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# National Immunization Program Transition from External Assistance

Case study from Georgia

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**Tbilisi, 2022**

## Disclaimer

This research was supported by funding from the Alliance for Health Policy and Systems Research, World Health Organization. The Alliance is supported through both core funding as well as project specific designated funds. The full list of Alliance donors is available here: <https://ahpsr.who.int/about-us/funders>

This research also benefited from technical support from the Alliance for Health Policy and Systems Research, World Health Organization, the Department of Health Systems Governance and Financing, World Health Organization and UHC 2030.

## Acknowledgements

The research team would like to express deep gratitude to Dr. Zubin Shroff, Dr. Susan Sparkes and Dr. Maria Skarphedinsdottir for their invaluable technical support during the implementation of the study.

The authors are grateful to the key informants for their invaluable cooperation and support in preparing the case study.

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# Abbreviations

Gavi Alliance	Global Alliance for Vaccines and Immunization
GeL	Georgian Lari
CHE	Current Health Expenditure
cMYP	Comprehensive Multiyear Plan
DPT	Diphtheria Pertussis Tetanus
EPI	Expanded Program of Immunization
HMIS	Health Management Information System
HPV	Human Papilloma Virus
HSS	Health System Strengthening
ICC	Inter-Agency Coordinating Mechanism
IPV	Inactivated Polio Vaccine
IMEM	Immunization Management Electronic Module
JICA	Japan International Cooperation Agency
LMIC	Low- and Middle-Income Countries
MIS	Management Information System
MMR	Measles Mumps Rubella
MoH	Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs
MoF	Ministry of Finance
MTEF	Mid Term Expenditure Framework
NITAG	National Immunization Technical Advisory Group
NCDC	National Centre for Disease Control and Public Health
NIP	National Immunization Program
NVI	New Vaccine Introduction
PHC	Primary Health Care
PCV	Pneumococcal Conjugate Vaccine
RI	Routine Immunization
UHCP	Universal Health Coverage Program
UNICEF SD	United Children's Fund Supply Division
USAID	The United States Agency for International Development
VAT	Value-added tax

# Introduction

The purpose of this case study is to understand the transition of the National Immunization Program (NIP) from Gavi assistance, how immunization coverage was sustained post-transition including health system adaptations and changes and identify interaction of the policy context and content factors, actors and processes that influenced the transition.

In this section we first present the overall country context that created ground for the transition process, followed by Health Sector and NIP related context description.

## Country context

Since regaining its independence in 1991, European aspirations have been a central part of Georgia's political agenda and identity (Mitchell, 2020). Georgia clearly looked Westward and became a member of the Council of Europe in 1999. Furthermore, Georgia's Euro-Atlantic aspirations determined by threats emerging from Russia, became most important political priority for the nation and shaped foreign policy agenda for the years to come. This westward drive featured more prominently after the Rose Revolution of 2003 and led to closer engagement with Western partners on numerous fronts. Eventually Georgia signed an Association Agreement with the EU in 2014 (Lejava, 2021). A transparent and external accountability mechanism, set in motion by the EU, allowed the Georgian public to actively engage and monitor the government's compliance with the agreement promises.

The EU association agreement, and not only, set in motion many structural, policy, legal and institutional changes which occurred in the country thereafter. Just to note a few.

With support from the EU and other donors, the public finance management (PFM) system has gradually evolved. Since 2007 the medium-term budgeting framework was first introduced, followed by new budget code approved by the Parliament in 2009, which established basic rules and responsibilities for budget planning, execution and monitoring and evaluation. PFM was further enhanced with several electronic management systems such as a fully integrated e-Budget, e-Treasury, e-Customs, etc. As a result of these reforms, in the open budget survey ranking, Georgia moved from 34<sup>th</sup> place in 2010 to 5<sup>th</sup> in 2019 with a high budget transparency score of 81 (out of 100) albeit scoring low on public participation 28

(out of 100), especially in budget formulation and execution parts.<sup>1</sup> Such developments proved conducive for financial transition of the programs.

Along with economic developments, Georgia demonstrated significant progress in all six dimensions of the Worldwide Governance Indicators, especially in fighting corruption. Albeit the pace of the country's development has slowed down since 2014 as Georgia has been unable to keep up with the high standards shown in 2014.<sup>2</sup> Nonetheless, the 2021 Worldwide Governance Indicators still ranked Georgia among the top 20 European countries regarding the rule of law, control of corruption, government effectiveness and regulatory quality.

Finally, Georgia capacitated its state entities and organizations within and outside the health sector over the course of these years. Increased budget revenues on the back of improved economic performance allowed the government to prioritize human capital development in the national policy priority agenda and invest more in health, education, and improved social protection. Thus, the political commitments for these investments were also important for the transition process.

## Health sector context

After the economic shock caused by independence from the Soviet Union Georgia saw a slow recovery. The Government's comprehensive reforms after the Rose revolution in 2003 focusing on the liberalization strategy and sustainable economic growth through private sector development rendered double-digit GDP growth during 2004-2007, expanding the economy by 35%.<sup>3</sup> However, the 2008 war with Russia, the global financial crisis and external regional shocks negatively affected Georgia's economic performance and annual GDP growth averaged around 5% during the past decade.

Georgia's healthcare system underwent significant reforms aiming to expand access to healthcare services for the entire population. In 2013 the Universal Healthcare Program (UHCP) was launched, which significantly increased the number of people able to benefit from state-funded health services. The introduction of UHCP and the removal of financial access barriers led to increased service utilization for both outpatient and inpatient service and drew current health expenditure (CHE) from 1.1 billion US in 2010 to 1.5 billion in 2018,<sup>4</sup> or 7.2% of GDP, which

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<sup>1</sup> Open Budget Index <https://www.internationalbudget.org/open-budget-survey/country-results/2019/georgia> Accessed April 28, 2022

<sup>2</sup> IDFI 2021: World Governance Indicators – Georgia in the World Bank Ranking 2021 [https://idfi.ge/en/world\\_governance\\_indicators%E2%80%93georgia\\_in\\_the\\_world\\_bank\\_ranking\\_2021](https://idfi.ge/en/world_governance_indicators%E2%80%93georgia_in_the_world_bank_ranking_2021) Accessed April 28, 2022

<sup>3</sup> National Statistics Office of Georgia <https://www.geostat.ge> Last Accessed January 6, 2022

<sup>4</sup> WHO Global Health Expenditure database <https://apps.who.int/nha/database/ViewData/Indicators/en> Accessed August 2, 2022

in per capita terms translates to an increase from 634 \$PPP in 2010 to 970 \$PPP in 2019.<sup>5</sup>

The Government spending levels grew faster than private, which gradually increased the share of government spending in CHE from 22.3% in 2010 to 39% in 2019. Out-of-pocket payments (OOP) places a significant financial burden on the population 47% (2019). Along with these developments, the share of voluntary pre-paid financial resources pulled by private insurance companies also grew, though the percentage in CHE has not exceeded 7% (2019).<sup>6</sup>

Along with these reforms Georgia strengthened purchasing arrangements and established single national purchaser – the National Health Agency (NHA) which pays for all services under UHCP, along with the National Center for Disease Control and Public Health (NCDC) which funds public health and infection control programs through uniform purchasing arrangements with public and private providers alike. All contracted providers (private or public) are reimbursed with case-based, fee-for-service or capitation payments, depending on the program and service type.

## NIP context

The NIP was established in 1996 as a dedicated state program coordinated by the National Center for Disease Control and Public Health, a leading public health institution that had been established the same year (Gamkrelidze et al., 2003). Due to economic decline and weak financial management systems, state health programs were severely underfunded at that stage. In the period 1997-2000, execution of the central budget was between 45-62 percent (The World Bank, 2002).

Since 1994, various multi and bi-lateral donors (UNICEF, WHO, the Rostropovich-Vishnevskaya Foundation, USAID, JICA, US CDC) have provided significant support to the NIP by donating traditional vaccines and injection supplies, introducing new vaccines, and supporting health system strengthening activities (improving the cold chain system, reform of the immunization management information system, human resource capacity building communication activities, etc.) (Government of Georgia, 2011). The NIP heavily relied on donor support. By the year of 2002 all vaccines, supplies and cold chain equipment were funded through external sources.

Georgia first applied for Gavi financing in 2001 with a request to fund the Hepatitis B vaccine. Although Gavi support began in 2002, the transition period commenced

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<sup>5</sup> WHO Global Health Expenditure database

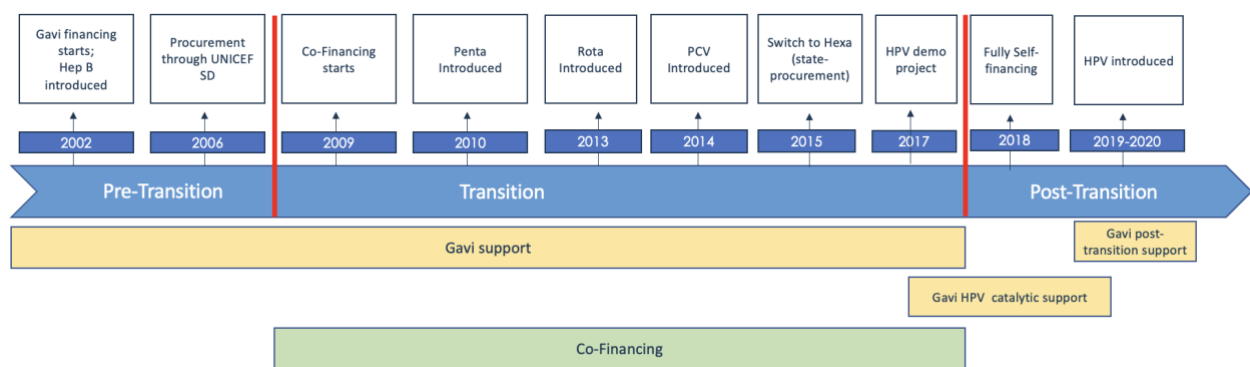
<https://apps.who.int/nha/database/ViewData/Indicators/en> Accessed May 23, 2022

<sup>6</sup> Ibid

in 2009, when Gavi introduced co-financing requirements, and lasted until 2018, when Georgia became a fully self-financing country. Hence, we define the following periods for our research: pre-transition – 2002–2008, transition – 2009–2017, and post-transition – 2018 and beyond (see Figure 1).

During the period of Gavi’s support, five traditional or new and underutilized vaccines were introduced to Georgia’s national immunization calendar: the Hepatitis B vaccine in 2002, the Pentavalent vaccine<sup>7</sup> in 2009, the Rotavirus vaccine in 2013, and the Pneumococcal Conjugate Vaccine (PCV-10) in 2014. A year before the full financing responsibility was handed over, Georgia applied for and received a Gavi catalytic grant for the introduction of the HPV (human papillomavirus) vaccine. Following a two-year demonstration project, the HPV vaccination was scaled up for nationwide introduction with full government financing. However, the scale-up coincided with the COVID-19 epidemic in the country, which negatively affected the overall performance of the NIP and the introduction of the new HPV vaccine in particular, which required extra programmatic attention. Since we were not able to evaluate the outcome of the HPV vaccination, we decided not to cover this vaccine in this case study but rather to focus on those vaccines introduced prior to HPV. Following the transition, Georgia received final support from Gavi in the form of a post-transition grant that included HPV implementation support in the form of supportive supervision and broader capacity building activities and HMIS support. Post-transition grant execution was also affected by Covid-19 epidemic and was postponed to 2021–2022.

*Figure 1 Georgia NIP transition periods and key milestones, 2002–2020*



All Gavi-supported vaccine introductions were implemented countrywide, with other initiatives such as the Health System Strengthening Support (HSS), Injection Safety Support (ISS) and graduation grants targeting both the national and operational (district) levels.

A detailed list of Gavi support to Georgia is given in the Table 1.

<sup>7</sup> Contains Diphtheria, Pertussis, Tetanus, Hepatitis B and Hib vaccines



Table 1 Gavi support to Georgia

Category	Years of Gavi support	GAVI Support in USD
HepB mono vaccine	2002–2008	167,917
Pentavalent vaccine	2009–2015	2,194,350
Rotavirus vaccine	2013–2015	456,176
PCV (Pneumococcal conjugate vaccine)	2014–2017	2,194,349
New vaccine Grant	2002–2013	400,000
HSS (Health system support)	2007–2011	435,500
INS (injection supplies)	2002–2004	61,451
ISS (injection safety support)	2002–2007	135,500
CSO support	2009	10,000
Graduation Grant	2016–2017	619,267
<b>Total support before graduation</b>	<b>2002–2017</b>	<b>6,674,510</b>
HPV (human papillomavirus) vaccine	2017–2018	275,821
Injection safety devices	2017–2018	8,457
HPV cash support	2017	172,000
<b>Total HPV support</b>	<b>2017–2019</b>	<b>456,278</b>
<b>Post transition grant</b>	<b>2019–2020</b>	<b>466,000</b>

#### Text Box 1: The Evolution of Gavi’s Co-Financing Policy

Gavi’s co-financing policy became effective in 2008. Prior to that period, co-financing by governments was voluntary. However, the new policy required countries to co-procure newly introduced vaccines. Co-financing differed across country groups by income level and UN classification, and variable shares for first and subsequent vaccines were defined. The revised policy became effective from 2012, requiring economically stronger countries to pay higher shares. The co-financing policy was aligned with the eligibility policy and a clear trajectory towards financial sustainability was defined.

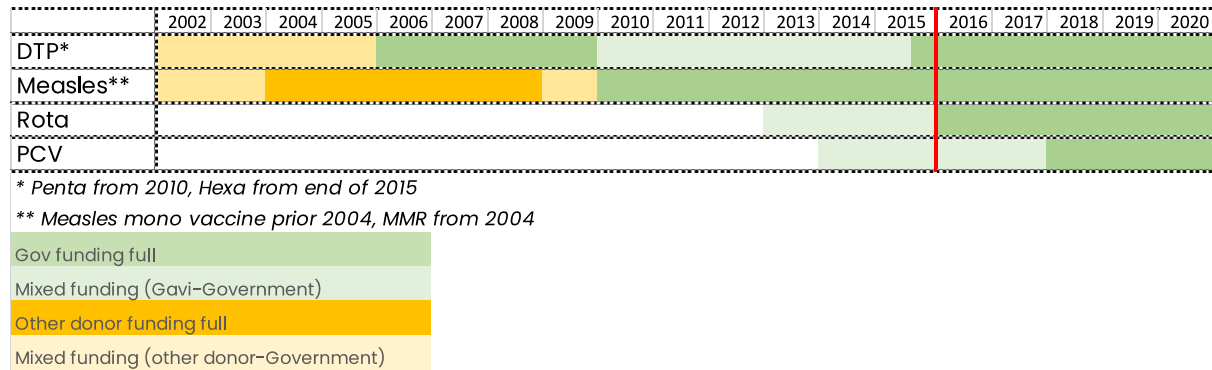
The co-financing requirement starts at US\$0.20 per dose for the poorest countries. As a country’s gross national income per capita reaches the intermediate category, its co-financing requirement increases up to 15% annually. In the graduation phase, countries face annual incremental increases of 20%, which means that they should fully finance their vaccines within five years.

The policy was subsequently updated in June 2016 to include co-financing requirements for measles and measles-rubella periodic follow-up campaigns. (Gavi, 2020)

The Gavi support transition to NIP was evaluated by examining coverage levels for traditional and Gavi-supported new vaccines after transitioning from Gavi. The vaccines include the DTP containing vaccine and MMR (traditional vaccines) and

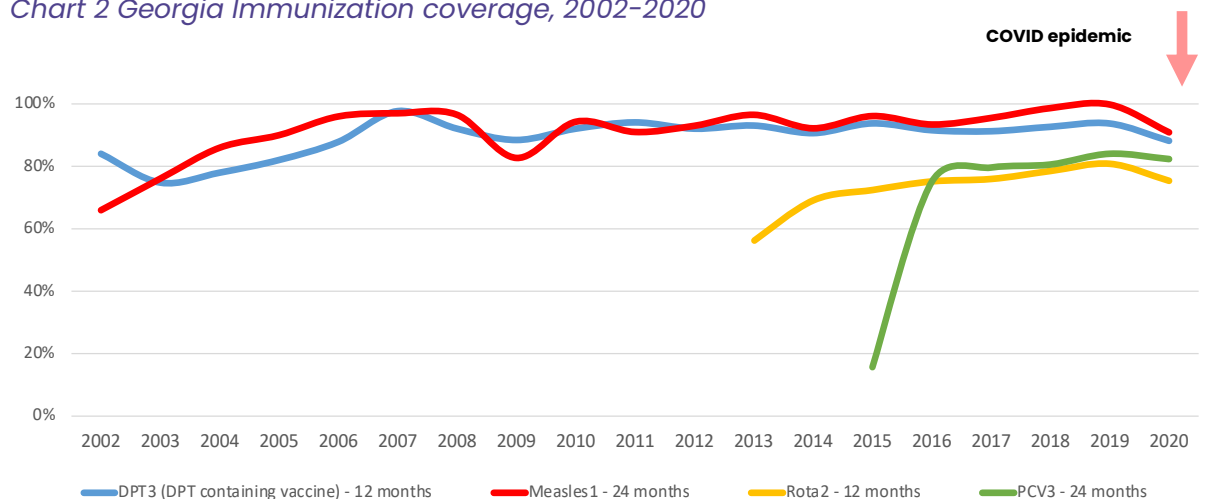
the Rotavirus and PCV (new vaccines supported by Gavi). Gavi supported the DTP containing vaccine through the Pentavalent introduction, which the government later substituted with the Hexavalent vaccine.

Chart 1 Vaccines funding 2002-2020



Specifically, the case study investigates coverage levels for DTP-3 and MMR-1 (traditional vaccines) and the Rotavirus-2 and PCV-3 (new vaccines supported by Gavi).

Chart 2 Georgia Immunization coverage, 2002-2020



Specifically, the case study investigates coverage levels for DTP-3 and MMR-1 (traditional vaccines) and the Rotavirus-2 and PCV-3 (new vaccines supported by Gavi).

Chart 2 shows that after the transition, in 2018 and 2019 Georgia maintained high coverage levels for DTP-3 under one-year and MMR-1 under two years of age, and suboptimal coverage for Rota-2 under one-year and PCV-3 under two years of age. Data for 2020 is not included because of influence of the COVID-19 epidemic.

The case study intends to further unpack the factors that contributed to high coverage levels for some vaccines but led to unsatisfactory coverage rates for Rota-2 and PCV-3. Specifically, we will examine what was the role of the health

system, how contextual factors, programme content and policy processes influenced this outcome.

## Methods

The study uses an analytical case study design with a mix-method approach using an adapted Walt and Gilson policy triangle framework (Walt & Gilson, 1994).

Because the transition from donor support occurred over the years, we looked at policy and health system adaptations over the years. As mentioned above, using program-specific historical information, for each intervention, we defined three time periods: pre-transition, the transition from the date of transition commitment until its completion, and post-transition, and looked at how a range of decisions and/or actions, taken at different periods, have accumulated over time and shaped the performance of the selected programs and interventions after the transition. Therefore, the study was longitudinal with a retrospective analysis of past events and experiences.

Three primary data sources were used: 1) a review of relevant documents; 2) key informant interviews; and 3) immunization administrative and NIP financing data.

We conducted a document review to retrieve data on the context, content, and role of actors across the transition timeline. In total, 67 documents were reviewed, including state programs, Gavi proposals, annual programmatic or technical assistance reports and decision letters, comprehensive Multi-Year Plans, assessment reports, and briefs. To be conclusive about transition outcomes i.e., sustaining or expanding public health gains (or lack of it) achieved with donor assistance, we first looked at what has changed during and post-transition in terms of coverage rates. After that, we qualitatively explored why and how these changes occurred in each health system building block and applied Walt and Gilson's policy triangle framework for describing these developments over time. We extracted data in Excel 16.0® from reviewed documents and used the coding conventions to classify the qualitative information. Each extract was characterized with at most five qualifiers/codes (if all were applicable). They included **Policy Triangle Codes** to denote the content, the context, actors who played the role, or the process used for the change to occur. Furthermore, all process-related **codes** were subdivided into WHAT, WHY and HOW codes to increase the explanatory power of the quote during analysis. The next set of codes denoted the **Health System** block in which the described change occurred. Where applicable, we also coded transition **outcomes** and **outputs** based on changes observed in coverage or in the NIP due to the transition. Finally, **barriers** and **enablers** spotted in the document were as well coded to systematically capture inhibiting or facilitating factors for the program or transition process.

After coding, we applied thematic analysis and reached agreements on the findings through iterative discussions among researchers involved in the study.

The findings from the desk review were complemented with secondary quantitative data and in-depth interviews with purposefully selected individuals.

Key informants were carefully selected based on their past or current role in the immunization field at the national level. Overall, 10 in-depth interviews were conducted with stakeholders representing the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs (MoH), the NCDC, the Ministry of Finance (MoF), the Parliamentary Health and Social Issues Committee and development partners. Only one of the intended policy actors could not be interviewed. Key informant interviews were valuable in validating some of the findings arising from the literature review and in understanding the roles of different actors and why and how certain changes did or did not happen.

Administrative data about immunization were primarily used for trend analysis, subnational performance evaluation and analysis of the timeliness of the certain vaccine coverage. NIP programmatic budgets and external financing data were retrieved from public sources to understand the share of government financing across the transition periods.

The study followed all ethical rules spelled out in the IRB decision letter # 2021-055.<sup>8</sup>

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<sup>8</sup> Georgia National Center for Disease Control and Public Health Institutional Review Board Letter # 2021-055 from July 14, 2021, on approving the study protocol for „Sustaining adequate coverage in the context of the transition from external assistance – Lessons from Georgia.“

# Findings

The findings presented below are based on the triangulation of information from the document review and key informant interviews. We present the findings through the lens of a health policy triangle structured around the health systems building blocks and laid out for the three transition periods. As Leadership and Governance are cross-cutting by nature, its themes appear under various blocks.

Each building block is followed by summary boxes. We summarize intermediary outcomes which, in our opinion, are important to reach and sustain the final transition outcomes. If the outcome is at risk, we describe it separately. Enabling factors are also presented in the summary boxes.

The roles of different actors are described in the relevant sections and are also provided in Annex .

## Leadership and Governance

In this section, we mainly focus on the *coordination and decision-making* and *management* functions, while the *legal framework* will be described in the Inputs (drugs) section. Prior to describing the *coordination and decision-making*, it's worth explaining the level of political commitment to childhood immunization. Under political commitment to immunization, we define the intent and action of the government to **introduce new vaccines** and **mobilize domestic resources** to finance traditional or new vaccines.

Childhood immunization has always been highly prioritized in Georgia and has maintained its place at the top of the government's agenda. The national health strategic documents in the pre, transition and post-transition periods acknowledge immunization as a strategic objective to improve the health and wellbeing of children (Government of Georgia, 2007, 2011, 2016). Immunization is well recognized as a highly effective public health intervention positively influencing children's health and has been part of the global developmental agenda for some time (MDGs and now SDGs). Immunization achievements are monitored on a global level, which facilitates national external accountability and the importance of immunization on the national agenda in Georgia.

## Management

The MoH is responsible for policy development, regulation, and overseeing the implementation of the state health programs, including the NIP. The NCDC is responsible for planning and overseeing immunization activities in the country, providing technical guidance to providers and municipal public health centers, monitoring and supervision, surveillance and national level reporting, forecasting and procurement of vaccines and injection supplies and central level logistics. The vaccine procurement function was transitioned from the MoH in late 2011 to the NCDC. The NCDC's dedicated Expanded Program of Immunization (EPI) unit is responsible for all technical content of the immunization activities, while another department is involved in financial projections and procurement. The NCDC's nine regional branches and municipal public health centers ensure vaccine storage at the sub-national level, surveillance and performance monitoring of immunization activities, and

immunization information system management at the sub-national level. Immunization services are offered through primary health care facilities and village doctors in rural areas. Almost all primary care facilities are private. Immunization services are integrated in the UHCP outpatient (OP) care and purchased within the OP package by a single public purchaser – the Nation Health Agency.

### Text Box 1: The NCDC functions

The NCDC is the main public health institution in Georgia established in 1996 following major reform of existing sanitary-epidemiological system. The reform implied separation of sanitary and epidemiological functions and decentralization, by shifting responsibilities to local municipalities with central oversight. The NCDC core functions include administration of public health state programs, preparedness and response to disease outbreaks and other health emergencies, health promotion and disease prevention, surveillance and monitoring of the population health and public health research. Administration of the public health programs such as immunisation, communicable diseases surveillance, blood safety, hepatitis C and others is accomplished through the purchasing arrangements with private and public providers. The NCDC has an operational unit for The Global Fund supported programs administration. Timely detection of pathogens for public health response is ensured through network public health laboratories countrywide and referral laboratories of highest biosafety level at the Richard G. Lugar Center which is housed under the NCDC. The latter also represents as a hub for the public health scientific research.

From the start of Gavi support in 2002, all management functions such as planning, procurement and reporting were integrated into the national system, indicating that no special staff were hired or salary top-ups provided.

## **Coordination and decision-making**

Decisions on the introduction of new vaccines and increasing government allocations to the NIP involved multiple actors at different time periods. Starting from the transition period (2009), decisions on the introduction of new vaccines were considered through the lens of a gradual increase of government financing for vaccines, which was not the case for the first vaccine introduction in 2002.

The Intersectoral Coordinating Committee (ICC) was established in 2000, as a precondition for Gavi support. The ICC represents an important platform for the coordination and key decision-making of policy decisions, including the introduction of new vaccines, official endorsement of Gavi applications, programming Gavi funds, etc. The ICC is chaired by MoH and has a multisectoral representation comprised of officials from the MoH and the Ministry of Finance (MoF), the NCDC, the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), and other development partners and experts. Respondents highlighted that the ICC was a place of active discussions where the MoH always had a central role in decision-making, while the MoF usually followed the MoH's decisions.

*"The ICC was a place of active discussions and deliberations, this was something different to what I have seen in other countries .." (Respondent N9)*

The technical content for the ICC, in terms of scientific data on public health impact, vaccine safety and cost-effectiveness data, was initially developed by the NCDC, but from 2014 it was provided by the National Immunization Technical Advisory Group (NITAG). Development partners, including the WHO Regional Office (WHO-RO) in particular, played a significant role in advocating for and supplying scientific evidence. The WHO, as a key actor globally to accelerate and strengthen independent advisory groups for evidence-informed decision-making in Low- and Middle-Income Countries (LMIC), promoted and supported the establishment of the NITAG.

As mentioned above, the transition period lasted from 2009 to 2018, during which three new Gavi-supported vaccines (Pentavalent, Rotavirus and PCV) were introduced. Applications submitted to Gavi during this period acknowledged the vaccine co-financing schedules and thus the government's obligations to gradually take over this responsibility. The decision-making on the introduction of the Pentavalent vaccine was smooth and easily accepted by the MoH and the MoF. Discussions were supported by the WHO's estimations of the Hib disease burden (the Hib vaccine is part of the Pentavalent vaccine) and related cost-savings data. However, the decision-making process about the introduction of Rotavirus and PCV vaccines, which took place a couple of years later, lasted longer. The ICC chair (the Deputy Minister of Health, who represented new leadership at the MoH) was not

confident in the vaccines' cost-effectiveness. Nevertheless, after lengthy deliberations which were supported by economic evaluations and budgetary saving estimations, the MoH made a positive decision.

Advocacy carried out by in-country partners and experts from the WHO regional office, in particular, was key in New Vaccine Introduction (NVI) at all stages of Gavi support, particularly for the introduction of the Pentavalent, Rotavirus and PCV vaccines. This included supplying scientific evidence on vaccine safety and effectiveness, the disease burden and economic impact data. Advocacy work was delivered through meetings with key decision-makers during expert missions, including participation in ICC meetings, and learning sessions for technical staff at the regional meetings.

The role of the actors changed in 2014 during the decision-making process to introduce the Hexavalent vaccine<sup>9</sup>. Georgia prioritized the inclusion of the Inactivated Polio Vaccine (IPV) in the immunization calendar from 2015, in line with the Polio Eradication and Endgame Strategic Plan 2013–2018 recommendations.<sup>10</sup> At that time, Georgia was using a western manufactured Pentavalent vaccine that was no longer available to UNICEF's supply division (Gavi, 2014). The country had a choice whether to continue with an alternative Pentavalent vaccine plus an additional IPV vaccine, both of which were procured through UNICEF, or to shift to a Hexavalent vaccine via state procurement. The NITAG supported the Hexavalent vaccine for several reasons: the avoidance of additional injections and thus associated programmatic errors and complicated logistics, and a high level of trust towards western manufactured Hexavalent vaccine in the private sector (LNCT, 2019). In general, public scrutiny of vaccines is high in Georgia. A survey conducted by US CDC identified that 13% of the child population in large urban settings were vaccinated with commercial vaccines in 2013 and 2014 (CDC, 2017). The preference for commercial vaccines was due to their western origin (NCDC, 2016). In addition, the Hexavalent vaccine contained an acellular Pertussis component associated with fewer side effects compared to the whole-cell Pertussis in Penta. Respondents confirmed that there was high support for the Hexavalent vaccine among the NCDC, the MoH and in-country partners due to confidence that switching to it would have led to better acceptability and convenience from the population and thus better coverage levels.

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<sup>9</sup> Contains Diphtheria, acellular Pertussis, Tetanus, Hepatitis B, Hib and Inactivated Polio (IPV) vaccines

<sup>10</sup> A comprehensive, long-term strategy to deliver a polio-free world by 2018. The plan was developed by the Global Polio Eradication Initiative (GPEI) in response to a directive of the World Health Assembly.

<https://polioeradication.org/who-we-are/strategic-plan-2013-2018/>



Gavi and WHO-Euro informed the country of the possible cost implications of this switch, considering that Gavi could not provide support and a pooled procurement mechanism could not be used (Gavi, 2014). The respondents even recalled the WHO-Euro expert mission to discuss the issue with the MoH leadership. However, the position of Georgia's key stakeholders under the leadership of the Minister of Health and the NCDC director was firm. The NCDC researched the market and leveraged available information to analyze price acceptability. Access to global market price data was crucial in negotiations with the manufacturers, resulting in comparable prices to larger markets. Nevertheless, the budgetary implications were significant, leading to a three-fold increase in the NIP budget (see data in the financing section). The MoF opposed such an increase in the context of growing government expenditures and overspending associated with the UHCP. After the UHCP introduction from 2013 the government expenditure increased annually by 97% in 2014 and 14% in 2015 .<sup>11</sup>

The MoH, with support from the Parliament Committee on Health and Social Issues and its partner, the Sabin Institute, carried out numerous advocacy activities to justify the needs to the MoF (LNCT, 2019). These advocacy efforts were successful, and Georgia succeeded in procuring the vaccine at an affordable price in 2015 (Gavi, 2016b).

*“The health sector was receiving significant budget with annually increasing expenditures, therefore the MoF felt that the NIP budgetary needs should be covered within the health budget by reallocation between the programs .... Finally, the MoF was convinced to increase the NIP budget by requested amount with additional allocations to health sector ” (Respondent N2)*

The participatory multisectoral process at the ICC facilitated the buy-in of stakeholders, including eventually the MoF, to assume financial ownership and to create a shared vision, particularly between the MoH and MoF. Other processes that encouraged country ownership of vaccine financing are discussed in the financing section.

## Financing

Since 1990s Georgia received significant International development assistance in the areas of monetary policy and other structural reforms, democratic governance, health and social welfare. In late 1990s and beginning of 2000s Georgia health sector was largely supported through donations, grants and loans. The US government and the WB were major players among development partners at that time. The USAID was a key donor for the EPI including other areas, while the WB

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<sup>11</sup> WHO Global Health Expenditure database

<https://apps.who.int/nha/database/ViewData/indicators/en> Accessed July 18, 2022

supported the health sector reform focusing on restructuring hospital sector and primary care. While in 2000, external donor funding for health was 7.4% of CHE, along with economic growth and increased public financing, it declined to 0.53% in 2019<sup>12</sup> revealing lower dependence of healthcare funding on external support and the transition trend from donor assistance.

As mentioned above, prior to 2002 all vaccines and injection supplies were funded through donations. The NIP was funded at only 50 percent of the planned budget and there was no government contribution to vaccines and supplies (Government of Georgia, 2001). However, after assuming national financial responsibility, Georgia consistently fulfilled its obligations on time following the start of co-financing arrangements in 2009. The country was briefly considered in default in 2010 due to a miscommunication on the modality of procurement of co-financed doses. However, this issue was cleared, and the country was considered a good performer by Gavi (Gavi, 2015).

The first mention of the financial transition in the high level policy documents appears in 2014 in the State Concept on Universal Health Coverage, where the Government declared its commitment to mobilizing investments to cover traditional or new vaccines in the context of economic growth and decreasing donor financing (Government of Georgia, 2014).

Table 2 describes government funding of NIP during the transition period.

*Table 2: Government financing of NIP, 2009–2021 (current 1000 Gel and 1000 USD)*

	2009	2010	2011	2012	2014	2015	2016	2017	2018	2019	2020	2021
									<b>Fully self-financing</b>			
NIP budget Gel	3,233	4,520	4,520	4,940	4,431	11,174	16,206	17,927	21,803	22,556	24,130	33,239
vaccine line	289	3,840	3,700	1,650	1,474	7,220	9,800	11,573	14,117	16,410	17,798	20,670
annual change %		40%	0%	9%	-10%	152%	45%	11%	22%	3%	7%	38%
NIP budget USD <sup>13</sup>	1,936	2,532	2,681	2,976	2,510	4,922	6,847	7,146	8,602	8,001	7,760	10,029
vaccine line	173	2,151	2,195	994	835	3,180	4,141	4,613	5,570	5,821	5,723	6,237
annual change %		31%	6%	11%	-30%	96%	39%	4%	20%	-7%	-3%	29%

The NIP budget covers the costs for: a) routine immunization vaccines and injection supply; b) vaccines and other pharmaceuticals for the epidemiological indication (rabies, tetanus); c) influenza vaccine and service costs (from 2014); d) cold chain

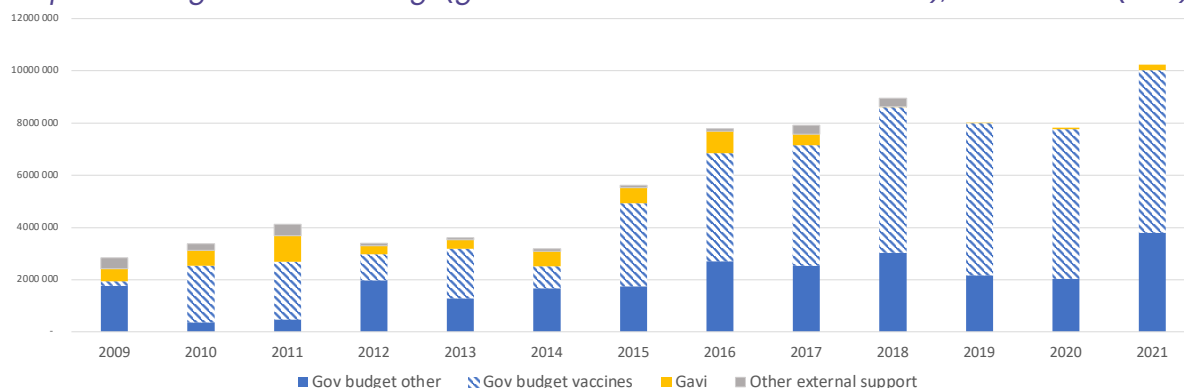
<sup>12</sup> WHO Global Health Expenditure database

<https://apps.who.int/nha/database/ViewData/Indicators/en> Accessed May 23, 2022

<sup>13</sup> USD/GeL exchange rate - average for the period. Source: National Statistics Office of Georgia.

support; and e) communication and information system support (from 2020). However, the NIP budget is not the only governmental fund spent on immunization. Routine immunization delivery costs are integrated into the consolidated budget for primary health care services under the UHCP. NIP management cost, such as EPI unit staff cost, is part of the NCDC’s institutional budget, while personnel costs for immunization supervision at the municipal level are covered by the municipal budgets.

*Graph 1 Georgia NIP financing (government and external sources), 2009-2021 (USD)<sup>14</sup>*



The NIP vaccine budget-line increase in 2010 was after handing over from the Rostropovich-Vishneckaya Foundation to fully fund MMR vaccine procurement. Fluctuations in subsequent years (2014-2014) was due to two-year vaccine stock procurement for some of the vaccines. Sharp increase in 2015 was associated with a switch to the Hexavalent vaccine, which was fully covered by government sources. The share of routine vaccines and injection supply has constituted 60-70% of the total NIP budget since 2015. Gavi allocations in 2020-2021 are post-transition grant funds.

The Georgian Government’s allocations to health increased significantly from 2013 following the introduction of the UHCP. During 2012-2016, government allocations for health increased two-fold from a low base of 1.6% to 3.1% of GDP<sup>15</sup> and despite economic shock in 2015 increased financing for health was maintained by the Government. The UHCP receives the highest priority in the health budget and consumes about 70 percent of the Government’s health allocations. The NIP budget forms a small share in the government health expenditures ranging from 0.8%(2014) to 1.6%(2015) and highest 2% (from 2018).

Since 2017, the government budget has included costs for cold chain strengthening, with the biggest investment coming in 2019. Government sources also cover limited needs for communication and information system support (1-0.2% from 2020).

<sup>14</sup> Gov budget other includes a) vaccines and other pharmaceuticals for the epidemiological indication (rabies, tetanus); b) influenza vaccine and service costs from 2014; c) cold chain support; and d) communication and information system support.

<sup>15</sup> World Bank data. <https://data.worldbank.org/> Accessed July 5, 2022

Capacity-building activities or operational costs for supportive supervision are externally supported. In 2021, the increase in the routine immunization vaccine budget line is associated with the procurement of the tetravalent<sup>16</sup> and HPV vaccines, while the increase in the other government budget line relates to the procurement of an increased amount of influenza and two-year storage rabies vaccines.

In the Leadership and Governance section, we describe how the ICC's multisectoral process, with the involvement of a range of external and internal actors, contributed to the fulfillment of co-financing requirements and further increased government financing. However, there were other contextual factors, processes and actors that played a role in achieving the financial sustainability of the NIP.

The budgetary reform that started in Georgia from 2004 implied the introduction of a *Medium-Term Expenditure Framework (MTEF)* from 2006 (Kraan & Bergvall, 2006). The MTEF requires linkages between priorities and expenditures and advance planning over a four-year period with annual revisions. The key informants stated that, although the integration of growing projections of the NIP budget in the medium-term planning does not secure respective funding, the MTEF creates favorable conditions for the MoH to negotiate budget growth with the MoF.

*“During the budget approval process the MoF looks at the MTEF and the MoH has to have a justification for increasing expenditure projections, otherwise negotiations will be tough” (Respondent N7)*

*“The MTEF is a useful instrument for the MoH to exercise long-term planning and for the MoF to request justifications for deviation from these projections.... The NIP is one of them, which is seriously taken by both sides...” (Respondent N2)*

Results-based budgeting (reporting on program performance indicators) has been effective in Georgia since 2008. While we do not explore the quality of budget performance monitoring, we certainly confirm the importance of results-based budgeting in encouraging accountability between the MoH, the MoF and the government. The MoF identifies this exercise as an important step in the judgment for next year's funding of the NIP with increases to the budget if targets set in the annual budget are achieved and results delivered. The dedicated vaccine budget line in the NIP has appeared since 2010. Respondents indicated that the budget line is helpful in the negotiation process but has little power in securing funding.

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<sup>16</sup> Since 2021, children vaccinated with the hexavalent vaccine with the first three doses have been offered a tetravalent vaccine (diphtheria, acellular pertussis, tetanus, inactivated polio) for booster doses at 18 months and 5 years of age, prior to the use of booster DPT and oral polio.

Different key informants commented on the high standing of the NIP during the prioritization process:

*“Immunization as a high priority program always wins in competition with other state programs” (Respondent N3)*

*“The MoF will request a justification for the budget increase, but they understand how important this program is, it could be ranked second after the UHCP ... ” (Respondent N2)*

As mentioned above, co-financing was donor-driven and thus the country was externally accountable to fulfill the requirements. Co-financing terms and conditions were embedded in all of Gavi’s formal communications with the government. Decision letters, which constitute a binding document between the Gavi and the country, included a description of the co-financing terms. The WHO-CO and UNICEF-CO, which were important immunization advocates in general, played an intermediary role between Gavi and the government. The WHO-CO and UNICEF-CO were copied in all formal communications, sending reminders, holding regular advocacy meetings, and participating in ICC discussions.

One important *process* that played a central role in raising the awareness of national stakeholders was the WHO European Regional Working Group for Gavi. The Georgian delegation, which was comprised of mid-level officials from the MoH, the MoF and the NCDC, actively participated in the Working Group’s annual workshops to present progress, challenges and lessons learned, new vaccine introductions, co-financing achievements, and plans towards transition. These workshops provided an effective platform for communication with partners and experience sharing between peer countries during the transition period. Mid-level managers/officers played a key role in shaping the decisions of key policymakers. One positive outcome underlined by the respondents was Georgia receiving a “leader country” status with new vaccine introductions and achievements in co-financing and financial sustainability.

*“Georgia from year to year was viewed as a model - leader country and we (the Georgia team) always strived to maintain this status” (Respondent N3)*

Another important exercise (*process*) that helped in building political commitment during the transition period was Joint Appraisals (JA). From 2012 to 2017, one transition assessment and four JAs took place. JAs implied the participation of national stakeholders and partners organizations and Gavi secretariat staff in the assessment process, providing feedback to the government and reaching a consensus on transition activities. JAs ensured that the timelines, responsibilities, gaps and priorities were clear and agreed. (Gavi, 2014, 2015, 2016b, 2017; Saxenian et al., 2015).

Yet another useful *process* that helped in awareness raising was the Comprehensive Multi-Year Plan (cMYP) development. The cMYP was a Gavi conditionality, constituting a first step in applying for assistance. The cMYP was a prospective planning and budgeting tool. Key stakeholders from government structures along with partners were involved in programmatic planning, cost projections, and the identification of financial needs and gaps for the next five-year period. As reported by respondents, the cMYP was used as an advocacy tool with development partners but less so with the government.

One of the policy content factors related to immunization financing and influencing outcomes was the immunization service reimbursement scheme. However, to be more coherent we will describe it in the service delivery section.

#### Intermediary Outcomes:

- *New Vaccines introduced, including in the post-transition period*
- *Gavi co-financing requirements met - Georgia fully self-financed from 2018 as planned by the transition (vaccines component)*
- *A steady increase in NIP funding from government sources, including in the post-transition period*
- *The NIP government funding has included auxiliary activities (cold chain, HIS support, communication activities) in the post-transition period*

#### Enabling factors:

- *Political commitment (context)*
- *External demand and Accountability (content)*
- *Multisectoral engagement (process)*
- *External Technical Assistance (actors)*
- *Advocacy (actors)*
- *Pride and self-satisfaction of actors at being recognized as regional leaders (context)*

## Service Delivery

Starting from the pre-Gavi period, childhood immunization services have been provided free of charge countrywide without geographical access barriers. At the beginning of the 2000s, immunization coverage rates started to improve after a dramatic drop in the 1990s. Coverage rates reached 70-90% for traditional vaccines, however, they were subject to careful interpretation given uncertainty over the basic denominator (Chanturidze et al., 2009). In the mid-2000s, national coverage for DPT-3 remained below 90%, with one-third of the districts reporting less than 80% coverage with high drop-out rates (Government of Georgia, 2007). In the beginning of the transition period in 2011, DPT-3 coverage improved, reaching

over 90% with fewer discrepancies between country official reports and WHO/UNICEF estimates (Gavi, 2013). There was a fluctuation of national DPT-3 coverage between 91%-94% during the transition period. At the subnational level, a substantial number of districts demonstrated below 90% coverage (see *Table 3*). Newly introduced vaccines were below target due to “false” contraindications, safety concerns among health care providers and parents, and an ineffective call and recall system (Gavi, 2014, 2015).

Following the transition (2018-2019) national coverage for DPT-3 (Hexavalent vaccine) ranged between 93-94%, and for MMR-1 between 98-99%. A fewer number of districts out of 64 demonstrate below 90% coverage, with these poorly performing districts accounting for a fewer number of infants.

*Table 3: Districts with DPT-3 coverage <90%*

	2013	2016	2018	2019
Number of districts with DPT-3 coverage <90%	19	37	13	12
Proportion of <90% coverage districts infant population from the total infant population	47.9%	38.1%	12.3%	10.9%

There is still suboptimal coverage for Rota-2 and PCV-3. While the target population is the same for the DPT-3 containing vaccine and Rota-2 (children under one), coverage between these vaccines differs. The same is observed for MMR-1 and PCV-3, which have the same target population – children under two years of age.

Several explanatory factors were identified. *Firstly*, there are different international and internal accountability requirements for these vaccines. For example, the DPT-3 and MMR coverage rates are included in the country profiles and are subject to international reporting, scrutiny, and country ratings. Also, traditionally national systems allocate high attention to DPT, Polio (the Hexavalent vaccine includes inactivated polio) and MMR coverage rates as the diseases prevented by these vaccines could be deadly to children or lead to severe disability. The rotavirus infection and pneumococcal disease might be less severe, not leading to child mortality in health systems like Georgia’s, and so do not generate similar societal attention at the primary care level or from the public health system. *Secondly*, the late initiation of vaccinations contributes to relatively low coverage for the Rotavirus vaccine. About 70% of infants start vaccinations at PHC on time within the 8-16<sup>th</sup> week.<sup>17</sup> DPT-1 could be administered without age limitations and those

<sup>17</sup> There is a small difference between the DPT-1 and Rota-1 timely vaccination coverage rates (69.2% vs 67.7%).

delaying with first shot catch up with the third vaccination by 12 months, while Rota-1 has an age restriction by the 16<sup>th</sup> week and Rota-2 by the 32<sup>nd</sup> week indicating that those who start vaccination late after 16<sup>th</sup> week (about 30% of infants) are not eligible for the Rota vaccination.<sup>18</sup>

Primary health care system, public health system and the NIP programmatic shortcomings contribute to these deficiencies:

- The free choice of family doctor resulted in a loosening of the geographical catchment principle, particularly in large urban areas. In addition, linkages between maternity and primary care services that existed during Soviet times were lost and never restored, leading to a loss of information about incoming newborns in the catchment population (Government of Georgia, 2011, 2016). As a result, primary care personnel are unaware of a newborn child among their coverage population unless parents show up at the PHC.
- To address this and other issues, certain developments of the Health Management Information System (HMIS) took place over the years (as described in the Health Information section). Currently, the Immunization MIS automatically sends SMS notifications to the mothers of all newborn babies to prompt timely vaccination. It also allows the identification of infants who are not vaccinated on time, although this capability of the MIS is not fully utilized at the national level.
- The managers of primary care facilities, the majority of which are private, have low levels of interest in immunization. The primary health care financing mechanism does not create incentives for improved immunization coverage, nor are facility managers held accountable for it. Instead, the immunization service is integrated into the UHCP benefit package and per capita payments that are not linked to performance outputs are used for primary care reimbursement. The per-capita tariff is low and has not been adjusted since 2012 to keep pace with increased costs and inflation. This has been identified as one of the key barriers which has been under discussion since 2012 (Gavi, 2015, 2016a; Government of Georgia, 2011, 2016; Sabin Vaccine Institute, 2017). The PHC reforms up to now have not resulted in any changes with respect to provider payment mechanisms. However, according to the respondents, planned reforms for 2022 aim to rectify this situation:

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<sup>18</sup> The WHO allows a deviation from the strict age restrictions of the Rota vaccination particularly in countries with high mortality from diarrheal diseases, however in Georgia the National Regulatory Agency strictly follows the manufacturer's instructions, which do not allow this deviation.



*“family doctors do care to have their children vaccinated, however, they will not apply extra efforts to improve immunization indicators as the manager would not encourage for good indicators or punish for bad ones and they (family doctors) always have what to complain in front of the public health.... ” (Respondent N3)*

*“There is good understanding that PHC fails ... there is a plan to reform its payment system, where immunization will be one of the performance indicators” (Respondent N1)*

- Municipal public health personnel are responsible for immunization performance monitoring (supportive supervision) at the primary care level. However, their support is limited to primary care personnel capacity strengthening, problem identification and solving data accuracy issues, immunization technics, false contraindications, etc. Public health has no leverage to make any changes related to system barriers, organizational culture, etc. and their efforts could have been diminished because of PHC structural barriers.

*“Epidemiologists at public health centers are not empowered enough to influence private clinics' performance, there were cases when private clinic managers were not welcoming epidemiologists to come and verify their data ..” (Respondent N5)*

Supportive supervision activities have played a crucial role over the years in strengthening the NIP. This involves EPI staff from the NCDC central and regional branches visiting poorly performing facilities for joint problem identification and solving. Appraisal reports suggest that these activities were useful in creating confidence among front-line service providers and their capacity strengthening in many directions such as false contraindications, missed opportunities, and data management that ultimately lead to performance improvement. These activities were supported mainly through Gavi funds, other partners' financial resources and technical support, such as guidelines development and skill-building (Gavi, 2015, 2017). At the same time, some respondents suggest that supportive supervision activities should be more targeted and more intelligently utilize the HMIS capabilities. Up to now, these activities have still been supported by Gavi funds through the post-transition grant. The allowances paid from externally supported programs create incentives for staff to undertake such supervisions. Respondents admitted that, since the government reimbursement rates are disproportionately small and below the real costs of meals and accommodation, personnel lack the incentive to provide these activities through government funding. All the above puts at risk the continuation of the full supportive supervision function after full Gavi graduation.

#### Intermediary Outcomes:

- *Improved subnational coverage with DPT but inadequate PCV and Rota coverage*

#### Enabling factors:

- *Strong external and in-country accountability for some vaccines and less for others (context)*
- *External Technical Assistance (actors)*
- *Development of the national systems – geographical access to PHC services (context)*

#### Barriers and Risks:

- *Structural barrier – Immunization service reimbursement not stimulating performance improvement*
- *Supportive supervision not fully reaching its aims and not legally empowered municipal public health centres (context)*
- *Risk – Continuation of supportive supervision function through government funding risking the deterioration of the service quality*

## Inputs – Human Resources

Human resource capacity building was one of the key investments throughout the years of Gavi support. Notably, other development partners (USAID, JICA, VRF, UNICEF, WHO) contributed significantly to Georgia's immunization workforce capacity strengthening prior to and in the first years of Gavi support.

During Gavi's support period, various types of personnel underwent capacity development activities such as program managers, epidemiologists, primary care professionals, cold chain specialists, administrative staff responsible for procurement and budgeting, HMIS personnel, and NITAG experts. These activities included traditional and on-the-job training, participation in knowledge-sharing forums, regional workshops, and site visits mainly for national level EPI staff, financial and procurement focal persons, NITAG members, and key decision-makers.

Each new vaccine introduction was preceded by extensive training of public health and primary care workers on the respective disease burden, vaccine characteristics, eligibility and schedule, vaccine handling, immunization safety, Adverse Effects Following Immunization (AEFI), and immunization MIS and communication technics. Trainings were assessed through pre- and post-tests. Prior to vaccination rollout, refresher trainings were conducted.

During Gavi support, the UNICEF-CO and WHO-CO channeled and administrated Gavi funds for capacity building activities, with in-country partners also

contributing some of their own funds in this direction. The Sabin institute was instrumental in immunization financing advocacy capacity strengthening in the later phase of the transition period, with the US CDC also contributing to the health workers' capacity strengthening (Gavi, 2015, 2017).

Following the transition in 2019-2021, major efforts were made to enhance communication skills for health professionals with Gavi HPV catalytic and post-transition grants, through trainings, materials and on-the-job assistance in practice. According to the respondents, communication remains one of the weakest functions of front-line health workers. This is linked to the low involvement of primary health care in health promotion activities in general.

In order to institutionalize the immunization training modules for primary care doctors and nurses, immunization theory and practice modules were developed and incorporated for pre-service, postgraduate and continuous medical education (CME) curricula under the Gavi post-transition grant. The CME was suspended from 2006 to 2018 in Georgia. It has since been restored for some medical fields (e.g. perinatal care) but not yet for primary care. This creates a risk to the sustainability of immunization knowledge and practice in the long run.

As mentioned above, significant investments were focused on public health workforce capacity strengthening at the national and subnational levels. Gavi funds primarily targeted personnel involved in immunization activities, while other investments covered wider public health workforce. However, respondents mention that the public health system in general, and municipal public health centers in particular, face severe human resource challenges such as the lack of qualified professionals. Low pay and poor employment and career development prospects make this field unattractive to young people. At the same time, local municipalities' HR policies do not prioritize the qualification and expertise of the public health center workforce, even though the NCDC and MoH do.

*"Public health professionals are a chronic problem of our system, municipal funding and local governments positions for public health does not encourage hiring qualified staff ... while the existing staff are aging, and their knowledge and skills are waning" (Respondent N4)*

#### Intermediary Outcomes:

- *Increased capacity over time of the public health and program administrative personnel in the planning, procurement, budgeting, cold-chain; NITAG strengthening*
- *Improved capacity of primary care personnel in immunization theory and practice*

#### Enabling factors:

- *External Technical Assistance (actors)*
- *External funding support (context)*

#### Risks:

- *Weak immunization promotion and communication activities at the PHC level*
- *Sustainability of the immunization knowledge and practice at PHC through in-service trainings*

# Inputs – Health Management Information System

In this section, we describe the evolution of the Immunization HMIS and Gavi reporting. Although Gavi did not contribute to the Immunization HMIS development, the existence of reliable immunization coverage and other data facilitated the NIP transition.

In the pre-Gavi period, Georgia NIP had significant data quality issues. Administrative and survey data revealed huge discrepancies across all parameters, which indicated poor data quality, the inadequate use of the data in NIP planning and management, or both. The immunization data quality issues were mentioned in all public documents, WHO/UNICEF dashboards and global reports that included both country administrative data and survey-based estimates. Consequently, with USAID support, the immunization information system was first reformed in 2003–2005. Revised registration, reporting and monitoring forms were institutionalized by Ministerial decree and implemented countrywide. An excel based software tool “Geovac” was developed to track a range of indicators on a routine basis, improve the accuracy and reliability of data for sub-national and national levels, and strengthen the use of data for program planning and management. The Geovac, with further modifications, was in use until the next generation system became operational in 2016 (Government of Georgia, 2016).

During the transition period, data quality issues re-surfaced when significant differences between the number of live births from the civil registry and the number of surviving infants reported by the health facilities were spotted and the difference was not explained by the infant mortality (Government of Georgia, 2016). By 2011, the country implemented major reforms in online civil registration, including for births and deaths, which significantly improved the quality of data. These developments facilitated the development of a new Immunization Management Electronic Module (IMEM) with UNICEF support, which was accomplished in 2014. The IMEM was built around a citizen’s national ID, allowing individual vaccination profiles, tracking vaccine administration (historical and ongoing), and registering adverse events to vaccines. Most importantly, it enabled the generation of real-time reliable coverage rates for each vaccine. Moreover, data quality on surviving infants (denominator) improved after the IMEM was integrated with the birth registry in 2016.

The IMEM was gradually expanded and strengthened with an SMS immunization notification/reminder function for parents, with analytical modules, etc. A separate module was developed for vaccine stock management and monitoring. Consequently, the quality of administrative immunization data improved and now concurs with the WHO/UNICEF estimates.

In the post-transition period, the full transition to the IMEM platform has not yet happened. Immunization registration and reporting regulations have required electronic reporting of data since 2020. At present, data entry and reporting from the PHC level are done through the IMEM. While data quality has improved, its full-scale use for programmatic management remains to be weak. For instance, the public health system mostly use the previous version (Geovac), which does not produce case-based and real-time data. The main reasons for this shortcoming include weak programmatic accountability, weak ownership of the IMEM, the failure to resolve some of the system's functional shortcomings promptly, etc. There was no clear definition of who is responsible for overseeing the system in terms of functionality, logic, business processes resulting in IMEM ownership problems.

As part of the post-transition grant from Gavi, a further upgrade of the IMEM was planned in 2020, with capacity strengthening activities at the national and subnational levels for data analysis and real-time decision-making. However, since the Covid-19 epidemic required the mobilization of resources to modify the system and respond to COVID-19 vaccination needs (with support from the WHO), subnational capacity strengthening activities were limited. Following respective modifications, the software has been used for COVID-19 vaccination registration and reporting since 2021.

After USAID, the key actor in Immunization HMIS development in the pretransition period was UNICEF. UNICEF's contribution also included capacity-building activities for the roll-out of IMEM implementation. US CDC also played a role in the system modification. Further updates of the IMEM, as well as maintenance and continuous capacity strengthening activities, are one of the areas that should be fully taken over by the government. The government is gradually taking over the HMIS function, as for example the NIP budget already includes some, but not all, funds for IMEM technical maintenance. According to the respondents, about 30% of the maintenance costs were covered from domestic sources in 2021.

Gavi reporting was fully integrated into the national systems. Annual reporting on indicators was carried out through a joint WHO/UNICEF reporting form. In addition, the EPI unit was responsible for annual progress reporting to Gavi. The reporting process held EPI accountable for program performance as it required reporting on what has been done, resources spent, and an explanation or justification of actions that were not performed. At the same time, annual reporting helped capacity building: while the first reports were developed with external technical support, subsequent reports were produced with the EPI's own resources.

#### Intermediary Outcomes:

- *Gradual improvement of administrative immunization data quality, as at present the national HMIS produces rigorous data (with no discrepancy between administrative-reported and survey data)*

#### Enabling factors:

- *External demand and Accountability (context)*
- *External Technical Assistance (actors)*
- *Development of the national systems – electronic data management systems (context)*

#### Barriers and Risks:

- *Barrier – Inadequate use of Immunization HMIS possibilities due to suboptimal internal accountability (context)*

## Inputs – Drugs

In this section, we describe the *legislative framework* for vaccines, *procurement*, and *supply management (PSM) function*, *vaccine prices* and *cold chain* issues.

In the pretransition period prior to 2006, vaccines and injection supplies were either directly donated to Georgia or were procured through the state procurement mechanism. Procurement from the UNICEF supply division started following **legislative amendments** in 2006. Since this year, the National Law on the state budget has included a provision that vaccines were to be procured either through the UNICEF procurement mechanism or through state procurement. Other substantial changes in the legislative framework directly influencing vaccine procurement practices took place in 2009–2010. Following the Procurement Law amendment, state procurement procedures became transparent, helping to ensure robust competition and minimizing the corruption risk. The amended Law on Drugs and Pharmaceutical activities in 2009 recognizes the registration issued by stringent regulatory authorities for pharmaceutical products, including vaccines, and allows these products on to Georgian market without further registration. These amendments were introduced in 2009 and simplified imports of drugs and vaccines. The recognition regime also allows WHO-prequalified vaccines to be brought into the country using waivers, without requiring national registration (Gavi, 2015).

In the pre-transition and early transition periods (by the end of 2011), the **procurement function** was distributed between the NCDC and MoH. The NCDC was responsible for vaccine planning and quantification, while the procurement was the responsibility of a single public purchaser – the SSA. This split function between two entities led to some disruptions in vaccine supply, as described later. Eventually, the procurement function was transferred to the NCDC in late 2011, when one institution became responsible for the whole procurement and vaccine supply management cycle for the NIP.

During the pre and early transition periods up to 2013, vaccine planning, forecasting, procurement and supply management had significant shortcomings, leading to stockouts. Stockouts were caused by challenges in stock management, improper planning and/or complete reliance on the UNICEF supply division without using buffer stocks. Stockouts in 2010–2012, which were caused by delayed procurement, led to organizational reforms in 2012, as noted earlier. Gavi's assessment in 2012 identified a misalignment between planning and the national budget cycle (Saxenian et al., 2015)

The main player in procurement capacity strengthening was the UNICEF-CO and UNICEF-SD. Key NCDC specialists responsible for planning, forecasting and procurement participated in numerous capacity building workshops, site visits, and joint learning forums, where they gained access to relevant tools. Respondents indicate that participation in co-procurement has also led to improved capacities. Embarking on the self-procurement for Hexavalent vaccine in 2015 (see the Leadership & Governance section for a detailed description) revealed additional capacity needs, such as market intelligence (information on prices and global trends, access to analytical tools). As mentioned by the key informant:

*“Prior working experience with the UNICEF-SD and access to relevant information sources were extremely helpful in the self-procurement process” (Respondent N7)*

A comprehensive assessment of the vaccine procurement system in 2016 found the system performance was good, with a total score of 86%. It found vaccine forecasting and budgeting to be well planned, while the procurement process was open, transparent and efficient. Customs clearance procedures for vaccines were simplified and VAT was not applied. Procurement legislation that allows for multiyear contracting and other procurement practices has also improved flexibility and transparency. These mechanisms include an e-platform for online participation and accountability, international access to the procurement database, and acceptance of international electronic tender documentation prepared in English (LNCT, 2019; UNICEF Georgia & NCDC, 2016).

At present, Georgia uses both procurement mechanisms: all routine immunization vaccines are procured through the UNICEF pooled mechanism, while hexavalent



vaccine is procured through state procurement, as the latter is not available through the UNICEF SD.

Georgia benefits from Gavi's negotiated prices for Gavi-supported vaccines procured through the UNICEF SD (Rotavirus, PCV and HPV). According to this arrangement, Georgia pays the same price that was paid in a country's final year of support for the subsequent 10 years (WHO, 2017). Access to Gavi prices was a conducive factor in the financial sustainability of the transition. However, this right will expire in 2025 (for Rota), 2027 (for PCV) and 2029 (for HPV), which may lead to a 4%, 21% and 29% respective increase in the current vaccine line-item in the NIP budget.

A key component in the NIP performance is the cold chain and vaccine logistics system. The cold chain received significant investments from donors, starting from early pre-Gavi, Gavi transition and post-transition periods. The support included the provision and continuous replacement of cold chain equipment at the national, subnational and service provision levels, and capacity strengthening at all levels through extensive training and supervision.

The main actors in the cold chain and logistics strengthening during the transition period were UNICEF (market intelligence, procurement skills and knowledge) and the WHO (system assessments, trainings, guidelines development). In the post-transition period, WHO and US CDC contributed to cold chain strengthening through the Covid-19 vaccination program.

#### Intermediary Outcomes:

- *No vaccine and supply stock-outs at national, sub-national and service delivery level; No excess wastage*
- *Streamlined procurement processes (forecasting, planning, procurement) through UNICEF SD and state procurement*
- *Continuation with UNICEF SD procurement for the majority of routine immunization vaccines, thereby assuring access to guaranteed vaccines*

#### Enabling factors:

- *Internal accountability (content)*
- *External Technical Assistance (actors)*
- *Institutionalisation / Integration (content)*

#### Barriers and Risks:

- *Risk - Expiration of Gavi negotiated price conditionality and a consequent vaccine budget increase*
- *Risk of paying a high price for self-procured vaccines due to Georgia being a small market with low negotiating power*

# Discussion

In the case study, we have tried to identify the outcome of the NIP transition from Gavi support, how, why and under what circumstances the transition happened and what factors contributed, sustained and/or constrained this outcome.

The NIP transition was evaluated by reaching and sustaining high coverage levels of traditional (DTP containing vaccine and MMR) and new vaccines supported by Gavi (Rotavirus and PCV) after transitioning from Gavi support.

Gavi's support to Georgia started in 2002 and included a significant contribution to the National Immunization Program (NIP) by introducing new vaccines, injection supplies, and system strengthening activities. Georgia graduated from Gavi support in 2018, since when the NIP has been fully financed from the State budget and managed by a national entity, the NCDC.

Following the transition from Gavi support, for two years Georgia has maintained high coverage levels for DTP-3 under one-year and MMR-1 under two years of age, and suboptimal coverage levels for Rota-2 under one-year and PCV-3 under two years of age, leading to the conclusion that the transition has led to stronger, but still imperfect, national immunization program performance.

To achieve and sustain the transition outcome described above, certain **intermediary outcomes** were reached, which are structured across the health system building blocks. From the Governance & Leadership and Financing perspectives, Georgia's NIP policy decisions provided the basis for the transition's achievements. Specifically, Georgia used Gavi support to introduce five new vaccines in the national immunization calendar, one of which was introduced in the post-transition period. Georgia fully met Gavi's co-financing requirements and became a self-financing country in 2018. The NIP budget, which had been heavily dependent on donor support, received increasing domestic financing over the years, with this positive trend continuing in the post-transition period. Following the transition, Georgia initiated financing of NIP auxiliary activities (such as cold chain, HMIS maintenance, and communication activities) from domestic sources that prior to the transition were solely funded from external sources.

At the service delivery level, a look at disaggregated sub-national data shows a reduction in the districts and the number of children with suboptimal immunization uptake, thus indicating improvements towards equitable access to and utilization of services.

The ability of the NIP to achieve its outcomes depends largely on the knowledge and skills of the human resources responsible for planning, organizing and delivering immunization services. Over the years, the capacity of the public health and program administrative personnel responsible for planning, procurement,

budgeting, cold chain management and logistics has strengthened, the technical expertise of NITAG members has increased and the capacity of primary care personnel in immunization theory and practice has improved.

Reliable programmatic data is fundamental for any health intervention. Administrative immunization data in Georgia suffered from significant deficiencies. The gradual improvement of data quality generated through the national HMIS led to immunization data that could be trusted with confidence.

The NIP transition was greatly influenced by the existence of effective vaccine procurement and supply management systems. Georgia practices streamlined procurement processes (forecasting, planning, procurement) through UNICEF SD and via state procurement. Continuation with UNICEF SD procurement for most routine immunization vaccines ensures access to guaranteed vaccines at Gavi's negotiated price. The NIP has a strong cold chain and logistics system, resulting in no vaccine and supply stock-outs at the national, sub-national and service delivery levels and no excess wastage.

This analysis shows that the NIP transition appears to be complex. Assessment of the transition by several outcome indicators, each of which has its own specific explanatory factors, contributes to this complexity. The results show that the factors/elements driving the transition are multifactorial, dynamic, and interconnected. They could also change over time, depending on the context.

Another challenge was to find a balance between assessing the transition and an overall assessment of the NIP, as the outcome indicators and driving factors are overlapping: some are related to donor support while others are explained by the country's developmental path. We found that NIP transition was an incremental process spanning over a 10-year period, during which many changes happened. These included the macroeconomic development of the country (which is not covered in this case study), transformations in the health sector including governance and legislative changes that are not directly linked to immunization or donor support, the evolution of systems for civil registration, digital developments for data management, improved public financing and management, etc.

From this analysis, we have identified the following nine **enabling factors**:

1) **Political commitment**: the case study findings suggest that high political commitment to childhood immunization positively influenced decision-making on *new vaccines introduction and fulfilment of Gavi co-financing obligations and led to sustainable and increased financing of the vaccine procurement part of the NIP budget*. Historically, childhood immunization in Georgia has received a high priority in health policy decision-making. Its public health value and contribution to child wellbeing are well-acknowledged and never questioned. This *contextual factor* has been influenced and strengthened through **external accountability demands** (contribution to MDGs/SDGs, country positioning in global ratings), and by **various**

**external and internal actors** who played different roles in maintaining high political support.

2) **External Demand / Influence and Accountability.** *The introduction of the new vaccines as well as the fulfilment of co-financing requirements* were externally imposed requirements. As mentioned above, external accountability factors helped to sustain political commitment to the immunization program. In addition, influence and encouragement from donors have shaped national decision-making on new vaccine introduction. The latter was operationalized through external actors' involvement via technical knowledge transfer, advocacy work, and the involvement of in-country stakeholders in knowledge-sharing forums.

Since co-financing was also a donor-imposed condition, the country was accountable to fulfill these requirements. Another important factor is the transition strategy from Gavi's support, which was planned and scheduled in advance of the start of the transition and was embedded from the early stages of Gavi's support. In other words, the co-financing requirements were incorporated in the binding agreement between Gavi and the government for each new vaccine support. Moreover, this strategy (or co-financing requirements and schedule) was clearly articulated and transferred to country stakeholders in a variety of ways (formal communication, reminders, advocacy meetings, Joint Appraisals, national stakeholder participation in the Gavi regional meetings, cMYP exercises). All these efforts ensured that the transition plans, government responsibilities, and gaps were well understood and agreed upon by the government and other national stakeholders. The external demand and accountability also triggered a gradual improvement in the quality of *immunization administrative data* generated by the HMIS.

And lastly external demand created *differentiated attention to the vaccines*, e.g., the vaccines that are part of the international reporting and country ratings are given higher attention compared to other vaccines that are not part of global databases.

3) **External Technical Assistance (TA).** External TA had a pivotal role in strengthening various components of the NIP, which contributed to achieving intermediary outcomes and ultimately helped reach the final outcomes. Importantly, external TA was supported not only by Gavi but also by other development partners, starting from the pre-transition period. External partners, while providing TA, worked in a collaborative partnership, while their investments were complementary to each other and tailored to the country's needs.

External actors played a critical role with their technical advice during the new vaccine introduction. The MoH, NCDC, and NITAG were continuously supported by scientific evidence on vaccine effectiveness and cost-effectiveness to positively shape the opinions of mid and high-level decision-makers towards vaccine

introductions. External TA was critical in HR capacity building (primary health and public health professionals, program planners, vaccine procurement officers, NITAG experts). Technical assistance was substantial and critical in strengthening cold chain and logistics system in the country as well as in the Immunization MIS development and scale-up.

4) **Advocacy.** Advocacy work from external actors and country level partners was crucial with regards to influencing decisions on NVI. The Sabin Institute's advocacy role was prominent in promoting sustainable immunization financing and domestic resource mobilization for immunization. National mid-level immunization officers also played an advocacy role on NVI following their awareness and technical knowledge in vaccine safety, with their effectiveness growing after being exposed to relevant information from external partners.

5) **Multisectoral engagement.** Participatory multisectoral processes enabled the creation of a shared vision among national stakeholders and early buy-in in decisions on new vaccine introductions, as well as taking on financial ownership in these introductions. The most important multisectoral engagement platform throughout the transition period was the ICC. Other multisectoral engagement processes included Joint Assessments, program reviews, participation in the Gavi regional group meetings, and cMYPs development.

The role of actors during these engagements (particularly at the ICC) was mostly similar across the transition period. The MoH played a key decision-maker role, while the MoF, which was involved in all discussions, followed the MoH's proposals. The MoH was backed by the NCDC and the NITAG and supported by external partners with technical advice. The power dynamics between the MoH, the MoF and external partners changed once the Hexavalent vaccine introduction discussions started.

## **6) Institutionalization / Integration**

Gavi did not create parallel systems in the country. All functions (reporting, management, procurement) were integrated into the national systems. Moreover, there were no salary top-ups. The only incentives created by Gavi were per-diem allowances for supportive supervision, although the transition to government funding now risks their continuation. The legislative changes created a conducive environment for participation in UNICEF pooled procurement mechanisms and streamlined state procurement processes.

7) **Development / developed national systems.** The development of national systems in parallel to the transition process created an enabling environment for the transition. The most prominent example relates to the HMIS, particularly the availability of reliable immunization administrative data as a key attribute of the strong NIP. Prior to and at the early stages of the transition, Georgia suffered from a lack of quality data for decision-making. Immunization MIS underwent a significant

evolution over the years, ensuring the availability of quality and real-time data at the national, subnational and service delivery levels. These developments were made possible due to the evolution and integration of information systems in the country, such as the national registry and the perinatal HIS.

Another example relates to the development of the public finance management system. It was found that the MTEF creates a conducive environment for sustainable NIP funding. While the MTEF does not guarantee an increased budget in the planned years, it is a useful instrument for budgetary negotiations and increase justifications.

Having well-developed national systems in place means that fewer investments and transformations are required to achieve transition goals. For example, the Georgia NIP transition benefited from the primary care system, which ensures access to immunization services without geographical and economic barriers.

8) **Internal accountability.** The transfer of the vaccine procurement management function between the institutions (MoH and NCDC) led to the housing of vaccine planning, budgeting and procurement under one institution (NCDC), which was also responsible for immunization program management. Coupled with strengthened capacity over the years, this allowed for the smooth administration of procurement processes after the transition. The evidence suggests that this integration helped with the internal programmatic and/or organizational accountability. Consolidation of NIP key management roles including procurement in a single place helped to increase the NCDC institutional responsibility and respectively of individuals to fulfil NIP administrative functions.

9) **Pride and self-satisfaction of actors being recognized as regional leaders.** Georgia was identified as a leader country by Gavi and regional partners in terms of fulfilling its co-financing obligations, introducing new vaccines and increasing NIP financing from government sources. This generated national pride among national stakeholders and the ambition to maintain its status among peer countries. As this continued over the years, we argue that this could have also stimulated the political commitment to succeed in new vaccine introduction and self-financing.

The analysis identified **barriers and risks** that are hindering efforts to reach transition outcomes or may prevent these achievements from being sustained.

The main structural barriers in the way of progress are related to the PHC financing. The reimbursement scheme for the UHCP primary care package, where immunization is one of many services, does not create a favorable environment for performance improvement. Another barrier relates to the organizational set-up of municipal public health services, which legally are not empowered to influence immunization performance at the PHC level beyond monitoring data accuracy, PHC personnel capacity building in safe immunization, and cold chain logistics.

A number of barriers were identified with regard to human resources. Health promotion, including immunization communication, remains one of the weakest functions of the PHC. The sustainability of immunization knowledge and practice remains at risk due to the suspension of CME for primary care personnel. At the public health level, municipal public health centers have severe human resource challenges in terms of replacing qualified staff.

One of the shortcomings of the NIP is the inadequate use of immunization HMIS data for real-time decision-making. The low use of data for more targeted managerial decisions, which is currently attributed to some technical deficiencies of the HMIS software, is ultimately linked to suboptimal internal accountability. The continuation of supportive supervision remains at risk once the function is transitioned to government financing, as government rates are disincentivizing the provision of these activities. All above have already led to suboptimal immunization uptake or may lead to the deterioration of immunization performance.

On the supply-side, the expiration of Gavi's negotiated price will be associated with an increase in the vaccine budget over the next four to six years. In addition, instead of the competitive price for self-procured vaccines that it currently pays, Georgia may pay a higher price due to its small market size and negotiating power. These factors pose additional financial risks to the NIP.

## Conclusion

In this case study, we examined the outcome of the NIP transition from Gavi support, how, why and under what circumstances the transition happened, and what factors sustained or constrained this outcome.

NIP transition was measured by immunization coverage for selected vaccines. The analysis showed that the NIP transition was successful as coverage rates of two out of four examined vaccines reached and remain at high levels. However, the uptake for the other two vaccines remains suboptimal, which is explained by existing structural barriers in the health system, control of which was outside Gavi's support. The study identified multifactorial, interconnected, dynamic and context-dependent factors, processes and actors that drove the NIP transition.

# Annex – Role of Actors

	Pre-transition	Transition		Post-transition
	2002–2008	2009–2012	2013–2017	2018 and beyond
MoH high officials (Ministers, deputy ministers)	High commitment to NIP Main decision-maker in NIP Strongly supported NVI (Penta)	High commitment to NIP Main decision-maker in NIP Supported NVI following solid justifications on cost-effectiveness (Rota, PCV) were supported	High commitment to NIP Main decision-maker in NIP Strongly supported Hexa switch and advocated among MoF & Parliament Committee	High commitment to NIP
MoH EPI lead	Strongly supported NVI (Penta)	Supported NVI (Rota, PCV)	Strongly supported Hexa switch	
Parliament Committee	In general, high commitment to NIP No role in NVI	In general, high commitment to NIP, supported increased allocations No role in NVI	In general, high commitment to NIP, supported increased budget allocations Strongly supported and advocated Hexa switch to MoF following technical instructions from NCDC/Sabin	In general, high commitment to NIP, supports increased budget allocations Held discussions on NIP performance improvement through legislative changes



	Pre-transition	Transition		Post-transition
	2002-2008	2009-2012	2013-2017	2018 and beyond
				Strongly supported and initiated mandatory immunization policy
MoF	No role in NIP funding Part of ICC composition	Followed MoH decisions, no objections to NIP increased funding Part of ICC composition Attending Gavi supported regional meetings	In general, no objections to NIP increased funding Initially opposed increased allocations for Hexa leading to NIP budget three-fold increase. Coincided with the UHCP increased expenditures, therefore urged MoH to reallocate within Health budget. Following advocacy and justifications from MoH/ Parliament Committee & NCDC the MoF approved NIP budget increase. Part of ICC composition Attending Gavi supported regional meetings	No objections to NIP increased funding
NCDC high officials (directors, deputy directors)	Important decision-maker in NIP	Important decision-maker in NIP Strongly advocated NVI (Penta, Rota, PCV)	Important decision-maker in NIP Strongly supported Hexa switch Initially resisted HPV introduction	Important decision-maker in NIP
NCDC (EPI unit, Programs unit)		Prepared technical recommendations for ICC on NVI (Penta, Rota, PCV).	Initiated and strongly supported Hexa switch (justifications: only India manufactured Penta available through UNICEF)	

	Pre-transition	Transition		Post-transition
	2002-2008	2009-2012	2013-2017	2018 and beyond
		With external technical assistance developed Gavi proposals. Influencing	mechanism, additional IPV injection, low adverse events due to acellular Pertussis in Hexa, high demand on Hexa among urban residents through private sector). Prepared costing analyses for MoH on Hexa switch.	
NITAG		NA	Strongly supported Hexa switch Prepared technical recommendation on Hexa justified by above arguments	Since 2021, mainly occupied with COVID-19 vaccinations
WHO-CO	Wide range of NIP strengthening activities	Wide range of NIP strengthening activities Strongly supported NVI (Penta);	Strongly supported NVI (Rota, PCV) Managing Gavi transition grant	Managing Gavi post-transition grant, which was postponed due to COVID-19
UNICEF-CO	Assisted NCDC in Gavi proposals development Wide range NIP strengthening activities	Wide range NIP strengthening activities Strongly supported NVI (Penta)	Strongly supported NVI (Rota, PCV) Strongly supported Hexa switch Participated in Joint-Appraisals, transition plans development Managing Gavi transition grant	Managing Gavi post-transition grant, which was postponed due to COVID-19
Sabin Institue			Advocacy role to secure increased domestic financing for NIP, particularly with Parliament commission.	

	Pre-transition	Transition		Post-transition
	2002-2008	2009-2012	2013-2017	2018 and beyond
			Workshops on legislative and regulatory changes to improve immunization coverage. Advocated for Hexa switch.	
WHO-RO	Advocated for Penta Estimated Hib disease burden used for justification of Penta introduction	Shared scientific evidence on Rota and PCV vaccines efficacy and safety, cost-effectiveness data	Advocated for Penta and IPV combination and opposed Hexa because of its cost implications on the budget	Guidance to maintain routine immunization during COVID-19 epidemic

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