PLAN OF ANALYSIS

ENDLINE SURVEY

PROJECT

HOME BASED MANAGEMENT OF YOUNG INFANTS (0-60 days)

Funded by:

MINISTRY OF HEALTH & FAMILY WELFARE &

INDIAN COUNCIL OF MEDICAL RESEARCH

Modified on 8/11/2010

INDEX

A. BACKGROUND:

The Indian Council of Medical Research is carrying out an effectiveness study on "Home Based Management of Young Infants" (0-60 days) in five rural sites of Yeotmal, Rajsmand, Barabanki, Patna and Cuttack districts in states of Maharashtra, Rajasthan, Uttar Pradesh, Bihar and Orissa respectively. It is a three arm study- Intervention through SR, Intervention through AWW and a control arm. There are two PHCs in each interventions and control arms at all the sites. A total of 1500 live births would be observed over a period of two years to demonstrate a 50% decline in young infant and neonatal mortality rates with 80% power and 95% confidence.

The package of interventions being delivered by a village based worker has been shown to reduce neonatal mortality by Bang et al. In the present operational study the feasibility of delivering the intervention in different settings in partnership of existing health system is being evaluated. The intervention package consists of essential newborn care to all babies at home level, care at birth including resuscitation, care of low birth weight (LBW) babies, treatment of local infections, identification of sepsis in babies using simple algorithm, referral and treatment of sepsis using oral cotrimoxazole and injection gentamicin. The strategy for newborn care consists of presence at the time of delivery, eight home visits to normal newborns during neonatal period and four in the second month, more frequent home visits in case of high–risk and sick babies. In addition the intervention package also includes Health Education focusing on care during pregnancy, care of normal and low birth weight babies, early initiation of breastfeeding and lactation counseling, prevention of infection, rational traditional practices, early detection of illness and early care seeking and. social mobilization for community participation by sensitizing the community through IEC and focus group discussions.

B. OBJECTIVE(S)

To study the effectiveness of a package of home-based interventions delivered by a trained community based newborn care worker in reducing mortality of neonates and young infants (<60 days) in the rural communities through a multi-site field trial.

Specific objectives

1. To determine the impact of a package of home-based interventions for neonates and young infants (<60 days), provided by a community based care worker, on mortality
2. To determine the utilization pattern of the services provided under this intervention package.

C. METHODOLOGY

C1. Area & Phases

The project is a multicentric study being carried in following five sites

STATE	DISTRICT	IMPLEMENTING institutes
• Bihar	Patna	Patna Medical College, Patna
• Maharashtra	Yeotmal	MGIMS, Wardha
• Orissa	Cuttack	NIHARD-NGO, Cuttack
• Rajasthan	Rajsamand	ARTH- NGO, Udaipur
• Uttar Pradesh	Barabanki	KG Medical College, Lucknow

The project is being carried out in three phases.

(i) Formative phase including baseline surveys and training;
(ii) Intervention phase and
(iii) Evaluation phase.

A baseline survey was conducted in the formative phase to generate baseline information on demographic characteristics of the populations being studied and to assess the birth rates, neonatal and infant mortality rates. The survey also generated information with regard to Government and private health service facilities available in the area.

C2. Levels of Data Collection:

The baseline surveys included:

- Village Level Information

- Baseline Mortality Survey- Household Information
- Baseline Mortality Survey- Delivery Record
- Facility survey
    - PHC facility
    - Sub centre facility
    - Survey of private medical practitioners (SPMP)

C3. Randomization:

After completing the analysis of the baseline survey randomization was undertaken at the Coordinating unit of ICMR. Out of the nine PHCs surveyed, six with similar mortality indicators were randomized into intervention and control arms. Result of the randomization procedure was communicated to the respective centers for beginning the processes of worker selection.

List of PHCs under each intervention arms are given below:

Districts	Model I – SR	Model II – AWW	Model III- Comparison
Cuttack	Khuntuni	Gurudijhatia	Rameshwar
	Bhadreshwar	Berhampur	Tentol
Barabanki	Dahilla	Udhauli	Tindola
	Mittai	Badagaon	Dadra
Rajsamand	Kelwa	Delwara	Sisoda
	Kurag	Kunwaria	Sakroda
Yeotmal	Dhanora	Dahegaon	Wadhona Bazar
	Waradh	Mardi	Sawargaon
Patna	Daniawan	Salimpur	Sampatchak
	Sherpur	Bir	Sabalpur

By December 2004 all the centers (Except AWW arm of Lucknow due to administrative problems) had completed the training workshops and post training evaluations.

During the year 2005 (commencing from January) all the components of the package of intervention was implemented at all the sites. However implementation of injection

treatment was delayed at all sites as additional training and field practice was required for injection skill

C4. Intervention arms:

Intervention was delivered by Shish Rakshak (SR) in one arm, Anganwadi worker (AWW) in another arm and there was a comparison arm / reference group with newborn care interventions as per usual health care system.

1. Shish Rakshak
2. AWW
3. Usual Health care system (Reference Group/ comparison group)

C 5. Impact evaluation:

A cross-sectional survey with complete enumeration of households was carried out in all the intervention arms (intervention and comparison) at (midterm if approve by DG) endline for assessing impact of intervention on mortality and change in key practices and care seeking.

"De facto" population was taken into consideration during impact evaluation survey and information was collected from both resident and non resident (visitor) populations at all the centers, as rates of migration may vary across centers

C 6. INSTRUMENTS (annexure 1)

The questionnaire have been prepared by the ICMR coordinating unit and approved by the Technical Advisory Committee constituted at ICMR.

Four major components of questionnaire are:

- Household questionnaire,
- Questionnaire for birth and death,
- Newborn care practices and care seeking
- Village level information
- PHC Facility survey

Definitions used in the survey:

Reference period: The reference period for the survey was two ~~one~~ years March 22/03/2008 (Holi) to March 21/03/2009 (Holi) and March 22/3/2009. to March 21/03/2010.Local events close to this dates were taken into consideration while collecting information on vital events and wherever available hospital records / cards if available with the family were checked. The surveyors recorded all the vital events occurring within this period.

Household : A household refers to group of people/persons living together in one dwelling and eating from the same kitchen.

Head of household: The head of household is the person who is acknowledged as such by other members of the family. The head of household is generally responsible for looking after /maintenance of household. He is a person by whose name the household is known.

Residents of the village: People who normally reside in the village with their families.

Visitors: People who have come to the village for a limited period (up to 3 months)

Respondent: Head of household or any elderly female member /responsible person / adult, or any ladies in reproductive age group (15-49 years)

Live birth: the birth of a living fetus (regardless of the length of gestation)

Stillbirth: Still birth is defined as late fetal death generally after 28 weeks EGA weighing >1000 gm in which the infant displays no sign of life (breathing, crying, and movement).

Antenatal check (ANC) up during pregnancy: ANC received from skilled personnel i.e. doctor / LHV / ANM / nurse,

Abortion: expulsion of product of conception before it is viable(<7 months), although, the most common definition of an abortion is any loss of a fetus that is less than 20 weeks' completed gestational age (since last menstrual period) or that weighs less than 500 grams

Home delivery: delivery at women's home

Institutional delivery: Delivery taking place in PHC / CHC/ District hospital / Tertiary care hospital / private hospital,

Delivery by skilled personnel: Delivery conducted by doctor / nurse / ANM /LHV

Exclusive breast feeding: not given any liquid other than breast milk

Delayed bathing: baby given bath after 24 hours

morbidity / sickness etc.)

C7. VARIABLES:

C7.1 OUTCOME MEASURES:

Primary outcome measures:

1. Neonatal mortality rate (NNMR): Neonatal deaths (upto 28 days) per thousand live births during March 22/03/2008 (Holi) to March 21/03/2009 (Holi) and March 22/3/2009. to March 21/03/2010.
2. Young infant mortality rate- death within first 60 days of life per thousand live births during March 22/03/2008 (Holi) to March 21/03/2009 (Holi) and March 22/3/2009. to March 21/03/2010.

Inclusion criteria:

1. All live births among resident and non resident mothers (visitors) in the village regardless of place of delivery during the reference period and for delivery taking place outside home if mother returns home within 2 months of delivery, will comprise the **denominator**(Q4 & Q7 of Schedule-1; Q12 & Q16 of Schedule-2)

During endline survey information on birth and death was collected for two reference period; March 22/03/2008 (Holi) to March 21/03/2009 (Holi) when active intervention was ongoing and March 22/3/2009. to March 21/03/2010.

Analysis for primary outcome measure will be done for both reference period pooled together and for each reference period separately.

Secondary outcome measures are:

1. Early neonatal mortality (number of deaths within ≤ 7days/1000 live births)
2. Late neonatal mortality (number of deaths within 8-28 days /1000 live births)
3. Post early neonatal young infant mortality (deaths during 8-60 days/1000 live births)
4. Young infant mortality rate (number of deaths in infants _<60 days/ 1000 live births
5. IMR (number of deaths of infants <1year (365 days)/1000 live births)

6. SBR (death of fetus weighing over 1000 gm i.e. equivalent to 28 weeks of gestation or more/1000 total births)
7. Perinatal mortality rate (number of still births (late fetal deaths weighing over 1000 gm) and deaths in the first week of life (within 7 days)/ 1000 live births weighing over 1000 gm at birth)

Others: (intervention related data)

8. Proportion with ≥ 3 ANC check up(if received from qualified provider i.e. doctor, nurse, ANM) (denominator all births to resident mothers), Q 26 of schedule 2
9. Proportion with 2 TT injection (Denominator all births to resident mothers), q 27 of schedule 2
10. Proportion of home delivery vs institutional delivery (PHC +CHC + district hospital+ tertiary hospital+ private hospital), question 20 in schedule 2
11. Proportion of delivery attended by skilled personnel(ANM+LHV+nurse +doctor) vs unskilled personal (TBA / dai+ family members/ neighbours), question 21 in schedule 2
12. Proportion of mothers receiving payment through Janani Suraksha Yojana(JSY) *(This information was not collected during baseline and midterm, hence only for comparison between the arms)* question 24 in schedule 2
13. Proportion of live births at home with known birth weight (worker was instructed to record birth weight as per interview) question 23 in schedule 2.
14. Mortality rates in relation to place of delivery (Home vs. others Q 20 31, schedule 2)
    b) Home and on way to hospital (1 &4)
    c) PHC / CHC/ district hospital /
    d) tertiary hospital /
    e) Private hospital
15. Mortality rates in relation to person conducting delivery (skilled vs unskilled), question 20 vs 30 in schedule 2
    a). 0-7 days
    b) 8-28 days
    c). 29-60 days

Denominator deaths amongst live born till 60 days of life, age at death <_60 days)

16. Mortality rates in relation to place of death (home vs others)
    a). 0-7 days
    b) 8-28 days
    c). 29-60 days
    Denominator deaths amongst live born till 60 days of life, age at death <_60 days)

Neonatal care practices (Schedule 3)(This questionnaire was filled for all live births that took place in the household within two months of date of survey..

17. Q6; proportion of babies, who did not cry after birth (only for home delivery (Q 6 yes vs no)
18. Q8 Did anyone provide care at birth at home (home deliveries only for cases having no response Q 6) (yes vs no)
19. Q9; Proportion of newborns bathed after 24 hours (4 vs 1-3), denominator all live births
20. Q 10. Proportion with no application to the cord (as per instruction in intervention package) (Denominator all live births) Q 10 of schedule 3
21. Q 11; Mother gave the milk that first came from the breast (yes vs no)(Q 11 in schedule 3)
22. Q 12; G give any liquid other than breast milk (exclusively breast fed) (Q 12 in schedule 3)
23. Q 13; Did the baby have any sickness in last 15 days (Q 13 schedule 3, yes vs no)
24. Q14. Did you seek care for your sick child (yes vs no)
25. Q15 Care seeking for sick newborn a) doctor b) ANM c) nurse d) AWW e) traditional healer f)others
26. Q 16; Was the baby treated at home (yes vs no)
27. Q17. Was the baby referred to health facility (yes vs no)
28. Q18. Baby taken to health facility (yes vs no)
29. Q19. Outcome of treatment (improved vs no improvement, referred)

Note: For antenatal and delivery indicators denominator will be all births during reference period. For newborn care practices during post intervention evaluation denominator will be number of infants <2months old at the time of survey i.e. with two months recall period for whom information was collected during evaluation.

C7.2. Baseline Characteristics

Characteristics	**SR**		**AWW**		**Control**	
	BL	EL	BL	EL	BL	EL
Demographic						
Distance from city(km)						
No. of villages						
No. of village with AWW centers						
No. of AWW centers with presence of worker						
Villages with access to motorable roads						
Villages with water supply system						
• Telephone facilities						
• Railway station						
• Post office facility						
• School						
Total household						
Religion						
• Hindu						
• Muslim						
• Others						
Caste						
• SC & ST						
• Others						

Educational status of mothers						
• Literate						
• Illiterate						
Place of delivery						
• Home						
• Health Facility						
• On way						
Delivery conducted by Skilled personnel (Doctor +ANM+nurse)						

BL= baseline, EL=endline

C7.3. Explanatory variables/Confounders:

C7.3.1. At Individual level:

2. Denominator: All live births among resident and non-resident mothers(regardless of place of delivery during reference period (Q4 & Q7 of Schedule-1; Q12 & Q16 of Schedule-2)
3. Place of delivery: Facility vs home. Home delivery also includes a small minority of those who were not born either at facility or home, eg. On way to facility, farm etc. (Q20 of schedule 2)
4. Who conducted delivery: delivery by skilled (ANM+ nurse+ doctor) vs others (rest of the options as per questionnaire no. 21)
5. Sex of child : male vs female (Q19 of schedule 2)
6. Religion: Q 2 of schedule 1, from household questionnaire as coded per individual births
7. Caste: Q 3 from household questionnaire as coded per individual births
8. Age of mother in yrs (mean +_SD) Q 13 in table 1, schedule 1)
9. Residential status of mother**:**. Usual resident vs visitor **(Q** 12 from schedule 2)

10. Education of Mother (Q 11 in schedule 2) (Three categories (i) Illiterate + Read & Write + Don't know; (ii) Middle + Primary; (iii) High school + college & above)
11. Proportion of still births out of total births (Q.16, schedule 2) still births / (still births + live births)
12. Crude birth rate = live births/ Total number of family members in household (Q.1, household information)
13. Singleton vs twins or more than two (Q.17)
14. Size at birth (Q.23)
    a) Birth weight (Mean (SD)
    b) Birth weight < 2500 g (%)
15. Place of death (facility vs Home) – Same procedure for delivery (Q.31)
16. ANC (Denominator - all births) Q 25 , 26 & 27
    a) Any
    b) $\geq$ 3
    c) Facility vs home
    d) TT $\geq$ 2
17. 15. Mother received payment through JSY Q24 (yes vs no) only for comparison between the arm

C7.3.2 At Cluster (Village) level:

1. Number of villages
2. Size of villages (population)
    a) Distribution
    b) Mean
3. Distance from district hospital (Q 5)
4. Access to motor able road (Yes vs No) (Q 8, yes vs no)
5. Water supply (Tap water + Hand Pump vs others)(Q 9)
6. Anganwadi Centre present (Yes / No)(Q 11)
7. AWW in position (Yes / No) (Q 12)
8. Health and related facilities

    (Mean ± SD) if yes _____

    - ICDS /AWW
    - Sub Centre

- PHC
- CHC / rural hospital
- District/ Govt. Hospital
- Govt. Dispensary.
- Private clinic
- Private hospital /Nursing Home
- Ayush health facility
- Others (Q 12,13, 14, 14, 17 yes vs no)

D. DATA QUALITY ASSURANCE:

1. Date of delivery and reference period outliers
2. Match total no of households having birth with no. of births in schedule 2
3. Total no. of deaths to be cross checked in Q 28, 30 &31 in schedule 2 for matching information
4. For Still birth, cross check
   a. Q 5.5 and Q 8 in schedule 1 to be matched
   b. Response 2 of Q 16 to be cross checked with Q 28, 29 & 30
   c. Cross match Q 5.5 and Q 8 in schedule 1 with birth weight (Q. 22 & 23)
5. Compare mismatch of outcomes in supervisor and field worker's proforma (5% data filled by supervisor)

E. ANALYSIS:

E1. Measures:

Since it is an effectiveness study all pregnant women / infants whether they received intervention or not will be included in analysis **(intention to treat).** Analysis will be done with two perspectives:

1. To estimate the primary outcome measure i.e. Neonatal and young infant mortality rates (95% CI) and see the differences in these mortality rates between Intervention arms (SR/AWW) and Comparison arm. (Demographic analysis)
2. To estimate the risk of death in Intervention arms vs. Control arms by adjusting the mortality with respect to other factors (which is different from process

indicators) which have potential to influence the outcome (e.g., age of mother, parity, education, village level characteristics etc.) only . Also, changes in village level characteristics between baseline and endline surveys will be assessed. In case of any difference in women characteristics across the arms, adjustment will be done for that particular characteristic. Though the unit of randomization is PHC, the outcomes within the village in a PHC can not be taken as uncorrelated, it would surely be influenced by the village level characteristics, therefore, village would be considered as a cluster in the analysis. In addition to women level covariates, cluster level variables (distance from city, access to motorable roads, water supply, telephone facility etc.) will also be included as covariates. Analysis will be done as cluster data **(Epidemiological analysis).**

The **rationale** for carrying out baseline and endline village level characteristics is to determine whether the changes in village level characteristics which could influence the outcome parameters are uniform within the group or not.

An **explanatory variable** will be labeled as confounder for evaluation of outcome if the p value for the differences between the arms is<0.10 in individual bivariate analysis. An explanatory variable could be at any level, individual or cluster

An outcome will be adjusted for confounders (if any) by multivariate analysis **(both analysis of covariance and logistic regression model)** using cluster correction only for the alternative approach for mortality outcomes

E2. Decision rule for primary analysis:

1. To compute the mortality rates, the Denominator will be "

Mortality Rates	Denominator	Numerator
NNMR	All the live births that took place in the household during the reference period. (Q. 16 in schedule 2	All the deaths in first 28 days of life that took place in the household among births during the reference period. (Variable "Age at Death" from the schedule -2, Q 30)
0-60	-do-	All the deaths in first 60 days of life that took

days		place in the household among births during the reference period. (Variable "Age at Death" from the schedule -2, Q 30)
ENMR	-do-	All the deaths in first 7 days of life that took place in the household among births during the reference period. (Variable "Age at Death" from the schedule-2, Q 30)
LNMR	-do-	All the deaths in late neonatal period of life (8-28 days) that took place in the household among births during the reference period. (Variable "Age at Death" from the schedule-2, Q30)
IMR	-do-	All deaths in 1year of life that took place in the household during the reference period. (Variable "Age at Death" from the schedule 2)
PNMR	All the births that took place in the household during the reference period.	All the deaths in first 7 days of life and still births, that took place in the household among births during the reference period. (Variable in schedule 2 Q 16 and "Age at Death" ,Q. 30
SBR	All births (LB+SB) that took place in the household during the reference period. (Q. 16 from the schedule 2	No. of fetal death after 28 weeks of gestation during reference period (variable Q 16 from the Table-1)

- Data from post intervention survey would be restricted in the intervention arms (Shishu Rakshak and AWW) to those villages in which a trained worker had performed intervention of any duration after January 2005.

- Baseline comparison will be done for the villages eligible for the post intervention survey, provided that the coding of village in both surveys was identical. Otherwise all villages sampled in the baseline survey will be compared.
- Criteria of comparability of randomized groups at baseline would be a difference of 5% of neonatal and young infant (0-60 days) mortalities. If the randomized groups are ascertained to be comparable at baseline(they were comparable and were then randomized into intervention arms), then data from post intervention arms will be compared across the three arms as opposed to a comparison of differences in change in outcome measures across the three arms.
- Measure of efficacy / coverage of intervention is desirable for exploratory analysis. No such measure can reliably emerge from the post intervention survey. A crude measure can be computed from the prospective (self reported) service delivery records from the two interventions arms realizing fully that these would be subject to reporting bias and are likely to be overestimates. A source of error is the out migration / in migration of the pregnant/ parturient mother from the designated trial area. To minimize this error, it is proposed to consider the coverage of intervention package in only those mothers who were registered in that area from pregnancy and also delivered in the same area. The proposed indicators will be considered for all the years (2005, 2006, 2007, 2008, 2009) and would be

  (a). Proportion of scheduled visits by the intervention worker (this will account for increased number of visits for high risk newborns and reduced visits for neonatal deaths)

  (b). Proportion of home deliveries where the intervention worker was present at birth.

- In Lucknow SR intervention five contiguous villages were added after the baseline survey. The post intervention survey was also conducted in these villages. These five villages will be analyzed as a component of SR intervention arm. In order to determine that no bias is introduced by including these villages a sensitivity analysis will be performed for the primary outcome measures by including and excluding these villages.

E3. Data source, numerator & Denominator for calculating mortality:

- For calculating all mortality rates numerator will be obtained exclusively from schedule 2
- For still birth rate (SBR)numerator will be from schedule 1
- For perinatal mortality rate (PNMR) numerator for still birth will be from schedule 1 and for deaths within 7 days from schedule 2
- **Early neonatal mortality: Denominator** will be all live births within reference period in whom information on survival status is available for at least 7 days after birth. **Numerator** will be all deaths <_ 7 days amongst above live births
- **Late neonatal mortality: Denominator** will be all live births within reference period in whom information on survival status is available from 8- 28 days after birth. **Numerator** will be all deaths between 8-28 days amongst above live births
- **Post neonatal and early young infant mortality: Denominator** will be all live births within reference period in whom information on survival status is available between 8-60 after birth. **Numerator** will be all deaths within 8-60 days amongst above live births

E4. Exploratory sub group analysis:

will be done only for primary outcome measures

- Facility vs home deliveries
- Personnel conducting delivery
- B.wt >2500 gms vs < 1500 gms, 1500-1999 gms, 2000-<2500 gms
- ANC visit nil vs <2, 2-3, >3
- Singleton birth vs multiple
- Male vs female
- First bath after 24 hours vs <24 hours
- Gave first milk coming from breast yes vs no
- Baby treated at home yes vs no
- Usual resident vs visitor mother
- Post hoc power calculation for primary outcome

Comparison of mortality rates at baseline and endline across study arms

	SR		***AWW***		***Comparison***	
	BL	***EL***	***BL***	***EL***	***BL***	***EL***
Live birth(n=)						
Still birth(n=)						
Deaths in early neonatal period n=						
ENMR (95% CI)						
Deaths in neonatal period n=						
*NNMR(95%CI)**						
Deaths in 0-60 days, n=						
*Young infant Mortality rate(95%CI)**						
Deaths in 0-<365 days n=						
*Infant mortality rate(95%CI)**						
*Still birth rate(95%CI)***						
Deaths in early neonatal period _ SB, n=						
*Perinatal (95%CI) mortality rate***						

BL= baseline, EL=endline

Demographic and maternal and delivery characteristics at baseline and end line

	SR		***AWW***		***Comparison***	
	BL	***EL***	***BL***	***EL***	***BL***	***EL***

E5. Comparison of mortality rates by study arms

Total births	*SR*	*AWW*	*Comparison*	*SR vs comparison*	*AWW vs comparison*
Live birth					
Still birth					
ENMR (95% CI)					
*NNMR(95%CI)**					
*Young infant Mortality rate(95%CI)**					
*Infant mortality rate(95%CI)**					
*Still birth rate(95%CI)***					
*Perinatal (95%CI)mortality rate***					

***per thousand live births**

****per thousand births**

E6. . Process Indicators: Will be compared among the three groups

E6.1Care during pregnancy:

Proportions of women receiving (denominator: live births)

Any ANC care

Any ANC from skilled personnel (ANM, doctor, nurses)

ANC in health facility

2 TT immunizations

E6.2: Place of delivery

Home/ institution

E6.3: Delivery conducted by

Skilled personnel(ANM/ Doctor/ nurses)vs Unskilled personnel (TBA,s(self, family members, neighbours)

E6.4: Newborn care practices

Application to cord at birth and within 1 week of birth (none vs others)

First bath to baby within 24 hours

E6.5: Care seeking for morbidity *Doctor / ANM / Nurses/traditional healers/AWWvs others*

Health worker provided care at home

Visit by health care worker for providing care to the newborns

E.6.6: Baby treated at home

E6.7: Baby referred to health facility

E6.8: Baby taken to health facility

We will also do **Per protocol analysis** in the intervention arms only for NNMR and YIMR in case of

- resident vs non resident mothers
- Worker present at the time of delivery vs not present
- Home delivery vs institutional delivery
- Received 2 or more Health education visit vs didn't receive
- Examined baby within 24 hours of delivery vs not examined
- Received 3 postnatal visit during early neonatal period vs didn't receive
- Six postnatal visit during neonatal period vs no visit
- Sepsis cases managed by workers vs referred

Sample size:

Assuming neonatal mortality as 40 per thousand live births, it is estimated that mortality among babies less than 2 months of age will be approximately 50 per thousand live births. The required sample size to detect 50 per cent reduction in mortality among babies less than 2 months of age with confidence level of 95% and power 80% would be 984 live births in each of the intervention areas and control area. Taking a design effect of 1.5 it will be required to cover about 1500 live births at each intervention and control sites. To have a study sample of 1500 live births in one year at a birth rate of 25/1000 population, it will be required to cover a population of about 60,000. It amounts to selection of about 60 villages (unit for intervention) of approximately 1000 population each for intervention 1, intervention 2 and control. This will be achieved by selecting two PHCs covering 30000 population each (about 30 villages).

This sample size will be sufficient for in-depth analysis for primary outcome measures at each site. In addition data pooled for two years of intervention will enable to detect smaller levels of reduction in above-mentioned mortality.

To reduce NNMR by 50% in 3 yrs
To reduce YIMR by 50% in 2 yrs
∞= 0.05, two tailed ß= 0.2
P0 =Baseline YIMR 50/ 1000 LB=0.05
D= expected reduction 50% of 0.05= 0.025
P1= probability of neonatal death after intervention= 0.05-0.025=0.025

P= (P0+P1) /2 =0.0375
Q= 1-P= 0.9625

N= {2 x (Z@+Zß)2 x pq} / D2 =905
Loss to follow up 10% = 90
N=905+90=1000
Design effect 1.5
Required no. of sample size= 1500

•