Reduction in pneumonia mortality and total childhood mortality by means of community-based intervention trial in Gadchiroli, India

ABHAY T. BANG RANI A. BANG O. TALE P. SONTAKKE J. SOLANKI R. WARGANTWAR P. KELZARKAR

In a community-based intervention trial to reduce childhood mortality from pneumonia the intervention area included 58 villages (6178 children aged 0-4 years) and the control area 44 villages (5947 children) in Gadchiroli, India. The interventions included mass education about childhood pneumonia and case-management of pneumonia by paramedics, village health workers, and traditional birth attendants (TBAs) who were trained to recognise childhood pneumonia and treat it with co-trimoxazole. Parents sought treatment, and coverage was 70% without active case-detection efforts. The case-fatality rate among the 612 cases treated by health workers was 0.8%, compared with 13.6% in the control area. After a year of intervention pneumonia-specific childhood mortality was significantly lower in the intervention than in the control area (8.1 vs 17.9 deaths per 1000 children under 5 years); the difference between the areas was greatest in children under 1 year. The differences in infant mortality (8.9 vs 12.1 per 1000) and total under-5 mortality (28.5 vs 40.7 per 1000) were highly significant. Mortality from other causes remained similar in the two areas but neonatal mortality due to birth injury and prematurity was significantly lower in the intervention area, presumably owing to the combination of better maternal and neonatal care by the TBAs trained in the project and the availability of treatment for pneumonia. The cost of co-trimoxazole was US $0.025 per child per year (62-64 per child saved).

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Introduction

Pneumonia accounts for more than 25% of deaths in children under 5 years (about 4 million deaths per year), two-thirds of these occur in infancy and more than 90% in developing countries. Although the incidence of upper respiratory infections in children is similar in the developed and the developing countries, the mortality from lower respiratory infections is at least thirty times greater in the developing countries. Since pneumonia accounts for most of these deaths, we have taken it as a practical equivalent of acute lower respiratory infections. The most common causative organisms of pneumonia in children are Streptococcus pneumoniae and Haemophilus influenzae. After a report on detection and treatment of pneumonia in children by medical auxiliaries the World Health Organisation recommended this case-management approach for further research. The findings that a respiratory rate of more than 50 per min is a reliable criterion for diagnosis of pneumonia in a child with cough and that careful observation of respiratory rate and movements is generally more reliable than auscultation with a stethoscope in assessing the severity of respiratory infection in children suggested the possibility of training non-physicians in the case-management of childhood pneumonia in rural areas. The technical advisory group of the WHO has recently reviewed the results of seven studies (two published and five unpublished) which have used a case-management approach to control childhood mortality from pneumonia. They identified three types of limitations of these studies: in the absence of active case-detection of pneumonia by periodic household visits to all children by the health worker, results were poor; simultaneous introduction of other interventions (control of diarrhoeal diseases, immunisation, nutritional care, treatment of malaria) made it difficult to evaluate the usefulness of the case-management approach; and though the rate of deaths from pneumonia fell, the infant mortality rate did not fall significantly or could not be measured. Thus, proof of the usefulness of case-management in reducing childhood mortality in rural populations has been lacking. Neonatal pneumonia and neonatal mortality have remained the main problems without effective solutions.

In this study we have tried to overcome most of these limitations. We studied the morbidity and mortality from acute respiratory infections in children under 5 years old in a rural area and aimed to develop a feasible and effective population-based intervention to reduce pneumonia mortality by at least 30% in 2 years by means of the case-management approach.

Subjects and methods

The study was carried out in the Gadchiroli district, in the central part of India. This is an underdeveloped area with low income, low rates of literacy, and poorly developed health services provided by the Government through one primary health centre for approximately 20,000 people. One male and one female paramedic worker per 3000 population provided the rural outreach. The Government agreed to allow SEARCH (Society for Education, Action and Research in Community Health) to carry out the population trial involving the paramedic workers of the primary health centre in the intervention against childhood pneumonia.

The necessary sample size was calculated to be 4000 children aged 0-4 years for 2 years in the intervention and control areas (\(x = 0.05\), two-tailed, baseline proportion of children dying of pneumonia \(= 0.01\), minimum difference to be detected = 0.10). Assuming 13% of the population to be under 5 years old, the total population needed in each area was 32,000.

A contiguous area of 120 villages previously not served by SARCHI was selected in the study area. Within an area covered by two primary health centres, one designated as the intervention area, since the area served by one primary health centre was insufficient to provide the necessary sample size. The intervention area therefore had a larger than necessary population. Two parts of the study area, on either side of the intervention area, were designated the control areas. Since primary health centres in the control area were not involved in the trial, it did not have to correspond to a primary health centre area, and could be limited to the necessary sample size. The intervention and control areas were similar in their socioeconomic characteristics and health services and were a continuous area except for "buffer" areas of a few villages.

A preliminary census of both areas was carried out in August 1987, with the help of 200 village volunteers, 43 of whom were selected for further work with the project as part-time village health workers (VHWs, 22 intervention area, 18 control area). Each VHW had to average 2000 people in 2-4 villages to look after. They carried out a register census in December 1987, and prepared a population register and list of children under 5 years old in each village. All births and deaths of children under 5 years of age were recorded by the VHWs; they were paid for each recorded and verified birth or death. In addition to this prospective recording, a house-to-house survey was conducted every 6 months by the VHWs from another villager to detect missed births and deaths. These two methods together provided 98% complete reporting of births and childhood deaths in the intervention and control areas; the estimate of 2% missed was made by the Chandrasekhar-Dasgupta method.

Field supervision at the 12-weekly intervals were carried out in the two areas. Supervision involved each VHW every 15 days. They verified all births and childhood deaths and carried out an inquiry about the cause of death by means of a pretested, structured questionnaire. This method (called verbal autopsy) was developed in the Nampapalai project to determine the cause of childhood death where medical certification of death is non-existent. Since then, various symptoms have been evaluated for making simplified diagnosis of illness and illness with a physician's diagnosis as the gold standard. A method of determining the cause of death has been validated in the UK and widely used in various field studies of childhood pneumonia and childhood mortality.

The supervisors practiced this technique on children in hospital for 4 weeks before using it in the field. A physician (A.G.) went through the recorded protocols and in discussion with the supervisors, decided the cause of death. A minimum list of causes of childhood death was prepared from the WHO guidelines. The final diagnosis of the cause of death was confirmed after discussion by the supervisors.

The criteria for diagnosing pneumonia as the cause of death was taken as cough and at least 3 continuous, noncoughing, nonnasal, nonnasal-stuffy, nonnasal-sneezing, nonnasal-stuffy, nonnasal-sneezing, nonnasal-stuffy, nonnasal-sneezing, nonnasal-stuffy, nonnasal-sneezing, nonnasal-stuffy, nonnasal-sneezing, nonnasal-stuffy, nonnasal-sneezing, nonnasal-stuffy, nonnasal-sneezing, nonnasal-stuffy, nonnasal-}
TABLE III—EXPECTED NUMBER OF PNEUMONIA CASES AND PROPORTION TREATED IN INTERVENTION AREA

<table>
<thead>
<tr>
<th>Age</th>
<th>No. of Children</th>
<th>Pneumonia cases (per child year)</th>
<th>Expected no. treated</th>
<th>No. treated</th>
<th>Coverage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 yr</td>
<td>704</td>
<td>0.44</td>
<td>312</td>
<td>238</td>
<td>71</td>
</tr>
<tr>
<td>1-4 yr</td>
<td>6172</td>
<td>0.38</td>
<td>4812</td>
<td>3186</td>
<td>66</td>
</tr>
<tr>
<td>5-9 yr</td>
<td>6170</td>
<td>0.23</td>
<td>2802</td>
<td>1905</td>
<td>68</td>
</tr>
<tr>
<td>10-14 yr</td>
<td>6170</td>
<td>0.12</td>
<td>500</td>
<td>450</td>
<td>90</td>
</tr>
</tbody>
</table>

*Percent mortality rates calculated from no. of children and pneumonia attack rates. Percentage of expected attacks treated.

Cough* produced by the WHO and a health caravan (Women’s Health and Awareness Team) organized by SEARCH in which 25,000 people took part.

For the case-management of pneumonia 30 paramedics from Government primary health centers and 25 VHWSs in the intervention area were trained to diagnose and treat pneumonia in children. The experience was encouraging but their outreach was not adequate and case-management did not become available in about half of the villages. Moreover, in the neonatal period, when most deaths occurred, children were inaccessible because traditionally parents never take newborn infants out of the home, even if it is sick. Only the TBAs lying in each village and who acquired rudimentary knowledge and who were trained in pneumonia case-management. Eighty TBAs almost all illiterate, were trained in the intervention area. They showed keen interest, because they were being offered a lucrative role for the first time, and trained functioning from January 1989. No active case-detection of pneumonia by house visiting was done and no incentives were offered for case-management.

Pneumococcal and VHF were treated to manage children with cough by means of the algorithm suggested by WHO. A respiratory rate of 50 per minute or more in a child with cough was used as the diagnostic criterion for pneumonia, which was treated with co-trimoxazole syrup. Children with clinical inattention, unconsciousness, fits, or inability to drink were referred to hospital, although no special referral care was provided by the project. The TBAs could not count up to 50, so they were trained to use their visual impression of tachypnoea and difficult breathing, which was made more precise by demonstrating pneumonia cases and by the video film. The TBAs had been trained to carry out safe deliveries in a nationwide Government programme 11 years earlier, but this training was repeated and reinforced in the intervention villages.

A case-record was developed which guided the workers in history-taking, examination, diagnosis, and choice of treatment. It was a powerful tool and reduced errors substantially. Paramedics and VHWSs filled in a case-record whenever they treated pneumonia, but the illiterate TBAs could not use the case-record. Supervisors visited the children treated by TBAs about 15 days later, verified the correctness of the diagnosis and treatments, inquired about the outcome and any side-effects, and filled in the case-record. Entries made by the TBAs or parents were also recorded.

Co-trimoxazone in 50 ml bottles (Locett, Vadodara) was given to children with pneumonia. The advice was half a teaspoonful twice a day for 7 days in children under 6 months and one teaspoonful twice a day for 5 days in children aged 6 months–1 year. Pneumococcal cultures were given for those above 37.7°C and cuff=

TABLE IV—CASE-FATALITY RATES IN TREATED AND UNTREATED CHILDREN WITH PNEUMONIA

<table>
<thead>
<tr>
<th>Pneumonia cases</th>
<th>Control area</th>
<th>Intervention area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposed</td>
<td>513</td>
<td>820</td>
</tr>
<tr>
<td>Treated by health workers</td>
<td>69</td>
<td>50 (50% treated)</td>
</tr>
<tr>
<td>Pneumococcal strept</td>
<td>69</td>
<td>50 (50% treated)</td>
</tr>
<tr>
<td>Case-fatality rate</td>
<td>50/513 (15.5%)</td>
<td>50/820 (6.2%)</td>
</tr>
<tr>
<td>All cases</td>
<td>50/513 (15.5%)</td>
<td>50/820 (6.2%)</td>
</tr>
<tr>
<td>Treated by health workers</td>
<td>-</td>
<td>45/513 (90.4%)</td>
</tr>
<tr>
<td>Not treated by health workers</td>
<td>-</td>
<td>45/509 (24.6%)</td>
</tr>
</tbody>
</table>

*Denominator is expected cases minus those treated by house staffs.

A number of studies in this area for neonatal and infant mortality showed that in most areas the survival rate for children aged 0-6 months was less than 60% and infant mortality was 100%. In this study, the survival rate for children aged 0-6 months was 70% and infant mortality was 80%.

TABLE V—CHILDHOOD MORTALITY RATES IN CONTROL AND INTERVENTION AREAS

<table>
<thead>
<tr>
<th>Age group</th>
<th>Control area</th>
<th>Intervention area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death rate (rate per 1000)</td>
<td>332/1000 (33.2%)</td>
<td>304/1000 (30.4%)</td>
</tr>
<tr>
<td>Death rate</td>
<td>304/1000 (30.4%)</td>
<td>256/1000 (25.6%)</td>
</tr>
</tbody>
</table>

*Difference in mortality rate between control and intervention areas significant at the 5% level.

**Results**

The control and intervention areas were similar in relevant characteristics (table I).

In the mortality study in 602 children (July 1989–June 1989) the attack rate of upper respiratory infections (cough or nasal discharge) was 6–9 per child per year (95% confidence interval [CI] 5–6) and that of pneumonia was 0.13 (95% CI 0.0–0.5) per child per year. There was no significant difference in these rates between the control and intervention areas between infants and 1–4-year-old children (0.14 (95% CI 0.0–0.5) per child per year). Owing to its short duration and the difficulty of access, the neonatal period was under-represented in these observations, which might have caused an underestimate of pneumonia attack rate in infancy.

The case-fatality rate in the treated cases of pneumonia in intervention area was very low (0%) and the outcome of treatment by the three types of workers was comparable (table III). The number of cases treated by TBAs was small, partly because they were introduced late in the programme.

Table II gives coverage (percentage of estimated pneumonia cases treated) by the health workers. There was excess coverage (146%) in infancy which may be due to oversaturation of infants or an underestimation of attacks among infants in the mortality study. The estimated number of pneumonia attacks, actual deaths from pneumonia, and the case-fatality rates in the control and intervention areas are summarised in table IV.

The effect of the case-management intervention on childhood mortality rates in different age groups is summarised in table V. The rates were significantly lower in intervention than control areas in all age groups except 3–4 years. There were significant differences between intervention and control areas in cause-specific mortality rates (CSMR) for pneumonia, birth injury, prematurity/ small baby, and bleeding disorders in newborn infants but not for other causes (table VI). Bleeding in newborn infants is...
often a sign of prematurity or infection such as pneumonia. The very low CSMR for measles, whooping cough, and tetanus in both areas may be due to good immunisation coverage as a part of universal immunisation programme which is in operation in the whole district. The training of TBAs in both areas for hygienic delivery in 1980 and immunisation of pregnant women may account for the low rates of tetanus.

The difference between the control and intervention areas in the CSMR for pneumonia (0.4 per 1000 children) accounts for 77% of the difference in total mortality among children under 5 years (4.07 vs 2.85 per 1000 children = 12.2/1000).

The decline in pneumonia CSMR is further examined in different age groups in table VII. It was significantly lower in the intervention area than the control area in all age groups except 1-4 years. The percentage difference in pneumonia CSMR was similar when only one primary cause of death was included (table VIII) rather than primary and additional cause of death.

The cost of co-trimoxazole used in 1 year was 2600 Rupees ($33). For other costs it is difficult to break expenditure down into research and server costs. The cost of co-trimoxazole was 2.47 cents per child aged 0-4 years in the intervention area, 2.8 cents per pneumonia case treated, and 2.54 per pneumonia death prevented.

No case of drug reaction to co-trimoxazole was recorded even after active inquiry. No adverse effects were seen even in newborn infants. Bronchial asthma in 0-4-year-old children was safely and effectively treated by paracetamol and VHF's except one case of overdose of salbutamol. TBAs did not treat asthma.

**Discussion**

In this intervention study a high level of community awareness about childhood pneumonia was generated. Without any active case-detection effort by the project, parents sought early care for a child when they suspected pneumonia. The involvement of TBAs in mass education and management of pneumonia improved outreach and access, particularly to normotensive pneumonia. An estimated 70% coverage of pneumonia cases in children was achieved. The healthworkers successfully managed cases of pneumonia with a case-fatality rate of less than 1%. Significant reductions in pneumonia-specific and total childhood mortality were obtained without other simultaneous interventions.

Since the trial used a concurrent control, to assess whether the differences in mortality were real and due to the intervention we must establish whether the intervention area had lower mortality rates than the control area at baseline. This seems unlikely, the important determinants of childhood mortality, such as socioeconomic level, female literacy, birth rate, and nutritional status of children were similar in the two geographically adjacent areas. Moreover, childhood mortality from causes such as diarrhoea, malnutrition, tetanus, meningitis, septicaemia, and fever was similar.

Can the results be attributed to the intervention? The significant difference in mortality rates between the areas was limited to pneumonia, birth injury, prematurity, and bleeding in newborn infants (table VII). The greatest absolute reduction (64/4000 children under 5 years) was in the pneumonia-specific death rate, which accounts for 77% of the difference in total childhood mortality. Improved maternal and neonatal care due to training of TBAs probably also contributed to the differences in neonatal mortality. Pneumonic case-management may also have been important in this age group because many deaths from pneumonia or birth injury are finally caused by pneumonia. The 75% difference in the CSMR for pneumonia in the postneonatal period seems to be due solely to the case-management.

Use of several causes of death (primary and additional) did not significantly affect the mortality analysis (table VIII). We believe that several causes should be used rather than a single cause. In special studies, when the investigator is particularly interested in one disease, selection of one cause at the primary or underlying cause of death can be biased. For example, in two studies on childhood mortality in Bangladesh, one on deaths from malnutrition and diarrhoea attributed only 6% of deaths to pneumonia, whereas the other attributed only 2% of deaths to pneumonia.

The first important element in our approach was to generate awareness in the community by external health education and community participation. Use of local terms...
to describe tachypnoea and difficulty in breathing ensured early and prompt intervention. Successful management of cases of pneumonia by the health workers increased the popularity of the programme. The outreach of the programme was greatly improved by the involvement of three types of workers: on average there were 2.3 providers of treatment per village. Combining intervention against pneumonia with better maternal and neonatal care by TBAs enhanced the access to pregnant women and newborn infants. Special training methods for VHWs and TBAs, educational supervision, and continued training ensured good quality care even in very low case-fatality rates. The project ensured an uninterrupted supply of medicines so that patients need not be turned away. The successful management of pneumonia by workers and TBAs greatly increased the demand for the services. Some rural medical practitioners began referring cases of childhood pneumonia to TBAs and VHWs. Some reasons for our success were not related to medical technology but to less visible factors. The project offered the health workers and TBAs dignity and respect. The professionals in the project sat on the ground, ate meals, sung and danced with the workers, and treated them as equals. A hierarchical or autocratic organisational structure may not produce a good performance from the village workers.

Despite the significant reduction in neonatal pneumonia mortality, it remains the major problem. 31 of 50 pneumonia deaths in the intervention area were in newborn infants. The high case-fatality rate (25.6%) in unvaccinated children (table IV) suggests that the residual mortality is in high-risk groups, such as newborn infants and the poorest or most isolated families, who do not or cannot seek care. The diagnostic criteria for neonatal pneumonia are far from satisfactory and need to be improved.

The sample size was not designed to provide significant results in age subgroups which may explain why the difference in pneumonia morality in children aged 1–4 years between the intervention and control areas was not significant. Coverage was lower in this age group than in infants, possibly because the diagnostic criteria of 50 breaths per min for pneumonia is sensitive in infants but not in toddlers, and workers may have missed many cases of pneumonia in children aged 1–4 years. New criteria of 50 breaths per min for newborn infants, 50/min for infants, and 40/min for children of 1–3 have been suggested.18 Such a change may improve coverage and outcome in children of 1–4 years and may reduce the false-positive rate and overtreatment among infants.

The literacy of TBAs necessitated special training and supervision. They did make many errors at first, but the error rate was gradually reduced with continued education and corrective supervision. Some cases of unnecessary use of co-trimoxazole in upper respiratory infection by TBAs were noted. Their inability to count up to 50 prevented their using the respiratory rate as the main diagnostic criterion. We have developed an instrument to enable TBAs to count respiratory rate. It is being field tested. More experience and data on TBAs need to be collected.

The cause of death and morbidity data were depended on the type of data given to the rural workers. The diagnosis of pneumonia as a cause of death may be less than precise, especially in newborn infants. This difficulty does not pose a problem, as long as most studies on pneumonia and childhood mortality have used the same method.19,20 Various studies of morbidity in the past 5 years are strong evidence that the parameter's history alone can be used to diagnose the illness or cause of death.21,22,23 An explanation of the meaning of the terms used by people in our area was helpful in improving precision.

Long-term careful observation will be necessary to see whether the fall in total childhood mortality is maintained or lost owing to replacement mortality or the emergence of antibiotic resistance.

Our approach is replicable in other developing countries because the problem is universal. The approach depends upon health workers who are part of virtually all primary health care programmes. The dignity of these workers and democratic relationships are crucial to the successful implementation of this approach. The results will be better if the intervention is combined with maternal care and supplementation as a part of community-based primary health care.

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