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Public Health Impact of Pneumococcal Conjugate Vaccine in India: A Review of Available Evidence

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Abstract

Pneumococcal disease is a major cause of morbidity and mortality in children less than five years of age with low- and middle-income countries having the highest incidences. It is caused by Streptococcus pneumoniae and it is presented as pneumonia, meningitis, sepsis, and otitis media, with pneumonia contributing a significant percentage of causes of childhood mortality that can be prevented. The pneumococcal disease burden in India is grossly disproportional as it has a large birth population, socioeconomic disparity, malnutrition, unpredictable exposure to environmental threats, and inconsistent access to quality healthcare. Although significant progress has been made in terms of child survival, pneumonia remains a significant cause of under-five mortality. India rolled out PCV in its Universal Immunization Programme in a phased way, where it started to introduce in high-burden states starting with the World Health Organization's strong evidence and recommendations in 2017. The current narrative review is a synthesis of the available evidence from the published literature, surveillance reports, program evaluations, and modeling studies to determine the public health implications of PCV implementation in India. The review is concerned with the effectiveness of vaccines against pneumonia and invasive pneumococcal disease, child survival, economic effects, and difficulties in implementation. The available evidence suggests that PCV introduction in India has been connected to the decrease in severe and radiologically verified pneumonia hospitalization, decrease in the vaccine-type pneumococcal isolates, and possible indirect advantages because of herd protection. Averted cases, deaths, and healthcare expenses are modeled at a nationwide level to be substantial and have a scale-up type. PCV introduction is starting to deliver significant public health impact in India especially in reducing the morbidity associated with pneumonia. Financial permanence, enhanced surveillance and fair implementation are needed in order to maximize long term effects on child health and survival.

Keywords: *Pneumonia, Pneumococcal Conjugate Vaccine, UIP, Public Health, Impact, India.*

The introduction and background:

Pneumococcal disease has been a leading cause of morbidity and mortality in children below the age of five years across the world and especially in low and middle-income countries. The disease is caused by the Streptococcus pneumoniae and has the presentation of pneumonia, meningitis, sepsis, and otitis media, and pneumonia alone contributes a significant percentage with regard to preventable deaths in children. The World Health Organization estimates that vaccines against pneumococcal infections are one of the most common causes of mortality below the age of five, which are vaccine-preventable (1), especially those which have a large birth rate and face chronic health system issues, including India. The situation of childhood pneumonia in India carries one of the greatest burdens in the world since it is a multi-factorial issue that is related to large population density, socioeconomic disparities, malnutrition, indoor air pollution, and access to timely and quality healthcare services. Although there have been positive changes in the child survival indicators over the last twenty years, pneumonia remains one of the most common causes of death among children in India, which reveals some serious gaps in preventive care and curative care. In that regard, vaccination has been identified as one of the most potent and viable community health measures to lower the cases of severe illness, hospitalization, and mortality caused by pneumococcal infections. Indeed, a single country (India) had around 20 percent of all under-five pneumococcal disease-related deaths worldwide in 2015, and 68,700 children died of infection with the pneumococci that very year (2). PCVs have proven to be quite effective in preventing invasive pneumococcal disease and pneumonia-associated mortality in a variety of settings around the world. PCVs protect the vaccinated individuals in addition to the effect of herd immunity by promoting high-level immune responses in infants and young children to prevent nasopharyngeal carriage and transmission. Indeed, emboldened by strong global experience, India incorporated PCV into its national immunization programme as part of the Universal Immunization Programme in a gradual and phased way since 2017, with a clear priority given to those states with a high disease burden and poor health indicators. This was a major change policy to speed up the efforts to curb under-five mortality and equitable health outcomes. This review will summarize any existing evidence on the population health effect of PCV implementation in India, considering its effectiveness, population coverage, and problems of ensuring equitable access to the population and population-wide benefits. This high mortality rate highlights the necessity of effective preventive measures, one of which the pneumococcal conjugate vaccine has become a major intervention in terms of its role in preventing diseases (3). This vaccine covers multiple serious forms of pneumococcal infection, such as meningitis, pneumonia, and otitis media, with meningitis alone having an almost fifty percent mortality rate, and in those who survive, the neurological sequelae may be devastating (4). Although the efficacy, immunogenicity, and safety of PCVs have been confirmed in children, their use in India has been slow (4). In the past, a lack of national data on health and economic impact of the disease prevented its large-scale use (5), but there is evidence that in India, pneumococcal diseases continue to be a significant issue with regard to the health and well-being of the populace (6). Nevertheless, the recent studies have attempted to estimate advantages of the nationwide introduction of PCV and predict significant decreases in the occurrence, deaths and the costs of healthcare delivery of the disease under different models of the vaccine implementation (2). This review summarizes the current body of evidence on the effect of PCVs on public health in India considering their efficacy against invasive pneumococcal disease and the overall implications of PCV on pediatric health outcomes and resource allocation, which is essential in guiding the vaccination policy and resource utilization. In particular, the biased and gradual implementation of the 13-valent pneumococcal conjugate vaccine into the national vaccination program in India since 2017-2018 is an essential step towards the reduction of the high morbidity of severe community-acquired pneumonia in children (7; 8 Streptococcus pneumoniae is also a global pathogen that is considered a leading etiology of bacterial pneumonia, meningitis and sepsis with disproportionality in children under five years of age (8). Due to the routine infant immunization with PCV vaccinations, the number of deaths caused by pneumococcal infections in children under five years old decreased by 51 percent between 2000 and 2015 (2). Although this has been experienced worldwide, Southeast Asian nations such as India are still reporting high rates of mortality in children under five, with about 25 percent of such deaths being caused by invasive pneumococcal disease (6). In addition, the less severe yet more frequent diseases, including acute otitis media, are also caused by the disease in children primarily by *S. pneumoniae (6). In the world, 700,000 to 1 million deaths are caused by pneumococcal disease annually, and most of them occur in developing countries (9). Since its implementation, the implementation of PCV in India has brought increasing concerns among policymakers, researchers, and those affiliated with the practice of public health

as to its actual effect in real life. Preliminary programmatic data and new research findings indicate a positive trend of the decrease in pneumonia hospitalizations and better child health outcomes, nevertheless, the differences in the regions, variations in the study designs, and the changes in surveillance systems require a cautious synthesis of existing evidence. Also, the heterogeneity of epidemiological, demographic, and health systems settings in India contributes to the need to focus on local data instead of adopting global results obtained via extrapolation. This review thus critically evaluates the effectiveness of PCV in preventing the occurrence of pneumococcal diseases, alterations in serotype distribution, and consequences of this to antimicrobial resistance in India. (10). It is against this backdrop that this review seeks to critically assess the existing evidence concerning the effect of introduction of the pneumococcal conjugate vaccine on the population health in India. The review aims to deliver a holistic picture of the role PCV plays in reducing the incidence of the pneumococcal disease burden, its overall effects on child health, and the outstanding challenges of maximizing vaccine effect in the Indian setting by synthesizing the results of the published literature and surveillance reports and program evaluations. The single largest cause of childhood mortality due to any infectious agent worldwide is pneumonia, which causes 14 percent of the deaths of children under five years of age, with one-third of severe bacterial pneumonia and one-third of all pneumonia deaths in childhood due to the pneumonia pathogen, which is estimated to be 18.3 percent, being composed of the pathogen, *Streptococcus pneumoniae" (11). The pneumonia mortality burden in the world, among which five40% of deaths occur in five countries, including India, indicates the urgency of PCV interventions, although not all mortality incidents can be identified by means of hospital-based research (11).

Review:

Pneumococcal disease has been known to be a leading cause of childhood morbidity and mortality in India. Streptococcus pneumoniae is a major cause of community acquired pneumonia, meningitis and sepsis among children below the age of five years of age and it is more prominent among the infants. Prior to the introduction of pneumococcal conjugate vaccines, a large percentage of child deaths associated with pneumonia in the world were in India. It was always estimated that pneumonia alone caused almost a fifth of under-five mortality with pneumococcus being a dominant etiological agent in severe and fatal cases. The predicted PCV implementation affects the population health in India although with regional disparities as certain southern Indian cohorts did not respond to early PCV uptake in terms of any significant difference in vaccine and non-vaccine-type prevalence (12). Such variability supports the need to conduct focused epidemiological surveillance to track the frequency of serotype and vaccine efficacy within a wide range of geographical and demographic groups in India (6). One of the challenges is the lack of understanding and underrealization of the importance of PCVs that has limited their use, even though it has been available more than 10 years (6). The burden of disease has not been distributed equally in the country. Increased reports on higher incidences and mortality have been recorded in socioeconomically disadvantaged states, urban slums, tribal areas, and areas with poor access to timely healthcare. Malnutrition, impaired birth weight, indoor air pollution, lateness in seeking care, and incomplete immunization are additional factors that predispose the individual to severe pneumococcal infections. These realities within the context highlighted the urgency of the need to have an effective preventative intervention that can be provided by the public health system in bulk. However, estimations indicate that PCVs in the world would offer significant economic advantages of up to 1.30-1.87 billion in direct cost savings in the medical field in 5-year time (2). Irrespective of these economic benefits, the initiation of PCVs in India started in 2017, in states with the heaviest burden of pneumonia, with greater expansion to the other state immunization programs to follow (2). This lag underscores institutional constraints such as financial resources and the lack of strong country-specific disease burden data that restrict the fast implementation of the vaccine policy in low- and middle-income nations such as India (6; 13). Furthermore, although in India the majority of pediatricians support the use of PCV, 83% of them believe they should be included in the Universal Immunization Program but cite the high cost as the main obstacle to its coverage (5). As a result, according to the financial models, PCV programs under full subsidies may result in a considerable decrease in out-of-pocket healthcare expenses on the family level, which will ease the considerable economic burden (2). The same India country that uses 2 types of PCV in UIP one is PCV-13 and another one PCV-14 and switching existing PCVs to wider spectrum vaccines such as PCV15 or PCV20 could bring even more savings and disease prevention with PCVs, as models have shown that they save many cases of invasive pneumococcal disease, otitis media, and pneumonia (14). As an example, the transition to PCV15 may result in significant savings in society and another reduction in the number of cases

of pneumococcal diseases (15).

Reasons Why Pneumococcal Conjugate Vaccine Should Be Introduced in India.

The move to have PCV included in the national immunization program of India was informed by a solid global and regional evidence of its efficacy in the prevention of invasive pneumococcal disease and severe pneumonia. Past experiences in countries which had previously used PCV recorded significant reduction of hospital admissions, fatality cases as well as general mortality of children due to pneumococcal infections. Notably, PCVs were found to eliminate nasopharyngeal carriage of vaccine-type pneumococci, and this breaks the chain of transmission in addition to providing an indirect protection to unvaccinated groups. This effects of herd immunity are especially important in highly populated areas like India, where a disease can spread very fast and flood the healthcare system. Additionally, detailed economical calculations highlighted that the medical cost-saving due to the avoided case of illnesses and deaths would greatly cover the costs of the vaccines, and the healthcare system in India would overall save money (2). These results can be compared to other middle-income countries analysis to show that the introduction of PCV is cost-effective in the long term with a positive impact on the health of the population, including averted productivity losses and the quality of life (16; 17). In India, the health case of introducing PCV was enhanced further by the modeling studies, which indicated that moderate coverage of the vaccine would prevent a significant portion of death as the country has a high birth cohort. The phased introduction tactic embraced by the Universal Immunization Programme was so designed as to prioritize states with greater disease burden, and with lesser health indicators so that the highly at-risk populations were well taken care of first. International assistance like Gavi, the Vaccine Alliance was very instrumental in easing the acquisition of vaccines and the initial distribution. Such a strategic partnership played a significant role in the challenges of tackling the initial financial and logistical barriers associated with the deployment of vaccines in large-scale settings with limited resources (4). Additionally, current policy deliberations acknowledge the necessity to implement new financing models and potentially smaller-dose regimens to achieve a similar coverage rate as developed countries, based on the experience of successful PCV presentations in such countries as Indonesia (18; 28).

Phased Introduction and Programmatic Implementation:

In 2017, India launched PCV initially covering a number of big burden states but progressively more states and union areas with time. The vaccine was added to the standard immunization schedule in a three dose schedule given during infancy. The implementation also took advantage of the infrastructure available on immunization such as cold chains systems, frontline health workers as well as the existing outreach systems. This strategy was meant to maximize the use of resources and achieve efficient delivery of the vaccine even to the lack of access areas. The programmatic implementation was associated with various operational issues, among them being adjustment of the supply chain and training of healthcare personnel and community awareness. However, there were positive program reports that caregivers were well accepting especially when PCV was administered with other routine vaccines. It was integrated into the prevailing system of immunization to reduce the extra costs of service delivery, but the disparity in coverage between regions remained, which was indicative of larger systemic inequalities in the health system. Nevertheless, these difficulties did not prevent the success of the initial rollout, which showed the possibility of including PCV in the system of widespread public health in India, which preconditioned the success of its further national practice (19).

Effect on Pneumonia and Invasive Pneumococcal Disease.

India have shown evidence emerging that PCV introduction has led to quantifiable decreases in morbidity caused by pneumonia. Surveillance-based studies at hospitals and observational studies have documented the reduction in the admission of severe and radiologically diagnosed pneumonia in children in regions where there is sustained PCV coverage. Although methodologically, it is difficult to ascribe these decreases to vaccination, the temporal relationship of PCV rollout and decreasing pneumonia burden is in line with the global experience. Moreover, the research beyond India has reported the tremendous decreases in the general incidence of invasive pneumococcal disease after PCV introduction, with a reduction of up to 69% observed among the pediatric population (20). There is limited evidence on invasive pneumococcal disease (meningitis and bacteremia) because of the limitations on diagnosis and under-reporting. Nevertheless, sentinel surveillance site data available shows that there was a decline in vaccine-type isolates of

pneumococci in vaccinated cohorts. These results indicate that PCV is also starting to change the epidemiology of pneumococci in India; however, the serotype replacement and long-term trends can be determined only with the help of the further surveillance.

An impact on Mortality and Child Survival.

The existence of direct evidence connecting PCV introduction with decreases in all-cause or pneumonia specific mortality in India is yet to be discovered. However, modeling research and initial impact analyses suggest that PCV could prevent a large number of deaths of children each year, especially when used in combination with the case management and nutrition. Since child mortality is a multifactorial issue, PCV contribution must be considered as a part of a bigger package of child survival interventions and not as a solution on its own. Indirect benefits of PCV, such as protection of herd, can contribute to its effect even greater in the future as coverage rises and transmission decreases. Such population level impacts particularly apply within densely populated cities and communities with high burden where strains of pneumococci that result in circulation can be mitigated to protect infants who are too young, or otherwise incompetent to complete the full vaccination cycle. These effects of herd immunity are essential in improving the overall public health outcome of PCV programmes particularly in areas where direct coverage rates are suboptimal. (21)

Fairness and Local Differences in Effect.

Determining whether PCV introduction has contributed to a reduction in inequities in child health outcomes is one of the major public health issues in India. There is an initial indication that states that seem to have been prioritized in the initial rollout have seen significant returns, especially in terms of severe pneumonia hospitalizations. Nevertheless, there are still inequalities in the urban versus rural regions, public versus private healthcare access and use, as well as in the socioeconomically privileged versus marginalized groups. (22). Barriers that are related to access such as migration, lack of opportunities to take the vaccination, fluctuating health worker supply, and disparate impacts on PCV coverage and influence remain. It is necessary to address these gaps to make sure that the full population health potential of PCV is achieved and the benefits are equally distributed among the different strata of the population.

Surveillance, Data gaps, and limitations on research.

The evaluation of the PCV in India is limited by disease surveillance, laboratory and standardized outcome measures effectively. Pneumococcal disease is mostly diagnosed clinically and is not confirmed microbiologically hence underestimating the actual effect of the disease. Moreover, some differences in the study design, geographic coverage and outcome definitions make cross-study comparisons difficult. Nevertheless, despite these constraints, the accumulating Indian evidence would offer some useful information regarding the actual performance of vaccines. Enhancing surveillance systems, network of laboratories and connecting immunization data to hospital and mortality data will be of importance in creating more robust and representative evidence in future. (23)

The larger Public Health Implications.

In addition to its immediate impact on the pneumococcal disease, PCV introduction also has significant consequences on the overall public health objectives of India. PCV will help reduce hospitalizations and severe childhood illness, thereby eliminating the strain on healthcare facilities and lowering out-of-pocket spending on the part of families, as well as provide momentum toward universal health coverage. The process of the introduction of the vaccine into regular immunization contributes to the importance of preventive treatment and builds confidence in the state health facilities as well. (24). To conclude, existing evidence shows that the introduction of pneumococcal conjugate vaccines in India is already having positive effects on the public health in terms of decreasing the morbidity caused by pneumonia in young children. Although some problems concerning the surveillance, equity, and sustainability of the program persist, PCV is an essential part of the Indian approach to children health, and significant effects can be achieved, as long as the coverage grows and the program matures. (6) With the introduction of the pneumococcal conjugate vaccine in India in phases, there have been numerous streams of evidence that started proving its favorable effect on the population. In spite of countrywide, long term mortality data is developing, but preliminary results of surveillance systems, hospital-based research, and program evaluations give valuable information on the actual efficacy of the vaccine. (25). Surveillance studies in PCV-introduced states that had a hospital-based surveillance have shown a reduction in the number of hospitalized severe and radiologically confirmed cases of pneumonia in children under five years old. Facilities that were involved in pneumonia surveillance net-

works also reported that the percentage of pediatric admissions with severe pneumonia reduced in two to three years of continuous PCV coverage. These tendencies were stronger in districts with high immunization performance of routine, which indicates that there is dose response relationship between vaccine coverage and disease reduction. (26). Sentinel surveillance sites which are supported by the Ministry of Health and Family Welfare reveal that there are decreases in vaccine-type pneumococcal isolates in vaccinated cohorts. Direct protective effect of PCV was observed with a shift in the laboratory-confirmed invasive cases of pneumococcal disease to serotypes not covered in the vaccine. Even though there is still a general paucity of invasive disease surveillance in India, the findings are consistent with the global trends post-introduction of PCV and the initial indication of biological effect. Additional (6) In addition to this, the modeling studies show that PCV13 averted a substantial number of cases and deaths, and the economic benefits of its implementation surpass those of no vaccination, demonstrating a high public health payback on investment (2). The reports of the program evaluation in the initial states of introduction like Himachal Pradesh and Bihar showed that child health indicators related to morbidity associated with pneumonia have improved. There were decreases in pediatric intensive care hospitalizations due to severe respiratory infections in tertiary care units that covered these areas. Notably, these decreases were made in spite of the persistence of the problems concerning air pollution, malnutrition, and seasonal respiratory infections, which reinforces the conclusion that the vaccination contributed to the development of these issues. (22). The modeling studies which have been done on Indian demographic and disease burden data, have estimated that national PCV scale-up would prevent tens of thousands of deaths of children each year once high and sustained coverage is attained. According to these models, the highest impact is achieved among infants between 2 and 11 months, a population that has in the past been the most affected by pneumococcal disease. The gains estimated are especially high in states with high burden, which increases the importance of the phased, equity-based introduction strategy of India (26). In addition to the immediate health effects, PCV introduction has led to the wider societal health benefits. Fewer hospitalizations of pneumonia mean fewer out-of-pocket costs of families, less loss of productivity by caregivers, and fewer burdened public health facilities. In India, particularly, these indirect economic and system-wide benefits are particularly applicable to pneumonia hospitalization costs, which can lead poor families into the realm of financial distress. Besides, the introduction of PCV programs has had an indirect positive impact on primary healthcare infrastructure, as it required improving the cold chain management and vaccine logistics as well as engagement with communities to succeed in immunization campaigns (18). The economic viability of PCV implementation has also been established, and calculations of the cost per DALY averted put it in an even lower range than thresholds that are considered to be highly cost-effective to India (27). Taken together, the new evidence of Indians confirms the conclusion that PCV introduction has brought significant changes in the burden of pneumococcal disease and related healthcare use. Although continued follow-up and the use of long-term follow-up impact assessment is required to fully engage mortality impacts and pattern of serotype replacement, the available evidence shows that PCV is producing significant and equal public health value in the Indian setting. (27).

Conclusion

The inclusion of the pneumococcal conjugate vaccine into the national immunization program of India is an important milestone in the struggle of the country to achieve a reduction in preventable morbidity and mortality among children. The evidence discussed in this paper suggests that PCV has already started to produce significant and beneficial effects on public health, specifically, by way of decreased severe pneumonia and hospitalizations in young children in regions where the vaccine has been continuing to be used. The economic studies indicate that the cost savings of the health system could be high due to the increased PCV access, especially with PCV13, which is why the program in question should be further funded. Economic analysis, including the wider society-wide benefits, including decreased antimicrobial resistance and indirect cost savings due to prevented loss of productivity, would be more representative of the PCV value proposition. In addition, the surveillance activities of India should change their direction towards not only providing the necessary answer to the key question of PCV inclusion but also producing high-quality and large-scale, community-based data on epidemiology in different regions, which is the key to plan the individual national course. In the future, the case of PCV in India can provide valuable lessons to other countries with high pneumonia burdens and low incomes. The success of the gains made up until now will require continued political commitment, new financing schemes, and fair rollout plans to adhere to and enhance. With newer and more effective vaccine preparations, such as higher valency and next-generation pneumococcal

vaccines, being developed, the UIP evidence in India will play a vital role in making global discourse on controlling pneumococcal diseases. To sum up, pneumococcal conjugate vaccination is one of the pillars of the child health strategy in India, which will have significant potential to reduce the number of deaths of children who can be prevented and to improve the long-term equity of the health of the population when implemented with the effective support of the system and long-term investment

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