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Integrated Management of Neonatal and Childhood Illnesses: Baseline assessment of childhood morbidity & mortality in selected districts in India

Project Proposal

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Integrated Management of Childhood Illnesses: Baseline assessment of childhood morbidity & mortality in selected districts in India

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CONTENTS

I. INTRODUCTION

Every year some 2.4 million children die in India before reaching the age of 5 years. Infant Mortality makes up for 70% of under-five deaths and currently stands at 63 per 1000 live births (SRS, 2004). Within the infant mortality, neonatal mortality component constitutes about 65% of the total IMR. While IMR has halved in the past 30 years, that progress is halting during the past decade. Malnutrition rates have also declined in past 30 years but remain high.

Main causes of Under-5 deaths (U5MR) death in sequence of importance are: diarrhea (23%), pneumonia (23%), birth asphyxia (10%), prematurity (9%), severe infections in newborn (9%), neonatal tetanus, other neonatal complications, measles and malaria.

Research estimates have shown that full coverage of key interventions can prevent 57% of these annual 2.4 million deaths. The interventions include early & exclusive breastfeeding, adequate complementary feeding, clean delivery, immunization against tetanus toxoid, measles & HiB, zinc & vitamin A supplementation, newborn temperature management, ORS use for diarrhea, antibiotics for sepsis and pneumonia.

- Nutrition interventions (breastfeeding, complementary feeding, vitamin A and zinc supplementation) can prevent 25% of deaths.
- Case management interventions (ORT, antibiotics for diarrhea, pneumonia, neonatal sepsis, and anti-malarial) can prevent 30% of deaths.

In India, as many as 1.72 million children die each year before reaching their first birthday and of these 72% die during the neonatal period. NFHS data shows that only 16.5% of women were visited in the first two days of birth and 42% of deliveries were conducted by skilled personnel.

The millennium development goal (MDG) for India envisages reducing infant and child mortality by two- thirds between 1990 and 2015 (World Bank 2004). Research has shown that low technology solution combined with political will and financial commitment could save the vast majority of lives of mother and babies (*State of the World's Mother 2006, Report of Save the children*).

Integrated Management of Neonatal Childhood Illnesses (IMNCI), the adapted version of IMCI in India, involves putting these interventions in place, both at the family as well as at the health facility level. IMNCI has emerged as a promising approach to deal with the issues related to child survival in a more holistic manner and has shown promise in other countries, where it has been implemented. This strategy was designed to include coordinated activities within three components:

(1) Improving health worker skills,

(2) Improving community practices related to child health and development

(3) Strengthening of health system supports for child health activities.

The Ministry of Health, Government of India has agreed in principle to implement the IMNCI strategy as part of the Reproductive and Child Health Programme – II (RCH-II). However since the implementation of the IMNCI requires training a huge number of health functionaries across the country as well as improvement in the overall health systems, it is only prudent that the relevance, feasibility and effectiveness of this strategy is studied in some detail before its countrywide implementation is effected.

IMNCI will be rolled out in a phased manner and the initial phase involves implementation in 8 districts of the country. These districts will be carefully chosen to represent major socio-cultural areas of the country so that decision to expand IMNCI in the entire country could be taken based on the experience of implementation in these districts.

Evaluation of effectiveness of the IMNCI strategy would require a sound and detailed baseline assessment of key demographic parameters related to child survival. The Ministry of Health, GOI and UNICEF - India mission have asked IndiaCLEN Program Evaluation Network (IPEN) conduct a study to establish the baseline for key indicators related to child survival.

Why IndiaCLEN Program Evaluation Network (IPEN)

Currently, Clinical Epidemiology Units (CEUs) are functioning at eight medical colleges in India (New Delhi, Lucknow, Nagpur (2), Chennai (2), Vellore and

Thiruvananthapuram). CEU faculty members have been trained in clinical epidemiology, health social sciences, biostatistics and health economics under the global International Clinical Epidemiology Network (INCLEN) program. Members of all the eight CEUs have formed a national body called Indian Clinical Epidemiology Network (IndiaCLEN). The main objectives of the body include disseminating the knowledge and skills of clinical epidemiology to other academic and non-academic medical institutions in the country and participating in policy relevant research activities. Since 1997, IndiaCLEN expanded itself to partner with medical institutions and NGOs beyond the six CEUs and form IndiaCLEN Program Evaluation Network (IPEN). In addition to participation in several public health program evaluation studies, members of the group have had the benefit of attending workshops on program evaluation, qualitative research methods and continuous quality assurance.

Over a period of last 8 years, IndiaCLEN Program Evaluation Network (IPEN) has emerged as a professional and cohesive network of 84 partner institutions (medical colleges / NGOs / public health institutions). IndiaCLEN Program Evaluation Network has supported program managers in refining the existing public health programs to make them client friendly and in harmony with their socio-cultural beliefs. IPEN has successfully evaluated the Pulse Polio Immunization Program for four consecutive cycles [1997-98, 1998-99, 1999-2000 and 2000-2001] and was also involved in the evaluation of three rounds of Family Health Awareness Campaign [1999, 2000, 2002] in the country. This network has also completed the evaluation of Vitamin-A and Iron folic acid Supplementation Program(s) (2001-2002). It is heartening to note that policy makers have incorporated several key recommendations made by this network in the subsequent cycles of the respective programs. Most recently, nation-wide Assessment of Injection Practices and Routine Immunization had been conducted.

Apart from undertaking research activities, IPEN has tried to develop capacity of its network partners to undertake policy and program relevant studies in their respective regions and states independently.

II. AIMS

- To determine the baseline morbidity and mortality of children under five years. (Phase I)
- To capture the process of implementation and the different strategies adopted by the state health department in implementation of IMNCI. (Phase II)
- To evaluate impact of IMNCI package on child survival indicators. (Phase III)

OBJECTIVES

Objectives of Baseline study: Phase I

1. To assess child survival indicators
    i. Mortality rate, establish causes, and pathway analysis of events prior to death
    ii. Morbidity prevalence and pathway analysis of events prior to improvement / recovery

2. To assess sickness management practices
    i. Household Level
    ii. At community
    iii. At health facility level (Out Patient)

3. To assess health behavioral practices
    i. Household Level
    ii. At community
    iii. At health facility level

4. To assess the skills and care providing competencies of the health care providers (Public and Private)
    i. Doctors
    ii. Heath Worker
    iii. AWW/ANM
    iv. Other Community level Service Provider, including ASHA (wherever in place)

5. To assess the perspective of policy makers, program managers and health providers at district and state level about sickness

6. To assess health system support for
    i. Logistics
    ii. Referral mechanism
    iii. Intersectoral coordination
    iv. Social mobilization
    v. Monitoring & supervision

7. To assess the client and health provider perspective on existing child health services in terms of their
    i. Availability,
    ii. Accessibility,
    iii. Perceived Affordability,
    iv. Appropriateness,
    v. Quality of care and
    vi. Socio-cultural acceptability.

8. To determine the role of civil society (NGOs, Community Based Organizations, community leaders) in promoting, providing, utilizing and monitoring child health services.

III. METHODOLOGY

The proposed study would be a field trial that would be completed in three phases: Phase I – baseline survey; Phase II - concurrent observation/documentation of implementation; and, Phase III – end line survey for impact assessment.

Phase I: Baseline Survey

Phase I of the study will make a baseline assessment of various parameters and dimensions related to child survival and health systems in both the intervention and control districts. These would involve derivation of estimates for childhood morbidity due to the diseases covered under the IMNCI, the infant mortality rate and analyses of causes of infant deaths.

Current practices and mechanisms involved in care of newborns and children at the family/community, first facility and referral level will also be studied. Client perspective on existing child health services in terms of their availability, affordability and acceptability will be studied in detail.

The variables/dimensions for the baseline study will be selected in such a manner that their repeat assessment at the endline survey would enable us to capture the impact of IMNCI at different levels in the study areas.

Phase II: Concurrent observation and documentation of the process of IMNCI implementation in intervention districts.

The IMNCI envisages significant upgrade /inputs in the skill set of health providers at different levels to improve management of childhood illnesses; improved logistics and supplies; greater involvement of the community in child survival issues. It will be important to capture the process of implementation and the different strategies adopted by the health department in implementation of IMNCI.

Thus, this phase of the study will involve in-depth observation and documentation of the various facets of the implementation process. It is important to emphasize here that the

study investigators will not be involved in the process of either implementation or monitoring of the IMNCI so as to minimize bias.

Phase III: End line survey for impact evaluation

The aim of this phase will be to assess the impact of IMNCI on various parameters of child survival. It will also involve assessment of these parameters in the control districts. The data will then be analyzed to assess the effects of implementation and non-implementation of IMNCI on child **survival.**

The variables used for assessment in the baseline survey will be replicated in the end line survey as well to allow for comparability.

1. Study Design for Phase I (Baseline Survey)

It is a baseline assessment of existing child care services in the community and will be a cross-sectional survey using qualitative and quantitative research method. For reasons of cost and logistics, rapid population based cluster survey at household and health facility level will be adopted. The sample communities will be selected using the 'probability proportionate to size' (PPS) technique. Using this method, the likelihood of a community being selected is in relation to the proportion of its population i.e. larger villages or towns are more likely to be selected than smaller ones. This study will be conducted in 16 districts representing 8 states. The sampling universe will be the district for drawing clusters.

Census data of 2001 (Registrar General of India) will be utilized for selecting clusters after adjusting for population growth rate. The clusters will be drawn separately for urban and rural areas due to inherent differences in the available health facilities, infrastructure of urban and rural areas and differences in socio-cultural and demographic features of urban and rural populations.

This rapid survey would be used to derive estimates for causes of childhood morbidity, NMR and IMR.

2. Identification of Study States and Districts

Study districts have been identified in consultation with the Division of Child Health, Ministry of Health and Family Welfare, Government of India, State Governments and UNICEF. Two districts have been identified in each state for the study. The following selection criteria were considered while choosing the study states and districts.

Selection of the study states

1 Four Empowered Action Group (EAG) states (Uttar Pradesh, Madhya Pradesh, Rajasthan, and Orissa); three non-EAG states (Karnataka, Haryana, Maharashtra) and one northeastern state (Meghalaya). The purpose is to sample a mix of states with different level of health system performance, health statistics and geographic location.

2 Demographic profile of the states

2.1. Recently formed EAG states not included

2.2. Non-EAG states dispersed over all regions of the country

2.3. States with good performance and low IMR (<40/1000 LB) were excluded because of potentially less visible impact of IMNCI implementation

2.4. Availability of functional IndiaCLEN Program Evaluation Network partner institution in the state to participate in the study.

Selection of the study districts

In order to minimize influence of status of health systems and governance variables a pair of districts is selected from each selected study states. While selecting districts, factors such as density of population, SC, ST Population, minority population, illiteracy rate, IMR etc. were considered, to have comparable population to the extent possible and later draw meaningful inference to assess the impact of IMNCI. Based on the recent available demographic and health service indicator data the district selection was based on

1. Poorly performing districts with IMR >50/1000 live birth and similar social and demographic features.
2. Non-contiguous districts
3. Consent of State Health Departments (planned IMNCI implementation districts)
4. Availability of IPEN- partner institution for implementation and **supervision**

Figure 1: Selected Districts and States for IMNCI:
Baseline Study of Childhood Mortality and Morbidity

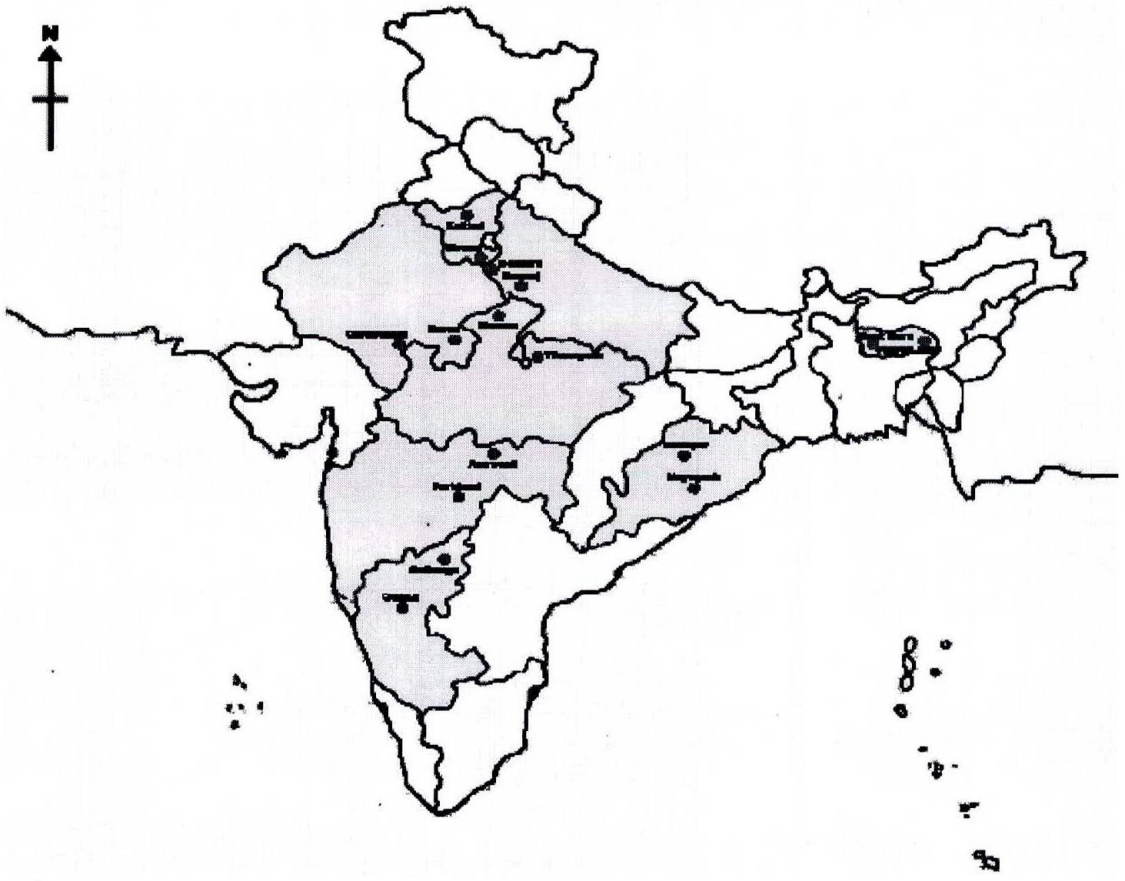

Table 1 - Study and Control Districts for Baseline Survey

State status	State	Study districts	Control districts
EAG States	Uttar Pradesh	Kanauj	Mathura
	Madhya Pradesh	Morena	Tikamgarh
	Rajasthan	Baran	Chittorgarh
	Orissa	Nayagarh	Sonpur
Non-EAG States	Maharashtra	Amravati	Parbhani
	Karnataka	Gulbarga	Gadag
	Haryana	Kaithal	Mewat
North-eastern State	Meghalaya	East Garo	Jaintia Hills

- **Study districts:** The districts for immediate implementation of IMNCI program.
- **Control districts:** The districts with ongoing RCH I child health activities and IMNCI program to be implemented after full operationalization of IMNCI in study districts for 2 years.

The total population of eight selected states is 39.6 crore (census 2001). Total population of districts under study is 2.14 crore; IMNCI will be implemented in 1.25 crore population of phase I districts (study area) and 0.9 crore is the population in control districts.

In case of a natural disaster (Flood, Famine/ earthquake/ riots) additional baseline survey will be done in the affected area within a span of 6 months. This will be done to take care of setback to health system due to natural disaster and this second baseline will serve as the comparison parameter for end line survey. It is assumed that Industrial and economic interventions are unlikely to affect major impact of the study within the study period. NGO/ CBO and other civil society activities related to health in the area will be documented and lists will be updated on yearly basis. Thus all major events, activities that are likely to impact health systems particularly in relation to child survival will be documented annually.

3. Study Procedure

3.1. Investigation Team

3.1.1. Investigation Team for Quantitative Component

Each survey team will consist of six members: two (SI) senior investigators (faculty from partner medical colleges), two doctors or interns (MO) and two research associates (RA). In every district eight survey teams will be constituted, each team will survey 10 clusters thereby approximately eight teams will be covering 80 clusters (40 urban & 40 rural) in the selected districts.

Table 2 - Survey Team

(2 Senior investigators, 2 medical officers, 2 research associates per team)					
Level	No. of Teams	No. of persons (6 Per Team)			
		SI	MO	RA	Total
District	8	16	16	16	48
Total per state (2 districts)	16	32	32	32	96
Total in 16 districts spread over 8 states	128	256	256	256	768

Table 3 – Job responsibility of each team member

Members	Responsibility	Work load
First Senior Investigator	1. Observation of prescriber client interaction (specific observation) 2. Interview of the doctor 3. Generic Observation of Health Facility 4. Scrutinize and complete all instruments/ Quality Assurance	1. 10 under 5 children per facility (40 Govt and private health facilities / district) 2. 40 Govt and private health facilities / district 3. All instruments to be verified for quality 4. Tracking of a neonate
Second Senior Investigator	1. Conduct Verbal Autopsy 2. Tracking of events (Deaths / recovered illness/ newborn). 3. Scrutinize and complete all instruments/ Quality Assurance	1. All death cases. 2. All deaths, 2 recovered non hospitalized sick children, and 1 recovered hospitalized sick child 3. All instruments to be verified for quality

First Doctor + First Research Associate	1. Screening of households 2. Observation of skills of ANM/AWW/Depot holder 3. Screening of households 4. Inform 2nd PI about all deaths, recovered illness, newborn, and sickness U5	1. One per cluster 2. One per cluster 3. 7 households
Second Doctor + Second Research Associate	1. Screening of households 2. Interview ANM/AWW/Depot holder 3. Inform 2nd PI about all deaths, recovered illness, newborn, and sickness	1. 7 households 2. Three per cluster

3.1.2. Investigation Team for Qualitative Component

Qualitative methods would be used to assess health care seeking practices; client perspectives in existing child health services; the role of civil society with regards to prevention and management of childhood illnesses. A separate team consisting of one Regional Coordinator, one Principal Investigator (PI) and two Research assistants (RAs) will be responsible for the qualitative component. All the interviews and FGDs will be recorded.

3.2. Sample size calculation for Quantitative Component

3.2.1. Mortality Survey

Sample size for cluster survey, was calculated on the basis available mortality indicators (U5MR, IMR, NMR) related to child health. Mortality is the least frequently occurring outcome (event) and hence we calculated the sample size according to mortality indices. It is estimated that neonatal mortality rate (NMR) is 30-50/1000 live births (3-5% of all live births) and infant mortality rate (IMR) is 60-80/1000 live births (6-8%), U5MR is 80-100/1000 live births.. To determine the NMR (4%) with an admissible error of +/- 1% with 95% confidence, we would require to survey approximately 1500 live birth in previous one year. This will allow detection of IMR (7%±1.3%), NMR (4%±1%) and under 5 mortality (9%± 1.5%) with acceptable precision (Table 1).

Table 4-Sample size for estimating NMR and IMR

S.N	Indicator	Estimated	Admissible error	Sample size (at 95% confidence level)	Estimated sample size
1	Neonatal Mortality Rate (NMR)	4%	± 1%	1454	≈1500 live births
2	Infant Mortality Rate (IMR)	7%	± 1.3%	1478	
3	Under 5 mortality (U5MR)	9%	±1.5%	1498	

We are proposing to take 80 clusters from a district (40 each from urban and rural areas) To obtain the desired sample size, we shall recruit 20 live births taking place in previous 12 months in each cluster. Thus we will consider 1600 live births in each district.

3.2.2. Morbidity Survey

One of the objectives of the study is to find out the morbidity density in the study population and pathway analysis of events prior to recovery. IMNCI considers 3 important morbidities – cough (ARI), fever (Malaria) and loose motion (diarrhea). These three indicator conditions will be used for tracking morbidity impact of IMNCI programme and hence for the baseline survey. According to NFHS II (1998-99), the all India prevalence of cough with fast breathing (ARI), fever and loose motions was 19.3%, 29.5% and 19.2% respectively. Among the 8 study states the least prevalence of these three morbidities was 7.9% (ARI), 23.7% (fever) and 13.9% (diarrhea). UNICEF and MOHFW-GOI conducted multi indicator cluster survey in 2000, covering all under 5 children. According to this, the least prevalence of these indicator conditions is 18.8% (ARI), 21.3% (fever) and 14.5% (diarrhea) in the eight states chosen for the study (Table 3).

Table 5 – Prevalence of child morbidity in India

	NFHS II -1998-99 (0-3 years)			MICS- 2000 (0- 5 years)		
	Cough	**Fever**	**Diarrhea**	**Cough**	**Fever**	**Diarrhea**
All India (% prevalence)	**19.3**	**29.5**	**19.2**	**29.1**	**29.8**	**23.1**
Least in 8 states (% prevalence)	**7.9**	**23.7**	**13.9**	**18.8**	**21.3**	**14.5**
(% prevalence)	**≈8**	**≈24**	**≈14**	**≈19**	**≈21**	**≈15**

Table 6-Sample size for estimating morbidity density

S. No	Indicator	Source	Prevalence	Admissible error (20%)	Sample size at 95% Confidence level	Sample size	Design effect	Estimated sample size
1	Diarrhea	NFHS II	14	± 2.8	590	615	1.5	923 ≈1,120
		MICS	15	± 3	544			
2	ARI	NFHS II	8	± 1.6	615			
		MICS	19	± 3.8				
3	Fever	NFHS II	24	± 4.8	304			
		MICS	21	± 4.2	361			

Since there is a wide variation in the prevalence of ARI reported in both studies (NFHS II - 8 %, MICS – 19%), we considered the mean prevalence to be 13.5 % and calculated the sample size with 20 % admissible error. Assuming a design effect of 1.5, we need to study approximately 923 under 5 children to estimate morbidity density. We will be taking 80 clusters from a district (40 each from urban and rural areas). To obtain the desired sample size, we shall recruit 14 under 5 children in each cluster. So, we propose to study a total of 1120 under 5 children to find out the morbidity density.

Table 7-Sample size for quantitative survey

	Cluster	Live births* (@ 20 per cluster)	Expected Mortality* (@1per cluster)	No. of under 5 children to be screened for morbidity density (@14 per cluster)
District	80	1,600	80	1,120
State(2 districts)	160	3,200	160	2,240
National (8 states)	1,280	25,600	1,280	17,920

* Live births and mortality will be considered in previous 12 months.

3.3 Sampling Technique for Quantitative Component

3.3.1. Methods of Drawing Clusters

Sampling universe will be one district from each state, which will be stratified into urban and rural areas. The data from census 2001 will be arranged in three columns: the first column lists the names of the villages or towns and cities [i.e. the community], second column indicates the total population of the communities and third column contains the cumulative population which is obtained by adding the population of all the communities preceding it on the list. The list is arranged in order given in the national census data. The sampling interval is obtained by dividing the total population of the district by the number of clusters desired. A random number between 1 and the sampling interval is chosen as the starting point and the sampling interval is added sequentially to the random number until the desired number of clusters is chosen. The villages / towns whose cumulative population includes these numbers are chosen for the cluster survey. The selected clusters are plotted on a map of the respective zone, and a logical sequence (route map) for the fieldwork is developed for each of the survey teams.

3.3.2 Selection of study participants

After reaching each selected cluster, the cluster (village) is mapped and the following steps are to be followed.

STEP 1: **Division of cluster**

Cluster will be divided into two equal halves. Teams will also be divided into two groups and each group will have one doctor with one research associate. Two groups will move in opposite direction and will follow each step given below separately.

STEP 2: **Selection of *Mohallas/* colonies**

A list of all *mohallas* /colonies/ tolas/ lanes in each half of the cluster will be prepared. A *mohalla* will be selected randomly using currency note available with the investigator 1.

STEP 3: **Selection of Household**

Following the selection of *mohallas* /colonies/ tolas/ lanes, first household will be selected randomly by using currency note available with the investigator 2.

STEP 4.a: **Screening households for live births in last one year**

All pregnancy culminating in last one year in the cluster, will be screened by using screening instruments. The screening will continue till 10 live births are included in the survey in each half of the cluster.

(For example if the date of survey is 25th October 2006, all the pregnancies culminated from 25th Oct 2005 till 24th Oct 2006 will be included in the study).

STEP 4.b: **Screening households for child death**

During screening each team will inquire about any death of child under 5 years in previous one year.

STEP 4.c: **Screening for neonate**

During screening for live births, any neonate between age of 10 -28 days as on date of survey will be identified and accordingly inform principal investigator will be informed for tracking.

STEP 4.d: **Screening for morbidity in children under 5 years**

First seven male and seven female children under 5 years will be identified by each team in their respective direction of household survey.

STEP 4.e: **Screening for recovered morbidity in children under 5 years who were non-hospitalized**

In addition to this, each team will identify one recovered case of morbidity in their respective area (i.e. 1 male/1 female in each half of the cluster) Children under 5 year with illness in previous two weeks before survey, who recovered without hospitalization and are asymptomatic for previous 3 days from any illness will be included in survey.

STEP 5: **Screening for recovered morbidity in children under 5 years who were hospitalized**

In addition to this, each team will identify one recovered case of morbidity in their respective area, which was hospitalized for any illness in previous 3 months. Only one such case (preferably female) will be included in the survey in each cluster (as per the discretion of principal investigator of the team).

3.4. Data Collection

3.4.1. Data Collection and Transmission for Quantitative Study

Data will be collected from forty rural and forty urban clusters each from sixteen districts. Collected data would be checked for completeness and quality at the study centers as well as regional centers. The regional centers would then send the data every fortnight to the CCO, Delhi. The Questionnaires and Observation Checklists are assigned unique numbers facilitating their identification such as the center, cluster and category they belong to. Within 72 hours of data collection; the team will make one set of photocopy of the completed instruments. While the original set is dispatched to the CCO, the other will be retained by the survey team and submitted to the Regional Coordinator at the end of the survey after completing all ten clusters. This is done to safe guard against accidental data loss during transmission.

3.4.2. Data Collection for Qualitative Study

District: At all 16 districts, all categories of stakeholders will be interviewed. Stakeholders at the district level from both rural and urban settings will be interviewed at all the study sites. In rural areas, population and officials of a PHC will be the sampling frame. For urban areas reference point will be the government hospital.

The various providers and clients will be identified in reference to these dispensary or PHC areas respectively.

A prior **written consent** will be obtained from all the study participants (interviewees) as per a format provided with questionnaires. Signatures of those refusing consent will also be obtained along with basic information about them

Efforts will be made to record all the interviews on the audiotape. In all situations, responses will be recorded in interview schedules verbatim (local language) as the interview is in progress, supplemented later by the tape recorded versions, and there after translated into English. An 'insider's view' will be obtained by ensuring that investigators are 'local'.

3.5. Study Instruments

A team of program evaluation experts, social scientists, epidemiologists and anthropologists at the central coordinating office conducted several brain storming sessions to identify key issues to be evaluated, keeping in mind the interest of policy makers, program managers, implementers and clients. Interview schedules would comprise of open-ended questions. The guiding principle will be that the responses should be able to achieve the stated objectives of the study. The draft instrument will be developed by the Team Leader, Principal Investigator, Project Coordinator and other CCT members in close partnership with the program managers, and the investigators from all participating institutions. The instruments will be translated into local languages and pilot tested at 4-5 centres and finalized during the National Protocol Finalization Workshop.

The interview schedules and observation checklists are developed keeping in mind the objectives of the study. The interview and observation schedules will have close-ended questions.

Focus group discussion topic guides

Guidelines for focus group discussions will be prepared in tune with the objectives of the study.

Unique serial number: Every interview schedule will be given a unique serial number and every participating institute will have a set of unique numbers assigned to it. Thus from unique serial number- the institutions, rural or urban and category of stakeholder could be tracked.

3.5.1. Verbal Autopsy and Tracking of Events for death:

In order to establish the cause of death, those households where neonate/ infant/ child death had occurred within the last one year from the date survey would be visited by one of the senior investigator. Senior Investigator would visit these households and establish the cause(s) of death by using standard pre-tested verbal autopsy questionnaire. Pathway analysis will be undertaken to dissect the sickness seeking behavior of the household. If no caretaker is available repeat attempt will be made in next 48 hrs as per the convenient time for the family.

Selection of clients for verbal autopsy:

- All deaths in the cluster will be included in the study sample for verbal autopsy and tracking of events.

3.5.2. Tracking of events

- **For Recovered Morbidity**

Two households with children with illness in previous two weeks before survey and who have recovered (symptomatic for at least 3 days prior to survey) will be included in the study for comparison of sickness behavior related to illness resulting in recovery or death. **In this, children who have been hospitalized within last six months (severe morbidity) and recovered and the children who have not been hospitalized (mild recovery) and recovered will be included to track for the severity of illness.** The pattern of sickness behavior related to illness will be compared with that related to child death.

Table 8-Criteria of Selection of under 5 children in household survey

S.N	Age group	No. of children
1	2-12 months	1
2	13-36 months	4
3	37-59 months	2

- **For New Borns**

During screening one neonate per cluster in the age group of 10-28 days will be evaluated for their care seeking behavior. It is assumed that at least one neonate will be present in a cluster at the time of the survey.

3.5.3. Household Survey

Fourteen households in each cluster will be studied for childhood morbidity related health behavior and sickness behavior of the households. 7 households with male index child and 7 households with female index child will be taken for survey.

3.5.4. Health facility observation

In a district, total of 20 urban and 20 rural health facilities will be selected for generic observation. Two health facilities (1-government and 1- private health facility) will be selected for the survey for every alternate cluster. Observation of health facility will also be made in terms of available facility infrastructure/ available manpower, logistics, and referral services.

Selecting Health Facilities for Observation

Government: Government Health Facility (PHC / CHC / district hospital which are not attached /linked to medical college) located in (or nearest to) the selected cluster. With OPD facility will be selected for direct observation and prescriber interview.

Private: Private Health Facility, which is located in (or nearest to) the selected *(formal / Informal Practitioner)* cluster where the newborn care or childcare OPD is available will be selected. (If more than one private health facility exists in the cluster, select one, who treats more number of children.

3.5.5. Assessment of skills of health care provider

One doctor, delivering child health services, will be selected for assessment of skills from each of the selected health facility (government /private). He will be directly observed by one of the senior investigator for appropriateness of treatment for management of 5 cases. Out of 80 clusters in a district, we propose to observe the skills of health care provider from 40 health facilities (20 urban, 20 rural). Out of these, 50% health care providers will be from government and rest will be from the private sector.

3.5.6. Assessment of skills of paramedical workers

Skills of ANM/AWW will be assessed for management of common childhood illness by the doctor of the team. Management of one newborn and one child under five will be observed for each worker (ANM/AWW). During the time of survey the district authorities will be requested to coordinate availability of ANM/AWW in their respective villages. The cases for this purpose will be made available from the same cluster. After observing the skills of ANM/AWW the doctor in the survey team will advice regarding management. If on first day the team is unable to find the cases for observation, the team will complete the activity on the next day.

Out of 80 clusters in a district, we propose to observe the skills of one ANM and AWW in alternate cluster (40 clusters for ANM and 40 clusters AWW). In urban areas, instead of ANMs lady health visitor (LHV)/ public health nurse (PHN) will be considered.

3.5.7. In-depth interviews

Selection of stakeholders for In-depth Interview

District would be the sampling unit. The purposive sampling will be done keeping in view the convenience of data collection. It is important to interview all stakeholders i.e. the health care provider, community leaders and clients to understand and assess the situation. Stakeholder will be selected from both urban and rural areas.

Providers: Health and non-health officials at the district level and block level i.e. Chief medical Officer, RCH officer, District MS/ Pediatrician and District magistrate at district level.

Facilitators: Representatives from local NGO/ CBO and Community Leader.

3.5.8. Focus group discussions (FGDs)

FGD's will be conducted among the community health worker and health care provider to assess the health promotional and sickness behavior, client and health provider perspective about existing child health activities and problems related to them. In each district 4 FGDs with mothers of target children and 2 FGD each with health workers, ANM and AWW will be conducted.

3.6. District Level Workshops

Sixteen district level workshops would be organized, where research teams and investigators from each district would participate. The aim of these workshops is to familiarize the research teams about the study instruments and other operational details. Two CCT members also participate in each workshop. These workshops act as a quality assurance mechanism, thereby ensuring that the entire research staff for the study operates out of the same principles.

3.7.Data analysis and reporting

Data would be collected, collated and organized at the CCO, Delhi. A multidisciplinary team guided by the CCT and followed by report writing would do the data analysis.

TABLE 9 – Summary of Activities						
MORTALITY STUDY						
	S.N.	**ACITIVITY**	**CLUSTERS**	**TOTAL / DISTRICT (80 clusters)**	**STATE (2 districts)**	**TOTAL (8 states)**
		URBAN	RURAL			
1.	Verbal Autopsy	All deaths <5 yrs	All deaths <5 yrs	Actual	Actual	Actual
2.	Tracking of events for death	80	80	160	320	2560
3.	Tracking of newborn	40	40	80	160	1280
4.	Tracking of events for sickness (2 per cluster- one hospitalized and one non hospitalized)	80	80	160	320	2560
5.	Household survey (14 per cluster – 50% males and females each)	560	560	1120	2240	17920
OBSERVATION						
1.	Health facilities (Both govt./private) (One facility every alternate cluster)	20 (10 govt. 10private)	20 (10 govt. 10private)	40	80	640
2.	Prescriber client interaction. (5 cases per prescriber)	20 (10 govt. 10private)	20 (10 govt. 10private)	40	80	640
3.	Doctors Interview at the health facility (one every alternate cluster)	20	20	40	80	640
4.	ANM (2 cases observed per ANM/AWW per cluster)	20	20	40	80	640
5.	AWW/AWW Interview (one per cluster)	20	20	40	80	640
6.	Depot holder			5	10	80
INTERVIEW						
1.	Prescriber (both govt./private) (one facility every alternate cluster)	20 (10 govt. 10private)	20 (10 govt. 10private)	40	80	640
2.	ANM/AWW	20	20	40	80	640
3.	DM			1	2	4
4.	DHO/CMO/RCHO			1	2	4
5.	NGO/CBO			4	8	16
6.	Community leader			1	2	4
FOCUS GROUP DISCUSSION						
1.	Mothers			4	8	64
2	ANM			2	4	32
3	AWW			2	4	32

1. Network Dynamics: The objective of network dynamics will be to:

- Maintain high level of motivation and commitment to the project activities
- Maintain highest level of quality assurance and
- Foster camaraderie among all partners

2. Network Structure and Dynamics

2.1. Constitution of the Central Coordination Team

The central coordinating team (CCT) is a multidisciplinary team comprising of 10-12 investigators co-opted from various medical colleges and professional institute. The Central Coordinating Team has guided in all the previous IPEN studies. The CCT operates from the Central Coordinating Office (CCO). The CCT holds several meetings to arrive at a draft protocol for the study and to discuss other operational details. The CCT will facilitate development of operational manual, study instruments, undertake quality assurance visits to the study sites, supervise and conduct a focus group discussion and provide inputs at the time of project report writing.

2.2 Central Coordinating Office – CCO, Delhi

Central Coordinating Office (CCO) of the study is located at International Clinical Epidemiology Network office, New Delhi. The CCT and IPEN office will provide technical and quality assurance support for the study. CCO will manage the network activities and will be responsible for coordinating with all partner medical colleges, monitoring progress of the network, screening the data to ensure quality, processing and analyzing the data. Queries from partner medical colleges will be entertained and responded by CCO.

2.3 Regional Centers

The study will be conducted in 16 districts representing eight states. Eight institution centers will be nominated as a regional center in each state. The regional coordinator along with the investigator from other medical college in vicinity to eight districts and CCT member will implement the study. The regional center will coordinate data collection and quality assurance activities of both the centers.

2.4 Partner Institutions

There will be 5 to 6 partner medical college involved in each state. Each partner medical college will be responsible for formation of 2-3 survey teams. These network partners are medical colleges or NGO's or institutions working in the field of health.

2.5 Field teams

Survey Teams at Partner Institutions: In every district eight survey teams will be constituted, each team will survey 10 clusters thereby approximately eight teams will be covering 80 clusters (40 urban & 40 rural) in the districts. Each survey team will consist of six members: two senior investigators, two doctors or inters and two research associates (if possible one male and one female). All centers are encouraged to co-opt the social scientist / anthropologist of the institution into the team. Research associates with social science or social work background will be preferred. Thus it will be a unique opportunity when senior faculty members along with the whole research teams will be in the field to undertake data collection of highest quality.

2.6 Teams at Regional Center: In addition to field teams, one Principle Investigator and two additional research associates will be provided to Regional Coordinator at each regional center for a quality assurance and organize a interview at district level.

Fastest mode of communication will be maintained between all partner medical colleges and CCO to clarify any doubts regarding various components related to baseline survey. In addition, the study centers will work according to a fixed time line with close and regular monitoring of all activities at partner medical colleges by regional centers and CCO. Deadline will be strictly adhered to.

Movement of survey teams in the field

Each team will cover 10 clusters. This would include data collection in both urban and rural clusters. It is estimated that each team would be able to cover one cluster in two days and 10 clusters in about 20 days time.

3. Network Monitoring

3.1 Regional coordinator: The regional coordinator will be in constant touch with the CCO, Delhi. Soon after the regional workshop, the plan of field activities will be faxed to CCO. Regional coordinator will speak to CCO, Delhi every alternate day to update the progress till that day. They will also fax the details of network progress of their Partner Medical College's (PMC) to CCO on every Monday, Wednesday and Friday and communicate the problems faced by any team.

To coordinate the activities in each state, each regional centre will have a regional coordinator. *The tasks of regional coordinator will be to*

1. To conduct and organize a three-day orientation workshop in two-selected district separately in coordination with the PMC's to understand the objectives and methodology including hands on training for all team members to conduct the interviews and health facility observation. In hands on training selected clusters are not included.
2. Help / guide the PMC to prepare a route map for every team to cover ten clusters per team.
3. Funds will be transferred to regional coordinator office from CCO. It is the responsibility of the regional coordinator to disburse funds for the field travel.
4. Coordinate movements of all teams, solving problems and facilitating local arrangements.
5. Identify triggers of a problem and taking pre-emptive actions.
6. Monitor movements of teams on the field and facilitate quality assurance visit by CCT member.
7. Facilitate smooth data collection and data transmission.
8. To conduct the district level interviews (DHO, MO, RCHO) and conduct FGD's.

3.3 Monitoring network progress: All partner medical colleges will prepare an activity planner to accomplish the targeted number of interviews within the stipulated time frame. This will be closely monitored through weekly interview log sheets. The network progress regarding interview accomplished during the week will be monitored at CCO. Whenever a partner medical college defaults in sending the weekly interview log sheets, contact will be made through telephone/fax/email to remind them or to know if there was a problem. Such phone calls will be entered in monitoring sheets. In addition, the medical college will dispatch the completed interview schedule to their regional centers after initial quality checks. After the regional center finishes with the quality checks, these will be forwarded to CCO.

3.4 The CCT member who is out in the field to ensure quality will contact the CCO Delhi, every evening regarding

- Details of cluster survey
- Any problem in methodology
- Corrective measure taken
- Plan for the next day

4. Network Communication

This would be critical for operating the network. Its significance would be emphasized during all contacts and correspondence with regional centers and partner institutions. A network directory containing office and residential addresses along with the telephone and fax numbers of senior investigators will be compiled and circulated to every member of the network with the explicit request of establishing contact with their regional coordinating centre or central coordinating office in case of need at any time. Motto of the network communication is to use "the fastest mode of communication". Decisions will be made quickly and no matter would be kept pending for more than 24 hours at the coordinating center. All network letters and completed study instruments will be mailed through speed post / courier, ensuring quick and safe delivery.

5. Quality Assurance

Understanding the limitations of multi-centric project, quality assurance measures will be incorporated at every stage of the study. This will be done at four levels:

Level 1: Program Managers Meeting: one day program manager meeting will be organized for seeking partnership from the respective state government and to facilitate the activities of the project.

Level 2: **One day International Advisory board meeting** will be held after the National Workshop to share experiences and get technical inputs for the present study.

Level 3: National Protocol Finalization Workshop at Delhi: A 3-day workshop will be held for all the investigators including CCT members, and partners from Ministry of Health & Family Welfare, Government of India, donor agencies and other stakeholders. Objectives of the national workshop will be to finalize the study protocol including the study instruments. Modalities of data collection and transmission would also be finalized.

Level 4: Regional Orientation Workshops: Three day regional workshops will be conducted by CCT members and regional coordinators for principal investigators and research teams from partner institutions in the region. Data collection techniques and all the study instruments are discussed in detail at these workshops. Participation of CCT members ensures that there are no distortions or dilutions in communicating the study protocol to the research teams across the network. All participants will have hands on experience to conduct interviews and observation of health facilities in the near by village under the close supervision of regional coordinator and CCT member.

Level 5: Quality Assurance visits: These will be undertaken by the central coordinating team members during the data collection phase to supervise the process. Each CCT member will visit at least four clusters in every district to assess two parameters

- Authenticity of data that has actually been collected
- Quality of interviews being conducted by the researchers though direct observation

Level 6: After completing a cluster, the investigator sits with the RA and scrutinizes the filled schedules for completeness and appropriate marking of the answer. If satisfied they will counter sign the schedule or else the researcher will be asked to do an extra interview to replace it.

Level 7: Quality check at regional centers: At each regional centre, all the study instruments sent by the partner medical colleges would be checked for correctness and completeness before transmission to CCO, Delhi.

VI. Expected outcomes of the study

Following are the expected outcomes of the study:

1. Baseline estimates for burden of childhood Illnesses covered under IMNCI (Neonatal Sepsis, Cough, Fever, Diarrhea)
2. Baseline estimates for infant mortality in the study districts and causes of infant mortality.
3. Existing sickness care seeking and referral pathways.
4. Determinants of health seeking behavior of community regarding preventing childhood illnesses.
5. Availability of facilities, quality of care in public and private health care facilities in the study districts.

VII. Limitations and challenges

The potential limitations of Rapid Appraisal Procedures (RAP) are both intrinsic to the methodology and extrinsic for the purpose of generalization. The problems are primarily related to:

(i) Accuracy of the information

(ii) Representative nature of the respondents and their responses.

(iii) Cultural appropriateness

(iv) Subjectivity of the investigators leading to a bias in the interviews and subsequent interpretation of data.

VIII. Timeline of Baseline Survey

IMNCI Baseline survey-Phase I																												
TIME LINE																												
Activity	JULY				AUGUST				SEPT				OCT				NOV				DEC							
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
1.Development of study instruments and operational manual																												
2.Field testing																												
3. Finalisation of Study Instruments																												
4.Meeting of State Health Secretaries and Program Officers																												
5.Identification of Regional coordinator and PMC																												
6.Preparation of national level worhshop																												
7.international advisory borad meeting																												
8. National workshop																												
9. Preparation of district level workshop																												
10.District level workshop (16)																												
11.Data collection																												
12.Data analysis																												
13.Draft report																												

Annexure 1: Field Activity

FIELD ACITIVITY

Quantitative survey

Qualitative survey

STEP 1

Visit the cluster, prepare a rough map and divide it into two halves

A team of
1 RC + 1 PI + 2 RAs

STEP 2

In each half of the cluster, list of all the *mohallas* and identify the starting point using currency note from PI -1

STEP 3

Identification of the first house within the mohalla by using currency note from PI-2

- Interviews of
  DM, CDMO, Prescriber (Govt, Pvt), NGO/ CBO, Community Leader
- FGDs
  Mothers, community leaders, CBOs, NGOs, SHGs, HWs (ANM, AWW, MPW, ASHA)

STEP 4

In each half of the cluster, the following steps will be **followed**

a) Screen households for **live birth**. (Each half continues screenings till 10 live births in previous 1 year)
b) Screen for **death** in under 5 children in previous 1 year within the sampling frame of households i.e. 20 live births (**e.g.** if survey on 25th Oct-06. So death between 26th Oct -2005 to 25th Oct -2006 will be included). The identified case will be taken for verbal autopsy and tracking events of death by principal investigator 2.
c) Screen households for **Neonate** aged 10- 28 days. The identified neonate will be taken for tracking events of early infancy by principal investigator 1
d) Screen for **childhood morbidity** in under 5 children. (First 7 **male** children, to be taken in one direction and first 7 **female** children in the other direction). Conduct household survey in each of them. Conducted by doctor and research associates.
e) After the seven cases (male/female) are completed then screen for **recovered morbidity (non –hospitalized)** one case– in last two weeks and three days of asymptomatic recovery.

STEP 5

Recovered morbidity (hospitalized) one case – in last three months – preference given to female

Observations

- Generic observation of health facility (govt/private)in every alternate cluster will be don by principal investigator -1
- Specific observation of prescriber client interaction.-5 cases (under 5 children suffering from any illness)- done by principal investigator -1
- Skill assessment of ANM AWW/ASHA – 1 case (any morbidity) and Neonate (ill/ not ill)per cluster alternatively (identified during survey in the cluster) – done by doctor

Annexure 2: Study Instruments to be Utilized for Each Cluster

	Component	Description	Tools
At Community Level			
1	**Mortality**	All the deaths in the cluster will be considered to establish the cause of death	Screening Format, Verbal Autopsy and Tracking of Events.
2	**Morbidity**	14 households per cluster will be considered to assess the morbidity density	Screening Format and Household Survey
3	**Tracking of Events**		
3.1	Mortality (U5)	All deaths in the last one year	Tracking of Events for Morality
3.2	Morbidity (U5)	• Hospitalized Child in the last three months (1) • Non-hospitalized Child (Recovered) (1)	Tracking of Events for recovered Morbidity
3.3	Neonate	• Neonate (10-28 days) for studying practices related to neonatal care (1)	Tracking of Events for Neonate
4	**Assessment of ANM/AWW**		
4.1	Skill	A sick child having symptoms such as cough, fever and diarrhea will be managed by ANM in presence of senior investigator (1)	Specific Observation
4.2	Knowledge, Practices and Barriers	ANM/AWW will be interviewed (1)	ANM/AWW interview schedule
At Health Facility Level			
5	**Assessment of**		
5.1	Doctor's Skills	For every alternate cluster, 1 government and 1 private health care provider will be selected. (1)	Specific Observation
5.2	Doctor's Knowledge, Practices and Barriers	Conducted by the doctor of the team (1)	Doctor's Interview Schedule
5.3	Health Care Facility	For every alternate cluster, 1 government and 1 private health facility will be selected for generic observation to assess the logistics and equipment available for child health (1)	Generic Observation