

## **Pneumonia Research Initiative in Rural Areas and Urban Slums of Maharashtra**

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## **EXECUTIVE SUMMARY**

### **1. Title of the research proposal project:**

Pneumonia Research Initiative in Rural Areas and Urban Slums of Maharashtra

### **2. Executive Summary:**

Pneumonia is a leading cause of death among children under 5 years of age in India. Simple interventions at community level, case-finding and community-based management are effective management strategies. The study proposes to reduce the incidence and consequently death due to pneumonia by community based interventions.

This will be a cluster randomized control trial (C-RCT) conducted in Pune and Sangli district under field practice area of two medical colleges of Bharati Vidyapeeth University for a period of two years. The overall budget for the project is Rs. 11,449,580. The aim is to assess the efficacy of community based interventions in reducing incidence of pneumonia. To achieve 80% power and assuming intra-class coefficient of variation of 0.5, the study will randomly select and enrol 16 clusters with around 4800 children into intervention and comparison arm. The community based interventions in the form of behavioural change communication (BCC) activities under following domain will be implemented viz. child feeding practices, immunization, indoor air pollution, hand hygiene of mother at 4 occasions (after defecation, after cleaning child's bottom, before food preparation, before feeding the child), knowledge attitude and practices of mother about pneumonia, cough etiquettes. These interventions will be implemented by the project appointed field supervisors in the interventional clusters for mothers of under five children. These supervisors will be trained through project. Pneumonia surveillance will be conducted at fortnightly visits by ASHA/Anganwadi worker in both the arm for a period of one year. Incidence of pneumonia will be compared in both the arms. Quality will be assured by continuous monitoring of activities through sub-investigators. The progress of project will be reviewed in monthly meetings with partners. Assessment of efficacy of community based interventions in reduction of incidence pneumonia will done.

## Protocol

### 1. Title of the research proposal project:

Pneumonia Research Initiative in Rural Areas and Urban Slums of Maharashtra

### 2. Problem statement:

Recent statistics indicates that in Maharashtra the fortnight period prevalence of ARI among children under 5 years of age is 8.5 % and 9.3% in urban and rural areas respectively (DLHS-4). Some children develop pneumonia which is responsible for 14% of total under five deaths (UNICEF 2012). Pneumonia is a leading cause of death among children under 5 years of age. One of the reasons for not achieving the Millennium Development Goal 4 (reduction in child mortality) is poor access to health facilities and paucity of trained human resources in primary health setups.

The problem of pneumonia is manageable with simple interventions at community level (Jai K Das 2013) however it is still persisting because risk factors for the same are not tackled in a comprehensive manner and treatment seeking behaviour for pneumonia is poor (DLHS-4 Maharashtra). Breast feeding, hand washing, improved nutrition and reduction of indoor air pollution are suggested as primary strategies to protect against pneumonia. Case-finding and community-based management are effective management strategies, but have low emphasis in India due to policy and programmatic barriers. Families residing in urban slums, rural and remote areas with under five children are at higher risk. The study proposes to reduce the incidence and consequently death due to pneumonia by community based interventions.

Background Information of the problem:

(The evidence on how community based interventions reduce pneumonia and by how much)

1. Mother's lack of education and inexperience as a caregiver is one more risk factor for childhood pneumonia that may be amenable to public health intervention.

Commencing exclusive breastfeeding early after birth and continuing up to the age of 6 months and continued breastfeeding to the age of 12 months help maintain a good level of nutrition and immunity against most infections in early childhood. These measures on their own have been estimated to prevent 1,301,000 deaths or 13 per cent of all child deaths. Proper attention to complementary feeding can reduce malnutrition by up to 20 per cent, reduce deaths caused by pneumonia by 10 per cent and reduce the overall child mortality by 6 per cent.

(Ghimare M., Bhattaraya SK, Narain J P. Pneumonia in south east Asia region:Public health perspective.Indian J Med Res 135, April 2012,pg459-468M)

2. Community Case Management (CCM) of pneumonia could result in a 70% reduction in mortality from pneumonia in 0–5-year-old children.

(Das JK,Lassi ZS,Salam RA,Bhutta ZA. Effect of community based interventions on childhood diarrhea and pneumonia: uptake of treatment modalities and impact on mortality. BMC Public Health 2013, 13(Suppl 3):S29 [Internet].Available from: <http://www.biomedcentral.com/1471-2458/13/S3/S29> Accessed on 15th September 2014. )

### **3. Hypothesis:**

Community-based interventions in the form of behavioural change communication(BCC) activities for mothers, targeted towards risk factors reduction may reduce the incidence of childhood pneumonia by about 50%.

### **4. Aim and objectives:**

**Aim:** To assess the efficacy of community based interventions in reducing incidence of pneumonia.

**Objectives:**

To compare the incidence of pneumonia among under five year children from intervention and comparison clusters after selected community based interventions.

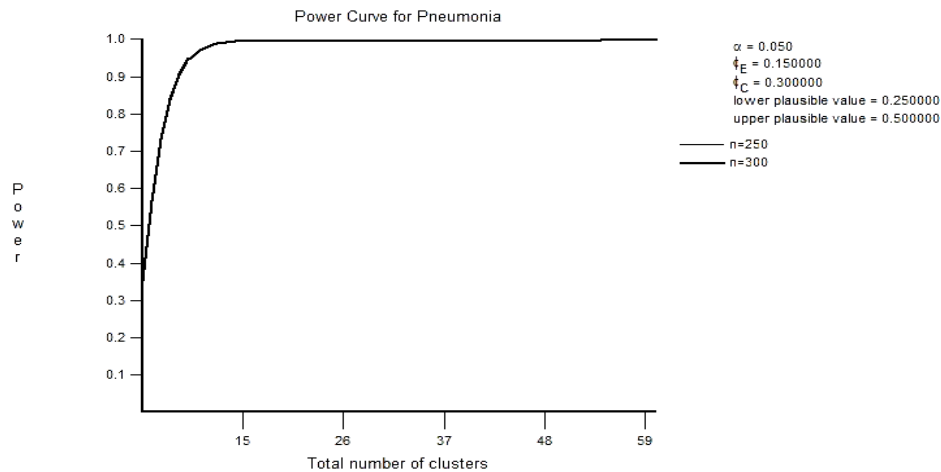
### **5. Study Protocol/Detailed research plan:**

**Study design:** A cluster randomized trial in Pune and Sangli district stratified by urban slums and villages.

**Study area:** Bharati Vidyapeeth University is a multidisciplinary and multi centric university having two medical colleges in Pune and Sangli districts of Maharashtra state of India. This study will be carried out in 4 sites under the urban and rural field practice area of these two medical colleges. Each site is having 9-16 clusters of slums/ villages.

**Number of clusters and sample size calculation:**

Figure-1



A review article indicates that incidence of childhood pneumonia is 0.2 to 0.5 per child per year (Ghimire M.*et al* 2012). This is equivalent to 20% to 50% of incidence of pneumonia. For sample size calculations we have assumed the incidence rate at 30%. Community based intervention is expected to reduce the incidence rate by 50%. The curve required for various powers and number of clusters is shown in figure-1. Sample size assumptions and estimations are reviewed by a statistician.

To achieve 80% power and assuming intra-class coefficient of variation to be 0.5, the study will need to enrol minimum 15 clusters of average 300 size. However we have decided to include 16 clusters.

Thus the total number of children under 5 years to be enrolled in the study will be about 4800.

The field practice areas of both medical colleges together have 47 available clusters; 16 clusters will be selected randomly and allocated to intervention arm and comparison arm by randomization. Thus there will be 8 clusters in intervention arm and equal number in comparison arm.

All under five year children residing in the selected clusters and their mothers (including expectant mothers) will constitute study subjects. The process of inclusion of subjects (mothers and children) will continue throughout the study period. Those children who complete five years of age in the project period will be excluded. However, these children will be considered while calculating denominator of children-months.

Study tools: Following tools will be developed and used for data collection and intervention

1. Trainer's modules
2. Proforma for collection of information from study subjects(baseline survey)
3. Behavioural Change Communication(BCC) material
4. Booklet for mother
5. Fortnightly Pneumonia surveillance tool (Diary).

Operational Definition of Community Based Interventions (CBI): These are Behavioural Change Communication (BCC) activities conducted by ASHA/Anganwadi worker (AWW) for mothers of under five children with respect to following domains:

1. Child feeding practices which include exclusive breast feeding and appropriate weaning.
2. Immunization of under five children.
3. Indoor air pollution (reduction in use of biomass fuel and smoking).
4. Hand hygiene of mother/care taker of child: Correct hand washing steps at following 4 occasions: After defecation, after cleaning child's bottom, before food preparation, before feeding the child.
5. Knowledge Attitude and Practices of mother about pneumonia: Signs and symptoms of pneumonia, danger signal of severe disease and appropriate care seeking.
6. Cough etiquettes.

The BCC activities will include interpersonal communication, group discussions and demonstration etc. Outcome of these Community based interventions will be measured in children i.e. incidence and also deaths due to pneumonia.

Study duration: Two years.

### **Methodology:**

The study will be conducted in phase wise manner. The activities in different phases are listed below:

#### **Phase 1: Preparation (2 months)**

1. Development and validation of research tools: Tools as described above will be developed and used for data collection. These tools will be quantifiable and objective. The team of investigators including paediatrician, biostatistician and anthropologist/social scientist will be involved in development and drafting of study tools. While preparing the tools available training booklets will be extensively used. All the tools will be bilingual and will be piloted for validity, question framing, relevance, sequencing and time required for filling the tools. The tools then will be finalized after making necessary modifications.
2. Appointment of Field supervisor (FS) and training. Training of FS
3. Baseline data in brief and with limited objectives will be collected from all clusters prior to randomizing them into intervention and control clusters.

Objectives of baseline survey:

- a. To obtain basic socio-demographic information of the family (age, sex, income, education & occupation)
- b. To determine proportion of women in reproductive age group

- c. To determine incidence of pneumonia in last one year and incidence of ARI in last one month and also to measure child mortality in last one year including mortality due to pneumonia.
  - d. To determine sources contributing to indoor air pollution like type of fuel used for cooking, smoking by family member, overcrowding.
  - e. To measure proportion of other risk factors like low birth weight, birth order, malnutrition, breast feeding, immunization status of under five year old and KAP of mother about pneumonia including care seeking behavior .
4. Intervention cluster will be geographically separated so as to reduce contamination. There are minimal chances of contamination however some may occur during non-formal communication of ASHA AWW with each other.
  5. Identification and orientation of private medical practitioners, concerned Taluka Health Officer, Medical Officers, Auxiliary Nurse Midwives (ANM).
  6. Accredited Social Health Activist (ASHA), Anganwadi workers (AWW) from the selected clusters will be identified and they will be incentivized through the project.

Field supervisors will be trained regarding

- a. Introductory contents pertaining to pneumonia: protocol specific training, IMNCI guidelines for ARI/Pneumonia, diagnosis and standard management of pneumonia, problem statement of ARI/Pneumonia in their area.
- b. Intervention related training: Relevance of selected risk factors in reduction of pneumonia. Methods to reduce the same through Behavioural Change Communication activities.
- c. Surveillance related supervisory training:
- d. Communication skills and conducting session for mothers above mentioned areas. Over and above their role as a supervisor will be explained and taught to them.
- e. Initial Training: Two days and one additional day for hands on training in the field. The material intended to be used by them for Behavioural change communication (BCC) during interpersonal communication with mothers will be shared with them and their competency will be assessed in the field through demonstration of conducting a BCC session for mothers.

**Phase 2: Baseline/Enrolment (3 months):** Enlisting of study subjects in intervention and comparison clusters. This will be done through house to house visits by ASHA/AWW in their respective cluster. Written informed Consent will be taken from mother by ASHA/AWW

In first visit following details will be obtained after informed consent.

- a. Basic socio demographic information(will be collected prior to randomising them into intervention and control cluster)
- b. Enlisting all mothers of under five children and expectant mothers.
- c. Enlisting all under five children
- d. Selection and random allocation of the clusters to intervention and comparison arm

All the data collected will be entered in predesigned excel sheet and database will be generated for further analysis.

### **Phase 3: Intensive Community based Intervention (4 months)**

1. First round of BCC activities for mothers: This will be conducted by the trained and equipped Field supervisor in small groups consisting of about 10 mothers. Every week she will conduct one session for about 10 mothers in anganwadi /community hall in intervention clusters only. Some of these sessions will be attended by investigators. All mothers in her cluster will be educated in two months.

The content of BCC activities will be

- Child feeding practices which include exclusive breast feeding and its distinctive advantages and appropriate weaning.
- Role of Immunization of under five children in preventing various vaccine preventable diseases.
- Hazards of biomass fuel and use of substitutes like smokeless chulla, LPG etc.
- Hand hygiene of mother/care taker of child: Correct hand washing steps at following 4 occasions: After defecation, after cleaning child's bottom, before food preparation, before feeding the child.
- Knowledge, Attitude and Practices of mother about pneumonia: Signs and symptoms of pneumonia, danger signal of severe disease and appropriate care seeking, timely contact by mother or care taker to the ASHA/AWW etc.

BCC material in local language developed especially for mothers will be handed over to them. This material will help mothers to adopt practices which will minimize risk factors of pneumonia. Subsequently enrolled subjects (delivered women, newborns, including migrated) will also be receive BCC activities in a special session.

2. Second round of BCC activities: This will be conducted for reinforcement of the information delivered in first round. It will be conducted again in small groups after 2 months of first round and completed in two months. In this round emphasis will be given on skills acquired and demonstration by participants.

Various BCC activities will be supervised by sub-investigators.

Training of ASHA/AWW:

Investigators will train AWW & ASHA from intervention arm to orient them about the objectives, importance of project and their role in the project for surveillance.

Contents of the training modules:

- a. Introductory contents pertaining to pneumonia: protocol specific training, IMNCI guidelines for ARI/Pneumonia, diagnosis and standard management of pneumonia, problem statement of ARI/Pneumonia in their area.
- b. Surveillance related training: Fortnightly surveillance, maintenance of diary
- c. Communication skills and conducting session for mothers.  
Investigators will train all AWW and ASHA from both the arms regarding surveillance. Duration of training for ASHA/AWW:One day.



ASHA/AWW/FS from intervention arm will be requested to share their mobile numbers with mothers so that in case of any need like of sickness of child mother can contact them. The importance of response to mothers call will be emphasized as it may ensure appropriate management of child's illness and prevent the mortality. Training about fortnightly surveillance will be imparted to them.

Information about available emergency services like help line 108,102 will be given and ASHA/AWW/FS will communicate their mobile numbers to mothers/expectant mothers and will appeal to contact on same whenever the child is sick.

#### **Phase 4: Followup and continued Intervention (12 months)**

**Pneumonia surveillance:** This will be done in intervention arm for a period of one year by AWW/ASHA in rural area and AWW in urban slums through fortnightly house to house visit and enquiring about signs and symptoms related to pneumonia in preceding fortnight. This will help to calculate the fortnight incidence of pneumonia. Fortnightly visits will be adequate to get incidence of pneumonia in addition to this the mobile numbers of ASHA will be shared to mothers so that in case of any need like sickness of child mother can contact them. This will help to record attacks of pneumonia if any between the two fortnight visits.

Following definitions from IMNCI Guidelines will be used:

**Pneumonia:** child with cough or difficulty in breathing as having pneumonia.

**severe pneumonia:** If the symptoms are associated with lower chest wall in drawing or subcostal retraction,

**Very severe pneumonia:** If there is a danger sign such as central cyanosis, or severe respiratory distress, convulsion, inability to rouse the child or if the child is unable to drink.

**Interval:** An episode of pneumonia after 7 days of previous episode will be counted as a new episode.

If answer is yes then ASHA/AWW will enter the information in the diary maintained by her and submit information to site investigators(SI). They will confirm the pneumonia using WHO IMNCI protocol.

Appropriate management of child's illness will be ensured. This record will be submitted in fortnightly meeting (one will coincide with their monthly meeting) with FS and the same will be updated periodically. In addition, information about any death among under five children will be collected and the cause of death will be ascertained.

**Continued intervention:** Will be given by field supervisor (FS) through monthly house to house visits During her house to house visits in intervention arm FS will interact with all mothers and enquire about practicing the methods, skills steps learnt during intensive intervention. In case of unsatisfactory response FS will reinforce the knowledge and skills.

The sub investigator will supervise a pair of cluster from intervention and comparison arm and will do surprise home visit to cross check information collected by AWW/ASHA.

In comparison clusters ASHA/AWW will continue their role as per existing guidelines and collect information about pneumonia and deaths due to pneumonia through fortnightly house to house visits and submitted to FS fortnightly. And AWW and ASHA will continue to

promote all activities that are part of national programme (immunisation, optimal feeding practices) in control sites.

Midterm evaluation of the project will be done by third party at the end of three months of surveillance.

Detection and referral of pneumonia cases is a part of routine activity of ASHA/AWW workers so stopping of these duties is not advisable. And they will be closely monitored by field supervisors and sub investigators.

Standard care for ARI / Pneumonia will be provided to referred children through our own institutions and partner in public sector in two districts.

### **Phase 5: Data Analysis (2 months) and Final Report writing (1 month)**

1. Information about Incidence of pneumonia will be generated and findings will be compared to determine the change in intervention and control clusters. Separate analysis for overall change in childhood mortality and morbidity will be done.

Report will be shared with all stakeholders for review, discussion and comments. Final report will be prepared by incorporating comments. The final report will be shared in the closure meeting and then submitted to the funding agency.

**Continuous monitoring:** Will be done through on job supervision and monthly review meetings with all the stakeholders.

### **Process indicators:**

1. Evaluation of competencies learned by ASHA through training
2. Percentage of mothers trained in first round of BCC activities.
3. Percentage of mothers trained in second round of BCC activities.
4. Percentage of children diagnosed with pneumonia (fortnightly)
5. Number of cases cross checked by the field supervisor per month
6. Number of cases cross checked by the sub-investigator per month.

### **Key Outcomes:**

Primary Outcome-Incidence of pneumonia in both the arms will be calculated and compared. Secondary Outcome-Morbidity rates including diarrhea in both the arms.

**Data Management:** Procedures involving design of data collection forms, data entry system and data quality management will be outsourced to a reputed statistical firm which has senior statistician with PhD with more than 15 years of experience of handling various international projects.

Data collection and entry: Each study subject will have a unique serial number which will be mentioned on every tool. Validity checks for the data will be applied and outliers will be confirmed.

Plan of data analysis: Data will be analyzed and summarised as proportions, percentages, mean and standard deviation. Data will be analyzed using STRATA (version 6.0).

**Data Preservation:**

All hard copies of the study tools and other study documents will be archived for at least five years after submission of final report in the department of Community Medicine, BVU Medical College, Pune. Soft copies will be stored in DVDs and external hard disc for minimum seven years. The data if requested may be shared for the purpose of research in future at other sites with due acknowledgement.

**Timeline of the research:**

| Activity  | Months |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |   |
|---|--------|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---|
|   | 1      | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |   |
| <b>Phase 1: Preparation</b>   |        |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |   |
| Development of research tools   | █      |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |   |
| Validation of research tools  |        | █ |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |   |
| FS appointment and training   | █      | █ | █ |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |   |
| <b>Phase 2: Baseline survey, randomisation of clusters, enrolment of study subjects</b> |        |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |   |
| First round of BCC activities to mother   |        |   |   | █ | █ | █ | █ | █ |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |   |
| second round of BCC activities to mother, training of ASHA/AWW                          |        |   |   |   |   |   |   |   | █ | █  |    |    |    |    |    |    |    |    |    |    |    |    |    |    |   |
| <b>Phase 4: Continued intervention &amp; Surveillance</b>                               |        |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |   |
| ARI/Pneumonia Surveillance  |        |   |   |   |   |   |   |   |   |    | █  | █  | █  | █  | █  | █  | █  | █  | █  | █  | █  | █  | █  | █  | █ |
| Continuous assessment of reporting/ surveillance system                                 |        |   |   |   |   |   |   |   |   |    | █  | █  | █  | █  | █  | █  | █  | █  | █  | █  | █  | █  | █  | █  | █ |
| Midterm evaluation  |        |   |   |   |   |   |   |   |   |    |    |    |    | █  | █  |    |    |    |    |    |    |    |    |    |   |
| <b>Phase 5: Analysis &amp; Report Writing</b>   |        |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |   |
| Data Analysis   |        |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    | █  | █ |
| Report Writing, dissemination workshop  |        |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | █ |
| submission of report  |        |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | █ |

**Highlights of the Project:**

1. Multi-centric, multi-disciplinary and multi-partner project

2. The study will have active involvement of mothers in care of the child which will have long term implications with regard to sustainability.
3. Novelty of the study is that intervention is initiated among even expectant women also. These will be included for a specific targeted approach with respect to hand hygiene, importance of exclusive breast feeding etc. Infants will be benefited from day one due to correct practices related to feeding of colostrum, exclusive breast feeding and appropriate weaning etc.
4. This study involves maximum utilization of existing government functionaries, services and resources.
5. The study aims at capacity building of existing peripheral government health functionaries. These measures will improve surveillance and reduce morbidity and mortality due to pneumonia.
6. Important activities includes simple interventions like hand washing and active surveillance by ASHA/AWW etc. which are feasible and cost effective and can be expanded on a larger scale and wider geographical area.
7. Interventions incorporated in this study will have enormous collateral benefits in the form of reduction in morbidity and mortality due to major infectious diseases specially diarrhea and vaccine preventable diseases. As well as positive behavioral change in mothers will lead to similar effect on siblings.

**Patents:** None

**Quality assurance in the project:**

Following measures will be incorporated into the study implementation design at several levels:

Meeting of all partners and investigators will be conducted for assuring high standard of quality of the study. Periodical meetings will be conducted to discuss interpretation of the statistics generated and to review the progress of the study at all sites.

Quality checks will be applied at data collection and entry level. File supervisor will randomly cross check 5% of the study tool for completeness and appropriate coding of the answers and sub-investigator will cross check 2% of the forms through surprise visits. Necessary actions will be taken at appropriate level.

**Ethics and Research Governance:**

The study will be started after obtaining approval from the Institutional Ethics Committee (Registration No. ECR/313/Inst/MH/2013) which is approved by competent authority and Health Ministry Screening Committee (HMSC). Confidentiality of all the study participants will be maintained. It will be ensured that personal identity of any of the participant will not be revealed.

**Public Engagement:**

The host organization being an academic training institute health awareness programmes are routinely conducted in the field practice areas of urban and rural health centres. In the initial stage of the project, investigators will personally orient community leaders about the

intentions of the research project. They will be requested to appeal the community for active participation in the study. The initiation and findings of the project will be shared with the community through routine community oriented/based activities.

#### **Dissemination of the Findings:**

We desire to disseminate the study results in various international and national scientific journals and also present in various scientific platforms. The study findings will be shared with policy makers in government sector through investigators and partners.

**6. Risk mitigation:** Minimum risk is predicted in this project.

- Attritions specially amongst field supervisors: This will be addressed by training and subsequent appointment of wait listed candidates.
- Introduction of new strain of influenza virus: In such circumstances we will augment interventions like hand washing, cough etiquettes etc.
- Change in vaccination policy: Segregated analysis
- Major disaster including epidemic: Rescheduling of the activities

#### **7. Team quality relevant to undertaking this project:**

The team of investigators is an appropriate mix of epidemiologist, public health specialist and paediatrician from two constituent units of Bharati Vidyapeeth University, Pune (CV attached in section 1.3). Frequent interactive meetings are routinely convened between faculty from different disciplines and both the colleges. The team members are presently working in different capacities like head of departments, faculty members and in-charge of Urban & Rural Health Training Centres. The team members have experience of clinical management of sick child, clinical trials and some are senior public health experts with wide experience of working in government health sector.

Partners identified through these projects are District Health Officers (DHO) and Medical Officer of Health (MOH) of both the districts and corporations respectively. The department of Community Medicine has already worked with these partners in various field activities.

Some investigators are familiar with the field practice area and have developed rapport with the local community through conduction of various activities like family health survey, celebration of public health days, health camps etc. Thus it will be helpful for selection of area and selection of subjects as prior interaction with community leaders, Mahila Mandals, Self Help Groups has already taken place.

#### **8. Suitability of Institution:**

Bharati Vidyapeeth University is a 50 year old institution with 32 constituent units and is one of India's largest multi-disciplinary multi-campus universities. In line with its Motto of "Social transformation through Dynamic education" BVDU nurtures a holistic education approach that not only academically enriches the students, but also contributes to the students' personality by nurturing innovation, creativity and practical work experience. The University is a member of Association of Indian Universities and the Association of Commonwealth

Universities. It is really credible for this nascent University to have received and continued 'A' Grade from the National Assessment and Accreditation Council (NAAC).

Both the medical colleges are having 840 bedded tertiary care hospitals which provide super specialty services. Both the institutes are fully equipped NICU and PICU. Faculty from both the colleges is highly qualified with varied experience. Faculty members were involved in various projects funded by PATH, ICMR and RNTCP. Some extension activities through the peripheral health centres are conducted in collaboration with NGOs and government sector including women and child welfare board (Public private partnership).

Infrastructure and Facilities for training, treatment of children and excellent data management are available in the two institutes.

As partners identified through this project are District Health Officers (DHO) and Medical Officer of Health (MOH) of both the districts and corporations, active participation from the government field level functionaries is feasible.

For successful conduction of the study following manpower is required:

| <b>Category</b>        | <b>Number</b> |
|------------------------|---------------|
| Principal Investigator | 1             |
| Co-investigator        | 4             |
| Sub-investigator       | 8             |
| Project coordinator    | 1             |
| Field Supervisor       | 8             |
| Data entry operator    | 2             |
| Data manager           | 1             |
| Accountant             | 1             |
| Statistician           | 1             |
| Total                  | 27            |

ASHA and Anganwadi workers 50 in number

| Name and responsibilities of project personnel |                     |  |                        |   |
|--|---------------------|--|------------------------|---|
| Sr. No.  | Name                | Designation  | Position Title         | Responsibilities  |
| 1  | Dr. J. S. Gothankar | Professor & Head,<br>Department of Community Medicine<br>BVDUMC,<br>Pune | Principal Investigator | <ul style="list-style-type: none"> <li>• Liasoning with all partners</li> <li>• Protocol development and finalization</li> <li>• Appointment of FS and Project coordinator</li> <li>• Training and sensitization of all project personals</li> <li>• Finalization of study area</li> <li>• Overall in-charge of the project</li> <li>• Overall monitoring and supervision of the project</li> </ul> |
| 2  | Dr. S. K. Lalwani   | Professor & Head,<br>Department of Pediatrics,<br>BVDUMC,<br>Pune        | Co-Investigator        | <ul style="list-style-type: none"> <li>• Pediatrician</li> <li>• Protocol development</li> <li>• Training of investigators, field supervisors and field workers</li> </ul>  |
| 3  | Dr. P.P. Doke       | Professor<br>Department of Community Medicine<br>BVDUMC,<br>Pune         | Co-Investigator        | <ul style="list-style-type: none"> <li>• Protocol development</li> <li>• Training of the investigators, field supervisors and field workers</li> <li>• Coordinate with partners particularly public sector</li> </ul>   |
| 4  | Dr. G. B. Dhumale   | Professor & Head,<br>Department of                                       | Co-Investigator        | <ul style="list-style-type: none"> <li>• Responsible for project implement at Sangli</li> <li>• Protocol development and training of</li> </ul>   |



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|   |                       | Community<br>Medicine<br>BVDUMC,<br>Sangli   |                      | the investigators, field supervisors<br>and field workers<br><ul style="list-style-type: none"> <li>• Conduct monthly meetings of all project staff under his centre</li> </ul>  |
| 5 | Dr. P. D.<br>Pore     | Professor<br>Department of<br>Community<br>Medicine<br>BVDUMC,<br>Pune   | Co-<br>Investigator  | <ul style="list-style-type: none"> <li>• Responsible for project implement at Sangli</li> <li>• Protocol development and training of the investigators, field supervisors and field workers</li> <li>• Conduct monthly meetings of all project staff under his centre</li> </ul>   |
| 6 | Dr. S. K.<br>Murarkar | Asst.<br>Professor,<br>Department of<br>Community<br>Medicine<br>BVDUMC,<br>Pune.<br><br>In-charge Rural<br>health Training<br>Centre, Lavale,<br>Pune | Sub-<br>investigator | <ul style="list-style-type: none"> <li>• Involved in training of the FS</li> <li>• Supervise and monitor the work of field supervisors in rural area of Pune</li> <li>• Coordinate work with other sub investigators</li> <li>• Confirm the case of pneumonia and refer to hospital if required</li> <li>• Attend meetings and coordinate the work</li> <li>• Involved in fortnight meetings of FS</li> <li>• Continuous assessment of existing reporting/surveillance system will be done by sub investigators by checking record of AWW/ASHA/ANM and doing home visits.</li> <li>• Random cross check 2 % of data by house visit</li> <li>• Responsible for one pair of intervention and comparison cluster</li> </ul> |

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| 7 | Dr. R. S. Patil  | Asst. Professor,<br>Department of Community Medicine<br>BVDUMC,<br>Pune<br><br>In-charge Urban Health Training Centre, Pune | Sub-investigator | <ul style="list-style-type: none"> <li>• Involved in training of the FS</li> <li>• Supervise and monitor the work of field supervisors in Urban area of Pune</li> <li>• Coordinate work with other sub investigators</li> <li>• Confirm the case of pneumonia and refer to hospital if required</li> <li>• Attend meetings and coordinate the work</li> <li>• Involved in fortnight meetings of FS</li> <li>• Continuous assessment of existing reporting/surveillance system will be done by sub investigators by checking record of AWW/ASHA/ANM and doing home visits.</li> <li>• Random cross check 2 % of data by house visit</li> <li>• Responsible for one pair of intervention and comparison cluster</li> </ul> |
| 8 | Dr. S. H. Palkar | Tutor,<br>Department of Community Medicine<br>BVDUMC,<br>Pune   | Sub-investigator | <ul style="list-style-type: none"> <li>• Responsible for pooling of data from various clusters under Pune area</li> <li>• Attend meetings and coordinate the work</li> <li>• Involved in fortnight meetings of FS</li> <li>• Supervise and monitor the work of field supervisors in Urban area of Pune</li> <li>• Coordinate work with other sub investigators</li> <li>• Confirm the case of pneumonia and</li> </ul>   |

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|  |  |  |  | refer to hospital if required<br>• Responsible for one pair of intervention and comparison cluster |
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| 9  | Dr. N. S. Malashe   | Asso. Professor,<br>Department of Pediatrics<br>BVDUMC,<br>Pune           | Sub-investigator | <ul style="list-style-type: none"> <li>• Pediatrician in Pune area</li> <li>• Involved in training of the FS</li> <li>• Responsible for one pair of intervention and comparison cluster</li> <li>• Coordinate work with other sub investigators</li> <li>• Confirm the case of pneumonia and refer to hospital if required</li> <li>• Attend meetings and coordinate the work</li> <li>• Involved in fortnight meetings of FS</li> <li>• Random cross check 2 % of data by house visit</li> <li>•</li> </ul>  |
| 10 | Dr. Randhir Dhobale | Asst. Professor,<br>Department of Community Medicine<br>BVDUMC,<br>Sangli | Sub-investigator | <ul style="list-style-type: none"> <li>• Involved in training of the FS</li> <li>• Supervise and monitor the work of field supervisors in rural area of Sangli</li> <li>• Coordinate work with other sub investigators</li> <li>• Confirm the case of pneumonia and refer to hospital if required</li> <li>• Attend meetings and coordinate the work</li> <li>• Involved in fortnight meetings of FS</li> <li>• Random cross check 2 % of data by house visit</li> <li>• Responsible for one pair of intervention and comparison cluster</li> </ul> |
| 11 | Dr. Vivek           | Asst. Professor,  | Sub-             | <ul style="list-style-type: none"> <li>• Responsible for pooling of data from various clusters under Sangli area</li> </ul>   |

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|    | Waghchoure            | Department of<br>Community<br>Medicine<br>BVDUMC,<br>Sangli                        | investigator         | <ul style="list-style-type: none"> <li>• Attend meetings and coordinate the work</li> <li>• Involved in fortnight meetings of FS</li> <li>• Responsible for one pair of intervention and comparison cluster</li> </ul>   |
| 12 | Dr. Kirti<br>Rasote   | Asst.<br>Professor,<br>Department of<br>Community<br>Medicine<br>BVDUMC,<br>Sangli | Sub-<br>investigator | <ul style="list-style-type: none"> <li>• Involved in training of the FS</li> <li>• Supervise and monitor the work of field supervisors in urban area of Sangli</li> <li>• Coordinate work with other sub investigators</li> <li>• Confirm the case of pneumonia and refer to hospital if required</li> <li>• Attend meetings and coordinate the work</li> <li>• Involved in fortnight meetings of FS</li> <li>• Continuous assessment of existing reporting/surveillance system will be done by sub investigators by checking record of AWW/ASHA/ANM and doing home visits.</li> <li>• Random cross check 2 % of data by house visit</li> <li>• Responsible for one pair of intervention and comparison cluster</li> </ul> |
| 13 | Dr. Sanjay<br>Kureshi | Asst.<br>Professor,<br>Department of<br>Community<br>Medicine<br>BVDUMC,           | Sub-<br>investigator | <ul style="list-style-type: none"> <li>• Pediatrician in Sangli area</li> <li>• Involved in training of the FS</li> <li>• Responsible for one pair of intervention and comparison cluster</li> </ul>   |

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|    |                       | Sangli   |                     |  |
| 14 | Mrs. Mahima Dwivedi   |  | Project coordinator | <ul style="list-style-type: none"> <li>• Will assist Principal investigator in coordinating development of study tool, training booklet ,arranging meetings and project implementation</li> <li>• Will report to PI</li> </ul>   |
| 14 | Mr. Sane & Mrs. Garad | Biostatistician<br>Department of<br>Community<br>Medicine<br>BVDUMC,Pune | Data Entry Operator | <ul style="list-style-type: none"> <li>• Entry of data into computer at periodic interval</li> </ul>   |
| 15 | Dr. Nikhil Gupte      | Statistical Consultant,  | Statistician        | <ul style="list-style-type: none"> <li>• Protocol development</li> <li>• Sampling size calculation</li> <li>• Database development &amp; design</li> <li>• Data analysis, interpretation</li> </ul>  |
| 16 | Accountant            | -  | Accountant          | <ul style="list-style-type: none"> <li>• Keeping accounts of project related expenditure</li> </ul>  |
| 17 | Data manager          | -  | Data manager        | <ul style="list-style-type: none"> <li>• Data Quality check</li> <li>• Quality assurance etc.</li> </ul>   |
| 18 | Field supervisors     | -  | Field supervisor    | <ul style="list-style-type: none"> <li>• Conduct Baseline survey with the help of ASHA/AWW</li> <li>• Provide intervention /BCC activities to mothers</li> <li>• To monitor the work of ASHA/AWW</li> <li>• To conduct meetings with ASHA/AWW</li> <li>• Coordinate with other FS</li> <li>• Report the progress of the activities to</li> </ul> |

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|    |          |   |          | <p>sub investigators</p> <ul style="list-style-type: none"> <li>• Assist ASHA/FW to establish rapport with local private practitioner for management of ARI</li> <li>• Randomly cross check 5% of the study samples</li> <li>• Provide continued intervention through monthly house to house visits</li> </ul>  |
| 19 | ASHA/AWW | - | ASHA/AWW | <ul style="list-style-type: none"> <li>• Help Field supervisor in baseline data collection and enrolment of study subjects in her cluster</li> <li>• Fortnightly pneumonia surveillance</li> <li>• In case of child with ARI she should provide or ensure adequate management as per the guidelines through appropriate referrals to the ANM/designated practitioner.</li> <li>• Report her work at fortnightly or as and when required interval to field supervisor.</li> <li>• Attend meetings</li> <li>• Maintain daily diary of her work</li> </ul> |