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Cost-effectiveness of rotavirus vaccination in Kenya and Uganda

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ABSTRACT

Introduction: Rotavirus vaccines have the potential to prevent a substantial amount of life-threatening gastroenteritis in young African children. This paper presents the results of prospective cost-effectiveness analyses for rotavirus vaccine introduction for Kenya and Uganda.
Methodology: In each country, a national consultant worked with a national technical working group to identify appropriate data and validate study results. Secondary data on demographics, disease burden, health utilization, and costs were used to populate the TRIVAC cost-effectiveness model. The baseline analysis assumed an initial vaccine price of $0.20 per dose, corresponding to Gavi, the Vaccine Alliance stipulated copay for low-income countries. The incremental cost-effectiveness of a 2-dose rotavirus vaccination schedule was evaluated for 20 successive birth cohorts from the government perspective in both countries, and from the societal perspective in Uganda.
Results: Between 2014 and 2033, rotavirus vaccination can avert approximately 60,935 and 216,454 undiscounted deaths and hospital admissions respectively in children under 5 years in Kenya. In Uganda, the respective number of undiscounted deaths and hospital admission averted is 70,236 and 329,779 between 2016 and 2035. Over the 20-year period, the discounted vaccine program costs are around US$ 80 million in Kenya and US$ 60 million in Uganda. Discounted government health service costs avoided are US$ 30 million in Kenya and US$ 10 million in Uganda (or US$ 18 million including household costs). The cost per disability-adjusted life-year (DALY) averted from a government perspective is US$ 38 in Kenya and US$ 34 in Uganda (US$ 29 from a societal perspective).
Conclusions: Rotavirus vaccine introduction is highly cost-effective in both countries in a range of plausible 'what-if' scenarios. The involvement of national experts improves the quality of data used, is likely to increase acceptability of the results in decision-making, and can contribute to strengthened national capacity to undertake economic evaluations.

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1. Background

Diarrhea is the second leading cause of death worldwide among children aged 1–59 months [1]. Rotavirus is the main cause of severe childhood diarrhea [2,3] accounting for about 192,700 deaths each year (range 133,100–284,400), with about 50% of the deaths occurring in the World Health Organization (WHO) Africa Region [4]. WHO also estimates that 7.3% of deaths among children under 5 in Uganda and 6.4% in Kenya are attributable to rotavirus [5].

Rotavirus vaccines offer an opportunity to avert a substantial amount of childhood morbidity and mortality [6,7]. Currently, there are two rotavirus vaccines that are prequalified by WHO and supported by Gavi, the Vaccine Alliance (Gavi): the pentavalent Merck RotaTeq® (RV5), and GlaxoSmithKline Biologicals' monovalent Rotarix® (RV1). Both are orally administered vaccines given to young infants via a 2-dose (Rotarix®) or 3-dose (RotaTeq®) schedule. Post-introduction studies in the USA and elsewhere have shown that vaccine introduction has led to a reduction in the disease burden, and especially a reduction in the number of hospitalizations due to rotavirus [8].

Several African countries have introduced rotavirus vaccines into their national immunization programs. The vaccine was introduced in July 2014 in Kenya, while introduction in Uganda is planned for 2016. Both countries have shown a preference for the monovalent (RV1) vaccine which has fewer recommended doses than the pentavalent vaccine (RV5). In Kenya, another important practical consideration was the vaccine vial monitor which comes with RV1 but not RV5.

The cost-effectiveness of a new health intervention is one of the several important factors considered by decision-makers before an intervention is introduced. Therefore, a key objective of this analysis was to evaluate the cost-effectiveness of introducing RV1 into the routine immunization programs of Kenya and Uganda. The study used a decision support model and country-led process first developed under the ProVac Initiative of the Pan American Health Organization (PAHO) [9]. This study also aimed to strengthen national capacity to collect, use, and interpret epidemiological and economic evidence.

2. Methods

2.1. The process of conducting the country studies

In both countries, a national consultant was hired who then convened a national team of experts (the technical working group [TWG]), which had expertise in rotavirus, surveillance, immunization, and health system costs. Each team worked together to identify possible data sources for the model inputs and to determine the best choice of data to be used in the model. A comprehensive review of all published literature with special focus on local studies was supplemented by other local unpublished data, where relevant. The consultants also worked with the TWG to identify appropriate national sources of evidence, including government reports and national epidemiological studies. The TWG also reviewed the model results and helped develop a set of plausible 'what-if' scenarios. The study results were presented to national stakeholders by the national consultant on behalf of the national team.

2.2. TRIVAC model overview

The TRIVAC cost-effectiveness model (version 2.0) was used. This model was developed by PAHO's ProVac Initiative in collaboration with researchers from the London School of Hygiene and Tropical Medicine. The TRIVAC model is an Excel-based model (Microsoft Corporation, Redmond, Washington, US) used to evaluate the cost-effectiveness of three childhood vaccines (*Haemophilus influenzae* type b, pneumococcal conjugate vaccine, and rotavirus vaccine) [10]. The model has been designed for use at country level, and it has been used to train national teams and carry out cost-effectiveness evaluations in over 20 countries around the world.

The model input parameters are demographics, burden of disease, vaccine schedule, vaccine efficacy, vaccine coverage, vaccine costs, health service utilization, and health service costs. Mid estimates are entered for all parameters and used in the base-case scenario. Low and high values are entered for the most uncertain parameters and used in 'what-if' scenario analysis.

2.3. Comparator and key outcomes

In this study, a *status quo* of no vaccine introduction was compared to RV1 introduction in the routine immunization program. The model estimates the number of deaths, hospital admissions, and outpatient visits, as well as disability-adjusted life-years (DALYs) that can be averted by vaccine introduction. It also estimates vaccination program costs and healthcare costs that could be averted. Cost-effectiveness was estimated in terms of the cost per DALY averted. Based on WHO CHOICE guidelines, our criteria for cost-effectiveness was: if the incremental cost per DALY averted is less the gross domestic product (GDP) per capita then the vaccine was considered to be very cost-effective, if between one and three times the GDP per capita it was cost-effective, and if greater than three times the GDP per capita, then it was not cost-effective [11].

2.4. Conceptual framework for the analyses

In both Kenya and Uganda we evaluated the impact of RV1 introduction on rotavirus gastroenteritis (RVGE) outpatient visits, inpatient admissions, and deaths. In addition, the TRIVAC model allows the user to select whether or not they wish to consider the morbidity associated with RVGE cases, irrespective of whether or not they use health care services. RVGE cases were not included in the Kenya analysis, but in Uganda we evaluated the impact of the vaccine on non-severe and severe RVGE cases. The choice of the type of analysis was driven by the local context, i.e., the type and quality of disease burden data available and the type of evidence considered to be most relevant for national decision-makers.

2.5. Model set-up parameters

Based on country introduction plans, 2014 was selected as the year of vaccine introduction for Kenya; 2016 was selected for Uganda. Cost-effectiveness was evaluated for 20 birth cohorts because this is the maximum number of birth cohorts included in the TRIVAC model and it allows for trends in influential parameters such as RVGE mortality and vaccine price. It was assumed that rotavirus vaccine would be given with no age restriction, i.e., that vaccination can be initiated for children older than 15 weeks. This assumption was based on a recent WHO recommendation to lift the age restriction in countries with high rotavirus mortality [7]. Costs and benefits were discounted at 3% [12].

For Kenya, the analysis was done only from the government perspective due to insufficient data on lost wages and indirect medical costs incurred by households. For Uganda, both government and societal perspectives were evaluated.

2.6. Demographic data

Projections of live births, child mortality rates, and life expectancy over the 20-year period evaluated were obtained from