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Cost-effectiveness of rotavirus vaccination in Albania

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ABSTRACT

Background: Rotavirus vaccines have been introduced in several European countries but can represent a considerable cost, particularly for countries that do not qualify for any external financial support. This study aimed to evaluate the cost-effectiveness of introducing rotavirus vaccination into Albania's national immunization program and to inform national decision-making by improving national capacity to conduct economic evaluations of new vaccines.

Methods: The TRIVAC model was used to assess vaccine impact and cost-effectiveness. The model estimated health and economic outcomes attributed to 10 successive vaccinated birth cohorts (2013–2022) from a government and societal perspective. Epidemiological and economic data used in the model were based on national cost studies, and surveillance data, as well as estimates from the scientific literature. Cost-effectiveness was estimated for both the monovalent (RV1) and pentavalent vaccines (RV5). A multivariate scenario analysis (SA) was performed to evaluate the uncertainty around the incremental cost-effectiveness ratios (ICERs).

Results: With 3% discounting of costs and health benefits over the period 2013–2022, rotavirus vaccination in Albania could avert 51,172 outpatient visits, 14,200 hospitalizations, 27 deaths, 950 disability-adjusted life-years (DALYs), and gain 801 life-years. When both vaccines were compared to no vaccination, the discounted cost per DALY averted was US$ 2008 for RV1 and US$ 5047 for RV5 from a government perspective. From the societal perspective the values were US$ 517 and US$ 3556, respectively.

Conclusion: From both the perspectives, the introduction of rotavirus vaccine to the Albanian immunization schedule is either cost-effective or highly cost-effective for a range of plausible scenarios. In most scenarios, including the base-case scenario, the discounted cost per DALY averted was less than three times the gross domestic product (GDP) per capita. However, rotavirus vaccination was not cost-effective when rotavirus cases and deaths were based on plausible minimum estimates. Introduction of RV1 would yield similar benefits at lower cost.

1. Introduction

Rotavirus diarrhea is among the main causes of childhood illnesses in developing and developed countries [1]. Children experience their first episode of rotavirus diarrhea before reaching 12 months of age in developing countries and between 2 and 5 years of age in developed countries [2,3]. The World Health Organization (WHO) estimated that approximately half a million children died from rotavirus gastroenteritis (RVGE) in the year 2008, and the majority of this burden was borne by low-income countries [4]. RVGE often accounts for a large number of outpatient visits and inpatient admissions and can therefore represent significant health care costs to governments and households [3].

In Albania, rotavirus has been observed since 1988. In Tirana, rotavirus was detected in 25.1% of young children hospitalized with severe gastroenteritis during 1988–1991 [3] and in 10.3% of cases during 1993–1994 [5]. In 2000, rotavirus was the cause of a large gastroenteritis outbreak, mainly among children under 5 years old [6]. Despite the declining trend observed during the 1990s, unpublished data from the Institute of Public Health (IPH) indicates that in 2011–2012 rotavirus was detected in 31.7% of samples collected from five sentinel hospitals in the country. The main rotavirus serotypes circulating in Albania are G4 (the majority of cases), G1, G2, G9, P4, and P8 [7,8].

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Several studies have shown that rotavirus vaccination is a cost-effective intervention in different economic and epidemiological contexts [9–12]. The two rotavirus vaccines available today are the monovalent vaccine (RV1, Rotarix®, *GlaxoSmithKline*) and the pentavalent vaccine (RV5, RotaTeq®, *Merck*) [13].

RV1 has a recommended schedule of two doses, whereas RV5 requires three doses. Both vaccines are considered safe by the WHO [14] and are included in immunization programs of several countries [1].

The Albanian immunization program has historically been a success story; 99% of children are expected to be covered. The rotavirus vaccine is planned to be introduced by 2015 in Albania and efforts were made to change from an oral polio vaccine (OPV) to an inactivated polio vaccine (IPV), in line with European Union (EU) immunization schedules [15]. Lately, rotavirus vaccination has been a matter of energetic public debate in Albania. This has highlighted the pressing need for the group of experts that is the national advisory committee on immunization to assess the cost-effectiveness of introducing new vaccines and provide further evidence to the country decision-makers.

To conduct this exercise, Albania requested technical support from the WHO's Regional Office in Europe. The support came from the ProVac International Working Group (IWG) with the contribution from WHO Office in Europe, the United States' Centers of Diseases Control and Prevention, the Agence de Médecine Préventive, the Program for Appropriate Technology in Health, the Sabin Vaccine Institute, and the London School of Hygiene and Tropical Medicine. ProVac is an Initiative of the Pan American Health organization that was officially launched in 2006 [16]. Albania was the first country outside of the Americas to conduct a cost-effectiveness analysis (CEA) with ProVac tools, assisted by the ProVac IWG.

The aim of this paper is to evaluate the cost-effectiveness of introducing rotavirus vaccine in the Albanian national immunization schedule by comparing rotavirus vaccination to the status quo (i.e., no rotavirus vaccination).

2. Materials and methods

2.1. Analytic framework

The cost-effectiveness of introducing the rotavirus vaccine was estimated using the TRIVAC model, version 2.0. TRIVAC is a decision-support model designed for use by a national country team to explore the impact and cost-effectiveness of rotavirus vaccination under a range of plausible scenarios [17]. The model provides information on disability-adjusted life-years (DALYs) over the lifetime of the cohorts evaluated, with and without vaccine introduction, and provides an incremental cost-effectiveness ratio (ICER), which indicates the cost-effectiveness of rotavirus vaccination in terms of US$ per DALY averted. The TRIVAC model was used to evaluate both RV1 and RV5.

In each analysis, 10 consecutive birth cohorts of children between 0 and 59 months of age were considered; 2014 was assumed as the year of introduction. The model tracked each birth cohort from birth until death. All costs, cases, and deaths were calculated from birth up to age 5 years. The analysis accounted for the full stream of life years and DALYs lost following a death using life expectancy estimates. The costs and benefits attributed to each birth cohort were aggregated to provide results for a 10-year vaccination program, thus allowing the model to capture trends in vaccine price and rotavirus mortality over time. The input parameters included in the TRIVAC model are demography, burden of disease, vaccine coverage and efficacy, health services utilization, and costs of both vaccination and health services. Based on the WHO guide [18], a 3% discount rate was used for both benefits and costs.

2.2. Demographic data

The following demographic data were used: (1) number of live births per year (34,498 in 2011), from the cohort database (1–12 months old) of the National Immunization Program (NIP) housed by the IPH; (2) infant mortality per 1000 live births, from the Bureau of Statistics Ministry of Health; and (3) mortality in children under 5 per 1000 live births and life expectancy at birth, from the National Institute of Statistics (INSTAT). The life expectancy projections from the United Nations Population division (UNPOP) were rescaled using the national estimates.

2.3. Burden of disease

We estimated the incidence of rotavirus outpatient visits and rotavirus admissions and the rotavirus mortality rate in children younger than 5 (see Table 1). To estimate the timely burden of rotavirus diarrhea in children in that age cohort, a sentinel surveillance system was set up in 2010–2011 in Tirana, Durres, Lezha, Vlora, and Fier hospital districts. In 2011, records show that there were 8649 rotavirus gastroenteritis (RVGE) outpatient visits and 2400 inpatient RVGE admissions. Because there were no reliable national data available on rotavirus mortality, the WHO projections for mortality figures due to rotavirus were used [19] instead.

2.4. Costs related to rotavirus burden: governmental and societal perspectives

We addressed the rotavirus costs from governmental and societal perspectives. The governmental perspective includes the costs of medical care related to rotavirus disease incurred by the public sector because the cases are generally handled by public facilities. Albania's healthcare system has a single entity that pays for healthcare services delivered by public and private providers: the Health Insurance Fund (HIF), a government agency.

2.5. Governmental perspective: health utilization costs

Healthcare costs saved by preventing rotavirus infection were estimated for three levels of service providers: primary (health centers), secondary (district hospitals and emergency rooms [ER]), and tertiary (Tirana hospital and ER). According to the sentinel system, 60% of outpatient visits were treated in primary care clinics and 40% in the ER of public hospitals. The methodology used for estimating the economic burden of rotavirus consists of a bottom-up technique [18], including direct medical costs such as salaries of pediatricians and nurses, costs of examinations, food, consumables, and pharmaceuticals, as well as utility, cleaning, laundry, administration, maintenance, and depreciation costs (Table 2). The costs were calculated in Albanian Lek (ALL) currency and then expressed in United States dollars (US$) using the 2011 exchange rate of 100.812 ALL = US$1 [20].

2.6. Societal perspective: household costs as social costs

Societal costs included all government costs plus costs to households. Household costs were calculated based on transportation cost and costs in the form of loss of productivity (LoP) due to caretakers taking time off from work. To estimate lost productivity, we used the WHO guide, which is based on the GDP per capita [18].

Rotavirus disease in a child is likely to have an impact on parents. However, in Albania, the impact is not expected to be the same for both parents, since mothers bear the weight of childcare. Consequently, the cost of only one caregiver was used to measure lost productivity (Table 2).