



Decision-making for New Vaccine Introduction: Three Key Takeaways from Georgia's Experience Introducing the Rotavirus and Human Papillomavirus Vaccines

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THE LEARNING EXCHANGE

The Linked Immunisation Action Network facilitated a discussion with Georgia immunisation and finance experts to support the Ministry of Health of Azerbaijan to learn from their neighboring country's decision-making process for new vaccine introduction and the key factors driving their decisions.

INTRODUCTION

Many middle-income countries (MICs) have not yet introduced the critical, life-saving pneumococcal conjugate vaccine (PCV), rotavirus vaccine, or human papillomavirus (HPV) vaccine. Driving the sustainable introduction of these missing vaccines in both former- and select never-Gavi eligible countries is a key objective of Gavi's MICs Approach.

The process by which a country determines whether to introduce a new vaccine is complex and dynamic. It involves many factors, including the burden of disease; vaccine characteristics, such as safety, effectiveness, and dosage requirements; financial feasibility and sustainability; programmatic feasibility, such as the available cold chain capacity; and public perceptions and confidence in the vaccine.



Photo credit: UNICEF/UN0326765

The last decade was particularly hot for Georgia's national immunisation programme (NIP) – five new vaccines were introduced, and the country's NIP became fully self-financing, which means Georgia can no longer access new financial support from Gavi. As Azerbaijan is considering whether to introduce critical new, life-saving vaccines, representatives from the Ministry of Labor, Health, and Social Affairs (MoH) approached

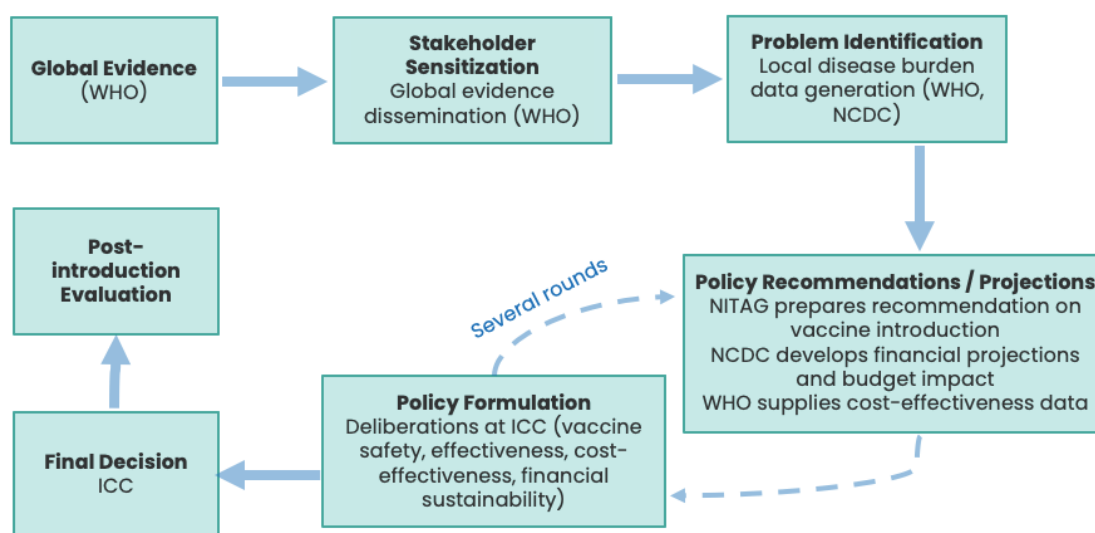
the Linked Immunisation Action Network to learn about Georgia’s experience. The Linked network organized a virtual discussion for Georgia experts from the National Center for Disease Control and Public Health (NCDC), which reports to the MoH, and the MoH to describe the decision-making process that the country followed leading to the introduction of the rotavirus and HPV vaccines (in 2013 and 2019, respectively). This virtual twinning exchange focused on Georgia’s new vaccine introduction (NVI) decision-making process, the key inputs into this process, and the factors that drove the decisions to introduce these vaccines.

Azerbaijan’s key questions for Georgia were:

1. What is the decision-making process for NVI?
2. What were the key barriers to NVI and how were decision-makers convinced?
3. What kind of preparatory work (e.g., research, assessments, evaluations) was conducted to support the decision-making process?
4. How was the introduction process initiated (pilot or nationwide)?
5. What was the attitude of the population toward NVI?
6. What results have been achieved after introduction?
7. How did the MoH and MoF coordinate decisions on increased budget for NVI?
8. What criteria are considered by the MoF during decision-making?
9. What is the cost of NVI, and can the country afford it?

MAPPING NVI DECISION-MAKING IN GEORGIA

The national NVI decision-making process engages multiple stakeholders with diverse roles, with active leadership from the MoH. There are seven key steps in the decision-making process, with two steps occurring over several rounds before proceeding to the next step (see below).



Georgia NVI National Decision-making process

THREE KEY TAKEAWAYS FROM THE DISCUSSION

1. Data was a key driver in the decision-making process.

Decision-makers need a sufficient understanding of the rationale for introducing a new vaccine and the common challenges that might arise to make informed decisions and ensure the vaccine's sustainable and equitable introduction.

- **Understanding the disease incidence and cost.** Before sentinel surveillance was established in Georgia, rotaviral infection was not considered a serious disease that caused a significant burden on children's health. Due to the relatively low risk of dying from rotavirus among children 0–5 years old (16 per 100,000), decision-makers were initially skeptical about introducing the vaccine. Once sentinel surveillance was established in 2006, the rotavirus disease burden became apparent, with 40% of diarrheal cases occurring in children between 0–5 years old. Although a cost-effectiveness study was not conducted in Georgia at this time, the Intersectoral Coordination Committee considered global and regional evidence of reduced hospitalizations and outpatient treatment leading to healthcare savings.
- **Understanding the knowledge and perceptions of the vaccine.** In 2009, Georgia launched a pilot program to introduce the HPV vaccine in Tbilisi, the nation's capital. Representatives from NCDC described the pilot as poorly prepared and poorly communicated. By 2017, the country was still reeling from this unsuccessful experience when discussions of another HPV demonstration project began. Vaccine safety concerns among health workers and parents in Georgia persisted and news from other countries in the region that experienced challenges in introducing HPV – anti-vaccination movements, religious objections, anxiety-related Adverse Events Following Immunisation (AEFI) – illustrated potential challenges that lay ahead in Georgia. However, the high burden of cervical cancer required a solution as it was the third-leading cause of cancer among women with nearly half of women receiving late-stage diagnoses. The global evidence on the effectiveness of the HPV vaccines showed an 80% reduction of HPV infection in adolescents and a 71% reduction of infection in young women.

Georgia conducted formative research to with the aim of understanding knowledge and attitudes towards the HPV vaccine. As expected, the study revealed low knowledge among parents and schoolteachers about HPV and cervical cancer, concerns about vaccine safety and adverse effects, and misinformation regarding infertility risks. The findings of the research were used to develop a communication strategy and to support targeted interventions during introduction.

2. Co-financing opportunities and favorable vaccine pricing drove a sense of urgency to introduce the vaccines.

Financial feasibility and sustainability play a critical role in NVI decision-making on vaccine introductions, especially when considering the typically high market price of new vaccines. When considering the introduction of both the rotavirus and HPV vaccines, the financially advantageous procurement opportunities available at the time were critical arguments in favor of introduction. For the rotavirus vaccine, Georgia was able to procure the vaccine at about one-third of the market price along with a 3-year co-financing agreement with Gavi. For the HPV vaccine, Georgia's ability to procure the vaccine significantly below the market price was set to expire given the country's upcoming transition from Gavi support.

3. Strong coordination with the MoF throughout the decision-making process was critical.

The Expanded Programme on Immunisation (EPI), National Immunisation Technical Advisory Group (NITAG), and other professional associations needed to persuade MoF decision-makers to increase the NIP budget for these new vaccines. During the decision-making process, the parameters of the budget were discussed among the MoF, other government units, and the Parliamentary Committee on Healthcare and Social Issues. **Among the factors considered by the MoF during budget negotiations were the significance of the disease burden, vaccine effectiveness, cost-effectiveness, availability of the vaccines, the competitiveness and stability of the vaccine prices, and the impact of previous vaccine introductions.**

"TO ENSURE THE SUSTAINABILITY OF ALLOCATED RESOURCES, BUDGETARY TRENDS BEFORE AND AFTER THE VACCINE INTRODUCTION, AS WELL AS VACCINE PROCUREMENT CHALLENGES AND OPPORTUNITIES NEED TO BE CONSTANTLY CHECKED AND CONSIDERED."

- VLADIMIR GETIA, GEORGIA NATIONAL CENTER FOR DISEASE CONTROL AND PUBLIC HEALTH (NCDC)

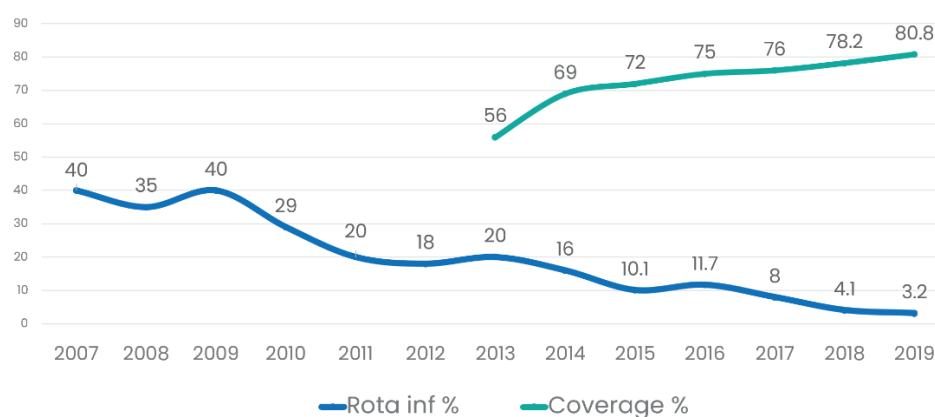
As the budget was successfully negotiated and approved for both vaccine introductions, the rotavirus vaccine comprised 5 - 23% of the EPI vaccine budget (under the 3-year co-financing scheme) and the HPV vaccine about 4-5%. However, financial concerns remain as Georgia plans for the impending expiration of Gavi pricing for the vaccines. For the rotavirus vaccine, this represents a projected 3.8% increase of the EPI budget in 2025, and for the HPV vaccine, a projected 29% increase in 2029.

NEW VACCINE INTRODUCTION OUTCOMES AND IMPACT

The Georgia experts described the importance of monitoring outcomes and impact post introduction through data on vaccine effectiveness. In 2018, five years after the introduction of the rotavirus vaccine, the hospital-based sentinel surveillance revealed an

85% reduction in hospitalization for severe gastroenteritis and a 78% reduction in outpatient visits for children 0–5 years old. As the vaccine coverage reached 80%, diarrheal cases caused by rotavirus were reduced from 40% in 2007 to 3.2% in 2019.

% of rotavirus diarrhea and coverage, 2013–2019, Georgia



Outcomes from the HPV vaccine introduction were not as impressive due to persistent HPV vaccine-specific hesitancy challenges. In 2019, the year of introduction, coverage for HPV1 was 48% and HPV2 was 36%. A post introduction evaluation of the HPV vaccine identified the following key barriers to increased coverage:

- Lack of intersectoral collaboration, particularly engagement of the education sector
- Lack of integration with preventive services screening and adolescent health
- Low confidence among health workers, due in part to insufficient training

For additional information on Georgia’s experience, access the [presentation they shared with Azerbaijan on our website](#). If you are interested in a peer-to-peer learning exchange with another country to discuss new vaccine introduction, please reach out to the Linked Immunisation Action Network at community@linkedimmunisation.org.