

## Original Article

## Alliance for surveillance of invasive pneumococcal disease in India – The ASIP Study: Design and methodology

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## ABSTRACT

Disease surveillance has been long recognized as the cornerstones for the public health decision making practices. In the regions of high childhood morbidity and mortality there is an unmet need of continued disease surveillance to identify the causes for menace. Pneumococcal surveillance in India has been heterogeneous with very few examples of attempts. Driven by the gap in the knowledge of nationwide epidemiological distribution of serotype and antibiogram pattern of *Streptococcus pneumoniae* in India we attempted to provide the most appropriate study design to establish Alliance for Surveillance of Invasive Pneumococci (ASIP) network in the country which we hope on further optimization will be of benefit to all surveillances in future. The various components of surveillance and the experienced gained are described, as the progress made in the establishment of sentinel network followed by strengthening the laboratory diagnostic abilities and the data management of each surveillance center participating. For the surveillance to play a role in public healthcare it is important that the local capacity of surveillance in terms of public health force must be developed along with support from global development partners. Also, an integrated approach must be explored for the parallel surveillance systems.

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## 1. Introduction

Invasive infections caused by *Streptococcus pneumoniae* continues to remain a major cause of childhood morbidity and mortality worldwide. According to World Health Organization (WHO) the estimated pneumococcal deaths per year is about 1.6 million, of which 1 million are children under 5 years, mostly from developing countries which makes the disease the number one vaccine-preventable cause of death in this age group.<sup>1</sup> From the public health view point, knowledge of local and regional epidemiology of the pneumococcal disease aids in the implementation of preventive strategies, the most important being the vaccination. A sound vaccination policy need to be supported by a good high quality surveillance data which further requires a constant and consistent monitoring of changes in pneumococcal serotype distribution patterns over a sufficient time period (both in pre- and post-vaccination introduction). Systematic identification

and evaluation of suspected cases, collection of clinical specimens and use of appropriate laboratory diagnostic are the key elements for good quality disease surveillance.<sup>2</sup>

Pneumococcal disease surveillances are complex and consist of four main goals (a) characterization of national and local trends, (b) detection of geographic and temporal trend of drug resistant *S. pneumoniae*, (c) monitoring impact of vaccine on the disease and (d) informing future vaccine development.<sup>3</sup> Unlike other infectious diseases determining the incidence of pneumococcal disease is relatively difficult. However, it is of prime importance for the children under 5 years as it helps identifying the population pockets that may not be receiving the vaccination and provides monitoring of the incidence of disease burden due to serotype replacements. In developing countries, there are limitations which are often encountered in pneumococcal disease surveillances which includes the diagnosis of disease etiologies, the stringent laboratory testing for *S. pneumoniae* identification, indiscriminant prehospitalization use of antibiotics prior to sample collection, variations (inter and intra) in the study methodologies, cost and other logistical constraints and above all quality of the surveillance systems. Recently published review by O'Brien suggest that India has the highest burden of pneumococcal disease worldwide (27%).<sup>4</sup> Yet, there is no comprehensive incidence data available for invasive pneumococcal disease (IPD) from India. Most of the

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information currently available are from observational and sentinel based studies.<sup>5–11</sup> However, the data generated through these studies are often fragmented and has limited usefulness to policy makers and other stake holders. This perhaps due to the differences in the choice of study populations, designs of the study and most important the heterogeneity in the case ascertainment, evaluation and enrollment methods which has resulted in compromised incidence data on the invasive disease burden in India. Hence, lacked national representation. In some studies, the disease incidence was rather underestimated due to the proportion of cases missed which were further adjusted to provide the adjusted incidence rate. Beside many studies had limited funding which is a historical problem in any disease surveillance in developing countries. Additionally, the restricted pneumococcal serotyping facilities within the country along with high cost of antisera prevented the routine use of typing studies in the clinical settings and during surveillance failing to show changes in the serotype prevalence over time.<sup>7</sup> Overall, there exist a huge gap in the epidemiological knowledge of IPD burden and pneumococcal serotype distribution among children in India which needs to be filled for the successful implementation of vaccine policy in the country.

Alliance for Surveillance of Invasive Pneumococci (ASIP) network was initiated with the aim to provide nationally representative epidemiological data on the trend of serotype distribution and the antimicrobial resistance (AMR) patterns of Invasive Pneumococcal Diseases among the children under 5 years in the country. Although the original results of the study are reported in detail elsewhere, in the present article we describe the study design undertaken in establishing and conducting the surveillance along with the challenges faced to derive the expected results in focus with the pneumococcal diseases outcome. We

believe that the lesson drawn from our experiences will be useful for considering the similar efforts in future surveillances.

## 2. Methodology

### 2.1. Study design

Between January 2011 to June 2015, Alliance for Surveillance of Invasive Pneumococci (ASIP) was conducted nationwide. The study was a prospective hospital and retrospective laboratory based multicentric, surveillance of IPD which included 18 hospitals/tertiary care teaching institutions, a sentinel network of 52 pediatricians and additional 10 sentinels/supporting microbiology laboratories participating across 10 states. The coordinating and microbiological reference center of the study was located at Infectious Diseases Training and Research Center (IDTRC), Christian Medical College, Vellore in South India. All the sites followed the same standard study protocol for clinical and laboratory procedures which was further reviewed and approved by each site's ethical review board.

### 2.2. Selection of surveillance sites

For the surveillance, institutional sites were selected based on (1) annual pediatric admissions in the hospital or tertiary care centers, (2) availability of pediatrician and microbiologist to participate in the study, (3) experience in handling sterile body fluids for isolation of fastidious organisms especially *S. pneumoniae* and (4) willingness of the institutional management in facilitating the surveillance. Sentinel sites in the study were selected based on their willingness and contribution of invasive pneumococcal isolates. Geographical and demographic representations of the

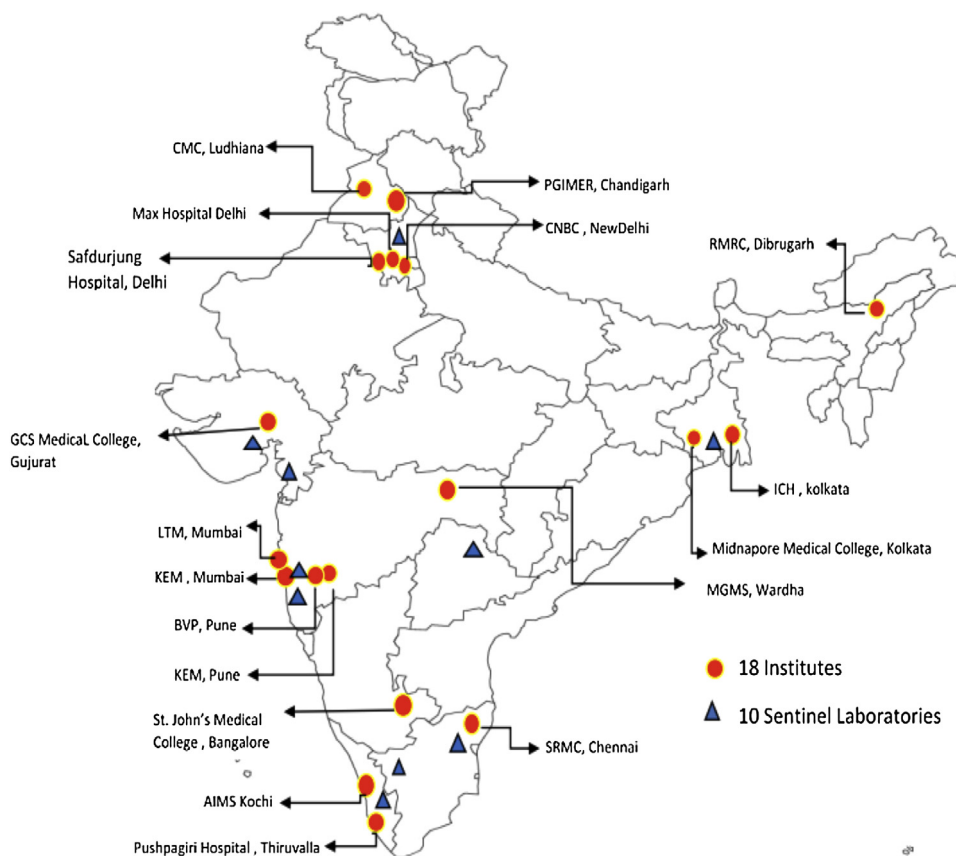


Fig. 1. Institutional and sentinel sites under ASIP surveillance.

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