

Library (2)

ICDDR,B LIBRARY

Date 23/9/86

ETHICAL REVIEW COMMITTEE, ICDDR,B, DHAKA - 12

Principal Investigator Bonita Stanton

Trainee Investigator (if any) DC

Application No. 86-034(P)

Supporting Agency (if Non-ICDDR,B) UNICEF & Belgium

Title of Study Case-control Study to

Project status: Belgium

Evaluate Risk Factors for Death in Urban

( ) New Study

Setting in Early Infancy

( ) 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

5. Will signed consent form be required:

- (a) From subjects  Yes  No *Signed by interviewed mothers*
- (b) From parent or guardian (if subjects are minors)  Yes  No *mothers were interviewed*

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

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

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

\* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

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 *NA*  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 *NA*  Yes  No

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)

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

Bonita Stanton  
Principal Investigator

SEP 28 1986

Trainee

REF

HB 1323.14.B2

S792c

1986

86-034(P)

25/9/86

SECTION-I: PILOT RESEARCH PROTOCOL

1. Title: Case-control Study to Evaluate Risk Factors for Death in Urban Setting in Early Infancy
2. Principal Investigator: Bonita Stanton
3. Co-investigators: John Clemsns  
KMA Aziz  
Tajkera Khair  
Khodeza Khatun  
Shahnaz Ahmed
4. Starting Date: 16 October, 1986
5. Completion Date: 15 July, 1987
6. Total Direct Cost: US\$ 4,413.00 (UNICEF & Belgian Govt.)
7. Associate Director for ELS Division:

This protocol has been approved by the Epidemiology and Laboratory Science Division.

Signature of the Assoc. Director for ELS Division: John Clemsns

Date: 22/9/86

8. Abstract Summary:

The purpose of this case-control study is to identify risk factors (including parental behavioral practices and attitudes) which are associated with an increased mortality of children <4 months of age in the urban setting. Subjects will include all mothers >7 months pregnant and their subsequent offspring who dwell in our 70 study clusters. Detailed questionnaires and prolonged observations will be made on each family. The only potential risk to a family or individual will be a potential invasion of privacy. This risk will be minimized by the fact that: (1) an informed consent that specifies that a family need not participate and may drop out of the study at any time; (2) the relative lack of sensitivity of the questions being posed; and (3) the identification of families by ID number only. No information will be withheld from the family. However, as over half of our women city dwellers are illiterate, we shall require

that the interviewer sign her name that she read and explained the consent form to each family, but shall not require the mother's signature. Further we shall request that if the interviewer remains uncertain as to whether or not the mother understands the consent in spite of repeated explanations, that this be noted on the consent form for follow-up by the senior field research officer. The interviews, which will take place in the household, will probably each require about 20 to 30 minutes. The observation period will be about 4 hours. There are no risks to the families and great potential gains to these families for future pregnancies as well as society as a whole. No records, organs, body fluids etc... will be required.

9. Reviews:

(i) Ethical Review Committee: \_\_\_\_\_

(ii) Director: \_\_\_\_\_

## SECTION - II: RESEARCH PLAN

### INTRODUCTION

#### Defining the problem

An estimated 20 to 25% of children born in many developing countries, including Bangladesh, die before reaching their fifth birthday (UNICEF, 1983; Shaikh, 1984). These high rates of mortality have increasingly been the focus of attention by the donor and scientific communities. In general there have been 2 principle approaches taken toward enhancing child survival: external curative and preventative strategies; and, the delivery of a few simple but effective technologies to large numbers of people (UNICEF, 1985). The later approach, which has received considerable promotion in recent years has also recently become the focus of criticism for being too supply oriented and ignoring social constraints and demand for effective use of health services (Mosley, 1984).

The identity of these constraints have become the focus of considerable interest and have been generally classified into 5 groups: 1) maternal fertility; 2) environmental contamination; 3) nutrient availability; 4) injuries; and, 5) disease control (Mosley, 1984). Not included in this list but probably of as great or greater importance than it is in developed countries is parental attitude towards the child (Klaus and Kennel, 1976; Scrimshaw, 1978).

Obviously the relative importance of individual risk factors would vary by age (DaVanzo, 1983) and geographic location (Ware, 1983). Similarly, the different subgroups within the targeted "under 5's" population are responsible for differing proportions of childhood deaths. In the urban setting we found that of the 38 deaths which occurred in children less than 5 years of age, 28 of these deaths occurred in children <1 yielding an infant mortality rate of 112/1000 live birth. By contrast only 10 of these deaths occurred in children aged 1 to 4, yielding a childhood mortality rate of 7.87. Further, 12 of these deaths occurred in children in the neonatal period and 23 occurred in children <4 months of age. Thus because such a high percentage of these deaths are clustered into a narrow age range, it is possible that a relatively small number of maternal behaviours might be identified as contributory towards or responsible for a substantial percentage of deaths in children <5 in the urban area in Bangladesh.

#### Choosing the approach

Because of both the differing mortality rates by age, the differing causes of death at various ages and differences in child rearing practices depending on the age of the children, it would be important to focus on as narrow an age span as possible. The determination of the age group on which to focus could be made in one of 2 ways:

- a) age span in which greatest percentage of childhood deaths occur; or,

- b) age span in which deaths are most likely to be potentially averted by interventions.

These are not necessarily the same. While clearly the majority of deaths occur in the first few months of life the neonatal mortality rate may be the most difficult to lower once tetanus mortality has been averted (Foster, personal communication). On the other hand, a decrease in mortality in the older groups would have substantially less impact on lowering overall infant-childhood mortality. (This contrast in mortality rate between infants and older children appears to be, if any thing, even more marked in the urban area than in the rural area.) Further, child-rearing practices become increasingly varied as children grow older and hence the identification of a few responsible behaviours might be quite difficult.

Recently we have shown that a case control methodology could be successfully employed to discern differences between water-hygiene practices of high-low diarrhea families. These behavioural differences were then used to form the basis of an intervention. It is our expectation that the same case-control methodology could be employed to differentiate the behavioural differences of mothers of children who die before a certain age (cases) from those of mothers of children who survive until a certain age (controls). However, because death is a rarer event and undoubtedly the interaction of behaviours leading to death are more complicated than those leading to diarrhoea, we propose to make more than the single observation used in the former study.

Therefore, we propose in the present study as a compromise between selecting the age span with the greatest mortality rate and selecting that in which the deaths are more likely to be averted by maternal behavioural changes, to contrast potential risk factors between all children born during the study period who survive until 4 months of age with those who die before reaching 4 months using a case control methodology. It is our expectation that an intensive intervention could subsequently be based on these findings. Such an intervention would have the advantage of being based on behavioural practices that were already being practiced locally (and hence were presumably culturally acceptable) and that were empirically associated with reduced mortality, rather than being based on a priori reasoning.

## **MATERIALS AND METHODS**

### **Selection of subjects**

The study would be conducted in urban Bangladesh in 70 clusters of 38 families each. 51 of these clusters are already identified and the selection of an additional 19 is ongoing. On each family in these clusters we have a sociodemographic profile which is periodically updated and morbidity information which is collected bi-weekly. This system has been in operation for 2 years in the 51 sites.

25 of the 51 communities have received a hygiene educational intervention which, while substantially lowering diarrhea rates

over-all, has had little impact on diarrhea rates of infants, particularly those <4 months of age. Otherwise the 10 health care interventions offered in those 70 sites, each of which is served by an urban volunteer, are similar to those offered by the 1200 volunteers throughout Dhaka city and include:

- ORS
- Treatment that with vitamin A
- Nutrition counselling (including BF)
- Immunization (including maternal tetanus)

Based on the observed crude birth rate of 27.67 children in the 51 clusters(250 births), we would anticipate a total of 235 births in 8 months in the 70 communities. Thus using the observed ratio of 23 deaths by 4 months of age out of 250 births, we would expect 22 of the 235 children born to die before 4 months of age during this study interval of 8 months.

The follow-up of the study would extend 4 months beyond the closure of enrollment(the study period).

October 1986

-----  
Enrollment of all  
births and followup--> June 1987

-----  
Followup period of children  
born after February 1, 1987-->October, 1987  
-----

Children to be excluded from the study would include all premature births (<34 months gestation), severe congenital abnormalities, life, or multiple births (twins, triplets). Based



on US figures it is anticipated that of the 235 births less than 5% of these births (approx. 12) should fall into one of these categories.

While migration is very high in urban Bangladesh (Stanton, in press) it is our observation that families tend to be less mobile after a birth and thus we expect the loss-to-follow-up during this short follow-up period of 4 months to be <10% (or 23 children.) Finally, because the enrollment period is only 8 months and because any child born after a gestational period of <34 weeks is not eligible for inclusion in the study, sequential births to the same mother could not be eligible for inclusion in the study as subjects. Rather, a subsequent pregnancy, if it occurred before the first child was 4 months of age, would merely be noted as a demographic event that would be analyzed as a risk factor.

Thus of the anticipated 235 births (with 21 anticipated deaths) we expect to be able to enroll and follow approximately 201 children for the duration of the study.

#### **Factors to be Analyzed**

6 Field research officers would perform prolonged observations on each family. In addition, as part of an ongoing project, certain data is already available on each family (Census, SES, 2-week health recall and 2-week health calendar.) (All "new data" to be gathered by the field research officers is

marked with an asterik.) This data form will be pre-coded and open-ended and high structured.

**Demographic:** (See census form, SES form, attached)

- maternal education
- maternal age
- # children <6 and gender distribution
- pregnancy interval.
- major demographic events (deaths births before or during the study period)

**Socioeconomic:** (See SES form)

- income
- wage earner versus salary
- access to water, sanitation
- # of rooms in house.

**Attitudinal:\*** (See prenatal questionnaire and attitudinal questionnaire for 2 day, 1 month and 2 1/2 month follow-up)

- planned pregnancy - on birth control at time of conception
- wanted pregnancy
- sex preference
- views of child
  - good/bad
  - healthy/unhealthy
  - smart/not smart.
- use of contraception after birth of child

**Biologic/nutritional:\*** (See 2 day, 1 month and 2 1/2 month observation form and illness form)

- gestational age (within 48 hours of birth - Dubowitz or modified Dubowitz)
- birth weight and weight at 1 month and 2 1/2 months
- estimated weight gain of mother during pregnancy
- morbidity (see 2-week health recall, 2-week health calendar, attached)
- 2-week history of illness in child and medical help seeking behaviour of mother. (See illness questionnaire for 1 month and 2 1/2 month visits and see questionnaire section for prenatal and 2 days visit)

**Behavioural characteristics of child care:\*** (See observation sheets for all 4 visits)

- breast feeding
- feeding
- umbilical care
- bathing (frequency, source, method)
- maternal sari use
- time spent holding/feeding child
- external employment status of mother
- principal caretaker of child
- holding of baby (length of time, by whom)
- maternal handwashing practices
- location of baby when not held

Obviously, some of these factors would change in importance depending on the age of the child at the time of the visit.

### Timing of Visits

1. Prenatal (during last trimester)
2. Perinatal (2 days)
3. 1 neonatal visit (1 month)
4. 1 visit at 2 1/2 months  
-----  
4 visits per child (mother)

x 235 births

-----  
940 visits in 12 months

= Approx. 80 visits per month

= Approx. 20 visits per week

÷ 6 field research officers

= 3.5 visits per FRO per week.

### Analysis

1. Contrast fixed sociodemographic and biologic variables -  
univariate analysis between families of cases and controls.
2. Contrast alterable socio-economic variables -  
univariate analysis between families of cases and controls.
3. Contrast attitudes between families of cases and controls  
univariate analysis.
4. Contrast behaviours between families of cases and controls.  
univariate analysis.

If some fixed or alterable sociodemographic or biologic variables or attitudinal characteristics differ significantly between families of cases and controls by univariate analysis, then we plan to control for these variables using a logistic regression model to determine which behavioural characteristics remain of importance. Analysis will also be performed excluding

all deaths which might reasonably be attributed to neonatal tetanus (e.g. deaths occurring between 7 and 21 days of life and with a clinical history compatible with such a diagnosis).

### **Implications**

An educational intervention could be designed based on the observed behavioural differences between families in which the child survived and those in which the child died. Families in which a woman was pregnant could be randomized to receive/not receive the education to determine if mortality could be lowered.

### REFERENCES

1. UNICEF. State of The World's children. UK: Oxford University Press, 1985
2. Shaikh K, Mostafa F, Bhuiya A, et al. Demographic Surveillance System - Matlab. Vol 14. ICDDR,B, Scientific Report #64, 1985.
3. Mosley WH. Child survival: research and policy. In: Child survival strategies for research. Mosley WH, Chen LC, eds. Pop Dev Rev 1984;10:25-45.
4. DaVanzo J, Butz WP and Habicht JP. How biological and behavioural influences on mortality in Malaysia Vay during the first year of life. Pop Studies 1983;37:381-402.
5. Ware H. Effects of maternal education, women's roles and child care on child mortality. In: Child survival: strategies for research. Mosely WH, Chen LC eds. Pop Dev Rev 1984;10:191-214.
6. Klaus MH, Kennel JM. Maternal-infant bonding. St. Louis, CV Mosby, 1976.
7. Scrimshaw S. Infant mortality and behavior in the regulation of family size. Pop Deve Rev 1978;4:383-403.
8. Stanton B, Clemens J. An educational intervention for altering water-sanitation behaviours to reduce childhood diarrhoea in urban Bangladesh: A randomized trial to assess the impact of the intervention on hygienic behaviours and diarrhoea rates. Am J Epidemol (In press).

SECTION-III: BUDGET

A) DETAILED BUDGET

	<u>Total Cost.</u>	<u>Incremental cost</u>
<u>Personnel:</u>		
Principal Investigator (Bonita Stanton)	-	-
Epidemiologist (John Clemens)	-	-
Anthropologist 1/3 (KMA Aziz NO.D)	2,000	-
6 FRO (V-2) (1 incremental)	12,600	1,575
1 SFRO (0 incremental)	3,144	0
13 Interviewers (III-2) (0 incremental)	14,400	0
1/2 Secretary (IV-1) (0 incremental)	612	0
1/2 DET (III-2) (0 incremental)	600	0
1/2 DCA (III-2) (0 incremental)	600	0
1/2 Programmer (NOB) (0 incremental)	1,356	0
Stipends for research volunteers 70 communities x 150 Tk. x 12 months (19 incremental)	4,200	855
		-----
	Sub total:	\$ 2,430
<u>Supplies and Materials:</u>		
Stationary etc. and supplies for field work	400	400
Forms	500	500
		-----
	Sub total:	\$ 900
<u>Travel and Transportation:</u>		
Local tranport costs: 70 trips per week to and from field approx.15 Tk./trip)	1,750	583
<u>Computer Costs</u>	500	500
		-----
	Grand total:	\$ 4,413 =====

B) SUMMARY BUDGET

<u>Category</u>	<u>Amount in US\$</u>
1. Personnel	2,430
2. Supplies and Materials	900
3. Travel and Transportation	583
4. Computer Costs	500
	-----
	Grand Total: US\$ 4,413
	=====

(The funds for this protocol are already available)



Attachment #1

Consent Form (Verbal)

We are interested in learning more about family life before and after a child is born to enable us to devise ways to try to keep babies healthy. While your participation in our study probably would not directly benefit your baby, it certainly would not harm the child. We would make 4 visits to your house over 3 months during which we would ask you some questions about your baby, weigh your baby and make observations on family life. You do not have to participate in this study if you would rather not and you may drop out at any time.

Name of interviewer who read form: \_\_\_\_\_

Did mother understand?    Yes ;  ;                      No ;  ;

If no, elaborate \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Date: \_\_\_\_\_

Time: \_\_\_\_\_

(BENGALI VERSION)

# অস্বাভি পত্র (জোখিত)

কিভাবে মিশ্রদের স্বাস্থ্যকাম করে তোলা যায়  
 সেই প্রচেষ্টা নিয়ে আমরা একটি মিশ্র জন্মে  
 পূর্ক ও পর্বর্তীকালের পারিবারিক জীবন সঙ্কর্কে  
 জানতে আগ্রহী। আমাদের সবেশনায় অংশগ্রহনকার  
 খুব অল্পবয়স্ক : অস্বাভিভাবে আপনাব মিশ্র নাও কাম  
 হবে না, তবে নিশ্চিতভাবে বলা যায় যে এতে  
 আপনাব মিশ্র কোন স্বাস্থ্য হবে না। আমরা  
 তিন সাত চারবার আপনাব বাড়ীতে আসতো  
 সেই সময়ে আমরা আপনাকে আপনাব মিশ্র  
 সঙ্কর্কে কিছু প্রশ্ন করতো, মিশ্র ও কন কে  
 এবং পারিবারিক জীবনের উপর কিছু পর্যবেক্ষণ  
 করতো। এই সবেশনায় অংশগ্রহন করা যা না  
 করা সঙ্কর্নে আপনাব ইচ্ছার উপর নির্ভরশীল  
 এবং যে কোন সময়ে ইচ্ছাকৃতভাবে আপনি এই  
 সবেশনা ছেড়ে চলে যেতে পারেন।

ইচ্ছাকৃতভাবে মাত্র  
 (যে ফর্মটা পড়তে)

আ ফর্মটা বুঝেছি কি? হ্যাঁ  না

যদি "না" হয়, ত্রুটিবিশিষ্ট নিম্নে \_\_\_\_\_

তারিখ \_\_\_\_\_ তারিখ \_\_\_\_\_

**PRENATAL QUESTIONNAIRE: FORM 101**

(To be administered to the pregnant woman (the "mother"))

Identity # of mother \_\_\_\_\_

(1 - 14)

Date \_\_\_\_\_

MM	DD	YY
_____	_____	_____
(15 - 20)		

# previous pregnancies	_____	_____
	21	22
# previous live-births (child survived >1 hour)	_____	_____
	23	24
# children <5 currently alive	_____	_____
	25	26
# boys <5 currently alive	_____	_____
		27

Estimated months of pregnancy	_____	_____
	28	29

Estimated weight gain of mother	_____	_____ (kg)
	30	31

Are you married?	1 = yes, living with husband		
	2 = yes, but separated		
	3 = yes, but husband has >1 additional wife		32
	4 = no, divorced		
	5 = no, widowed		
	6 = no, never married		

(If mother is divorced, do not ask questions of column 38, 39, 41 OR 42, just code "8". If never married do not ask these questions nor column 36, 44 or 45. Just code "8")

Were you practicing contraception some time in previous year?      1 = yes; 2 = no; 7 = uncertain	_____	33
--	-------	----

Were you trying to avoid pregnancy at time of conception		_____
---	--	-------

Were you trying to become pregnant	1 = yes	34
	2 = no	
	7 = uncertain	35

Was your husband hoping that you would become pregnant (if no husband or father unknown code 88)	8 = answer unclear	_____
		36

Is pregnancy now welcomed by :	You	1 = yes	
		2 = no	37

Your husband	7 = uncertain	
	8 = N.A.	38

Your mother-in-law		39
--------------------	--	----

**Sex preference:**

Do you care which sex the baby is	1 = boy	
	2 = girl	<u>40</u>
Does your husband care which sex the baby is	3 = doesn't matter	
	7 = uncertain	
	8 = N.A.	<u>41</u>
Does your mother-in-law care which sex the the baby is		
		<u>42</u>
Do you plan to breast feed the baby for the first 2 months? (Read out possible answers)	1 = yes, exclusive	
	2 = yes, some bottle too	<u>43</u>
	3 = no	
	7 = uncertain	
Who helped to decide whether or not you would get prenatal care?		
Husband	1 = yes	
	2 = no	<u>44</u>
Mother-in-law	3 = sort of; may be	
	7 = don't know about prenatal care	<u>45</u>
Other	8 = N.A.	<u>46</u>
Have you received any prenatal care?	1 = yes	
	2 = no	
	7 = uncertain (can't remember)	<u>47</u>
	8 = answer unclear	
If yes, from where?		
1 = hospital		
2 = clinic (municipal, CWF, other)	1st	<u>48</u>
3 = TBA		
4 = midwife	2nd	<u>49</u>
5 = obstetrician		
6 = other	3rd	<u>50</u>
7 = uncertain		
9 = none		
How many visits? (Exact #)		<u>51</u> <u>52</u>

If you had a baby boy what are the 4 most important qualities for him to have?  
(Read whole list)

01 = quiet		
02 = obedient	1st	
03 = happy		53
04 = good		54
05 = pretty/handsome	2nd	
06 = wants to please me		55
07 = gusty		56
08 = strong	3rd	
09 = smart		57
10 = please my husband		58
77 = uncertain	4th	
90 = other _____		59
91 = other _____		60
92 = other _____		
93 = other _____		

If you had a baby girl what would the 4 most important qualities be for her to have:

01 = quiet		
02 = obedient	1st	
03 = happy		61
04 = good		62
05 = pretty/handsome	2nd	
06 = wants to please me		63
07 = gusty		64
08 = strong	3rd	
09 = smart		65
10 = please my husband		66
77 = uncertain	4th	
90 = other _____		67
91 = other _____		68
92 = other _____		
93 = other _____		

How old do you expect your baby to be when you first wash her/him? (77 if uncertain) (days) 69 70

Does the umbilical cord require special care? | 1 = yes  
| 2 = no  
| 7 = uncertain 71

If yes, what kind of care?  
 (Donot read answers: more than  
 1 answer can be yes)  
 Code 8 if column 71 = 2

Not wet		72
Not dirty	1 = yes	
	2 = no	73
Needs ash	7 = uncertain	
	8 = N.A.(Column 71=2)	74
Needs gentian violet or other medicine		75
Other		76

Do you plan on having an attendant at the delivery?	1 = yes	77
--	---------	----

Do you plan on delivering the baby in the hospital or at a clinic?	2 = no	
	7 = uncertain	78

Do you plan to return to your village for delivery?		79
--	--	----

How many tetanus immunizations have you received	Code exact	
	0 = 0	
	1 = 1	
	2 = <u>&gt;2</u>	
	3 = uncertain, probably yes	80
	4 = uncertain, probably no	
	5 = doesn't know what it is	

Specific Plans for Delivery

Do you have specific plans for:

What you will use to cut the umbilical cord? Explain _____		81
--	--	----

How you will clean the area around the cord? Explain _____	1 = yes	
	2 = no	
	7 = uncertain	
	8 = deliver in hospital (column 78 = 1).	82

Clothes in which to wrap the child? Explain _____		83
--	--	----

Pads for yourself? Explain _____		84
-------------------------------------	--	----

OBSERVATION (Pre-natal) FORM:110

Identity # of mother

\_\_\_\_\_  
(1 - 14)

Date

MM DD YY  
\_\_\_\_\_  
(15 - 20)

Observation start

(Code exact hours 01 to 24 and exact  
minutes 01 to 60)

\_\_\_\_\_:\_\_\_\_\_  
Hour Minute  
(21 - 24)

Observation finish

\_\_\_\_\_:\_\_\_\_\_  
Hour Minute  
(25 - 28)

Garbage in yard (If no, code "8")

Feces in yard (If no, code "8")

Animals in house  
(8 if no animals owned by family)

Evidence that animals do go into house  
(8 if no animals owned by family;  
9 if column 31=1)

Birthing equipment ready: (8 if mother  
plans to go to village, hospital or  
clinic for delivery)

clean cloth to receive baby

safe delivery kit

scissor/knife clean to cut cord

Cooked food is covered

Mother/caretaker observed to use sari to:

wipe dirty hands

wipe soiled utensils

mop up a spill

\*wipe nose/blow nose (own or child's)

\_\_\_\_\_  
29

1 = yes \_\_\_\_\_  
30

2 = no \_\_\_\_\_  
31

7 = uncertain \_\_\_\_\_  
32

8 = N/A \_\_\_\_\_

\_\_\_\_\_  
33

\_\_\_\_\_  
34

\_\_\_\_\_  
35

\_\_\_\_\_  
36

\_\_\_\_\_  
37

\_\_\_\_\_  
38

\_\_\_\_\_  
39

\_\_\_\_\_  
40

*wipe child's anus (8 if child never stooled)	1 = yes	41
*wipe eyes (own or child)	2 = no	42
*dry child	7 = uncertain	43
*drys child's wound	8 = N/A	44
*wipe soiled child		45

**Mother washes hands:**

		<u>E p i s o d e</u>			
		<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>
after defecating	1 = yes, immed (<5 min)				
	2 = yes, 5-10 minutes	46	47	48	49
before eating	3 = yes, 10-20 minutes				
	4 = yes, >20 minutes	50	51	52	53
before preparing/ serving food	7 = uncertain (couldn't see her)				
	8 = N/A (did not defecate or eat or serve food)	54	55	56	57
	9 = no				

---

\* "8" if no child in family



ATTITUDES QUESTIONNAIRE FORM: 120  
(2 Days, 1 month, 2 1/2 month)

(To be administered only to mother)

Identity # of family	_____
	(1 - 12)
of child	_____
	(13 - 14)
of mother	_____
	(15 - 16)
Date	_____
	MM DD YY
	(17 - 22)

Age of child - 1 = 2 day	
2 = 1 month	
3 = 2 1/2 month	23

Sex of child - 1 = male	
2 = female	24

Is the baby a good baby?	1 = yes	
	2 = no	25

Does he/she make you happy?	7 = uncertain/more or less	
	8 = don't understand	26

From this list of pairs of qualities choose the one that better describes your baby. (Read list as choose quiet or noisy; choose obedient or naughty)

		<u>Can't say</u>	
1 = quiet	2 = noisy	7	27
1 = obedient	2 = naughty	7	28
1 = happy	2 = sad	7	29
1 = good	2 = bad/fresh	7	30
1 = pretty	2 = plain	7	31
1 = gusty	2 = no energy	7	32
1 = strong	2 = weak	7	33

Do you think he is a smart baby?		
1 = yes		
2 = no		34
3 = sort of		
7 = can't say, don't know		

Is your baby a healthy baby?

- 1 = yes
- 2 = no
- 3 = sort of
- 7 = can't say, don't know

35

Is your baby a good weight?

- 1 = yes
- 2 = no, too skinny
- 3 = no, too fat
- 7 = can't say, don't know
- 8 = N/A, doesn't matter

36

Are you breast feeding your baby?

- 1 = yes, exclusively
- 2 = yes and water
- 3 = yes and other milk
- 4 = yes and food (may also include other milk)
- 5 = no

37

Do you care if you become pregnant again right away?

- 1 = do care - do not want to become pregnant right way
- 2 = do care - do wish to become pregnant right way
- 3 = don't really care, doesn't matter
- 7 = not sure

38

Does your husband care if you become pregnant right?

- 3 = don't really care, doesn't matter
- 7 = not sure

39

What, if any method of family planning are you practicing since birth of baby?  
(Read whole list)

- 1 = natural
- 2 = condom
- 3 = pill
- 4 = injection
- 5 = I was sterilized
- 6 = my husband was sterilized
- 7 = IUD
- 8 = diaphragm
- 9 = menstrual regulation
- 10 = other (specific) \_\_\_\_\_

- 1 = yes, always
- 2 = yes, sometimes
- 4 = uncertain
- 8 = N/A (None)

40

41

42

43

44

45

46

47

48

49

(To be asked 2-day visit only)

Utensil used to cut umbilical cord: (only 1 choice)

- 1 = knife
- 2 = scissors
- 3 = rock
- 4 = glass
- 6 = other, specify \_\_\_\_\_
- 8 = N/A, done in hospital

50

Item had been before it was used to cut cord (only 1 choice)

- 1 = wiped only
- 2 = washed with water only
- 3 = washed with water and soap
- 4 = washed with boiled water only
- 5 = washed with boiled water and soap
- 6 = flamed

51

After it was cleaned but before the cord was cut, was it wiped with a cloth

- 1 = no, air dried
- 2 = yes, any cloth
- 3 = yes, clean cloth
- 4 = yes, cloth from safe birth kit

52

Did you use a safe birth kit

53

Who aided delivery (more than 1 answer possible)

hospital

54

clinic

55

TBA, untrained

1 = yes

56

TBA, trained (specify where \_\_\_\_\_)

2 = no

57

midwife

7 = uncertain

58

obstetrician

59

relatives, untrained (not one of above)

60

uncertain

61

other

62

OBSERVATION FORM: 131

(For 2 day, 1 month and 2 1/2 month visit)

(Infant must be present)

Identity # of family	_____
	(1 - 12)
of child	_____
	(13 - 14)
of mother	_____
	(15 - 16)

Date	_____	_____	_____
	MM	DD	YY
	(17 - 22)		

Observation start	_____	:	_____
	Hour		Minute
	(23 - 26)		

Observation finish	_____	:	_____
	Hour		Minute
	(27 - 30)		

Age of child		
1 = 2 days		
2 = 1 month		
3 = 2 1/2 months		_____
4 = other(specify)_____		31

Gender of child		
1 = male		
2 = female		
3 = twins(specify sex_____)		_____
		32

Child appears:

clean		
appropriately dressed	1 = yes	_____
	2 = no	33
well nourished	7 = uncertain	_____
		34
healthy		_____
		35
	If no or uncertain, explain	_____
		36
	_____	
	_____	
	_____	

How many times was child picked up during observation period? (Exact number)

37      38

Who picked up child?

mother		<u>39</u>
father		<u>40</u>
grand mother		<u>41</u>
grand father		<u>42</u>
other adult relative	1 = yes	<u>43</u>
neighbors.(adult)	2 = no, (but was present)	<u>44</u>
sibling >5	8 = no, (not around or doesn't exist)	<u>45</u>
sibling <5		<u>46</u>
other children >5		<u>47</u>
other child <5		<u>48</u>
religious leader		<u>49</u>
other		<u>50</u>

How long was total child held:

1 = >2 hours		
2 = 1 - 2 hours		
3 = 30 minutes to 1 hour		
4 = 10 - 30 minutes		<u>51</u>
5 = <10 minutes		
9 = not at all		

Were hands of person who picked up child washed before picking up child?

1 = yes, immediately (<10 minutes)	Episode #1	<u>52</u>
2 = yes, 11 - 20 minutes before	#2	<u>53</u>
3 = yes, >20 minutes before	#3	<u>54</u>
7 = uncertain		
9 = no, not while I was there		

Was any attempt made by mother to determine if someone was ill before they picked up the baby?	1 = yes		
	2 = no		
	3 = yes, but ill person still picked up child		55
Was any attempt made to keep on ill person away from infant?	7 = uncertain		

How often did the child go to the breast? (Total # of times)		56
	57	58

How many minutes total was the child at the breast? (Total # of minutes child at breast)		59	60	61
--	--	----	----	----

What else was placed in the baby's mouth? (or, Did the baby put in his own mouth?)			
finger (other than baby's)			62
pacifier	1 = yes		63
bottle/nipple	2 = no		64
eating utensil	7 = uncertain		65
toy			66
food			67
other (specific _____)			68

When baby was not held he was placed-			
on floor in corner away from traffic			69
on floor in middle or in other trafficked area heavily	1 = yes		70
on bed (adult's)	2 = no		71
in own bed or crib	8 = N/A, never was put down		72
outside on ground			73
next to fire/cooking stove			74
Other (specific _____)			74

Animals observed in household

76

- 1 = yes, constantly
- 2 = yes, in and out
- 3 = not seen but evidence that they do come in (e.g., hair, dung, feathers)
- 7 = uncertain
- 8 = N/A, family does not own animals - no animals around
- 9 = no (animals are around, but do not come inside)

Mother is:

- 1 = in bed
- 2 = up for simple chores
- 3 = up for normal light work
- 4 = up normally
- 5 = up and out of house for work
- 6 = N/A (dead, in hospital, abandoned family etc...)

77

Mother has help in household:

Identify -

- 1 = daughter (5-10 years old)
- 2 = daughter (>10 years)
- 3 = grand mother
- 4 = neighbor girl (5-10 years old)
- 5 = neighbor woman (>10 years)
- 6 = hired servant girl (5-10 years)
- 7 = hired servant woman (>10 year)
- 8 = other
- 9 = no one

1st 78

2nd 79

Mother/help wash hands before serving food

- 1 = immediately (<5 minutes)
- 2 = 5-10 minutes
- 3 = 10-20 minutes
- 4 = 20-30 minutes
- 7 = Uncertain
- 8 = N/A (no food served)
- 9 = None

1st 80

2nd 81

3rd 82

Does the family cover the floor/front step with cowdung mixture	1 = yes 2 = no 7 = uncertain	83
Does mother (primary caretaker) smile at new baby		84
talk to new baby		85
talk about new baby		86
play with new baby	1 = yes, a lot	87
Prepared food is left uncovered ("8" if no food in house)	2 = no	88
Garbage/feces in living area	3 = yes, but very little 7 = uncertain	89
Animals or animal feces in cooking area	8 = N/A	90
Children defecate in living area		91
Is cooking stove inside house	1 = yes 2 = no 7 = uncertain 8 = N/A, no stove	92
Childs umbilicus appearance	1 = clean & dry 2 = clean, moist 3 = dirty but dry 4 = dirty and moist 5 = other specify _____ 8 = N/A well healed	93
covered with clean cloth		94
has gentian violet or rubbing alcohol on it	1 = yes 2 = no 7 = uncertain	95
has homeopathic/herbal medicine on it	8 = N/A, already healed	96
Cow dung applied to it		97



Mother/caretaker observed to use sari to:

wipe dirty hands		98
wipe soiled utensils		99
wipe nose/blow nose (own or child's)		100
wipe soiled child		101
mop up a spill	1 = yes 2 = no	102
wipe child's anus	7 = uncertain 8 = N/A, no opportunity	103
wipe eyes (own or child)		104
dry clean child		105
drys child's wound/or umbical cord		106
Did child exclusively breast feed (nothing else)	1 = yes	107
If no, continue on:	2 = no	

**CHILD FED**

**Container:**

		<u>Cont- ainer</u>	<u>Food Prepa- Type</u>	<u>ration</u>	<u>Storag</u>
1 = From a bottle	Episode 1	108	109	110	111
2 = From a spoon	Episode 2	112	113	114	115
3 = From a cup	Episode 3	116	117	118	119
4 = By fingers/hand of caretaker	Episode 4	120	121	122	123
5 = By eating utensil other than spoon	Episode 5	124	125	126	127
6 = Other					

**Food:**

- 1 = Water
- 2 = Milk (powdered)
- 3 = Milk (package & store bought)
- 4 = Milk (fresh)
- 5 = Milk (bought from pail)
- 6 = Rice, chapati or biscuit
- 7 = Vegetable or fruit
- 8 = Meat, fish or poultry
- 9 = Other

**Preparation:**

- 1 = Raw, unboiled but washed with clean water
- 2 = Raw, unboiled and not washed
- 3 = Boiled or cooked stored with cover and  
and accessed by clean utensil or pouring
- 4 = Boiled or cooked, stored with cover but  
accessed by hand or dirty utensil
- 5 = Boiled or cooked stored without cover and  
accessed by clean utensil or pouring
- 6 = Boiled or cooked, stored without cover and  
accessed by hand or dirty utensils
- 7 = Uncertain

**Storage:**

- 0 = <1 hour
- 1 = 1-2 hours
- 2 = 2-4 hours
- 3 = 4-6 hours
- 4 = 6-10 hours
- 5 = 10-24 hours
- 6 = >24 hours
- 7 = Uncertain

**ILLNESS QUESTIONNAIRE FORM: 131**  
(For 2 day, 1 month, 2 1/2 month)

Family Identity # \_\_\_\_\_  
Child number \_\_\_\_\_ (1 - 12)  
Mother number \_\_\_\_\_ (13 - 14)  
Date \_\_\_\_\_ (15 - 16)  
MM DD YY  
(17 - 22)

Age of child -

1 = 2 day  
2 = 1 month \_\_\_\_\_ 23  
3 = 2 1/2 month  
4 = other, specify \_\_\_\_\_

Sex of child -

1 = male  
2 = female  
3 = twins, specify sex \_\_\_\_\_ 24

Has your baby been sick in the last 2 weeks?

1 = yes  
2 = no \_\_\_\_\_ 25

(ASK NEXT QUESTION REGARDLESS OF ABOVE ANSWER)

Has your baby had any of the following problems in the last 2 weeks? (Read list)

cough		_____ 26
fever		
rash (scabies impetigo, etc.)	1 = yes	_____ 27
	2 = no	_____ 28
vomiting		
diarrhea	7 = uncertain	_____ 29
eye problem		_____ 30
convulsion		_____ 31
		_____ 32

Did your baby have other problems not listed above?

Other, 1 \_\_\_\_\_

33

(Remainder of questionnaire to be administered only if baby had some illness or "other condition")

Did you feel that your baby needed to receive special care, food or medicine for any of these problems? (Specify interested in what mother and household members felt, not other persons)

1 = yes  
2 = no  
7 = I wasn't sure

34

What did you do on your own for the baby when he became ill? (Before seeking advice from someone outside of the household) (Probe "And anything else?" but do not read list) (May give example "Such as giving more drink")

Answer includes:

gave ORS		35
gave "hot" food		36
gave "cold" food	1 = yes	37
withheld food	2 = nocertain	38
herbal medicine had in house or buy without consultation	7 = uncertain	39
withheld drink	8 = N/A (child not taking food yet or not breast feeding child)	40
gave medicine had in house or could buy without consultation		41
stopped breast feeding		42
gave more drink		43
gave more food		44
other (specific) _____		45

Did you (the mother) think you should get advice from someone outside of the household?

- 1 = yes
- 2 = no
- 7 = uncertain

46

Whom did you talk with to decide whether or not to seek help and from whom to seek it?

Husband

1 = yes

47

Mother/mother-in-law

2 = no

48

Neighbours

3 = uncertain

49

TBA/UVP/health worker who came routinely to house

50

No one, I made the decision myself

51

Other (specific) \_\_\_\_\_

52

Did you or some one from your household finally seek outside help or advice

1 = yes

53

2 = no

3 = no, but outside help was sought any how (i.e., - by neighbor, health worker)

If help was sought from whom was it sought? (Do not ask this question if no help was sought (e.g., column 53=2) Do not read list but more than 1 answer is possible.

Religious leader

54

Quack

55

Pharmacist

1 = yes

56

TBA

2 = no

57

Health worker

3 = uncertain

58

Local doctor/clinic

8 = N/A, did not seek help

59

Hospital

60

UVP

61

Other, specify \_\_\_\_\_

62

From whom would you the mother have sought advice if the decision were yours alone? (More than 1 answer possible)

(Note: Do not ask this question if she answered "none" I made the decision myself; code 8 for all)

Quack			
Pharmacist			63
Religious leader	1 = yes		64
TBA/health worker	2 = no		65
Health worker	7 = uncertain		66
Local doctor/clinic	8 = N/A, did not seek help		67
Hospital			68
UVP			79
Other (specific)			70
			71

Whose advice or treatment was finally given to the child?

Pharmacist			72
Religious leader	1 = yes, all		73
TBA	2 = no, none		74
Health worker	3 = yes, some		75
Local doctor/clinic	7 = uncertain		76
Hospital	8 = N/A - did not seek his/her advice		77
UVP			78
Other (specific)			79
I ignored all advice (Must be "2", if any column 72-80 are 1 or 3)			80
			81

What were the reasons which describe why you did not follow all of the advice?

(More than 1 answer possible)

didn't make sense/seemed crazy			<u>82</u>
husband said no			<u>83</u>
mother-in-law/other said no			<u>84</u>
too much trouble/couldn't be bothered			<u>85</u>
conflicted with other advice			<u>86</u>
too confusing/didn't understand it			<u>87</u>
didn't seem to be working			<u>88</u>
child refused			<u>89</u>
I was scared			<u>90</u>
required overnight hospitalization			<u>91</u>
it is not something that is done			<u>92</u>
no one to take care of other children			<u>93</u>
no one to cook for husband			<u>94</u>
cost (too cheap, couldn't work)			<u>95</u>
cost (too expensive)			<u>96</u>
other (specific) _____			<u>97</u>
Weight of child (to nearest 1/10 kg.)	<u>98</u>	<u>99</u>	<u>100</u>
Length of child (to nearest 0.5 cm.)	<u>101</u>	<u>102</u>	<u>103</u>