RESEARCH PAPER

# Effect of Behavior Change Communication on the Incidence of Pneumonia in Under Five Children: *A Cluster Randomized Controlled Trial*

**JAYASHREE GOTHANKAR,[1] PRASAD PORE,[1] GIRISH DHUMALE,[2] PRAKASH DOKE,[1] SANJAY LALWANI,[3] SANJAY QURAISHI,[2] SUJATA MURARKAR K,[1] RESHMA PATIL,[1] VIVEK WAGHACHAVARE,[2] RANDHIR DHOBALE,[2] KIRTI RASOTE,[2] SONALI PALKAR[1]**

*From Departments of [1]Community Medicine and [3]Pediatrics, Bharati Vidyapeeth Deemed to be University Medical College, Pune; and [2]Department of Community Medicine, Bharati Vidyapeeth Deemed to be University Medical College and Hospital, Sangli; Maharashtra.*

*Correspondence to: Dr Jayashree Gothankar, Department of Community Medicine, Bharati Vidyapeeth Deemed to be University Medical College, Off Pune Satara Road, Pune 411 043, Maharashtra. jayashreesg@rediffmail.com*

*Received: November 25, 2020; Initial review: February 25, 2021; Accepted: August 18, 2021.*

**Background:** Improving health education of the mother by providing community-based interventions is known to help control pneumonia.

**Objective**: To determine the effect of behavior change communication (BCC) activities for mothers in reducing the incidence of childhood pneumonia.

**Design**: Open-label cluster randomized controlled trial.

**Setting**: Urban slums and villages in two districts of Maharashtra.

**Participants/Cluster:** Under-five children and their mothers from households in the randomly selected 16 clusters out of total 45 clusters, stratified into Pune and Sangli districts and further into rural and urban areas before randomization.

**Intervention:** Three forms of BCC activities were imparted, viz., interactive sessions of education using pictorial mothers' booklet, screening of a audio-visual film, and virtual hand wash demonstration and use of flashcard. Routine care under the National health program was provided by the Accredited Social Health Activists (ASHA) workers in both the arms.

**Outcome:** The primary outcome was pneumonia as per the IMNCI criteria assessed during fortnightly visits of the ASHA/ anganwadi workers to the houses of under-five children, who received at least one follow-up visit in a period of one year.

**Results:** The incidence of pneumonia in 1993 and 1987 under-five children in the intervention and control arm was 0.80 and 0.48 episodes per child per year, respectively ($P$=0.03).

**Conclusion:** BCC for mothers is not sufficient to reduce the incidence of childhood pneumonia.

**Keywords:** *Community intervention, Health education, Mothers, Surveillance*.

**Trial Registration:** CTRI/2017/12/010881

Pneumonia is one of the commonest cause of under-five mortality [1] with estimates showing that 23% of global pneumonia cases (around 43 million cases) occur in India annually [2,3]. Lack of exclusive breastfeeding, under-nutrition, low birth-weight, overcrowding, lack of immunization and poor healthcare-seeking behavior are a few of the leading risk factors for pneumonia in India and other low and middle-income countries (LMICs) [4,5]. Only one in five caregivers in the developing world know the two key symptoms of pneumonia -fast and difficult breathing [6,7]. One of the recommended critical activities in WHO's and UNICEF's Global Action Plan for the Control of Pneumonia and Diarrhea is improving health education of the mother by providing community-based interventions (CBI) [8,9]. Our study was conducted to determine the effect of behavior change communication (BCC) activities directed at mothers in reducing the incidence of childhood pneumonia.

## METHODS

An open-label cluster randomized control trial was conducted between December, 2015 and March, 2018 in Pune and Sangli districts of Maharashtra in the urban and rural field practice area of two medical colleges. Approval was obtained from institutional ethics committee, and written consent from the mothers was obtained prior to the enrolment.

Based on the reported incidence of childhood pneumonia of 0.2-0.5 per child per year in under-five children [10], and assuming the coefficient of variation (k) to be 0.4, the sample size was calculated as 15 clusters.The study enrolled sixteen clusters to cover for unforeseen eventualities precluding the BCC activities in any cluster.

A cluster was defined as one of the 45 notified slums or revenue villages in the field practice area of the two medical colleges. The 45 eligible clusters were first stratified into two

districts, further into urban and rural clusters, urban clusters were stratified based on the East or West. The rural clusters were stratified based on the primary health center (PHC). These clusters were then randomized in to intervention and control arms, based on a computer-generated randomization schedule and two clusters per site were randomly selected, thus 16 clusters were included. Participants were under-five children and their mothers from the households in the selected clusters (**Web Fig.1**).

Families residing for more than six months with under-five children were included in the study. All the under-five children and their mothers (including expectant mothers) were enrolled as study participants. **Fig. 1** shows the participant flow diagram. The new births were enrolled throughout the trial period ensuring that they receive at least nine months of surveillance. We excluded those children who completed five years of age during the surveillance period from further visits. All the children who had received at least one follow-up visit were analyzed. The literacy status of the mother was reported as per the census definition [11]. Ventilation status of the house was assessed using the availability of per capita floor space [12]. Due to the nature of the intervention provided, allocation concealment and masking were not possible after randomization.

The total study period included the following phases: preparatory (2 months), baseline survey and enrollment (3 months), intervention (4 months), and surveillance (12 months).

The components of the BCC activities for the mothers in the intervention arm consisted of imparting knowledge about child feeding, including the importance of feeding of colostrum, exclusive breastfeeding till six months of age, gradual introduction of food from the age of six months, causes of malnutrition among children, the importance of taking weight and plotting of growth charts in anganwadi; imparting knowledge about steps to prevent pneumonia in their children, such as complete immunization, prevention of indoor air pollution, the practice of cough etiquettes; hand hygiene including occasions and steps of hand wash; and, providing information about the signs and symptoms of pneumonia.

The BCC intervention was administered by trained field supervisors to an invited group of 8-10 mothers at a time, in an interactive manner using a validated mothers' booklet, and a hand wash demonstration. The second BCC activity was imparted by screening an audio-visual film for a larger group of 15-20 mothers and virtual hand wash demonstration. These two BCC activities were separated by a gap of two months. ASHAs and anganwadi workers were involved in planning and coordinating the BCC activities, thereby ensuring maximum cooperation of the mothers. The third BCC or continued intervention, through the house-to-house visit, was done three months after the second BCC activity by using flashcards. A total of eight trained field supervisors were involved in imparting the BCC activities, under supervision of the site investigators. Routine care under the national health program was continued in both the arms of the study.

The primary outcome was the incidence of pneumonia. Trained doctors confirmed the episode of pneumonia using

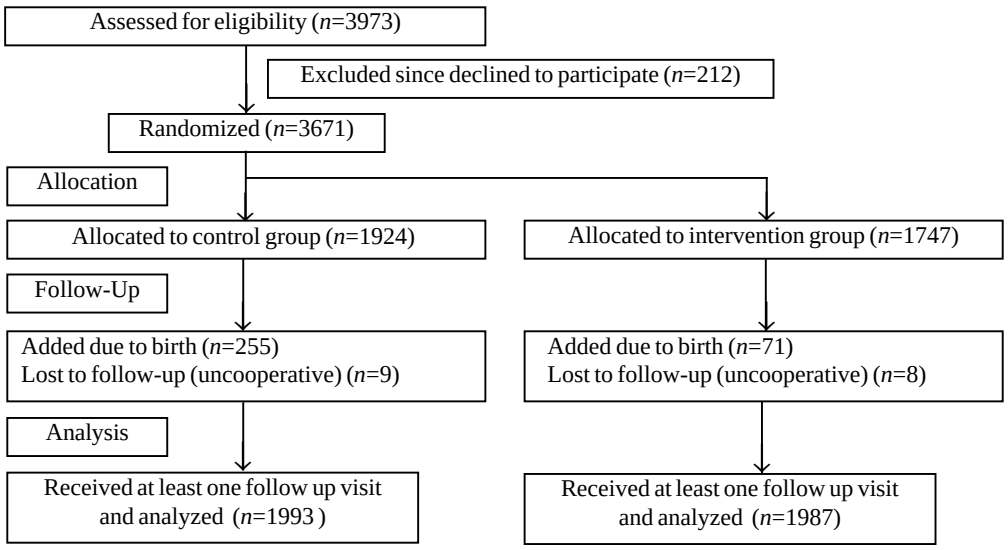



**Fig. 1** Study flow chart.

WHO Integrated management of neonatal and childhood illnesses (IMNCI) guidelines [13]. The outcome was assessed by fortnightly visits conducted for one year by the respective ASHAs of each cluster, except in Pune (urban), where anganwadi workers enquired about the current status of the child's health from the mother during the house-to-house surveillance visits. For labeling a new episode of pneumonia in the same child, a symptom-free period of a minimum of 14 days was considered essential, otherwise, it was presumed to be continuation of the preceding episode [14]. Besides, information about other illnesses and death among under-five children was collected by the field supervisors.

Quality checks were done randomly by site investigators and field supervisors. Site investigators conducted once-a-week field visits or as and when a case of pneumonia was suspected. For data entry, the critical fields in the tools were identified as a proxy to completeness and accuracy – discrepancy up to 0.1% and 1%, respectively were considered acceptable. Additionally, alternate forms were physically cross-checked for discrepancies related to data entry.

*Statistical analysis*: Intention to treat analysis was done to analyze the incidence of pneumonia (as episodes per child per year follow-up) in the intervention and control arm. The relative risk was calculated to compare the incidence between two arms. *P* value <0.05 was considered statistically significant.

## RESULTS

Sixteen clusters were randomly selected out of the 45 clusters, eight were in the intervention arm, and eight were in the control arm i.e., four in each urban and rural area of the two districts. The under-five children enrolled in the intervention arm were 1747 (20.1% aged <1 year) and in the control arm 1924 (20.8% aged <1 year) (**Fig. 1**). A total of 39 391 fortnightly follow-up visits were conducted in intervention and 40 288 in the control arm during one year. Baseline household and other demographic characteristics were similar between the arms except for higher unclean fuel use in control arm (20.1% vs 10.3%; *P*<0.05). Information related to the child was obtained from the mothers i.e., exclusive breast feeding for children between 6-12 months, primary immunization for children between 12-24 months, birthweight for children up to 6 months of age etc., hence the denominators varied as per the number of mother-child in that group (**Table I**).

There were a total of 5505 episodes of illnesses in the intervention arm and 6436 episodes in the control arm. Of these, there were 44 and 31 episodes of pneumonia in the intervention and control arm, respectively, constituting an incidence of 0.80 and 0.48 episodes of pneumonia per child per year, respectively in the two arms [RR (95% CI) 1.66 (1.05-2.62); *P*=0.03]. Three children in the intervention and two in the control arm had two episodes each. There was no case of severe pneumonia and very severe disease. Twenty-six (59.1%) episodes in inter-vention arm and 21 (67.7%) episodes in control arm were reported in boys [RR (95% CI) 0.87(0.62-1.23); *P*=0.77]. For 93.2% of pneumonia episodes in the intervention arm, children were taken to the health care provider as the first action, in contrast to 54.9% from the control arm [(RR (95% CI) 5.06 (2.58 to 9.92); *P*<0.001)] **(Table II)**. None of the children required hospitalization for pneumonia in both the arms. There were two deaths reported in each study arm, unrelated to pneumonia. The number of pneumonia episodes was highest in the winter season (51%).

**Table I Baseline Characteristics of Households and Under-Five Children Enroled in the Study**

| *Characteristics* | *Intervention arm n=1448* | *Control arm n=1374* |
|---|---|---|
| *Household characteristics* | | |
| Joint family | 871/1448 (60.2) | 812/1373 (59.1) |
| Hindu religion | 1278/1448 (88.3) | 1166/1374 (84.9) |
| SC/ST caste | 387/1448 (26.7) | 333/1374 (24.2) |
| Literate mother | 1295/1367(95.7) | 1334/1413(94.4) |
| Overcrowding[a] | 906/1444(62.7) | 839/1371 (61.2) |
| Inadequate ventilation[b] | 1349/1408 (95.8) | 1289/1315 (98.0) |
| Smoking indoor | 33/1442 (2.3) | 52/1368 (3.8) |
| Unclean fuel[c] | 149/1448(10.3) | 277/1374(20.2) |
| *Child characteristics* | *n*=1747 | *n*= 1924 |
| Male sex | 925/1747(52.9) | 1014/1924(52.7 ) |
| Age (y)[d] | 2.38 (1.36) | 2.39 (1.37) |
| Birthweight (kg) | 2.51 (0.61) (*n*=293) | 2.72 (0.60) (*n*=371) |
| Received colostrum[e] | 313/330 (94.8) | 333/370 (90.0) |
| Exclusive breast-feeding till 6 mo | 86/172 (46.0) 309/335 (92.2) | 111/249 (44.4) 296/304 (97.4) |
| Fully immunized[f] | | |
| *Nutritional status of the child*[g] | | |
| Wasting | 295/1678 (17.5) | 309/1852 (16.7) |
| Stunting | 720/1685 (42.7) | 916/1878 (48.8) |
| Undernutrition | 565/1693 (33.3) | 694/1864 (37.2) |

*Date presented as number/total number (%). [a]Number of family members per room criteria was used; [b]Inadequate ventilation was defined as households with less than 100 sq. ft. of floor area per person with, or without a fan; [c]Unclean fuel included biomass, coal stove, stove with kerosene for cooking purposes for most of the days of the week by the household; [d]This information was collected from mothers of infants upto one year of age only to remove the possibility of recall bias, and the intention was to assess the most essential i.e., primary immunization; [e]Information was analyzed for infants between >6 mo to one year of age only; [f]Immunization information was analyzed for children with cards and aged between 12-23 months. [g]WHO classification was used; results presented for <-2SD. Child characteristics are based on children enrolled during baseline phase only.*

**Table II Episodes of Common Illnesses in the Intervention and Control Groups**

| *Illnesses/action taken* | *Intervention arm, n=1747* | | *Control arm, n=1924* | | *RR(95% CI)* | *P value* |
|---|---|---|---|---|---|---|
| | *Number of episodes* | *Incidence (per child per y)* | *Number of episodes* | *Incidence (per child per y)* | | |
| Total illness episodes documented /total visits | 5505/39391 | 13.98 | 6436/40288 | 15.97 | — | — |
| Pneumonia | 44 | 0.80 | 31 | 0.48 | 1.66 (1.05 to 2.62) | 0.030 |
| Cold/cough | 2738 | 49.74 | 2770 | 43.0 | 1.15 (1.11 to 1.20) | <0.001 |
| Diarrhea | 128 | 2.32 | 242 | 3.76 | 0.62 (0.50 to 0.76) | <0.001 |
| Vomiting | 52 | 0.94 | 88 | 1.37 | 0.69 (0.49 to 0.97) | 0.03 |
| Contacting a HCP[a] | 41/44 | - | 7/31 | - | 5.06 (2.57 to 9.92) | <0.001 |

*Symptoms were assessed from mothers of the children,only pneumonia was diagnosed using IMNCI criteria. [a]Contacting a health care provider as a first action taken in case of pneumonia episodes.*

Out of all the episodes of illness, diarrhea contributed to 2.32 and 3.76 episodes per child per year in the intervention and control arm, respectively ($P$ <0.001).

## DISCUSSION

Our study shows that the incidence of all illnesses taken together, was significantly less with BCC intervention. The low incidence of pneumonia in both the arms of the study was comparable to that reported in South East Asian countries [10,13]. This low incidence may reflect the fact that Maharashtra has better health indicators, compared to other states of India [14]. A three-year follow-up study completed in 2008 in a Southern state of India reported an incidence rate of 0.4 (95% CI=0.3-0.7) in its first year [15]. However, the incidence of pneumonia in the current study was higher in children less than one year of age compared to those in 1-5 year age group, similar to the findings reported by other studies [16,17].

Like other studies, the fortnightly follow-up visits in the current study, for one calendar year, took into account the seasonal variation in the incidence of pneumonia [18,15]. Possibly, a more extended follow-up period or revisiting the clusters after a gap of two years might be required to observe benefits from these activities on health outcomes [19]. Though the WHO IMNCI tool for confirming pneumonia lacks specificity, it is the best measure of reporting pneumonia in children under five years of age [20]. The possibility of overdiagnosis of pneumonia by non-physician healthworkers was addressed by confirmation of these episodes by an expert. The seasonal trend of pneumonia in the current study was similar to those reported by other studies [15,21,22].

The care-seeking pattern for illness was similar in both groups with the commonest healthcare provider contacted being private practitioners. These findings are similar to other studies in India [23-26]. The current study reported fewer hospital admissions for pneumonia compared to other studies in India [15]. It may be due to early case detection and ambulatory management of pneumonia. Another study from India had concluded that trust in the public health system is essential for making the community-based pneumonia management program successful [27].

The overall morbidity and diarrheal episodes during follow-up were less than other studies in India [20]. The incidence of pneumonia was slightly higher in the intervention than the control arm, probably reflecting higher reporting by mothers about illness episode in their children in the intervention arm than in the control arm. There were significantly fewer diarrhea episodes in the intervention arm than in the control arm.

The current study has the potential for generalizability as the community health workers i.e., ASHA and anganwadi workers, were involved in surveillance visits. Routinely, ASHA and Anganwadi workers deliver incentive-based maternal and child health - related work, but in this trial, they received surveillance-related training, enabling them to timely identify sickness in a child as recommended by WHO [28]. It also helped to gain cooperation from mothers and other family members. However, external validity is limited to states with similar health parameters. BCC may be valuable in states with high under-five mortality, but further studies need to be conducted in these states. The limitation of the present study was a relatively short follow-up duration, which may be inadequate to observe the impact of BCC activities.

BCC alone is unlikely to be effective for the reduction of the incidence of pneumonia. The reduction in the incidence of pneumonia is influenced by factors such as economic status, birthweight, overcrowding, joint family, type of fuel, etc. So, intervention in the form of BCC activity may need support of additional strategies to reduce the incidence of pneumonia.

**WHAT IS ALREADY KNOWN?**

- Behavior change communication (BCC) interventions, alongwith efforts towards improving the immunization status of children and breastfeeding promotion, are documented to be efficient, cost-effective, and sustainable interventions in reducing the burden of childhood pneumonia.

**WHAT THIS STUDY ADDS?**

- BCC intervention alone, aimed towards mothers, was not found to be sufficient to reduce the incidence of pneumonia in under-five children.

**Acknowledgments**: Dr Nandini Malshe for her technical inputs.Mrs. Aruna Deshpande, Mr Sane, Statistical consultant; Mrs. Mahima Dwivedi and Dr. Supriya Phadnis, Project coordinators for their inputs in project implementation and report compilation; Dr. V N Karandikar, Ex-Director Health Sciences of Bharati Vidyapeeth University Pune; Dr. Manoj Das, INCLEN Trust International for technical guidance.

*Ethics clearance*: Bharati Vidyapeeth Deemed University Institutional Ethics Committee; No. ECR/313/Inst/MH/2013/RR-16 dated February 16, 2015. Bharati Vidyapeeth Deemed University Medical College and Hospital IEC, Sangli; No. ECR/276/Inst/MH/2013/RR-16 dated March 01, 2015.

*Contributors*: JG, PD, PP, GD, SL: conceptualization; JG, PP, GD: data curation; JG, PP, GD, PD: formal analysis; JG, SK, PD: funding acquisition; JG, PD, PP, GD: methodology; JG, GD, PP, SP: project administration; SL, JG, PD: resources; PP, VW: software; SQ, SM, RP, VW, RD, KR, SP: supervision; JG, PD, SL: validation; JG, PP: writing – original draft preparation; JG, PD: Writing – review and editing. All authors approved the final version of manuscript, and are accountable for all aspects related to the study.

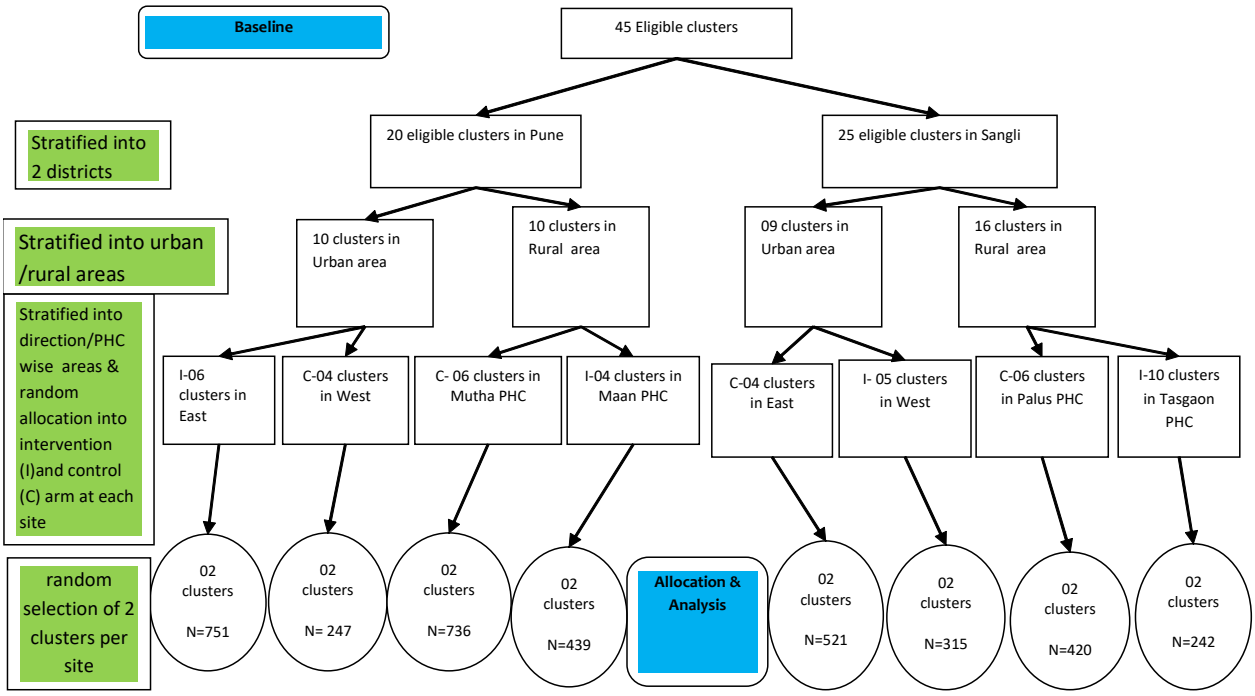
*Funding*: This work was supported by Bill and Melinda Gates Foundation through The INCLEN Trust International (Grant number: OPP1084307). The funding source had no contribution in study design, implementation, collection and interpretation of data and report writing. *Competing interest*: None stated.

*Note*: Additional material related to this study is available with the online version at *www.indianpediatrics.net*

## REFERENCES

1. Million Death Study Collaborators. Causes of neonatal and child mortality in India: a nationally representative mortality survey. Lancet. 2010;376:1853-60.
2. Rudan I, O'Brien KL, Nair H, et al. Epidemiology and etiology of childhood pneumonia in 2010: Estimates of incidence, severe morbidity, mortality, underlying risk factors and causative pathogens for 192 countries. J Glob Health. 2013;3:010401.
3. Watt JP, Wolfson LJ, O'Brien KL, et al. Burden of disease caused by Haemophilus influenzae type b in children younger than 5 years: Global estimates. Lancet. 2009; 374:903-11.
4. Farooqui H, Jit M, Heymann DL, Zodpey S. Burden of severe pneumonia, pneumococcal pneumonia and pneumonia deaths in Indian states: Modelling based estimates. PLoS One. 2015;10:1-11.
5. Walker CLF, Rudan I, Liu L, et al. Global burden of childhood pneumonia and diarrhoea. Lancet. 2013; 381:1405-16.
6. Cohen AL, Hyde TB, Verani J, Watkins M. Integrating pneumonia prevention and treatment interventions with immunization services in resource-poor countries. Bull World Health Organ. 2012;90:289-94.
7. Mull DS, Mull JD, Kundi MM, Anjum M. Mothers' perceptions of severe pneumonia in their own children: a controlled study in Pakistan. Soc Sci Med. 1994;38:973-87.
8. Qazi S, Aboubaker S, MacLean R, et al. Ending preventable child deaths from pneumonia and diarrhoea by 2025. Development of the integrated global action plan for the prevention and control of pneumonia and diarrhoea. Arch Dis Child. 2015;100:S23-8.
9. Van Ginneken JK, Lob Levyt J, Gove S. Potential interventions for preventing pneumonia among young children in developing countries: promoting maternal education. Trop Med Int Health. 1996;1:283-94.
10. Ghimire M, Bhattacharya SK, Narain JP. Pneumonia in South-East Asia region: Public health perspective. Indian J Med Res. 2012;135:459-68.
11. Government of India. Census of India 2011 [Internet]. Accessed October 5, 2020. Available from: *https://censusindia.gov.in/2011-common/censusdata2011.html*
12. Park K. Park's Textbook of Preventive and Social Medicine. 24th ed. Banarasidas Bhanot publishers; 2017. p.775-76.
13. Rudan I, Tomaskovic L, Boschi-Pinto C, Campbell H. Global estimate of the incidence of clinical pneumonia among children under five years of age. Bull World Health Organ. 2004;82:895-903.
14. Ram F, Paswan B, Singh SK, et al. Improvements in maternal health in India: Evidence from NFHS-4 ( 2015-16). Demography India. 2016; 43.
15. Gladstone BP, Das AR, Rehman AM. Burden of illness in the first 3 years of life in an Indian slum. J Trop Pediatr. 2010;56:221-6.
16. Bari A, Sadruddin S, Khan A. Cluster randomized trial of community case management of severe pneumonia with oral amoxicillin in children 2-59, Pakistan. Lancet. 2011; 378:1796.
17. Luby SP, Agboatwalla M, Feikin DR, Painter J, Billhimer W, Altaf A, et al. effect of handwashing on child health: A randomized controlled trial. Lancet. 2005;366:225-33.
18. Lanata CF, Rudan I, Boschi-Pinto C, et al. Methodological and quality issues in epidemiological studies of acute lower respiratory infections in children in developing countries. Int J Epidemiol. 2004;33:1362-72.

19. Boone P, Elbourne D, Fazzio I, et al. Effects of community health interventions on under-5 mortality in rural Guinea-Bissau (EPICS): A cluster-randomized controlled trial. Lancet Glob Health. 2016;4:e328-35.
20. Mortimer K, Ndamala CB, Naunje AW, et al. A cleaner burning biomass-fuelled cookstove intervention to prevent pneumonia in children under 5 years old in rural Malawi (the Cooking and Pneumonia Study): A cluster randomized controlled trial. Lancet. 2017;389:167-75.
21. Montella S, Corcione A, Santamaria F. Recurrent pneumonia in children: A reasoned diagnostic approach and a single centre experience. Int J Mol Sci. 2017;18:296.
22. Smith KR, Samet JM, Romieu I, Bruce N. Indoor air pollution in developing countries and acute lower respiratory infections in children. Thorax. 2000;55:518-32.
23. Minz A, Agarwal M, Singh JV, Singh VK. Care seeking for childhood pneumonia by rural and poor urban communities in Lucknow: A community-based cross-sectional study. J Family Med Primary Care. 2017;6: 211-7
24. Soni A, Fahey N, Phatak AG, et al. Differential in healthcare-seeking behavior of mothers for themselves versus their children in rural India: Results of a cross sectional survey. International Public Health Journal. 2014;6:57.
25. Bhandari N, Mazumder S, Taneja S, Sommerfelt H, Strand TA. Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNCI) programme on neonatal and infant mortality: cluster randomized controlled trial. BMJ. 2012;344:e1634
26. 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;13:1-0.
27. Awasthi S, Nichter M, Verma T, et al. Revisiting community case management of childhood pneumonia: Perceptions of caregivers and grass root health providers in Uttar Pradesh and Bihar, Northern India. PLoS One. 2015;10:1-18.
28. Revised WHO Classification and Treatment of Pneumonia in Children at Health Facilities: Evidence Summaries. World Health Organization; 2014. Accessed on Oct 5, 2020. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK264162/*




**Web Figure 1** Cluster flow diagram