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Prioritizing Pneumococcal Vaccine Introduction in the Developing World: the Indian Experience

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Abstract

Pneumococcal diseases in 'under 5 populations' are responsible for millions of deaths annually in the developing world. Effective vaccination against pneumococcal diseases is available using vaccines but their high cost has inhibited their adoption by governments in low and middle-income countries. Resistance to adoption of these vaccines also stems from the lack of population based data pertaining to disease burden and serotype prevalence which preclude the possibility of accurate cost-effective analysis and long-term impact of the vaccines in improving the health of susceptible populations. In India, the pneumococcal vaccine is set to be introduced in a phased manner in its Universal Immunization Program. The Indian experience shows that the vaccine can be adopted using justifications based upon disease burden estimates through mathematical modeling and serotype prevalence from hospital based studies especially when keeping the overarching ethical principle of protecting the lives of thousands of children in mind who cannot wait for theavailability of high quality evidence proving cost effectiveness of the vaccine. However, the replicability of such behaviour by comparatively poorer nations may be difficult which renders it necessary to correctly monitor and evaluate the impact of pneumococcal vaccine introduction in Indian populations in order to provide a roadmap for expansion of pneumococcal vaccines in other resource constrained settings of the developing world.

Keywords: Pneumococcus; Vaccines; India.

Introduction

Acute respiratory illnesses constitute a range of respiratory syndromes affecting either the upper or the lower respiratory tract with varying degrees of severity. Pneumonia is an acute respiratory illness (ARI) of the lower respiratory tract leading to inflammation or fluid accumulation in the lungs. Almost 90% of the 3.9 million deaths annually among under 5 children attributed to ARIs is due to Pneumonia which is predominantly bacterial in origin [1]. The majority of 'under 5 deaths' due to ARIs occur in the developing world [2]. This skewed pattern of childhood mortality is attributed to the increased incidence of pneumonia in the developing world which is almost 6-8 times higher compared to developed countries due to the high prevalence of risk factors like malnutrition, lack of exclusive breast feeding, low birth weight and indoor air pollution in the former [3].

The World Health Organization (WHO) estimatedthat in 2008, 476,000 HIV negative child deaths under five years of age occurred due to pneumococcal infections with majority of deaths occurring in Asia and Africa [4]. Furthermore, almost 7-13% of all pneumonia cases require hospitalization [5]. The control of pneumococcal infections therefore represents a major public health challenge.

In India, an estimated 13% of inpatients deaths in pediatric wards is due to ARIs with pneumonia being responsible for approximately 18% of all 'under 5 deaths' [6]. The decision of the government of India to initiate the inclusion of the pneumococcal conjugate vaccine (PCV-13) in its routine

immunization program beginning with districts in 3 states represents a major policy initiative which has implications for other developing nations [7].

Immunzation against Pneumococcal Diseases from an Indian Perspective

Vaccination can provide protection against ARIs and its complications and result in reduction of morbidity and mortality due to the disease especially in the vulnerable under 5 populations. An effective immunization regimen for protection against ARIs should include vaccination against measles, Haemophilus influenza Type B and pneumococcal pneumonia. A summary of the rationale for adoption of these vaccines in the Indian context is illustrated in Table 1 below.

Table 1: Vaccines for protection against pneumonia in the Indian context

Vaccine	Rationale	Introduction and expansion in Indian settings	Current status
Measles	Pneumonia may occur due to complications of measles associated with high childhood mortality.	Measles introduced in late 1980s in the UIP. 2nd dose of measles introduced only since 2011.	Measles-Rubella (MR-VAC) vaccine to replace existing 2 doses of measles
Pentavalent vaccine	Haemophilus influenza type (HiB) B is a major cause of pneumonia and meningitis among children in the developing world.	Pentavalent vaccine was introduced in India in 2011.[11]	Pentavalent vaccine is now a part of the UIP.
Pneumoccal accines	Streptococcus pneumonia is the most common cause of bacterial pneumonia. It also causes meningitis, sepsis and otitis media in 'under-5' populations.	In 2007, WHO recommended use of PCV-7 in high burden regions.[8] In 2012, WHO recommended PCV-13 with phasing out PCV-7.[14]	PCV-13 conjugate vaccine being introduced in 3 states of India as part of the UIP.

The introduction of pneumococcal vaccines in India under the Universal Immunization Program (UIP) has experienced major challenges. Pneumococcal vaccines are of two types: polysaccharide non-conjugate and pneumococcal polysaccharide conjugated vaccines (PCV). The former has been available for nearly four decades since the late 1980s but lacked efficacy among children less than 2 years of age. The PCV vaccines have been available for over 10 years. The WHO in 2007 recommended the inclusion of the PCV-7 vaccine for routine immunization in developing nations [8]. Nevertheless, there was a lack of consensus among experts with regards to introduction of the vaccine in India. The major objections raised were: (a). There was lack of studies which evaluated the burden of streptococcus pneumoniae in India especially among young children in order to prove it was a major priority in the Indian context. (b). The seven-valent conjugate vaccine, PCV-7 contained the serotypes which accounted for only 50% of the severe pneumococcal diseases in 'under-5 children' in India. (c) Pilot studies evaluating the effect of introduction of PCV-7 on pneumococcal disease burden were lacking and needed to be conducted prior to its inclusion. (d). Given the cost considerations, prioritization in introduction of the pentavalent vaccine according protection against Hepatisis B and Haemophilus Influenza Type B (HiB) was considered a more prudent option [9-10]. By 2011, the pentavalent vaccine was included in the UIP in India after a protracted legal battle [11]. The justification for inclusion of the HiB component was based on the disease burden of Hib pneumonia in young children using modeling estimates from hospital data and studies proving its efficacy in reducing incidence of invasive disease in resource constrained settings [12-13].

In 2012, the WHO recommended the inclusion of the PCV-13 vaccine in the UIP. Due to the superiority of the PCV-13 over the PCV-7, the latter was phased off from the market [14].

However, the Indian Academy of Paediatrics Committee on Immunization (IAPCOI) recommended further studies for evaluating the efficacy of the pneumococcal vaccines prior to their inclusion in the UIP [15]. It also recommended development of real time multisite surveillance network in order to

generate credible data on disease burden and serotype prevalencewhich were lacking [16].

As of date, there is still a paucity of population based data relating to the burden of pneumococcal diseases. However, like in the case of HiB, modeling based estimates have been published for pneumoccal disease burden [17-18]. Similarly, based on a few hospital studies, PCV-13 was found to contain most of the serotypes which were isolated from patient samples in India [19]. The introduction of the pneumococcal vaccines in the Indian context is thereby justified on the premise that it might be the most effective intervention for combating pneumococcal disease burden in Indian healthcare settings where the socioeconomic reality of poverty, malnutrition, poor sanitation, indoor air pollution and nutritional deficiencies cannot be eliminated in the near future. Furthermore, population based studies to generate high quality data assessing pneumococcal disease burden and serotype prevalence is not feasible in a short span of time and would take years of research during which time millions of children could be potentially saved from the disease through vaccination. There exist also potential for positive externalities like reduction of antimicrobial use for treating pneumococcal diseases thereby lowering antimicrobial resistance.

Nevertheless, it is important for Indian research institutions to evaluate the medium and long-term health outcomes and assess the impact of the vaccine in reduction of childhood mortality in India since the data generated can help more low-income countries to arrive at evidence based decisions pertaining to prioritizing pneumococcal vaccination in their populations.

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