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Vaccine

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## Cost-effectiveness of 13-valent pneumococcal conjugate vaccination in Mongolia

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### ARTICLE INFO

#### Article history:

Received 24 August 2016

Received in revised form 26 December 2016

Accepted 30 December 2016

Available online xxxxx

#### Keywords:

Pneumococcal conjugate vaccine

Cost-effectiveness

Mongolia

Vaccine

Budget impact

PCV13

### ABSTRACT

**Objective:** The Ministry of Health (MOH), Mongolia, is considering introducing 13-valent pneumococcal conjugate vaccine (PCV13) in its national immunization programme to prevent the burden of disease caused by *Streptococcus pneumoniae*. This study evaluates the cost-effectiveness and budget impact of introducing PCV13 compared to no PCV vaccination in Mongolia.

**Methods:** The incremental cost-effectiveness ratio (ICER) of introducing PCV13 compared to no PCV vaccination was assessed using an age-stratified static multiple cohort model. The risk of various clinical presentations of pneumococcal disease (meningitis, pneumonia, non-meningitis non-pneumonia invasive pneumococcal disease and acute otitis media) at all ages for thirty birth cohorts was assessed. The analysis considered both health system and societal perspectives. A 3 + 0 vaccine schedule and price of US \$3.30 per dose was assumed for the baseline scenario based on Gavi, the Vaccine Alliance's advance market commitment tail price.

**Results:** The ICER of PCV13 introduction is estimated at US\$52 per disability-adjusted life year (DALY) averted (health system perspective), and cost-saving (societal perspective). Although indirect effects of PCV have been well-documented, a conservative scenario that does not consider indirect effects estimated PCV13 introduction to cost US\$79 per DALY averted (health system perspective), and US\$19 per DALY averted (societal perspective). Vaccination with PCV13 is expected to cost around US\$920,000 in 2016, and thereafter US\$820,000 every year. The programme is likely to reduce direct disease-related costs to MOH by US\$440,000 in the first year, increasing to US\$510,000 by 2025.

**Conclusion:** Introducing PCV13 as part of Mongolia's national programme appears to be highly cost-effective when compared to no vaccination and cost-saving from a societal perspective at vaccine purchase prices offered through Gavi. Notwithstanding uncertainties around some parameters, cost-effectiveness of PCV introduction for Mongolia remains robust over a range of conservative scenarios. Availability of high-quality national data would improve future economic analyses for vaccine introduction.

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**Abbreviations:** AMC, advance market commitment; AOM, acute otitis media; CFR, case-fatality risk; DALY, disability-adjusted life year; GDP, gross domestic product; GNI, gross national income; Hib, haemophilus influenzae type b; ICER, incremental cost-effectiveness ratio; IPD, invasive pneumococcal disease; MNT, Mongolian tugrik; MOH, Ministry of Health; NPNM, non-pneumonia non-meningitis; OOP, out-of-pocket; PAHO, Pan American Health Organization; PCV, pneumococcal conjugate vaccine; WPR, Western Pacific region.

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<http://dx.doi.org/10.1016/j.vaccine.2016.12.070>

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Please cite this article in press as: Sundaram N et al. Cost-effectiveness of 13-valent pneumococcal conjugate vaccination in Mongolia. Vaccine (2017), <http://dx.doi.org/10.1016/j.vaccine.2016.12.070>

## 1. Background

*Streptococcus pneumoniae* caused an estimated 500,000 deaths worldwide among children under five years of age in 2008 [1]. In Mongolia, pneumonia is a leading cause of childhood mortality, as well as accounting for 51% of all-age respiratory disease admissions [2]. Severe air pollution, especially in winter, exacerbates the problems caused by pneumonia and other acute respiratory infections [3]. Shortage of equipment, drugs and skilled health professionals, mostly in rural areas, further contribute to high preventable mortality from pneumonia [4]. *S. pneumoniae* and *Haemophilus influenzae* type b (Hib) are leading causes of childhood pneumonia-related deaths [5] and cause a substantial portion of meningitis and sepsis, in the absence of vaccination. Since introduction of Hib vaccine in 2005 in Mongolia [6], the continuing high rate of childhood pneumonia is attributable to pneumococcus more than any other single cause.

In accordance with World Health Organization (WHO) recommendations to include pneumococcal conjugate vaccines (PCVs) in childhood immunization programs worldwide [1], Mongolia plans to introduce the 13-valent PCV (PCV13) into its Expanded Programme on Immunisation in a 3 + 0 schedule (three primary doses at 2, 3 and 4 months of age without a booster dose) that would coincide with the oral polio and pentavalent vaccine schedules [7]. PCV13 (or Pevnar-13<sup>®</sup>) protects against invasive pneumococcal disease (IPD), pneumonia and acute otitis media (AOM) from *S. pneumoniae*.

The pneumococcal Advance Market Commitment (AMC) is an innovative funding mechanism incentivising vaccine makers to produce affordable vaccines for the world's poorest countries. Ministry of Health (MOH), Mongolia applied to Gavi, the Vaccine Alliance (Gavi) in 2013 to purchase PCV13 through the AMC mechanism and received Gavi approval in March 2014 for PCV introduction starting in 2016, with the intent of scaling up to a nationwide programme. Although Mongolia's current Gross National Income (GNI) per capita is above Gavi's threshold and the country is therefore transitioned out of Gavi support in 2016, it remains eligible for PCV vaccine prices under the AMC even after being fully self-financed [8]. However, introduction of PCV will still require financing to cover costs of vaccine purchase and vaccination within the immunization programme. Mongolia's government has thus identified the need to assess the cost-effectiveness and financial sustainability of PCV13 introduction in the Mongolian context [7].

A collaboration between MOH, local and foreign investigators was established to conduct an economic evaluation for PCV introduction to inform decision making and establish the case for sustained investment. This evaluation is the first country-specific study to assess the costs and outcomes associated with PCV13, in order to determine whether PCV13 is cost-effective to introduce as part of Mongolia's national immunisation programme, as well as its likely budget impact.

## 2. Methods

### 2.1. Model overview and analytic framework

In order to investigate the value for money and financial sustainability respectively of vaccination the incremental cost-effectiveness of introducing PCV13 compared to no PCV vaccination was assessed using an age-stratified static multiple-cohort model (Fig. 1). The model assesses the risk of various clinical presentations of pneumococcal disease—meningitis (including sequelae), pneumonia, non-pneumonia non-meningitis (NPNM) IPD and AOM—for each year of life between 0 and 100, in both

vaccinated and unvaccinated individuals, and both with and without a vaccination programme. Each disease episode is associated with a cost and health utility loss. Thirty consecutive birth cohorts were assessed over a thirty year time period. The direct effect of PCV (direct population effects) is assessed by a proportionate reduction in pneumococcal disease risk in vaccinated individuals. The indirect effects of PCV introduction—herd protection (referring to a lower risk of infection among unvaccinated individuals due to increase in population-level immunity, generated by reduction in carriage of vaccine serotypes) and serotype replacement (a phenomenon referring to an increase in incidence of invasive disease caused by non-vaccine serotypes and proportion of carriage of non-vaccine serotypes after vaccine introduction)—are also considered by an adjustment to disease risk in unvaccinated individuals in the presence of a population-wide vaccination programme. Although there is substantial evidence for the existence of these indirect effects from post-introduction surveillance [9,10], the magnitude of such effects is uncertain, so we considered an alternative conservative scenario without indirect effects.

The budget impact analysis was conducted over a 10 year horizon. For each year of the analysis, costs were calculated from net costs from all modelled birth cohorts (including adult cohorts affected by indirect vaccine effects) that were born in the same or previous years. All direct costs were assumed to be included in the budget impact; indirect societal costs were also shown in a sensitivity analysis.

Costs were inflated to 2014 prices based on Mongolia's inflation rate of 15.0% in 2012 and 8.6% in 2013 [11]. Costs were then converted into United States (US) dollars using the average exchange rate for the year 2014 between the US dollar (US\$) and the Mongolian tugrik (MNT): 1 US\$ = 1804.50 MNT. Future costs and outcomes were discounted from the first year of vaccination at 3% per annum [12]. The analysis was done from the perspective of both the health system and society. Health system costs included vaccine costs (purchase, freight and administration), cold chain, surveillance, and hospitalization or health centre consultation costs. Societal costs considered productivity losses and out-of-pocket expenses in addition to health system costs noted above. Table 1 shows base case parameters used in the model.

### 2.2. Demographics

Population estimates for 2012 stratified by year of age were obtained in hard copy from the National Statistical Office, Mongolia and life expectancies were obtained from WHO's 2011 Life Tables for Mongolia [13].

### 2.3. Vaccine coverage

A 3 + 0 schedule with vaccine coverage of 98.2% and 97.6% for first and third dose, respectively, was assumed, based on administrative coverage data of diphtheria-tetanus-pertussis vaccine given at the same ages [14]. Second dose coverage was assumed to be the average of the first and third doses. In addition, buffer stock of 25% of first dose coverage and 2% wastage (based on wastage for pentavalent vaccine communicated through the Expanded Programme on Immunization) was assumed.

### 2.4. Vaccine cost

A per-dose cost of \$3.30 was used, since Mongolia is eligible to purchase pneumococcal vaccines at the Gavi AMC 'tail price' [8] set at \$3.30 from 2014 onwards based on the third AMC supply agreement (22 July 2013) [15]. An additional 4% was added to account for vaccine freight as well as \$0.0605 and \$0.008 per dose for

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