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Cost-effectiveness analysis of the introduction of rotavirus vaccine in Iran

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ABSTRACT

Background: Although the mortality from diarrheal diseases has been decreasing dramatically in Iran, it still represents an important proportion of disease burden in children <5 years old. Rotavirus vaccines are among the most effective strategies against diarrheal diseases in specific epidemiological conditions. This study aimed to evaluate the cost-effectiveness of the introduction of rotavirus vaccine (3 doses of pentavalent RotaTeq® (RV5)) in Iran, from the viewpoints of Iran's health system and society.

Methods: The TRIVAC decision support model was used to calculate total incremental costs, life years (LYs) gained, and disability-adjusted life years (DALYs) averted due to the vaccination program. Necessary input data were collected from the most valid accessible sources as well as a systematic review and meta-analysis on epidemiological studies. We used WHO guidelines to estimate vaccination cost. An annual discount rate of 3% was considered for both health gain and costs. A deterministic sensitivity analysis was performed for testing the robustness of the models results.

Results: Our results indicated that total DALYs potentially lost due to rotavirus diarrhea within 10 years would be 138,161, of which 76,591 could be prevented by rotavirus vaccine. The total vaccination cost for 10 cohorts was estimated to be US$ 499.91 million. Also, US$ 470.61 million would be saved because of preventing outpatient visits and inpatient admissions (cost-saving from the society perspective). We estimated a cost per DALY averted of US$ 2868 for RV5 vaccination, which corresponds to a highly cost-effective strategy from the government perspective. In the sensitivity analysis, all scenarios tested were still cost-saving or highly cost-effective from the society perspective, except in the least favorable scenario and low vaccine efficacy and disease incidence scenario.

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Conclusion: Based on the findings, introduction of rotavirus vaccine is a highly cost-effective strategy from the government perspective. Introducing the vaccine to the national immunization program is an efficient use of available funds to reduce child mortality and morbidity in Iran.

1. Introduction

The high prevalence and incidence of diarrhea are recognized as a major health problem. There were nearly 1.7 billion diarrhea episodes among children less than 5 years of age in low- and middle-income countries in 2010 [1]. Diarrheal disease is also the second leading cause of death in children under 5 years old, killing about one million children every year [2].

Rotavirus is the most important cause of severe diarrhea in infants and young children worldwide [3,4]. Rotaviruses are ubiquitous, and 95% of children are infected by the age of 5 years. Rotavirus is responsible for a large proportion of the above-mentioned deaths and 20–54% of acute diarrhea episodes worldwide [5–7].

Eesteghamati and his colleagues [8] reported that rotavirus is the most important cause of severe diarrhea among hospitalized children aged less than 5 years old in Iran. Those researchers also found that rotavirus disease accounts for more than one-half of all hospitalizations for severe diarrhea.

Recent studies show that rotavirus vaccines might be the best choice for preventing severe rotavirus disease and the deadly dehydrating diarrhea that it causes, particularly in low-income countries where access to treatment for RV is limited [9,10]. There are two rotavirus vaccines: the pentavalent RotaTeq® (RV5) (Merck and Co. Inc., West Point, Pennsylvania, USA) and the monovalent Rotarix® (RV1) (GlaxoSmithKline Biologicals, Rixensart, Belgium). Studies of the rotavirus vaccine have shown that the efficacy of RV5 and RV1, respectively, against rotavirus gastroenteritis of any severity was 74.0% (95% confidence interval (CI) 66.8–79.9) and 87% (95% CI 79.6–92.1) [11,12]. More importantly, the rotavirus vaccines can prevent approximately 98% of severe infections and 70% to 100% of emergency department visits and hospitalizations from rotavirus [12–14].

Decisions to adopt vaccination programs depend on multiple factors, including the disease prevalence and incidence, vaccine efficacy, and cost-effectiveness of a vaccination program. Although some studies have estimated the cost-effectiveness of rotavirus vaccination [15–18], most of them have been conducted in developed countries, not in developing nations. Results of cost-effectiveness studies can vary among countries due to differences in epidemiological patterns, patients' characteristics or health system variables (such as incidence/prevalence of disease, adherence to the treatment regimen, individuals' preferences for particular levels of health, unit costs of inputs into health care, and variation in how health care is delivered). Moreover, no simple rule is available to indicate how the results of cost-effectiveness studies in developed countries might translate to health care delivery settings in developing nations.

The major serotype of rotavirus in Iran is G4P [8] and other dominant strains are P [8] with G nontypeable, G4 with P nontypeable, G1 [P8], and G2 [P4] [8]. Although the major serotype can be covered by RV1 through cross-reactivity, RV5 provides direct protection against it. Also, based on a recent systematic review, RV5 was used in the unique study that reported vaccine efficacy against G4 and P [8] in middle-income countries [19]. Therefore, we conducted this study to evaluate the cost-effectiveness of RV5 vaccination compared to no vaccination in Iran.

2. Methods

2.1. Study design

This economic evaluation was conducted from the perspectives of Iran's government and its society; in the governmental perspective, those direct medical costs imposed on governmental health system were included and in the societal perspective, all direct medical costs that imposed on society including (patients' families or government) were included. The TRIVAC model, a decision-support model developed by the ProVac Initiative of the Pan American Health Organization (PAHO) in collaboration with the London School of Hygiene and Tropical Medicine (LSHTM) [20], was used to calculate total incremental costs, life years gained, disability adjusted life years (DALYs) averted due to the vaccination program, and an incremental cost-effectiveness ratio (ICER). A data collection procedure was used in order to obtain the necessary input data from the most valid accessible sources for the analysis.

We used the assumptions made by TRIVAC for the natural history of rotavirus. We classified rotavirus as non-severe or severe cases of rotavirus gastroenteritis (RVGE). TRIVAC is a static model that only crudely takes account of the indirect protection of the vaccination on unvaccinated children through herd immunity or of the negative effects of type replacement. A crude multiplier of direct vaccine efficacy can be applied to replicate a herd effect; also, vaccine efficacy can be decreased to reflect the circulating serotypes [20]. We assumed 2014 as the year of introduction of the vaccine and included children 1–59 months old for 10 sequential birth cohorts in the analysis (2014–2023). The time horizon for health and economic benefits has been defined in the TRIVAC model specifications [20]. An annual discount rate of 3% was considered for both health gain and costs.

2.2. Input epidemiological and effectiveness data

2.2.1. Demographic data

The number of live births was derived using data from Iran's National Organization for Civil Registration. We used the last Multiple-Indicator Demographic and Health Survey (IrMIDHS, 2010) to obtain mortality rates among children [21]. We also used the United Nations Population Division database to extract the estimates for current life expectancy of women and men in Iran and also estimates for the future [22].

2.2.2. Disease burden

An epidemiologic model was used to estimate the incidence of diarrheal diseases. According to the 2010 Demographic and Health Survey (DHS) report [21], the 14-day prevalence of all-cause diarrhea was 13.5% in Iran (the IrMIDHS study was performed between 22 December 2010 and 20 January 2011). This included all children who had a new episode of diarrhea within 14 days before survey or those whose episode started before the period, but still were symptomatic during the period. All cases of diarrhea started within (duration-1) days before the first day of study period, were among the prevalent cases at least in the first day of the period. We used the pooled estimate for the weighted median of duration of diarrhea in low- and middle-income countries for children 0–59 month old, which was 3.1 days (3.0–3.2) in a systematic review