

An External Evaluation on the INCLEN Research Program to Emphasize the Public Health Significance of Childhood Pneumonia in India

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Objective: An independent external evaluation of the International Clinical Epidemiology Network (INCLEN) research program to emphasize the public health significance of childhood pneumonia in India. **Method:** An independent evaluation based on desk reviews of available documents and reports, site visits to study sites, and structured interviews with study investigators, technical advisory group (TAG) members, INCLEN staff and the donor agency. **Findings:** The program elicited responses from a range of investigators across India. The selection process was transparent and objective, and the selected projects were of public health significance. The support provided through the program strengthened research capacity and improved study outputs. However, the available expertise was not fully exploited and protocol deviations in a few studies resulted in suboptimal outputs. **Conclusions:** The program represented a new and positive paradigm for research support in India, though a few improvements may result in greater impact for future programs.

Keywords: Assessment, Child Health, Health Program, Respiratory infection.

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The International Clinical Epidemiology Network (INCLEN) established a research program to emphasize the public health significance of childhood pneumonia in India [1]. A grant from the Bill and Melinda Gates Foundation (BMGF) was used to provide catalytic funding to Indian investigators to conduct research to generate data of public health importance on childhood pneumonia in India. In addition to financial support, the program also provided technical support to improve the design, management and implementation of the research studies through two expert bodies, the Joint Working Group (JWG) and the Technical Advisory Group (TAG). The JWG consisted of 14 national and international experts who guided the development of the program evaluation framework and identified the research priorities to be supported. The TAG consisted of 32 national and international experts representing different field of research. Its role was to review and select the research projects, support capacity strengthening of the study investigators and institutes, and guide the analysis and dissemination of research outputs. The INCLEN secretariat closely monitored the implementation of each study through the review of regular progress reports and quarterly phone calls with each project team.

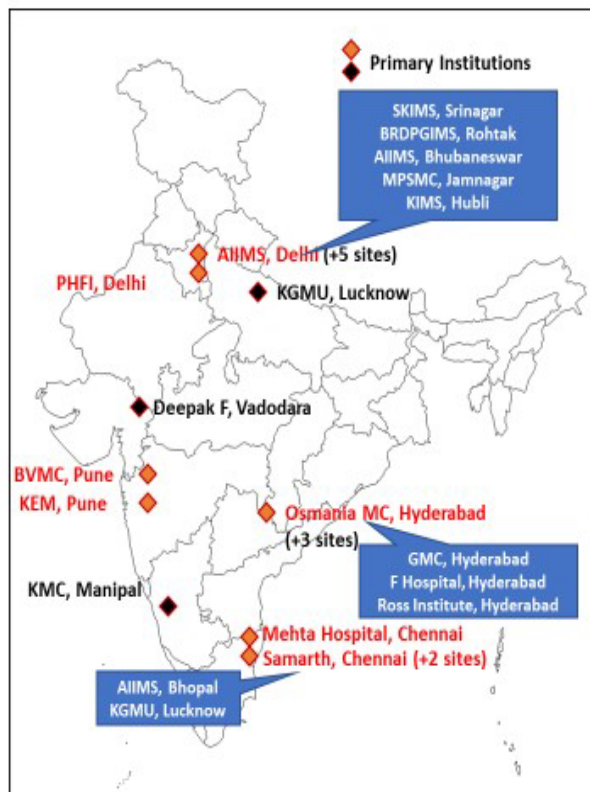
An external evaluation of the Program was conducted to obtain an independent, objective and credible assessment of the strengths and weaknesses of the

program that would help INCLEN and BMGF in making amendments to their programmatic operations, and to also enable other stakeholder and research funders to take informed decisions in supporting future research projects in India. This report briefly summarizes the methods, key findings and the recommendations from the evaluation.

METHODS

The authors of this paper were part of the three-member external evaluation team, which conducted the evaluation from 1-10 April, 2019. The evaluation focused on addressing the following four questions related to the overall program objectives: *i*) Was the research conducted under the Program of public health relevance? *ii*) Were the outputs from the Program likely to influence public health policy and programme planning and implementation? *iii*) Did the Program result in broadening of the researcher pool? *iv*) Did the Program strengthen research capacity in India?

The evaluation consisted of a desk review of all available documents and reports provided by the INCLEN secretariat, visits to seven of the ten research sites, telephone or Skype interviews with investigators at the three remaining research sites (**Fig. 1**), and interviews with a sample of TAG members, members of the INCLEN secretariat, and BMGF.



Childhood Pneumonia Program Site Visits

- 10 Projects: Combination of single site and multisite projects
- Visited 7 sites (Shown in red in the map)
- Interacted on video/teleconference with remaining 3 sites

Fig. 1 Site visits and interviews with research investigators.

FINDINGS

Based on the geographic spread and the range of investigators who responded to the Request for applications (RFA), it appears that this process was successful and achieved its objective of securing applications from around the country.

The evaluation indicated that the processes for the selection of research projects was transparent and objective for the first round of application. The choice of a single study in the second round was influenced by the funder's priorities. The process managed to draw in less-experienced investigators and strengthened their capacity to conduct high-quality research. The provision of financial support to institutions that did not have clearance from the government under the Foreign Contribution Regulation Action (FCRA) to accept international funds was a significant achievement of this program, which enabled researchers from such institutions to carry out more substantive research projects, which they may not

otherwise have been able to conduct.

All the selected proposals were of public health relevance in India. The close engagement and support provided through the JWG and TAG resulted in improved study design and implementation of most of the studies. The program also created a new paradigm for the conduct, oversight and engagement with individual research studies in India to optimize their outputs and impact. The support from the INCLEN secretariat, both technical and administrative, was greatly appreciated by all the investigators. The INCLEN secretariat also conducted a Research leadership and programme management (LAMP) workshop, which benefited many of the new researchers in the program.

The program did have a few weaknesses, primarily that the expertise of the JWG and TAG was not fully exploited. Closer engagement of these two bodies during the implementation of the Program may have resulted in better outcomes for a few of the studies. While the TAG was closely involved in the process of selection of projects and in the finalization of study design, its engagement thereafter in the monitoring process was patchy. In addition, protocol deviations or changes were not always conveyed to or endorsed by the TAG as envisaged. The monitoring by the INCLEN secretariat largely served to keep the projects on track and facilitated support for overcoming procedural bottlenecks. However, this oversight missed a few technical issues and protocol deviations that impacted the study outputs in a few projects.

Capacity strengthening was an important contribution made by the program. From all reports, the process and support provided far exceeded that provided by other national and international grant-making bodies and served in improving the design and implementation of the studies and resulted in better outputs. This was especially true for the less experienced investigators, though even the more experienced investigators reported having benefited from their participation in the program.

Of the ten research studies, seven are likely to make significant contribution to public health policy and program implementation in India. However, INCLEN may need to play a greater role in disseminating the results to policymakers and program managers to promote the translation of the study results into public health policy and practice. Four studies evaluated care-seeking behavior for pneumonia, of which two have been published [2,3]. Two of them, which were mixed-method studies, found that knowledge about pneumonia was poor and care was mostly obtained from private service providers who were not knowledgeable about pneumonia case management. Two other studies evaluated the impact of behaviour

change communications (BCC), one which looked at its impact on the incidence of childhood diseases including pneumonia and the other that combined BCC with capacity strengthening for case management in primary care facilities in the public sector. Taken together, the findings of these studies can make important contributions to improving care-seeking and the quality of care for childhood pneumonia if it is possible to translate the findings into public health practice.

A fifth study evaluated the use of high flow nasal cannula delivery of oxygen for children with pneumonia and found that the technique could be implemented in first referral level facilities could reduce the need for invasive ventilation, which is only available in tertiary care facilities. The sixth study used mathematical modelling to estimate the state level burden of pneumococcal disease and the cost-effectiveness of pneumococcal conjugate vaccine (PCV). The preliminary findings from this study informed the policy recommendations for the use of PCV in India. A seventh study, which is yet to be completed, is also likely to inform both global and national policies on the use of PCV.

RECOMMENDATIONS

The evaluation team made recommendation related to the current projects as well as for future projects supported by INCLEN; these are summarized below.

Recommendations for the Current Program

- a) Explore possibilities, in consultation with the JWG and TAG, to maximize returns from two studies which were not complete at the time of evaluation.
- b) The JWG/TAG should have a final closed meeting to review and score each project in terms of output and impact at the completion of the project and follow this up with a stakeholder meeting at national level to translate research to policy and practice.
- c) INCLEN secretariat should also facilitate engagement and advocate with state and district officials to promote translation of study findings to programmatic action, especially where site investigators are facing difficulties or did not have a dissemination plan.

Recommendations for Future Programs

- d) Consider higher weightage or special consideration to studies from under-researched areas/ populations on

topics that constitute important public health gaps.

- e) Provide only conditional approvals for proposals where TAG proposed major revisions, with final approval by TAG prior to study initiation.
- f) Provide greater oversight through TAG in study implementation, supplemented with mid-level researchers who can provide more regular handholding.
- g) Ensure that all changes in protocols are communicated to and approved by the TAG.
- h) Implement quarterly formal site audits to assess adherence to protocol, progress against defined milestones (e.g. enrolment rates) using structured checklists.
- i) Allow time and promote/ encourage networking at investigators' meetings to facilitate research collaborations.
- h) Make engagement with local level programme managers a requirement for studies with programmatic implications prior to study initiation.
- k) Make dissemination meetings a requirement for studies where the study results have a contribution to programme management.

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REFERENCES

1. Research program to emphasize public health significance of childhood pneumonia in India. 2017 [cited 2019]. Available from: <http://inclentrust.org/inclen/research-program-to-emphasize-public-health-significance-of-childhood-pneumonia-in-india/>. Accessed 17 December, 2019.
2. Awasthi S, Verma T, Agarwal M, Pandey CM. To assess the effectiveness of various communication strategies for improving childhood pneumonia case management: Study protocol of a community based behavioral open labeled trial in rural Lucknow, Uttar Pradesh, India. *BMC Pediatr*. 2018;18:279.
3. Mohanraj R, Kumar S, Jayakumar S, Agarwal M, Dhingra B, Jeyaseelan V, *et al*. Where do mothers take their children for pneumonia care? Findings from three Indian states. *PLoS One*. 2019;14:e0214331.