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Hospital-based surveillance for radiological pneumonia in children under 5 years of age in Uttar Pradesh and Bihar

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ABSTRACT

Background and rationale: Pneumonia is responsible for about 1.4 million deaths in children under five years of age, mostly in developing countries, including India. In India, *Streptococcus pneumoniae* (SP) and *Haemophilus influenzae* (HI) are the common bacterial etiologic agents of pneumonia, and often cause abnormal chest radiology. Vaccine against HI has already been introduced in India. Pneumococcal conjugate vaccine (PCV) roll out will begin in 2017–2018 in a phased manner using Gavi funding.

Objectives:

(1) To estimate the annual incidence of radiological pneumonia in children between 2 and 59 months of age, in prespecified districts.
(2) To document the clinical and demographic characteristics of cases of WHO-defined community-acquired pneumonia (CAP) with lower chest in-drawing (LCI) and severe CAP, by establishment of hospital-based surveillance network.

Study design: In a prospective design, surveillance for WHO-defined radiological pneumonia in patients hospitalized for CAP is being done in two districts each of Uttar Pradesh and Bihar. For this, a pneumonia surveillance network of public and private hospitals has been established. Data are abstracted from hospital records. One copy of routine chest X-ray is also collected, digitalized, and archived electronically. An independent panel of radiologists interprets the X-rays. Five milliliters of urine of a subset of cases is being stored at −20 °C for future antigen testing.

In Phase I, procedures were standardized, hospital network established, and recruitments initiated from Lucknow district. This was expanded in Phase II to include Etawah district, Uttar Pradesh and Patna and Darbhanga districts of Bihar.

Progress: A pneumonia surveillance network was established, having 120 health facilities in Lucknow, 60 in Patna, 64 in Darbhanga and 17 in Etawah. From 1st January 2015 to 30th April 2016, 745 CAP cases were enrolled in Lucknow. From 1st January to 30th April 2016 Patna recruited 229, Darbhanga 321 and Etawah 80 cases. Chest X-rays of all cases have been archived for interpretation by the panel of radiologists.

Implications: Baseline incidence of radiological pneumonia in Uttar Pradesh and Bihar will be estimated and follow-up data will enable assessment of the impact of PCV introduction.

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1. Introduction

Pneumonia is responsible for about 1.4 million deaths globally in children under five years of age.[1] Most of the deaths occur in developing countries, India being one of them. Every 19 s, a child dies in India due to causes that are easily preventable, such as pneumonia, diarrhea, neonatal complications, and malnutrition. Within India, the states of Uttar Pradesh and Bihar are reporting some of the highest rates of infant and under-five mortality. Dedicated efforts are required to improve health systems in these states, as well as to focus on strategies to reduce pneumonia specific morbidity and mortality.

Annually, there are approximately 1.2 million deaths in children under 5 years of age in India, of which 27% in the state of Uttar Pradesh and 22% in Bihar are due to pneumonia.[2] This translates into about 1,09,296 pneumonia deaths annually in Uttar Pradesh or about 300 deaths per day and 12 per hour. In Bihar, there are about 40,480 pneumonia deaths annually or 100 plus deaths/day and 5 per hour. It is clear that if India is to bend the curve of pneumonia cases and deaths, success in Uttar Pradesh and Bihar is paramount.

Community-acquired pneumonia (CAP) could be of viral or bacterial etiology. The etiology varies from country to country and also across different time periods. Pediatric bacterial pneumonia is predominantly caused by *Streptococcus pneumoniae* (SP) and *Haemophilus influenzae* (HiB). Besides, there are other bacterial and viral pathogens associated with clinical cases of pneumonia, as defined by the World Health Organization (WHO).[3] Bacterial culture and molecular techniques for identification of most common pathogens, SP and HiB, are difficult and give variable yields, especially in children who have received prior antibiotic treatment. Radiological confirmation of pneumonia is more reliable and operationally easier, and when the film is interpreted by standardized procedures, it gives a good inter-rater reliability and sensitivity and specificity for diagnosing clinical pneumonia.[4,5] Therefore, radiological identification of pneumonia has been used in multiple studies worldwide as a reliable surrogate marker for bacterial etiology.[6]

The research hypothesis is that precise estimate of radiological pneumonia in children between 2 and 59 months of age will provide data for informed decision making for the introduction of pneumococcal conjugate vaccine (PCV) in India and then to assess its impact. It is also hypothesized the occurrence of radiological pneumonia among those with symptoms of CAP with lower chest in-drawing (LCI) and severe CAP in the last one year, in a specific geographical area, can be estimated through a hospital pneumonia surveillance network.

The primary objectives of this study are as follows: (a) to estimate the annual incidence of radiological pneumonia in children between 2 and 59 months of age, with CAP, as defined by WHO, residing in a prespecified district and (b) to document the clinical and demographic characteristics of cases of WHO-defined CAP with LCI and severe CAP, by establishment of hospital-based surveillance network. The secondary objectives are to estimate the annual incidence of radiological pneumonia as follows: (i) in children in age categories of 2–11 months, 12–23 months, and 24–59 months; (ii) among males and females; and (iii) in those residing in rural and urban areas; and (iv) by preserving 5 ml urine at −20 °C for future antigen testing for the cases with radiological pneumonia.

2. Study methodology

2.1. Geographic location

This project is being conducted in two North Indian States of India, Uttar Pradesh and Bihar, both of which have poor health indices. Infant mortality rate (IMR) and maternal mortality rate (MMR) in both states are higher than the national average (Table 1). Uttar Pradesh, the most populous and fifth largest state in India, is divided into 75 administrative districts. Bihar lies to the east of Uttar Pradesh. It is the third most populous state in India and is divided into 38 administrative districts.

2.2. Study site

The study sites are shown in Fig. 1. All of these sites are teaching, government medical colleges with tertiary care hospitals that have departments of pediatrics and radiology (or radio-diagnosis). KGMU, Lucknow has 170 pediatric beds, while Patna Medical College has 230, Darbhanga Medical College has 117, and Uttar Pradesh Rural Institute of Medical Science, Etawah has 70.

2.2.1. Inclusion and exclusion criteria

Included are (a) children aged 2–59 months; (b) hospitalized with symptoms of WHO-defined CAP with LCI and severe CAP; (c) residing in the prespecified district where the medical institution is situated (catchment area); (d) digital or analog chest X-ray picture available; and (e) whose parent provides consent for participation.

Excluded are those (a) whose cough and respiratory symptoms have been there for more than 14 days (to exclude tuberculosis); (b) whose pleural tap/intercostal drainage has been done prior to hospitalization (as radiological picture would have altered); and (c) who have been admitted within 14 days of discharge from a hospital facility (as they are likely to have nosocomial infections).

The study is being conducted after ethical approval of institutional ethics committee of the coordinating center and initial study site King George's Medical University (KGMU) and

Table 1
Infant mortality rate (IMR) and Birth indicators in project locations.

India/state/district	Population (million) [2011][a]	Literacy (%) [2011][a]	Infant mortality rate[b]			Crude birth rate[b]		
			Total	Rural	Urban	Total	Rural	Urban
India	1210.2	74.0	40	44	27	21.4	22.9	17.3
Uttar Pradesh	0204.2	67.7	50	53	38	27.2	28.1	23.3
Lucknow	0002.8	77.3	44	53	34	18.4	22.4	15.2
Etawah	0000.2	70.1	73	72	76	22.8	23.8	19.0
Bihar	0099.0	61.8	42	42	33	27.6	28.3	21.5
Darbhanga	0000.2	64.0	48	47	63	26.3	26.7	21
Patna	0001.6	70.6	39	46	30	21.8	25.8	18.0

Source:
[a] Census of India. Available from: http://censusindia.gov.in/2011-prov-results/paper2/data_files/india/Rural_Urban_2011.pdf [accessed 25.05.16].
[b] Sample Registration System (SRS). Registrar General India. 2013. Available from: http://censusindia.gov.in/vital_statistics/SRS_Bulletins/SRS%20Bulletin%20-Sepetember%202014.pdf [accessed 25.05.16].

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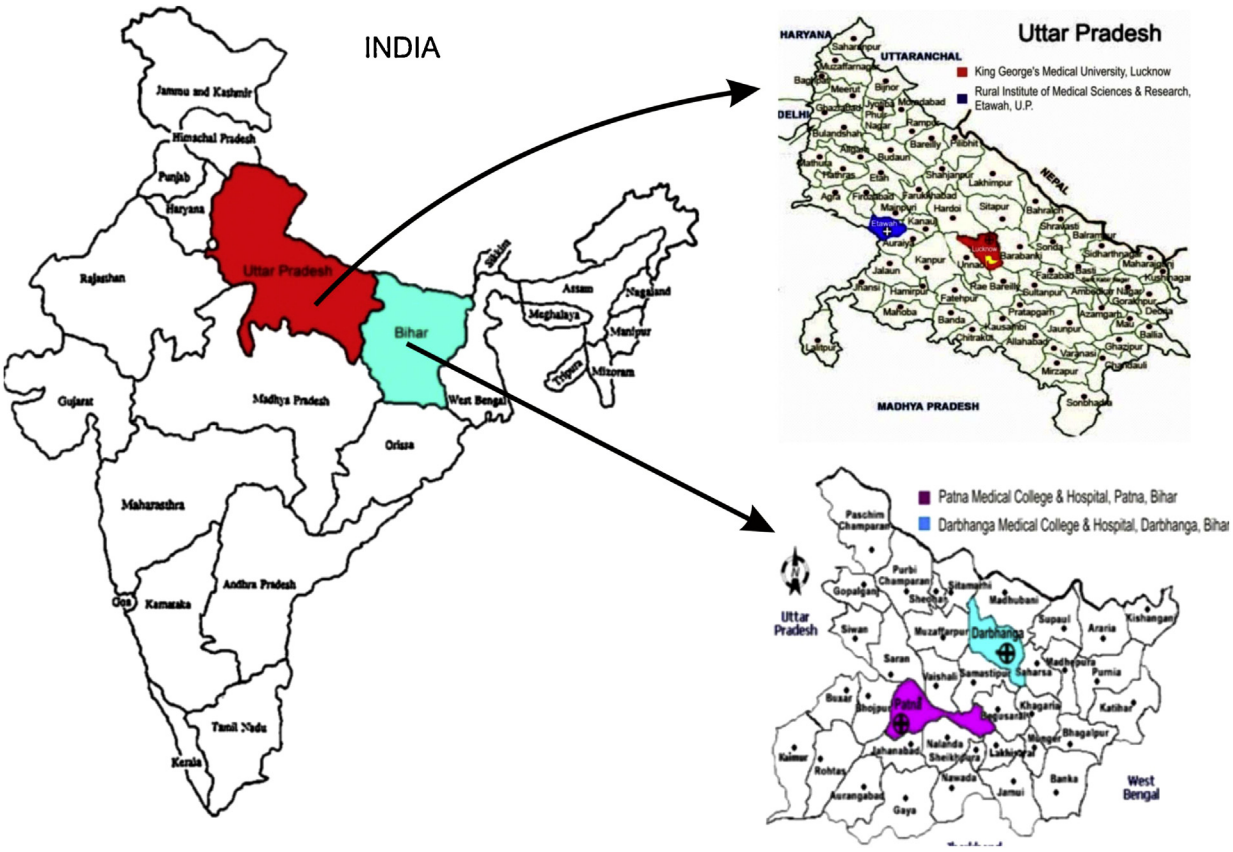

Fig. 1. Map of India showing districts participating in the project.

approval of the Health Ministry Steering Committee of the Indian Council of Medical Research, New Delhi. In Phase I, a Central Coordinating Unit (CCU) was established in KGMU for establishing linkages with the state government, local pediatricians, and association of private hospitals, as well as for the development of standard operating procedures (SOPs), data collection forms, customized, web-based data management software, equipment purchase, and other preparatory activities. Thereafter, the KGMU site established the pneumonia surveillance network of public and private hospitals and has begun recruitment in the radiological pneumonia surveillance. Five milliliters of urine sample of cases recruited from the medical college hospitals is collected and stored at −20 °C for future bacterial antigen testing.

In Phase II, after 12 months of experience in Phase I, each of the 3 additional participating sites have been initiated after approval from their respective ethics committees.

2.2.2. District pneumonia surveillance network

To ensure that most cases with CAP with LCI and severe CAP whose chest radiograph has been taken are included in the district pneumonia surveillance, a network of public and private hospitals admitting children with suspected pneumonia has been setup. For creating awareness and capacity building for identifying cases of CAP and reporting them, a one-day sensitization meeting was held. Each network facility has been requested to provide second copy of the X-ray of the patient. The cost of the X-ray is being reimbursed to the patient/provider, as the case may be.

Each time a hospital admits a patient who fulfills the study inclusion criteria, information is sent to the surveillance unit telephonically (passive surveillance). A data collector visits the reporting facility within 24 (+12 h) h of receiving information. He collects data from case records and obtains the second copy of the X-ray of patients of CAP, who fulfill the project's inclusion criteria. Case identifiers are being kept anonymous. The data along with the X-ray are sent to the CCU and digitalized using the digitizer Microtek.Medi-6000 Plus (manufacturer: Microtek International Inc., Taiwan).

In addition, irrespective of receiving information about admission of a case of pneumonia through passive surveillance, active surveillance is done by visiting hospitals. To ensure complete coverage, an extended telephonic active surveillance is also being done by weekly calls to the participating hospitals, to get information about cases of pneumonia admitted in the last 7 days, as well as reinforce project objectives and solicit continuous support. This will ensure that about 75% of children admitted with severe/very severe pneumonia anywhere in the four participating districts are enrolled.

Urine samples are being collected only from a subgroup of children admitted in the medical college pediatric wards. Urine sample (5 ml) is collected in sterile vials and stored at −20 °C in deep freezers for future use.

2.3. Trainings

The coinvestigators from the three sites were given a 3-day project orientation and hands-on experience in recruitment, data collection, and record keeping in Lucknow. They went back and identified project staff. The staff were then given a 4-day orientation and hands-on training in project work. The minimum qualification of staff hired was graduation with at least 3 years of experience in community-based medical research project work. A separate training was given to the computer operators of each site for using the customized, web-based software developed specifically for the project. Each site also conducted a 2 h orientation program for the pediatric resident

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doctors of the four medical colleges to create awareness and solicit their support. The panel of radiologists was imparted 2-day training using the standard set of the WHO radiographic images by an experienced trainer from ICDDRB, Bangladesh.

2.4. Variables for data collection

Data are being abstracted by trained project staff, from the hospital records on the day of recruitment of the subject. This is done within 24 h (+12 h) of admission of a case of pneumonia. The project staff request the nursing and medical staff of the facility to assist them, if required. Information is being collected on demographic and anthropometric variables (age, sex, weight, height, upper mid-arm circumference, and head circumference), clinical variables (history of presenting symptoms with duration, detailed examination including presence of audible/auscultatory wheezing, and signs of hypoxia and shock), and laboratory variables, when the test is done on the recommendations of treating physician (hemoglobin, total and differential counts, C-reactive protein, bacterial culture of sterile body fluids, viral antigen detection along with the method).

Surveillance X-rays (preferably digital) are usually done within 24 (+12) h of admission and obtained by the project staff after reimbursing the cost of the X-ray to the patient/provider, as the case may be. From participating medical colleges and their attached district pneumonia surveillance hospitals, simple X-ray films are obtained, which are then digitalized at the CCU. Digital images of all X-rays are uploaded on web-based data management program for blind interpretation by a panel of three independent/external experts.

For X-ray reading, we have trained readers – an arbitration panel with 3 radiologists. They have been trained using the methodology recommended by the World Health Organization[4] and used by the multi-nation PERCH (Pneumonia Etiology for Research in Child Health) study.[7] X-rays will be categorized (according to World Health Organization protocol) into: (a) end-stage consolidation; (b) non-end-stage infiltrates; and (c) pleural effusion.[4]

The radiologists assess quality of the CXR exposure, development, and positioning, and then grade quality as uninterruptable, suboptimal, or adequate.

Grading of quality will be as per the following WHO criteria:

(a) *Adequate*: if the features allow confident interpretation of endpoint, as well as other infiltrates.
(b) *Suboptimal*: An image is classified as "suboptimal" if the features allow interpretation of primary end-point but not of other infiltrates. No entries should be made for other infiltrates for such images
(c) *Uninterpretable*: if the features of the image are not interpretable in terms of presence or absence of "primary endpoint" without additional images.

Then findings are classified (according to World Health Organization protocol) as follows: (i) Normal; (ii) Primary endpoint/consolidation; (iii) Plural effusion; and (iv) Other infiltrate; (v) Uninterpretable. Description of classification is as follows:

(a) *Endpoint consolidation*: a dense opacity that may be a fluffy consolidation of a portion or whole of a lobe or of the entire lung, often containing air bronchograms and sometimes associated with pleural effusion.
(b) *Pleural effusion*: This refers to the presence of fluid in pleural space between the lung and chest wall. In most cases this will be seen at the costophrenic angle or as a layer of fluid adjacent to the lateral chest wall and is particularly associated with a pulmonary parenchymal infiltrate (including other infiltrate).
(c) *Other (non-endpoint) infiltrate*: Linear and patchy densities (interstitial infiltrate) in a lacy pattern involving both lungs, featuring peri-bronchial thickening and multiple areas of atelectasis. It includes minor patchy infiltrates that are not of sufficient magnitude to constitute primary end-point consolidation.

Concordance is defined as agreement by 2/3 members of the panel of radiological arbitrators. Final interpretation will be that given by 2 of 3. If all three are discordant, the radiological coinvestigator will make the final interpretation.

2.5. Data management

Data generated by the surveillance are entered in the web-based customized software. The coordinating center double enters the data on the web. The initial and double entered data are compared through the customized software. All discrepancies are sorted out by verifying from the original records and the final cleaned data will then be generated and stored.

2.6. Data analysis

Data will be analyzed using SPSS software. Frequency of variables will be displayed to look for outliers. Univariate analysis will be done to compute central tendency (mean, median, and inter-quartile range) of continuous variables and proportions with 95% confidence intervals of categorical variables. Data from hospital surveillance will be used to compute the incidence of radiological pneumonia within a predefined district. For this, denominator used will be total number of admissions from the district with WHO-defined pneumonia. Also, the population of children, 1 month to 5 years of age, will be taken from the recent census data and incidence will be given as number of cases of radiological pneumonia/100 child years. We will be using assumptions of various proportions utilizing health services from the surveillance network hospitals and will be conducting sensitivity analysis to define the robustness of the estimates.

Incidence of radiological pneumonia will then be computed by age categories, gender, and place of residence. Potential predictors of CAP with LCI, and severe CAP will be identified among the clinical, immunization, and nutritional demographic (including family characteristics), and environmental exposure variables collected. We will use Student's t test for continuous variables and chi-square test for categorical variables. A two-tailed distribution will be used and a p value of <0.05 will be taken as statistically significant. To test for association, Odd's ratio with 95% confidence interval and p value will be reported.

3. Interim results

Lucknow site established a pneumonia surveillance network of 120 health facilities (18 public and 102 private) in Lucknow. Similar networks were established in Patna, Darbhanga, and Etawah sites. 60 health facilities (8 public and 52 private) in Patna, 64 health facilities (26 public and 38 private) in Darbhanga and 17 health facilities (10 public and 7 private) in Etawah provided written informed consent to be a part of the network. After this, the

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Table 2
Number of network hospitals and recruitment in Uttar Pradesh and Bihar till date.

Site name	Number of network hospitals	Urban/rural hospitals	Public/private hospitals	Screened (*n*)	Included *n* (%)
Lucknow[a]	120	85/35	18/102	1577	745 (47.2%)
Patna[b]	60	40/20	8/52	487	229 (47.0%)
Darbhanga[b]	64	44/20	26/38	754	321 (42.5%)
Etawah[b]	17	8/9	10/7	274	80 (29.2%)
Total				3092	1375 (44.5%)

[a] Period of recruitment: 1st January 2015 to 30th April 2016.
[b] Period of recruitment: 1st January 2016 to 30th April 2016.

hospitals were categorized into high, medium, and low categories based on the following criteria:

1. *High burden*: Hospitals which had the following:
   (i) pediatric admission of ≥5 cases/week;
   (ii) total number beds more than 50, where children can also be admitted
2. *Medium burden*: Hospitals which had the following:
   (i) pediatric admission of 2–4 cases/week;
   (ii) total number beds between 31 and 50 where children can also be admitted;
   (iii) Pediatric hospitals.
3. *Low burden*: Hospitals which had the following:
   (i) Pediatric admission rate of 0–1/week;
   (ii) Total number beds less than 30;
   (iii) Maternity hospitals.

Till date, 3092 cases were screened in 4 project locations between 1st January 2015 and 31st April 2016, of which 1375/3092 (44.5%) were included. Lucknow site screened 1061 cases between 1st January and 31st December 2015, of which 518/1061 (48.8%) were included. Recruitment status of all, four project sites for the period 1st January 2015 to 30th April 2016 is given in Table 2.

4. Discussion

The approach described will establish a surveillance network of public and private hospitals admitting children with CAP in four districts. Using the population census data, as well as assumptions of community preference for various facilities for admitting their sick children, we will be able to provide an estimate of annual incidence of radiological pneumonia, which is most likely bacterial and therefore possibly due to SP/HiB, the commonly reported bacterial pathogens.

The criteria for clinical diagnosis of pneumonia have been developed by the World Health Organization and accepted and applied globally.[8] These are being used in the current study for case identification. World Health organization has categorized clinical pneumonia with fast breathing (cough/fever with fast breathing only), pneumonia with LCI (with additional chest in-drawing), and severe pneumonia (when there are clinical signs of hypoxemia like altered sensorium, refusal of feeds, convulsions, and bluish discoloration of lips).[8–10] While pneumonia with fast breathing is mostly treated at home and is perceived as a "minor" illness," for the treatment of pneumonia with LCI and severe pneumonia, parents consult a doctor and the latter are almost always admitted for administration of oxygen. For most patients of pneumonia with LCI and for all hospitalized patients of severe pneumonia, chest X-ray is done as a part of routine management. Hence, in the proposed surveillance for radiological pneumonia, systematic data collection is being done in patients without any extra procedure (investigation/intervention) other than that required for routine care only, and thus feasible.

In India, public as well as private health facilities are admitting and treating pneumonia. Among the public facilities, the preferred one is the academic medical institutions offering tertiary care. The other public hospitals like the Community Health Center and the district hospital are used if there is an active and efficient pediatrician posted there. Therefore, the parents' first choice is almost always a private hospital facility. All private facilities admitting patients are registered with the Chief Medical Officer of the district. Hence, this project is linked with the medical teaching institution, which is a part of this project; a surveillance network of all private and public hospitals admitting pneumonia patients will be established to ensure that information about majority of the incident cases of radiological pneumonia in the district are picked up.

It has been reported that there is a variation in the reporting of cases of radiological pneumonia. This can be due to interobserver variation or the quality of film.[4] To ensure that the quality of film is similar across all sites preferably digital high-resolution X-ray films are being interpreted. To minimize interobserver variation, a panel of radiologists, external to be project, has been set up. They serve as arbitrators.

Immunization is a major step to prevent CAP in children. In 1978, India introduced six childhood vaccines (BCG, TT, DPT, DT, Polio, and Typhoid) in its extended programme of immunization (EPI). Measles vaccine was added much later, in 1985, when the Indian government launched the Universal Immunization Programme (UIP). WHO review reports that 31–46% relative reduction in childhood mortality can be brought about by more than 80% coverage of measles vaccine. In India, DLHS-III reported 69.1% coverage of measles vaccine in the first two years of life. Vaccine against *H. influenzae* type b was not included in UIP; however, recently, pentavalent vaccine (Pentavac by M/s Serum Institute of India) was introduced in Kerala and Tamil Nadu in the year 2011 and later to the states of Goa, Pondicherry, Karnataka, Haryana, Jammu and Kashmir, Gujarat, and Delhi. At present, this vaccine is introduced in the rest of the states of India also. Since magnitude of invasive pneumococcal diseases in children in India is high, prevention through vaccination is desirable. In India, two types of pneumococcal vaccines are available. One is unconjugated pneumococcal polysaccharide vaccine 23 valent (PPSV23), which is not effective in children under two years of age. For use in children less than two year of age, pneumococcal conjugate vaccines (PCV10 and PCV13) are available. PCV10 covers 64% and PCV13 covers 73.3% of invasive pneumococcal strains, respectively.[11] Efforts are being made to include PCV into UIP. An Indian company with active support of Department of Biotechnology, Government of India is developing 15-valent vaccine containing two additional serotypes, 2 and 12F, to existing PCV13.

Recently, Bihar has been selected for introduction of PCV but not Uttar Pradesh. The study provides the opportunity to compare the impact of PCV introduction in two major states side by side, that is Bihar with PCV and Uttar Pradesh without PCV. Plans are being developed to add nasopharyngeal carriage evaluation in both states, with the goal of setting up a robust effort for impact

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assessment. We are developing surveillance for NP carriage baseline before PCV introduction to then demonstrate reduction in vaccine serotype carriage after PCV is rolled out.

Conflicts of interest

The authors have none to declare.

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