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Estimating the Cost-Effectiveness of the 7-Valent Pneumococcal Conjugate Vaccine in Shanghai, China

Shanlian Hu, MS[1,2,], Qiang Shi, MD, PhD[3], Shengfan Song, MS[1], Lixia Du, MS[2], Jiangjiang He, MS[2], Chieh-I Chen, MPH[4], Ronald Caldwell, PhD[5], Bruce Wang, PhD[6], Craig S. Roberts, PharmD, MPA[7]*

[1]*School of Public Health, Fudan University, Shanghai, P.R. China;* [2]*Shanghai Health Development Research Center, Shanghai, P.R. China;* [3]*Health Economics and Outcomes Research, Pfizer Investment Co. Ltd., Shanghai, P.R. China;* [4]*Health Economics and Outcomes Research, Pfizer Investment Co. Ltd., Beijing, P.R. China;* [5]*Department of Economics, University of Michigan, Ann Arbor, MI, USA;* [6]*Alliance Life Sciences, Somerset, NJ, USA;* [7]*Health Economics and Outcomes Research, Pfizer, Inc., Collegeville, PA, USA*

ABSTRACT

Objective: The goal of this study was to analyze the economic benefits of introducing the 7-valent pneumococcal conjugate vaccine (PCV7) into the City Immunity Program in Shanghai. **Methods:** A decision-analytic model designed for pneumococcal disease and outcomes of pneumococcal infection was populated with local, age-specific incidence and cost data to estimate the expected economic benefits from vaccinating a birth cohort of 172,183 infants in Shanghai over a 1-year period using a cross-sectional approach. The analysis was assumed to occur in a year at which time the direct and indirect effects of vaccination have reached a steady state. Costs were calculated from a payer perspective and included vaccination program costs and direct medical expenditures from pneumococcal-related disease. **Results:** The model predicts that 112,629 cases of pneumococcal-related disease could be prevented during a given year following the introduction of the PCV7 vaccine into the City Immunity Program in Shanghai, leading to a reduction of ¥187,923,359 (US $29,067,790) in direct medical costs. Overall, the inclusion of the PCV7 vaccine is estimated to have a cost-per-life-year saved of ¥37,468 (US $5,796) and a cost-per-quality-adjusted-life-year gained of ¥41,603 (US $6,435) when both the direct and indirect effects of the vaccine resulting from herd protection are taken into account. **Conclusions:** Results suggest that including PCV7 into the City Immunity Program in Shanghai could be considered cost-effective under generally accepted willingness-to-pay thresholds when both the direct and indirect effects of the vaccine are considered in the analysis.

Keywords: cost-effectiveness, herd immunity, PCV7, pneumococcal disease, vaccine.

Introduction

Streptococcus pneumoniae, which can result in both invasive diseases, such as bacteremic pneumonia, septicemia, and meningitis, and noninvasive diseases, such as pneumonia, otitis media, and sinusitis infections, is a leading cause of respiratory disease globally. One of the key risk factors for pneumococcal disease is age, with children younger than 5 years and the elderly being at the highest risk of developing pneumococcal-related infection. Pneumococcal disease is estimated to be the leading cause of vaccine-preventable morbidity and mortality among children younger than 5 years both globally and in China [1,2]. The World Health Organization has reported that approximately 1.6 million people die each year from pneumococcal-related diseases. Among this group, approximately 700,000 to 1 million are children younger than 5 years [3]. In addition to the mortality associated with pneumococcal-related diseases, there exists a significant effect on the overall quality of life among those inflicted with the disease, as well as a large economic burden for both patients and society.

The 7-valent pneumococcal conjugate vaccine (PCV7) was licensed for use in the United States in February 2000 and was subsequently recommended for routine vaccination of all infants in the United States starting at age 2 months [4]. Since its addition to the recommended vaccination schedule, the vaccine has had a dramatic effect on the incidence of pneumococcal-related disease due largely to the indirect effect from herd protection on unvaccinated children and adults [5,6]. A report by the Centers for Disease Control and Prevention indicates that most of the reduction in invasive pneumococcal disease (IPD) cases following the introduction of PCV7 into the routine vaccination schedule among infants in the United States was due to the indirect effect on the unvaccinated population by reducing the nasopharyngeal carriage of *Streptococcus pneumoniae* among immunized children [7].

The PCV7 vaccine contains seven serotypes: 4, 6B, 9 V, 14, 18C, 19 F, and 23 F. Although there are more than 90 known

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* *Address correspondence to:* Shan Lian Hu, Shanghai Health Development Research Center, Room 801, 1477 Beijing Road (W), Shanghai 200041, P.R. China.

E-mail: Hushanlian@hotmail.com.

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pneumococcal serotypes, a relatively small number account for most of the pneumococcal-related disease globally [8,9], and it is estimated that the serotypes contained in the PCV7 vaccine would account for approximately 76% of the serotypes associated with pneumococcal disease prevalent among children younger than 5 years in China [10]. As a result of both the impressive safety and effectiveness record of the PCV7 vaccine in the United States and elsewhere over the past decade, the World Health Organization has recommended the inclusion of PCV7 in childhood immunization programs worldwide [11].

Although there have been a number of studies demonstrating the cost-effectiveness of introducing PCV7 into the national immunization programs of various countries in Asia [12–17], there has not yet been an analysis of the potential economic effect of adding PCV7 to the routine childhood vaccination schedule in China. In this study, for several reasons, we focus attention on PCV7 rather than alternative, higher valency versions of the pneumococcal vaccine. At the time of this writing, PCV7 is the only pneumococcal conjugate vaccine that is approved for use in China, and it is currently listed as a type 2 vaccine on the Expanded Program Immunization, making it nonmandatory and not reimbursed [18,19]. Furthermore, higher valency pneumococcal vaccines, such as the 13-valent pneumococcal conjugate vaccine, are unlikely to be available in China before 2016. To estimate the effect of PCV7 in China, this study applies demographic, epidemiological, and medical cost data from local and regional sources to a mathematical model designed to estimate both the clinical and economic benefits of the PCV7 vaccine, and incorporates both the direct effect of the vaccine on children in Shanghai and the indirect effects of herd protection on the unvaccinated child and adult population. Given the lack of availability of higher valency versions of the pneumococcal conjugate vaccine in China, it would be difficult to effectively populate the model with local, Chinese-specific data necessary for a relevant evaluation of the effect of the vaccine in a Chinese population setting. In addition, given that PCV7 is not currently in widespread use in China, it is particularly relevant that many regional, Asian-specific studies have focused on PCV7, providing a set of relevant references with which our results can be suitably compared.

Methods

Model Structure

To estimate outcomes associated with various vaccination strategies, a previously developed decision-analytic model designed for pneumococcal disease and outcomes of pneumococcal infection [20] was adapted to estimate the health outcomes from including the PCV7 vaccine into the routine vaccination schedule for a birth cohort of infants in Shanghai using a cross-sectional analysis over a 1-year period. The clinical starting point of the model is the vaccination strategy, comparing the case of no vaccinations to a case in which the vaccination coverage level is 85% for all newly born infants in Shanghai. Vaccine administration for the birth cohort occurs with a primary series of three doses in the first 6 months and a booster dose at age 12 months. Individuals within the model had a probability of contracting invasive pneumococcal disease (bacteremia and meningitis), all-cause pneumonia, or all-cause otitis media. Outcomes were calculated over a 1-year period that was assumed to occur at a point at which the vaccine effects had reached a steady state, approximately 5 to 7 years after the introduction of the vaccine. Disease cases were estimated on the basis of disease incidence, serotype coverage, and both the direct effect of the vaccine and the indirect effect from herd protection on the unvaccinated population.

Estimates of the Shanghai population by age for 2011 are based on data from the 6th Population Survey of Shanghai [21]. The population within the model is broken up into seven age groups (<2, 2–4, 5–17, 18–34, 35–49, 50–64, and 65+ y). All children in the model younger than 5 years are considered to have been vaccinated in previous periods. The birth cohort, consisting of all children in the model younger than 12 months, is assumed to receive the infant series and booster dose in the current period with a vaccine coverage rate of 85%. This level of vaccine coverage is consistent with observed levels of coverage in the United States [22] and is therefore considered a more appropriate level of coverage expectation than the standard universal coverage hypothesis often used in similar analyses of vaccine cost-effectiveness studies. Based on population estimates for 2011, this incoming birth cohort is considered to be 0.88% of the total population of Shanghai, or approximately 202,568 individuals [21]. All children aged 5 years or older and adults are considered unvaccinated during all stages in the model.

Outcomes are assessed as a cross-sectional analysis over a 1-year period, which was assumed to occur after the vaccine effects have reached a steady state, for the entire population of Shanghai to capture both the direct benefits for the vaccinated population and the indirect benefits of herd protection among the unvaccinated. The disease states incorporated into the model include invasive pneumococcal disease (bacteremia and meningitis), all-cause pneumonia (inpatient and outpatient), and all-cause otitis media (mild, and moderate to severe). Disease states within the model are not mutually exclusive, so it is considered possible for individuals to experience multiple pneumococcal-related outcomes during the annual cycle. The model calculates the number of estimated pneumococcal infections for each age grouping and the anticipated mortality associated with these events.

Cost inputs included in the model and the cost-effectiveness results were calculated from a payer perspective. The cost data within the model include both the direct medical costs of treatment for each disease state and age group and the cost of the vaccine per dose and the direct cost associated with administering the vaccine. The cost-effectiveness outcomes calculated include cost-per-life-year saved, cost-per-quality-adjusted-life-year (QALY) gained, and cost-per-illness avoided. All cost data are reported using 2011 Chinese yuan, consistent with the source of the cost data incorporated in the model, and discounted at 5.0% per year. Cost-effectiveness outcomes are also reported in U.S. dollars using exchange rates as of July 2011 [23] to facilitate comparisons with previously published cost-effectiveness studies on the PCV7 vaccine from other countries.

Model Parameters and Input Data

Disease Incidence and Case-Fatality Rates

Baseline age-specific disease incidence rates and case-fatality rates for disease states included in the model are reported in Table 1. Because China does not officially require reporting of IPD cases, it is difficult to obtain accurate epidemiologic data regarding IPD incidence in China. As a result, the baseline incidence data and case mortality rates for IPD and all-cause pneumonia were based on estimates from the Taiwan National Health Insurance Administration for the years 2002 to 2007 [24]. The incidence rates for each age group were calculated as the number of observed morbidity cases per 100,000 population to provide the estimated baseline incidence rate. Case-fatality rates for each age group were calculated as the probability of death conditional on having a pneumococcal-related disease by age group. It is also assumed in the model that long-term sequelae can result from meningitis infection. The model assumes, on the basis of published sources, that approximately 13% of meningitis survivors