time were lower
throughout Bangladesh. As a result of the transportation infrastructure
destroyed during the war and the lapse of time which passed before developed
countries established full diplomatic relations with the new nation of
Bangladesh, food relief was delayed and poorly executed. It was not until
the Boro crop in 1972 that agricultural yields approached "normal". But
a drought later that same year caused a significant reduction in Aman crop
yields in much of Bangladesh including Comilla District.

In the 1973-4 harvest year, yields were normal, but the greatest
flood in 50 years which occurred in August and September of 1974 ruined
large quantities of crops throughout Bangladesh. The devastation of the
flooding was compounded by hoarding which helped drive the price of rice
up about four times normal and perpetuated the nation-wide food crises
for many months after the actual flood. Comilla District was particularly
hard hit by the flood. Aman crops and much of the Aus crop were destroyed,
resulting in exceptionally low yields for the 1974-5 harvest year.

The 1975-76 harvest year was relatively "normal" in most of Bangladesh
and Comilla District. But some flooding late in 1976 lowered Aman and
Aus crop yields and storm damage caused a somewhat lowered Boro crop yield
in Comilla District during the 1976-77 harvest year. The next years were
relatively free from crises with the exception of the drought which in
1980 which had a some   impact on the Boro and Aus yields in Comilla
District during the 1979-80 harvest year.

The changes in grain production during these years, which reflect various food crises, in Comilla District are recorded in Figure 1. Information about these disasters came primarily from Chen (1973) and the Bangladesh Bureau of Statistics.

iii) History of Chen's Matlab Food and Nutrition Survey

While Dr. Lincoln Chen was working at ICDDR,B the nutrition survey in which he was principal investigator was entitled the Matlab Food and Nutrition Study which was conducted in two phases between February 1978 and June 1980.

The first phase was a survey of approximately 900 children under 5 years old and there mothers who lived in 8 villages of the Matlab Demographic Surveillance Area. This part of the study collected data on weight, height, arm circumference, and socio-economic status in a cross-sectional survey between January and March of 1978.

The second phase followed 125-135 families selected from the first phase (in 5 of the villages) over a period of 2 years. Weight, height, and arm circumference measurements were made monthly for children under five and their mothers, trimonthly measurements were made of the rest of the family. This phase of the study was done between June 1978 and June 1980.

There is at this time no documentation for the first phase of this study in Dhaka. The filled up questionnaire forms from this phase of the study are stored in Matlab, and might be used to decipher the coding plan of the tape. The second phase of this file is on computer tape, although it is not fully documented in Dhaka.

Chen utilized this data set in two publications. On a prospective study of the risk of diarrhoeal diseases according to weight for age and change in weight, these data were used to conclude that anthropometry failed to demonstrate association with the subsequent risk of diarrhoeal diseases (Chen et al., 1981a).

In the other study, these data were used to support the conclusion that there is a sex bias in food allocation in the Matlab population-weight-for-age, height-for-age and dietary intake were shown to reflect discrimination against females in intrafamily allocation of food (Chen et al., 1981b).

3. Rationale

The entering of Chen's data to the MADB, is strictly clerical work necessary to prepare the way for comparisons of data from different years, Sommer's and Chen's data sets can be compared taking into consideration the agricultural situation of the years involved. Sommer's data collected in late 1970 and early 1971 was made on a relatively "normal" harvest year — Comilla District was minimally affected by the cyclone and tidal wave 2 months earlier in southern Bangladesh and the data were collected

prior to the onset of the War of Independence. This data is comparable
with Chen's data collected in early 1978, 1979 and 1980 each
taken after "normal" harvests.

Furthermore, comparisons can only be made with height and arm circumference
measurements (since the Sommer data do not include weight measurements),
and these indicators have less seasonal fluctuations than other nutritional
status indicators such as, weight-for-height, weight-for-age, and tricepts
skinfold-for-age (Brown et al., 1982). Height-for-age is especially good
for comparing data collected in different years because it only varies seasonal
only 1% during a year. This is consistant with the fact that height-for-age
is a indicator of long-term or chronic malnutrition (Waterlow and Rutishauser
1974), and therefore is less likely to fluctuate during times of crisis —
unlike weight-for-height which indicates acute malnutrition such as seen
in a crises situation of situation of food shortage.

B. **SPECIFIC AIMS**

1. Put the data in "Anthropometric Data Bank."

2. Do a monthly anthropometric analysis breaking data down to age groups
    and using indicators of weight-for-height, height-for-age, weight-for-age,
    arm circumference-for-age, arm circumference-for-height.

3. Compare Chen's data with Sommer's data to determine whether or not
    there has been an increase or decrease in various indices of malnutrition.

4. Divide Sommer's and Chen's data into same SES groups to determine if
    one SES group is getting worse nutritionally and how the overall change
    in SES is affecting nutrition.

5. Compare the two data sets with agricultural development indicators.

C. **METHODS AND PROCEDURE**

Chen's data will first be put in the MADB format which was delineated
in the background section of this protocol on the establishment of a Matlab
Anthropometric Data Bank. Then, preliminary analysis of Chen's data will be
done in the same manner as done with Sommer's. The data will be broken down
by month of measurement, age, and sex group to determine: 1) proportion of
children below a specified and arbitrary lower limit of each anthropometric
indicator, and 2) the specified populations' distribution range of the parti-
cular anthropometric indicator (as recommended by WHO, 1979).

Once the preliminary analysis is done, Chen's data will be plotted in
a manner such as done in Figure 1 (month by month) for each anthropometric
indicator.

Since the first phase of Chen's study collected data on 900 children under 5 and the second phase looked at a non-randomly selected sub-sample of 200 children from the first phase, it will be necessary to get an approximate idea of how representative these 200 children are. The 200 children will be isolated from the first phase sample of 900 children, and a comparison will be made between the Z-scores of the 200 children and all 900 children.

To get a rough idea of the change in nutritional status over a seven year span (1971-78) Sommer's data will be compared with Chen's, both data sets were collected on years of "normal" harvests in Matlab thana. If there are differences, changes in the socio-economic make up of the population and agricultural development will be looked at in relation to these changes in nutritional status.

There is some SES data for both Sommer's and Chen's data sets. Using only 0-5 year olds anthropometric data in Sommer's and in Chen's (first phase) data sets, the children in both studies will be divided into the same SES groups. Then with cross tabulations it will be possible to determine if individual SES groups are getting worse or better off nutritionally during the 7 year span. Also the overall changes in SES of the population over these years will be determined and related to changes in nutritional status and agricultural development.

Data on agricultural production for the unions (and if possible village data) of the Matlab census area will be collected from the Matlab Thana office for the years from 1965 to as recent as possible. If the data at the union level is not available, Bangladesh Bureau of Statistics data for the whole Matlab Thana will be used. This data will be plotted in a manner such as in Figure 1, looking particularly at:

    a)   annual grain production;

    b)   percentage of land used for High Yield Grain Varieties;

    c)   annual grain production per population;

    d)   production ratio of grain to pulses.

Cross tabulations and graphing (like Figure 1) will be done to link nutritional status with agricultural development, to determine if there appears any relationship between the two.

D.   SIGNIFICANCE

The goal of the Andre Mayer Research Fellowship is to relate trends in anthropometry (nutritional status) to trends in economic/agricultural development. This protocol alone will not be enough to establish trends, but is rather a step towards looking at these trends, establishing the ground work by which future comparisons and analysis can be done which

will give a more complete picture of the nutrition and development in
Matlab. Eventually, it is hoped this research will have implications
as to the direction economic/agricultural development should or should
not go in order to have the most favourable impact on the nutritional
status of country's people.

E. FACILITIES REQUIRED

    Computer Information Services

    Transport and accommodation at Matlab

    Medical Illustration

    Data Management Branch

F. COLLABORATIVE ARRANGEMENT

Under the agreement made with FAO and ICDDR,B, this fellowship will
be completely funded by the Andre Mayer Research Fellowship.

REFERENCES

Chen, L.C. et al. (1981a) A prospective study of the risk of diarrheal diseases according to the nutritional status of children. Am.J.Epid, 114(2): 284-92.

Chen, L.C. et al. (1981b) Sex bias in the family allocation of food and the health care in rural Bangladesh. Population and Development Review, 7(1): 55-70.

Brown, K.H. et al. (1982) Seasonal changes in nutritional status and the prevalence of malnutrition in a longitudinal study of young children in rural Bangladesh. Am. J. Clin. Nutr., 36: 303-313

Waterlow, J.C. and IHE Rutishauser (1974) Malnutrition in Man. In: J. Cravioto, L. Hambraeus, and B. Vahlquist (eds.) Early Malnutrition and Mental Development (The Swedish Nutrition Foundation: Almquist & Wiksell, Stockholm).

Sommer, A. and WH Mosley (1972) East Bengal cyclone of November, 1970: epidemiological approach to disaster assessment. Lancet, i: 1029-36.

Bangladesh Bureau of Statistics, Yearbook of Agricultural Statistics 1976, 1979, 1981.

Chen, L.C. (ed.) (1973) Disaster in Bangladesh: Health Crisis in a Developing Nation (Oxford Press, U.K.).

World Health Organization (1979) A Guideline for the Measurement of Nutritional Impact of Supplementary Feeding Programmes Aimed at Vulnerable Groups (WHO/FAP/79.1, Geneva).

SECTION - III : BUDGET
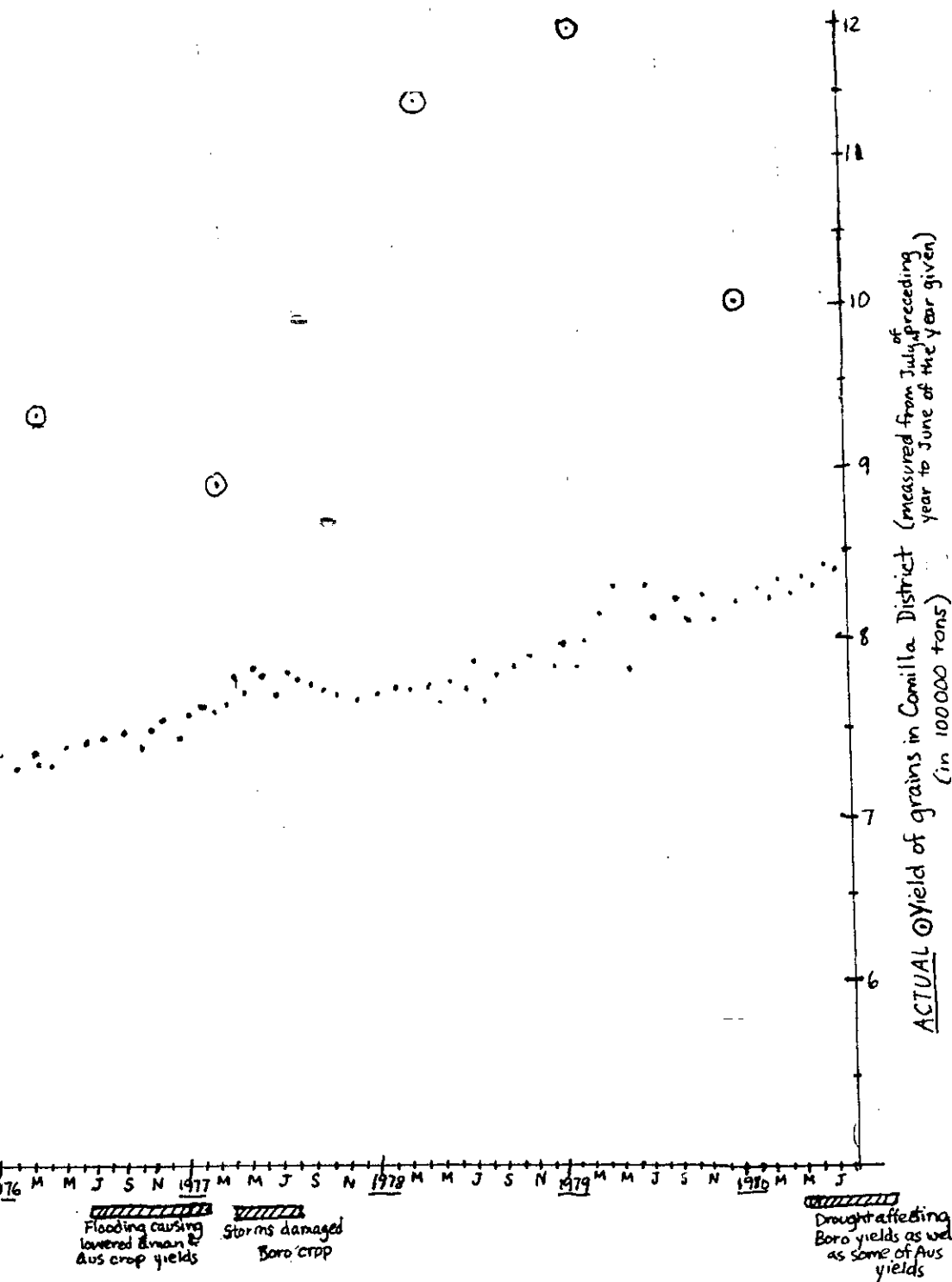
A. DETAILED BUDGET

PERSONNEL SERVICES

Since Capri Mara Fillmore receives a stipend for her fellowship from FAO, there will be no budget allocated for her salary. The work of Kashem Shaikh on this protocol is considered data management work, therefore his salary is paid by the Data Management Branch of ICDDR,B.

Position	% Effort	Man hours	Wage	Taka Requirement
Programmer (Nationl)	100%	300 hrs.	25 Tk/hr.	7,500
Statistical Officer	100%	160 hrs.	18 Tk/hr	3,000

MISCELLANEOUS

Computer Time	3,000
Computer Stationery & Diskettes	1,000
Medical Illustration	1,000
TOTAL:	**15,500**

B. BUDGET SUMMARY

Category	Takas
Personnel Services	10,500
Miscellaneous	5,000
Total:	15,500

Total in Dollars (Taka 24.00/$1.00) = US$ 646

Axis labels (right side, vertical): 12, 11, 10, 9, 8, 7, 6

ACTUAL ⊙ Yield of grains in Comilla District (measured from July of preceding year to June of the year given) (in 10000 tons)

From Bangladesh Agricultural Yearbook

X-axis months: M M J S N **1977** M M J S N **1978** M M J S N **1979** M M J S N **1980** M M J

(left edge) 976

Flooding causing lowered dman & Aus crop yields

Storms damaged Boro crop

Drought affecting Boro yields as well as some of Aus yields

n

olds over time
a District during

HYPOTHETICAL

% of 0-5 y.o. children stunted (<2 S.D. below NCHS Reference median)
Each dot represents a sample size of at least 200.

40% ⊙

30% ⊙

20%

10% ⊙

| 1971 | 1972 | 1973 | 1974 | 1975 |

M M J S N M M J S N M M J S N M M J S N M M J S N

Cyclone & tidal wave
in S. Bangladesh
Matlab minimally affected

War of Independence
affected agricultural
productivity nation-wide

Drought
decreasing Aman
yields

Major Flood → FAMINE

ACTUAL month the measurement was take

▨▨▨▨ marks approximate length of the
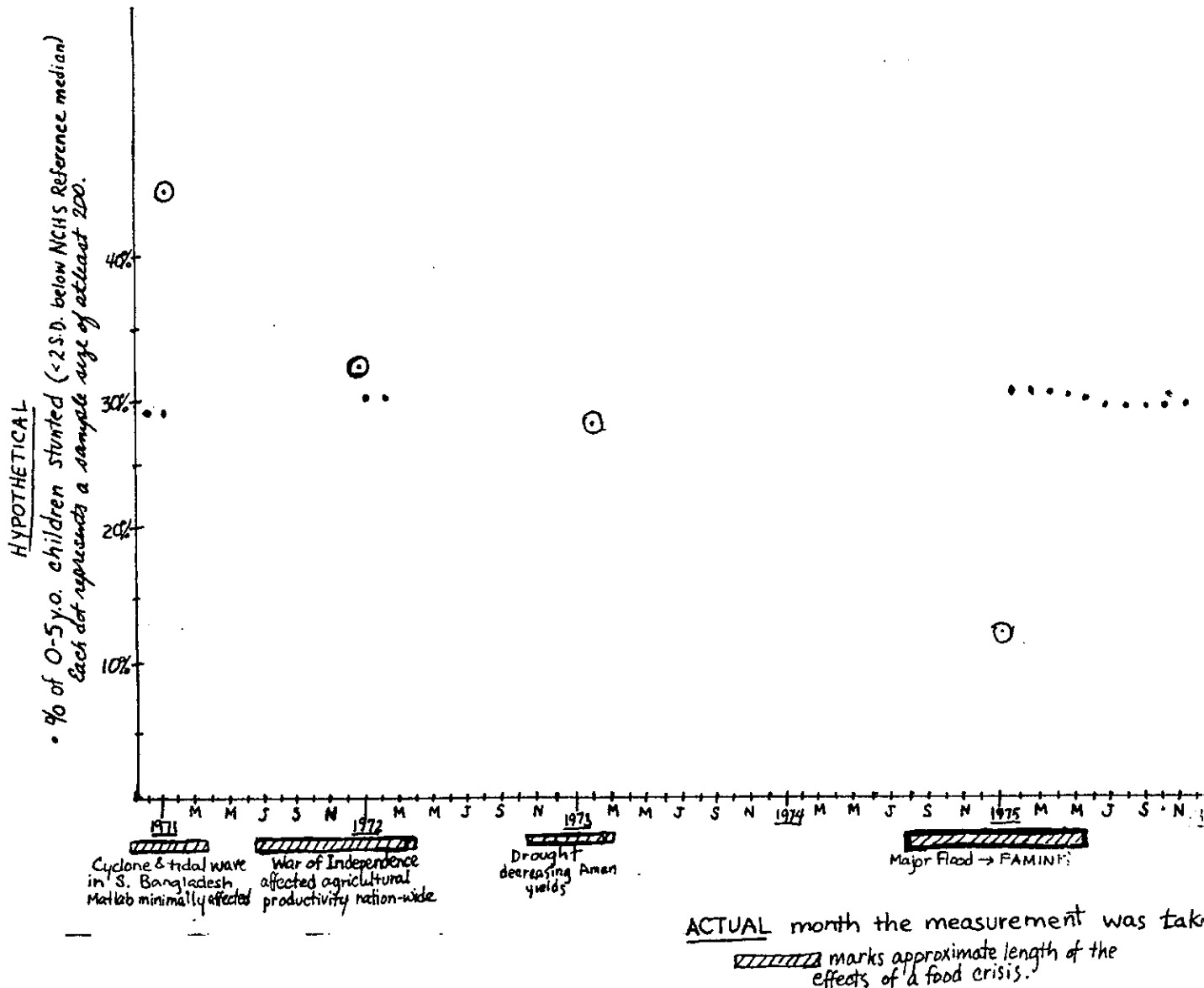effects of a food crisis.

Figure 1. Changes in percentage of stunted 0-5 year
as compared with grain produced in Comill
the same time period.