

Principal Investigator A.K.M. Alauddin Trainee investigator (if any) nilApplication No 77-028 Chowdhury Supporting Agency (if Non-CRL) \_\_\_\_\_Title of study ZPG vital rates 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):

1. Source of Population:
- a) Ill subjects 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 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 possibly damaging to subject or others Yes  No
3. 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
4. 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  NA
- 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
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 Board for review.

We agree to obtain approval of the Review Board on Use of Human Volunteers for any changes involving the rights and welfare of subjects before making such change.

Principal Investigator

Trainee

INFORMATION TO INCLUDE IN ABSTRACT SUMMARY

The Board will not consider any application which does not include an abstract summary. The abstract should summarize the purpose of the study, the methods and procedures to be used, by addressing each of the following items. If an item is not applicable, please note accordingly:

1. Describe the requirements for a subject population and explain the rationale for using in this population special groups such as children, or groups whose ability to give voluntary informed consent may be in question.
2. Describe and assess any potential risks - physical, psychological, social, legal or other - and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.
3. Describe procedures for protecting against or minimizing potential risks and an assessment of their likely effectiveness.
4. Include a description of the methods for safeguarding confidentiality or protecting anonymity.
5. When there are potential risks to the subject, or the privacy of the individual may be involved, the investigator is required to obtain a signed informed consent statement from the subject. For minors, informed consent must be obtained from the authorized legal guardian or parent of the subject. Describe consent procedures to be followed including how and where informed consent will be obtained.
  - (a) If signed consent will not be obtained, explain why this requirement should be waived and provide an alternative procedure.
  - (b) If information is to be withheld from a subject, justify this course of action.
6. If study involves an interview, describe where and in what context the interview will take place. State approximate length of time required for the interview.
7. Assess the potential benefits to be gained by the individual subject as well as the benefits which may accrue to society in general as a result of the planned work. Indicate how the benefits outweigh the risks.
8. State if the activity requires the use of records (hospital, medical, birth, death or other), organs, tissues, body fluids, the fetus or the abortus.

The statement to the subject should include information specified in items 2,3,4 and 7, as well as indicating the approximate time required for participation in the activity.

Received 27/9/77  
77-028

(Cover Page - Use this format exactly as outlined  
with numbers and headings)

SECTION I - RESEARCH PROTOCOL

- 1) Title: ZPG vital rates
- 2) Principle Investigator: A.K.M. Alauddin Chowdhury
- 3) Starting Date: May, 1977
- 4) Completion Date: January, 1978
- 5) Total Direct Cost: U.S.\$ 8,557.00

- 6) Abstract Summary (250 words or less):

This is a test of a new survey method of estimating fertility rates in ZPG area at Hajigonj. This new method is found to be applicable in the field at Matlab. If this method is again found suitable in Hajigonj then it can be used on national basis for estimating fertility.

- 7) Reviews: (Leave Blank)

- a) Research Involving Human Subjects: \_\_\_\_\_
- b) Research Committee: \_\_\_\_\_
- c) Director: \_\_\_\_\_
- d) BMRC: \_\_\_\_\_
- e) Controller/Administrator: \_\_\_\_\_

Approved Project Protocol No. 730807

Estimate of Yearly Vital Rates of ZPG Area

by

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A. INTRODUCTION :

The Principal Investigator himself has developed a new method and termed it as Pregnancy Prevalence survey. Details of the method with its advantages and limitations comparing to other methods is already published(1).

The fertility rates estimated by Pregnancy prevalence survey were found as good as that of vital registration system in Matlab. This new method should be field tested in an area in which intensive vital events registration has not been conducted as such as registration system may introduce bias through frequent questioning about births. Hajigonj thana is adjacent to the Matlab thana and may be expected to share many of the factors regulating fertility with pre-contraceptive distribution Matlab. If it is found to be suitable for field use and if it gives reliable estimates, the method can be expanded to a nationwide basis. It is simple, flexible and relatively low cost.

SPECIFIC AIMS :

- 1) Estimate the fertility rates of ZPG area, Hajigonj.
- 2) Examine the validity and the bias of the estimates.

METHOD OF PROCEDURE :

The ZPG program, Hajigonj needs accurate estimates of vital rates over an extended period of time for evaluation and planning, subsequent changes of activity. This method of estimating vital rates should provide accurate assessments and be relatively less expensive and independent of the program itself. Out of 69 villages of ZPG program in Hajigonj every third villages were selected as sample for the survey, covering over 3000 house-hold. The data is to be collected twice in one year from the same sample at an interval of six months.

In the first round survey variables to be included are similar to those in usual retrospective demographic surveys such as age, sex, parity, marital status and number of live births and deaths during last 12 months etc.

In addition to the above variables, another variable to be asked, whether a married woman age ( 15-49 ) at the time of survey are pregnant or not and if pregnant, data on the months of gestation are to be collected.

In the second round survey information on household change, pregnancy status and month of gestation is included, plus those who were reported as pregnant in first round are to be questioned to determine the fate of those pregnancies on or before round two. In addition to interview method, one can use Pregnancy test simultaneously to validate the response.

Because of non availability of pregnancy test kit during 1st round pregnancy test could not be done in the 1st round to compare response result and test results. However, pregnancy test will be done in 2nd round to 25 % of the married.

#### THEORITICAL ASPECTS OF THE METHOD:

##### Notations:

$t_1$  = Calendar time of the 1st round survey.

$t_2$  = Calendar time of 2nd round Survey.

$Z_i(t_1)$  = Proportion of women who are pregnant at time  $t_1$   
and who are at  $i$ th month of gestation.

$Z_i(t_2)$  = Proportion of women who are pregnant at time  $t_2$   
and who are at  $i$ th month of gestation.

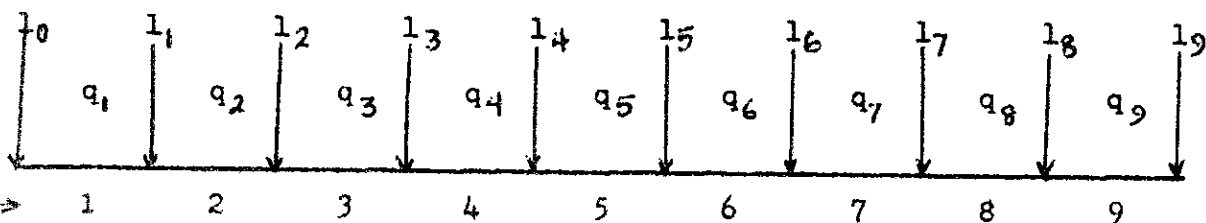
$q_i$  = Probability that a pregnancy which survived (i-1)th month of gestation terminates to non-livebirth during gestation month i .

$l_i$  = Probability that a pregnancy survives ith month of gestation =  $\prod_{j=1}^i (1-q_j)$

$l_0 = 1$

$l_9$  = Probability that a pregnancy terminates to a live birth.

Diagram showing the relationship of  $l$ 's,  $q$ 's, and  $l$ 's .



Total number of live birth (TB) out of all the pregnancies reported in 1st round Survey at time t will be distributed over next 9 month period.

$$TB = \sum_{i=1}^9 Z_i(t_i) \quad l_9/l_i - - - - (1)$$

As these livebirths cover only a 9 month period the estimate for next 12 month period could have been expanded from equation (1) by multiplying by a constant ratio if there, no seasonality of conceptions occur. However in many populations there exists a seasonality of births (Stoeckel et al.,1972) resulting from seasonality of conception.

In order overcome the difficulty resulting from observed seasonality of these events a second round survey at time  $t_2$  should be done at exactly six month subsequent to the 1st round Survey.

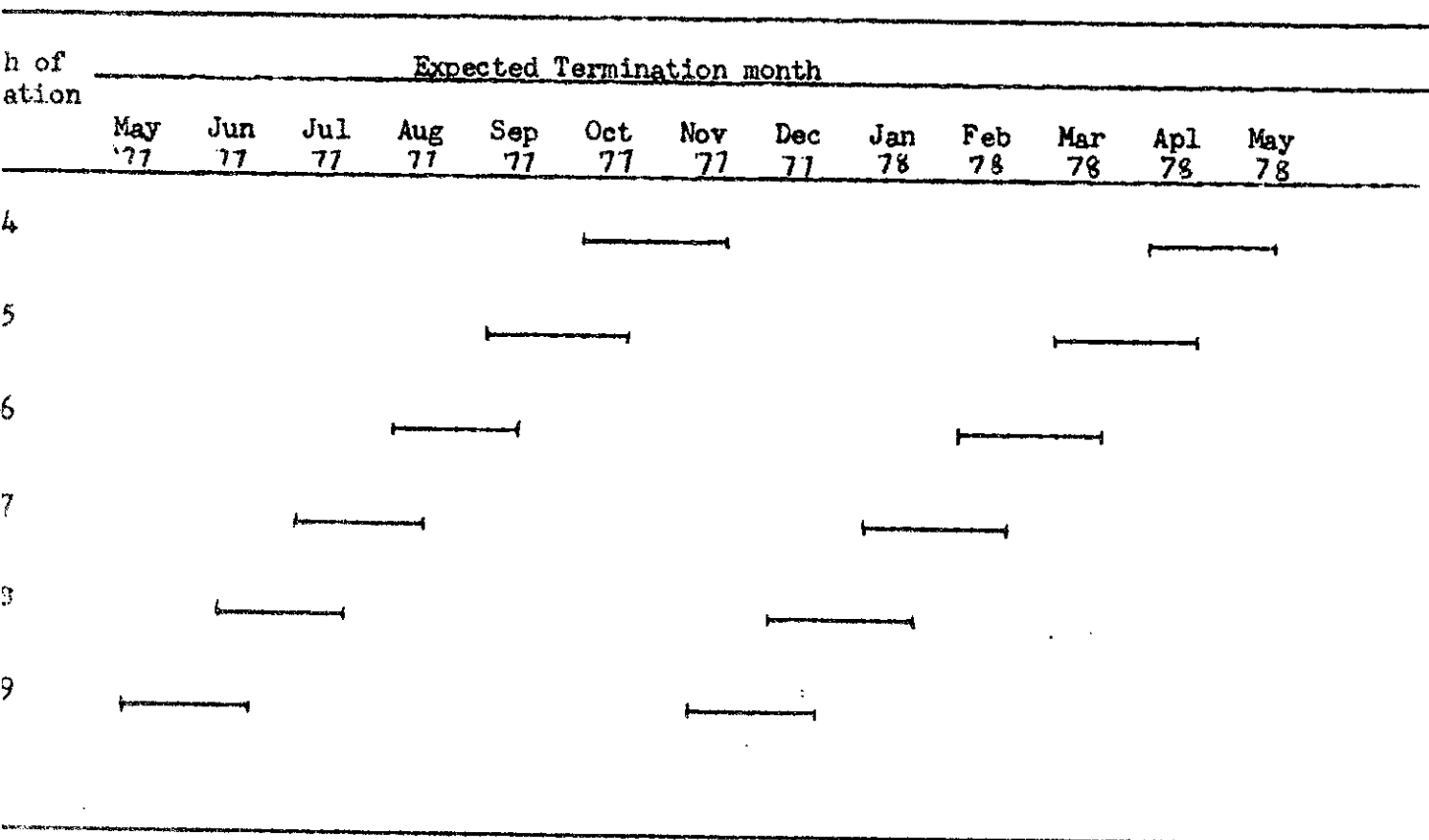
Total livebirths during 12 month period since  $t_1$

$$TB = \sum_{i=4}^9 Z_i(t_1) 19/li + \sum_{i=4}^9 Z_i(t_2) 19/li - - - (2)$$

In equation (2) only 2nd and 3rd Tremister Pregnancies are taken into account for both Round-1 and Round-2 . However Pregnancies of R1 are not the Pregnancies of R2 .

Diagram-1 showed time schedules of two Surveys and the months covered for the fertility rate :

Diagram- 1



Round - 1



Round- 2



SIGNIFICANCE:

This is a new advancement of survey methodology having sound theoretical basis. If it is found suitable for the field use and if it gives reliable estimates the method can be expanded to a nationwide basis. The method is simple, flexible and relatively low cost.

FACILITIES REQUIRED:

Office space is required at Hajigonj during Round 1 and Round 2 Surveys.

REFERENCE:

1. Chowdhury A.K.M.A. Double round survey on pregnancy Prevalence and estimate of traditional fertility rates.

Cholera Research Laboratory Scientific report series No.1, Dacca, Bangladesh.

B U D G E T S U M M A R Y

1977 - 78

Z. P. G.

Budget Categories	1977 - 78	
	TAKA	DOLLARS
1. Personnel Services	17,650	-
2. Supplies	24,100	-
3. Equipment	-	-
4. CRL Transport	4,200	-
5. Travel	10,400	3,000
6. Transportation of things	-	300
7. Rent Communication & utilities	600	-
8. Printing	-	-
9. Contractual	21,900	-
10. Construction, Renovation, alteration	-	-
Total	78,850	3,300

Tk. 34,500 already spent during the first round.

**BUDGET ESTIMATES  
FOR  
PREGNANCY PREVALENCE SURVEY  
ESTIMATES OF THE YEARLY VITAL RATES OF  
ZPG AREA, HAJIGONJ, COMILLA**

Budget categories	Descriptions	Preparatory Expenses	May 77 Round 1 Expenses	Expenses in between Rounds	November Round 2 Expenses	Expenses at the end of program	Total Amount Required
<u>PERSONNEL SERVICES</u>	Mr.A.K.M.Alauddin Chowdhury (approx)75% of his 60 days i.e. 45 days total time in two phases	-	4000	-	4000	-	8000
	Coding Assistants 2 at the end of prog. @Tk.10 per case say for 620 cases.	-	-	-	-	6,200	6,200
	Key Punch Operator 1 @ Tk.4.38 per hr.for 30X8= 240 hrs.	-	-	-	-	1,050	1,050
	Field Surveillance Assistant 1=75% of his time i.e. 45 days @H-4(1042)	-	1,200	-	1,200	-	2,400
	Total:		5,200	-	5,200	7,250	17,650
<u>SUPPLIES</u>	Forms for program(one time)25,000 @ 0.16 each form.	-	2000	-	2,000	-	4,000
	Office supplies(approximately) paper,pencils,pen,pads and other stationaries.	300	700	500	300	200	2,000
	Punch cards- 20,000	-	-	250	-	250	500
	Pregnancy Test Kits(10 boxes)	-	8,800	-	8,800	-	17,600
	Total:	300	11,500	750	11,100	450	24,100

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Budget categories	Descriptions	Preparatory Expenses	May 77 Round 1 Expenses	Expenses in between Rounds	November Round 2 Expenses	Expenses at the end of program	Total Amount Required
GR. TRANSPORT	Mileage-Hajigonj-Jeep= Programes activities land and water transport (Boat) approx. Tk. 70.00 per day for 60 days for Investigator and staffs.	-	2,100	-	2,100	-	4,200
Travel Local	Trips-Dacca-Hajigonj via Matlab 4 trips for Mr. Chowdhury and Field S. Assistant.	-	1,200	-	1,200	-	2,400
	Per diem-Mr. Chowdhury 4 trips X 7 days X 160.00	-	2,240	-	2,240	-	4,480
	Expenses during trips to H. Gonj	-	260	-	260	-	520
	Per diem-F.S.A. 7 trips X 4 X 95	-	1,330	-	1,330	-	2,660
	Expenses during trips to Hajigonj	-	170	-	170	-	340
		-	<u>5,200</u>	-	<u>5,200</u>	-	<u>10,400</u>
INTERNATIONAL	R/T Air Ticket cost for Investigator Dacca/U.S.A./Dacca	-	-	-	-	\$ 2000	\$ 2000
	Per diem approximately	-	-	-	-	\$ 1000	\$ 1000
TRANSPORTATION	Transportation of cards, documents etc. to U.S.A.	-	-	-	-	\$ 300	\$ 300
RENT	Office accomodation for 2 months @ 300.00 per month.	-	300	-	300	-	600

BUDGET ESTIMATES  
FOR  
PREGNANCY PREVALENCE SURVEY  
ESTIMATES OF THE YEARLY VITAL RATES OF  
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Budget categories	Descriptions	Preparatory May 77		Expenses in between Rounds	November Round 2 Expenses	Expenses at the end of program	Total Amount Required
		Expenses	Round 1 Expenses				
CONTRACTUAL	Field Supervisor-cost for 2 months @ 1200.00	-	1200X2	-	1200X2	-	2400
	Female field workers 10 @Tk.900 each	-	9,000	-	9,000	-	18,000
	Programmer one time at middle of the program to work out 10/15 programs.	-	-	1,500	-	-	1,500
		-	10,200	1,500	10,200	-	21,900
	Total:	300	34,500 *	2,250	34,100	7,700	78,850
						\$ 3,300	\$ 3,300

\* Amount already spent during the 1st round.

কম্বোয়া সিন্ডিকেট কর্তৃক প্রস্তুতকৃত  
মাসিক ও গর্ভবতী সাক্ষরতার  
সংবেদনায় জনস্বার্থে  
-----X-----

স্বাক্ষর

মাসিক, গর্ভবতী সাক্ষরতার এবং জনস্বার্থে জীবিত/মৃত ইত্যাদি  
বিষয়ে তথ্য সংগ্রহের জন্য সংশ্লিষ্ট কর্মী পরিদপ্তরে/সংশ্লিষ্টদেরকে কতকগুলি  
প্রয়োজনীয় প্রশ্ন জিজ্ঞাসা করা হবে।

সংশ্লিষ্টদের স্বতঃস্ফূর্তভাবে সীলিত স্বাক্ষর করুন।

স্বাক্ষর বা চিহ্নসহ

উত্তর দপ্তর/দপ্তরীয় নাম

স্বাক্ষর কর্তার নাম

উ.স.স. দপ্তরীয় পরিচালক