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Cost-effectiveness of pneumococcal conjugate vaccination in Georgia

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ABSTRACT

Objective: Financial support from the Global Alliance for Vaccines and Immunization (GAVI) to introduce the 10-valent pneumococcal conjugate vaccine (PCV10) into the routine childhood immunization schedule in Georgia is ending in 2015. As a result, the Interagency Coordination Committee (ICC) decided to carry out a cost-effectiveness analysis to gather additional evidence to advocate for an appropriate evidence-based decision after GAVI support is over. The study also aimed to strengthen national capacity to conduct cost-effectiveness studies, and to introduce economic evaluations into Georgia's decision-making process.

Methodology: A multidisciplinary team of national experts led by a member of the ICC carried out the analysis that compared two scenarios: introducing PCV10 vs no vaccination. The TRIVAC model was used to evaluate 10 cohorts of children over the period 2014–2023. National data was used to inform demographics, disease burden, vaccine coverage, health service utilization, and costs. Evidence from clinical trials and the scientific literature was used to estimate the impact of the vaccine. A 3 + 0 schedule and a vaccine price increasing to US$ 3.50 per dose was assumed for the base-case scenario. Alternative univariate and multivariate scenarios were evaluated.

Results: Over the 10-year period, PCV10 was estimated to prevent 7170 (8288 undiscounted) outpatient visits due to all-cause acute otitis media, 5325 (6154 undiscounted) admissions due to all-cause pneumonia, 87 (100 undiscounted) admissions due to pneumococcal meningitis, and 508 (588 undiscounted) admissions due to pneumococcal non-pneumonia and non-meningitis (NPNM). In addition, the vaccine was estimated to prevent 41 (48 undiscounted) deaths. This is equivalent to approximately 5 deaths and 700 admissions prevented each year in Georgia. Over the 10-year period, PCV10 would cost the government approximately US$ 4.4 million ($440,000 per year). However, about half of this would be offset by the treatment costs prevented. The discounted cost-effectiveness ratio was estimated to be US$ 1599 per DALY averted with scenarios ranging from US$ 286 to US$ 7787.

Discussion: This study led to better multi-sectoral collaboration and improved national capacity to perform economic evaluations. Routine infant vaccination against *Streptococcus pneumoniae* would be highly cost-effective in Georgia. The decision to introduce PCV10 was already made some time before the study was initiated but it provided important economic evidence in support of that decision. There are several uncertainties around many of the parameters used, but a multivariate scenario analysis with several conservative assumptions (including no herd effect in older individuals) shows that this recommendation is robust. This study supports the decision to introduce PCV10 in Georgia.

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1. Introduction

Georgia has faced civil conflicts and economic and social decline since it gained independence from the Soviet Union in 1991. However, over the past decade, the socio-economic situation has improved due to substantial economic and social reforms. While

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economic growth was adversely affected by the August 2008 conflict, growth rebounded again in 2010 and the World Bank now classifies Georgia as a lower middle-income country. Similarly, over the last 10 years (2002–2012) the infant mortality rate was cut by nearly half, dropping from 20.1 to 10.8 deaths per 1000 live births, according to national health statistics, and from 23.6 to 12.6 deaths per 1000 live births, according to vital statistics.

Among the main causes of infant deaths are diseases of the respiratory system, certain conditions originating in the perinatal period, infectious and parasitic diseases, congenital malformations, and external causes such as accidents, injuries, and poisoning. The highest proportion of child morbidity is related to respiratory system diseases. Two efficacious and safe pneumococcal conjugate vaccines (PCV) are currently available to help reduce mortality and morbidity due to pneumonia, meningitis, and other invasive diseases caused by *Streptococcus pneumoniae* (Spn). Both vaccines can currently be procured with the financial support of the Global Alliance for Vaccines and Immunization (GAVI), but the support ends December 2015 and the government will then bear the total cost of the program. Georgia had planned to introduce the 10-valent pneumococcal conjugate vaccine (PCV10) in 2013 but due to healthcare system reorganization and the late introduction of a rotavirus vaccination (RV), a decision was made to postpone introducing PCV until 2014. Therefore, in consultation with the World Health Organization (WHO) Regional Office for Europe, the Interagency Coordination Committee (ICC), which is the national advisory committee on immunization, decided to conduct a cost-effectiveness analysis (CEA) on the introduction of PCV10 with support from the ProVac International Working Group (IWG). The aim of the study was to inform the government about the economic and epidemiological impact of introducing PCV10. A multidisciplinary team of national experts from several organizations (including and led by a member of the ICC), was established and met regularly to collect and review the best available national data. The team conducted the CEA to evaluate whether or not introduction of PCV10 would be cost-effective compared to no introduction, and through this process, to decide whether or not to advocate for an appropriate evidence-based decision after GAVI support has ended.

2. Methods

The ProVac Initiative was begun in the Americas by the Pan American Health Organization (PAHO) and during a two-year pilot phase, it was expanded to other regions through the ProVac IWG [1]. Georgia was supported by the Agence de Médecine Préventive (AMP), an implementing partner of the ProVac IWG, in collaboration with WHO Europe. The TRIVAC decision support model, version 2.0, was used. This is an internationally recognized transparent Excel®-based model, described in detail elsewhere [2]. The parameters of the model required collection of data that included demography, burden of disease, health services utilization and costs, vaccine coverage, vaccine efficacy, and vaccination program costs.

2.1. Analytic framework

The analysis evaluated the costs and benefits of two alternative situations: (1) universal introduction of the PCV10 vaccination into the Georgian National Immunization Program and (2) no PCV vaccination. Ten consecutive births cohorts were modeled over the period 2014–2023. Following WHO recommendations, a 3% discount rate was used for both costs and health outcomes [18]. We assumed that PCV10 would be administered in three primary doses without a booster dose (3p + 0). Realistic estimates of vaccination coverage and timeliness were based on estimates available for DTP vaccination. Four clinical outcomes related to *S. pneumoniae* were included: (1) outpatient visits due to all-cause acute otitis media (AOM), (2) inpatient admissions due to all-cause pneumonia, (3) inpatient admissions due to pneumococcal meningitis, and (4) inpatient admissions due to pneumococcal non-pneumonia non-meningitis (NPNM) invasive disease. It was the opinion of expert members of the team, that all cases of severe pneumonia, pneumococcal meningitis and pneumococcal NPNM would be admitted to a hospital in Georgia; as a result, it was practical and reasonable to focus on admissions rather than all cases in the community. A government perspective was taken, so no household costs were considered. In Georgia, the majority of providers are private and costs of treatment are partly or fully covered by the government. Three types of providers were taken into account: primary care providers (private individual entrepreneurs, who receive salaries from government), secondary care (polyclinics), and tertiary care (hospitals). All three providers handle outpatient visits for AOM, but only hospitals (tertiary care) handle inpatient admissions for invasive pneumococcal disease.

2.2. Demography

The National Statistics Office of Georgia (Geostat) provided all demographic data [4]. The number of births for 2012 was 56,890. In the base-case scenario, a declining trend (based on the projection of the United Nations Population Division [UNPOP]) was applied to this figure to estimate the number of births in future years [5]. To take into consideration the uncertainty around the assumption of a declining population, a second scenario with no year-over-year trend was also evaluated. Estimates on mortality rates for infants and children younger than 5 years of age were provided by the National Centre for Disease Control and Public Health (NCDC). In 2012, 14 of every 1000 live births died before the age of 1; 16 of every 1000 live births died before the age of 5. The life expectancy for those born in 2012 was assumed to be 75. This was used to estimate the number of life-years lost and disability-adjusted life-years (DALY) due to mortality related to *S. pneumoniae*. The UNPOP projections for Georgia were applied to these estimates to generate a projection for the period 2014–2023 [3].

2.3. Burden of disease

Data concerning AOM and pneumonia were based on national statistical reports published in the statistical yearbook 2012 [6]. Two types of reports were available to estimate AOM incidence; therefore, two estimates of incidences were calculated. Both report types gather data from health facilities based on the International Classification of Diseases (ICD) 10th revision codes. However, one is from the Tbilisi-level case-based reporting system and the other one is from the national reporting system of notifiable diseases. These two reporting systems were used to estimate a Tbilisi annual incidence of 1695 cases of AOM per 100,000 under 5 years old and a national annual incidence of 3073 per 100,000 under 5 years. The more conservative Tbilisi incidence was used in the base-case analysis; the national incidence was used in the scenario analysis. The national-level reporting was sufficient to estimate the incidence of pneumonia admissions, 1603 per 100,000 under 5 years old. For pneumococcal meningitis and pneumococcal NPNM, no national data were available; instead, WHO 2008 estimates for Georgia were used [7], with annual incidences, respectively, of 10 and 62 per 100,000 under 5 years.

Data on the number of pneumonia deaths was based on the national reporting system. A case fatality ratio (CFR) was calculated by dividing the number of pneumonia deaths by the estimated number of pneumonia admissions. The CFR of 25% for

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