Country Case Study: Lessons Learned from Georgia's Experience Transitioning from Gavi Support

Photo Source: UNICEF/Geo-2019/Jibuti

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LNCT Learning Network for Countries in Transition

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Acronyms

Gavi Alliance	Global Alliance for Vaccines and Immunization
GDP	Gross Domestic Product
GeL	Georgian Lari
cMYP	Comprehensive Multiyear Plan
DPT	Diphtheria Pertussis Tetanus
EPI	Expanded Program of Immunization
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
LNCT	Learning Network for Countries in Transition
MCV	Measles Containing Vaccine
MIS	Management Information System
MMR	Measles Mumps Rubella
MoH	Ministry of Health
MoF	Ministry of Finance
MTEF	Mid Term Expenditure Framework
NHA	National Health Agency
NITAG	National Immunization Technical Advisory Group
NCDC	National Centre for Disease Control and Public Health
NRA	National Regulatory Agency
NIP	National Immunization Program
PHC	Primary Health Care
PCV	Pneumococcal Conjugate Vaccine
UHC	Universal Health Coverage
UNICEF SD	United Children's Fund Supply Division
USAID	The United States Agency for International Development
VAT	Value-added tax

Executive Summary

Gavi support to Georgia began in 2002 and included a significant contribution to the National Immunization Program (NIP), leading to the introduction of new vaccines, procurement of additional injection supplies, and system strengthening activities. Georgia graduated from Gavi support in 2018, and since then, the NIP has been fully financed from domestic sources.

Gavi played a catalytic role in Georgia's successful transition. Clear, timely, and transparent communication with the Government, directly and through its partners, as well as joint assessments involving national stakeholders, enabled coordinated efforts and helped build political commitment long before the formal transition (Gavi, 2015; Saxenian et al., 2015). On a national level, the Intersectoral Coordinating Committee (ICC), as champions of the immunization program, played a key role in moving the immunization agenda forward, sustaining political will, and successfully advocating for increased government allocations. Economic growth in Georgia and increased public allocations to health were critical in making progress towards transition. The NIP, which has traditionally received a high level of political commitment in Georgia, received sustainable funding, particularly for vaccine procurement. Prior to the full transition from Gavi, there was a sharp increase of NIP funding associated with switching to the Hexavalent vaccine, which the country prioritized despite the significant budgetary implications. The trend of increasing allocations to the NIP has continued, with Georgia managing to sustain a positive trend even through the COVID-19 crisis.

Before and after Gavi support, the Georgian NIP received significant contributions from multilateral and bilateral donors, through the provision of traditional vaccines, injection supplies, and system strengthening activities. Country level and regional partners played a crucial role in building the capacities of professionals at the primary care, public health, and programmatic levels, to improve data quality through the introduction of an immunization electronic system, to streamline vaccine forecasting and procurement processes, and in other technical areas.

Despite a successful transition and strong programmatic performance, the Georgian NIP faces challenges in sustaining the outcomes achieved to date. There are issues with immunization coverage rates, particularly in the context of the COVID-19 pandemic; insufficient government financing for communication activities, supportive supervision, and the information management system; challenges in sustaining human resource capacities; and weak institutional capacities in post-market authorization. In addition, the economic burden caused by the COVID-19 pandemic, coupled with simultaneous transition from other donor supported programs, brings additional financial uncertainties. The immunization program and health system need to adapt to these new realities and maximize their efforts to sustain and improve its outcomes.

Overview of the National Immunization Program in Georgia

Georgia first applied for Gavi financing in 2001, with a request to fund the Hepatitis B vaccination. By that time, all vaccines, supplies, and cold chain equipment were funded through external support with the NIP being (domestically) funded at only 50% of the planned budget with no government contribution to vaccines or supplies (Government of Georgia, 2001).

Gavi support spanned from 2002 to 2017, during which time four new and underutilized vaccines were introduced into Georgia's national immunization calendar: the Hepatitis B vaccine in 2002, the Pentavalent vaccine in 2009, the Rotavirus vaccine in 2013, and the Pneumococcal Conjugate vaccine (PCV-10) in 2014. All Gavi-supported vaccine introductions were implemented nationwide, and other initiatives, such as the Health Systems Strengthening (HSS), Immunization Services Support (ISS), and graduation grants targeted both national and operational (district) levels.

The Government gradually increased the financing of traditional vaccines, and, by 2009, covered the majority of them. Co-financing obligations began in 2009, and nine years later – in 2018 – Georgia became fully self-financing. After the transition in 2018, Georgia received additional Gavi support for the introduction of the Human Papillomavirus (HPV) vaccine through a post-transition grant.

The major milestones of the NIP in Georgia are given in the graph below.

Prior to gaining independence, the Georgian health system was part of the unified health protection system under the Soviet system between 1921-1991. Immunization was an integral part of the centrally planned sanitary-epidemiological system.[1] The immunization calendar was similar in all Soviet states and the list of recommended vaccines continued to be updated as more vaccines were developed.

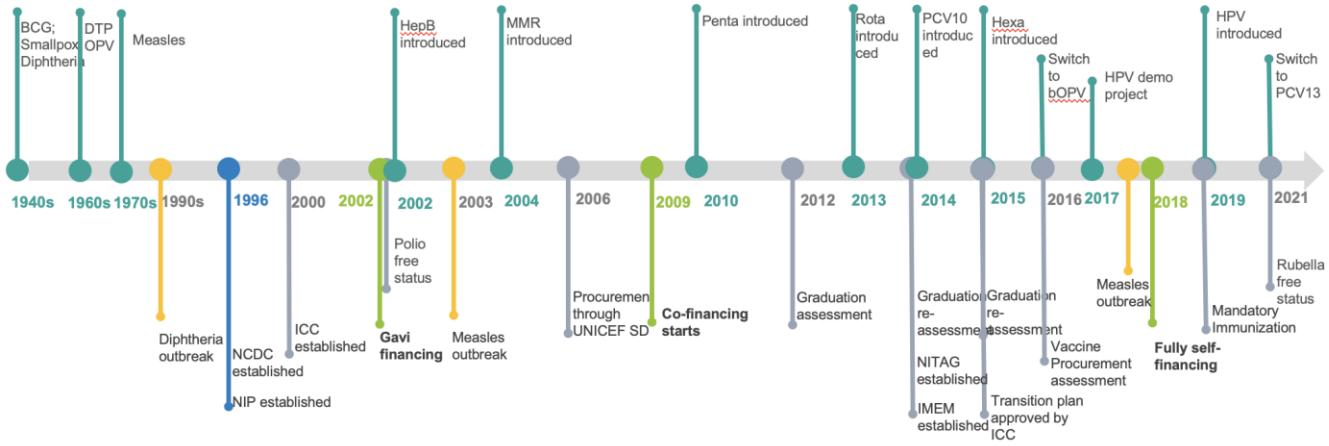
Since the break-up of the Soviet system, Georgia has undergone a profound economic and social transformation. Civil unrest and political changes in the early 1990s were accompanied by poor performance of the immunization program. Cohorts of the child population were left under-vaccinated due shortages of centrally supplied vaccines and widespread false contraindications, leading to outbreaks of vaccine-preventable diseases such as diphtheria and measles (Khetsuriani et al., 2010; Quick et al., 2000).

The sanitary-epidemiological model was no longer effective in responding to emerging public health challenges. Georgia carried out a radical reform of the existing system, separating sanitary and epidemiological functions and advancing toward decentralization, by shifting responsibilities to local municipalities with central oversight (Gotsadze et al., 2010). As part of these large-scale reforms, a leading public health agency - the National Centre for Disease Control and Public Health (NCDC) – was established in 1996, with further major reorganizations in 2007 and 2010. The National Immunization Program (NIP), which was established the same year, was a dedicated state program covering immunization services and the costs of vaccines and supplies (Gamkrelidze et al., 2003). Due to economic decline and weak financial management systems, the state health programs were severely underfunded. Execution of the central budget was subpar, falling between 45-62% during 1997-2000 (The World Bank, 2002).

Since 1994, various multi and bilateral donors (UNICEF, WHO, Rostropovich-Vishnevskaya Foundation, USAID, JICA, US CDC) have provided significant contributions to the NIP through the provision of traditional vaccines and injection supplies, introduction of new vaccines, and system strengthening activities (improving the cold chain system, reform of the immunization management information system, training health providers, communication activities, etc.) (Government of Georgia, 2011).

The Intersectoral Coordinating Committee (ICC) was established in 2000 and has since played a key decision-making role in the introduction of new vaccines and other important decisions related to routine immunization.

Graph 1 Georgia NIP key milestones



Organization of the Immunization Program: Service Delivery

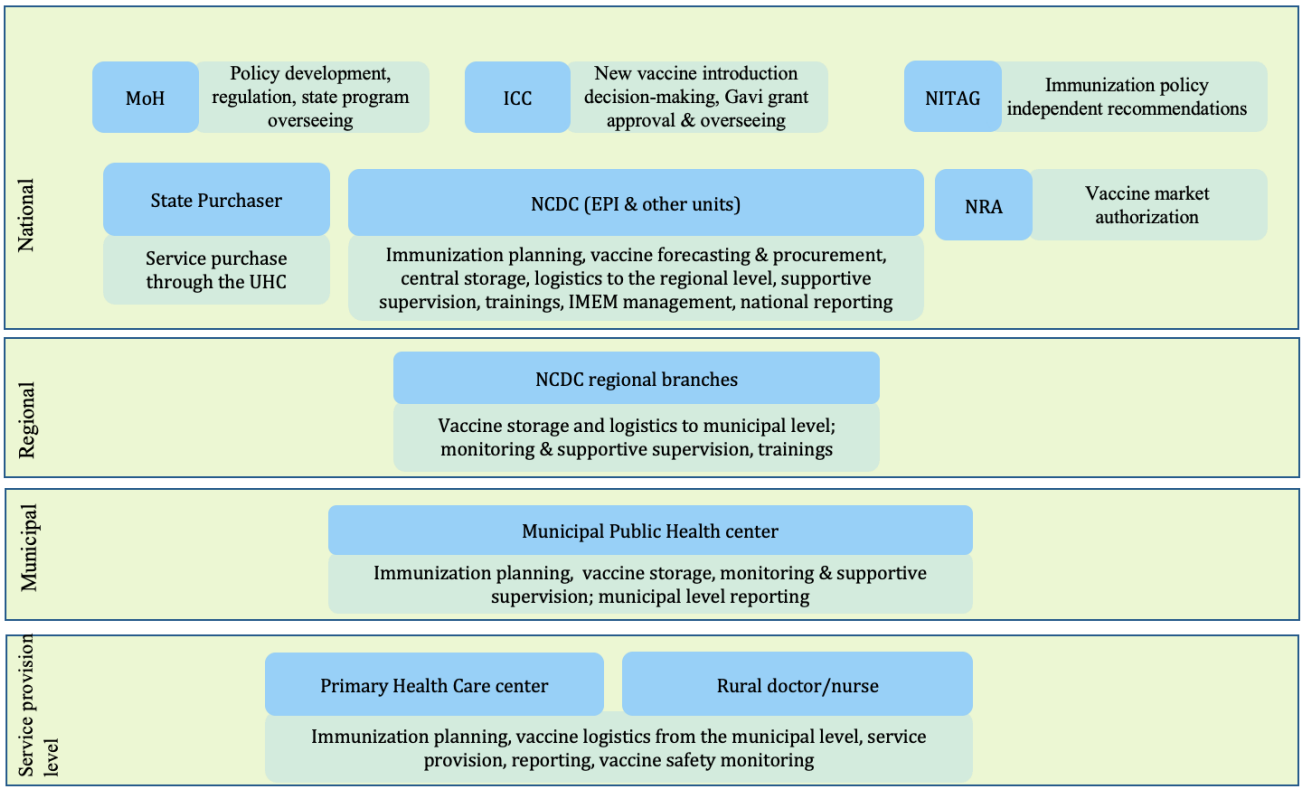
The Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs (MoH) is responsible for policy development, regulation, and developing and overseeing implementation of the state health programs, including the NIP. The National Centre for Disease Control and Public Health (NCDC) is responsible for planning and overseeing immunization activities, providing technical guidance, monitoring and supervision, surveillance, national level reporting, forecasting and procurement of vaccines and injection supplies, and central level logistics. The NCDC's dedicated EPI unit is responsible for all technical aspects of immunization activities, while other departments are involved in financial projections, procurement, and other tasks. The NCDC's nine regional branches and municipal public health centers ensure proper vaccine storage at the subnational level, surveillance and monitoring performance of immunization activities, and management of the immunization information system at the subnational level. Immunization services are offered through primary health care (PHC) facilities and village doctors (individual entrepreneurs) in rural areas. Almost all primary care facilities are private. Immunization services are purchased by a single public purchaser.[1] (see

[1] The single public purchaser underwent reorganizations over the years, from the SUSIF (State United Social Insurance Agency) to the SSA (Social Service Agency) and finally to the NHA (National Health Agency).

Graph **2**).

Per the current reimbursement scheme, the cost of routine immunization services is integrated into capitation payment for primary care services under the Universal Health Coverage (UHC) program, which has functioned since 2012. The previous payment mechanism for immunization varied from fixed salaries, with performance-based bonuses linked to coverage rates, to payment for each performed vaccination.

Graph 2 Organization of the Immunization Program in Georgia



Transition Governance

Smooth transition from external financing requires, amongst other prerequisites, a common understanding of the transition terms and responsibilities, timeframes, and clear roles and responsibilities of all actors involved (Gotsadze et al., 2019).

Gavi played a catalytic role in the transition. Communication with the Government of Georgia through its partners and through direct communication was clear, timely, and transparent. Joint assessments involving national stakeholders provided constructive feedback to the Government, enabled coordinated efforts, and helped in building political commitment long before the formal transition.

From the Government's side, the Intersectoral Coordinating Committee (ICC), chaired by the Minister of Health, with its multisectoral representation, played a key decision-making role through the transition process. The ICC was responsible for coordinating and guiding the use of Gavi funds. In addition, at different points during Gavi's support, the voices and positions of champions of the immunization program were critical in moving the national immunization agenda forward, sustaining political will, and successfully advocating for increased government allocations to the NIP.

The WHO European Regional Working Group for Gavi, which was formed with the purpose of coordinating support to country programs, also played an important role. Georgia actively participated in the Working Group's annual workshops to present the country's progress, challenges, and lessons learned around program implementation, new vaccine introductions, multi-year plans,[2] co-financing achievements, and transition plans. These workshops provided an effective platform for communication with partners and experience sharing between peer countries during the pre-transition period.

The role of country level partners was critical in many ways, as described above.

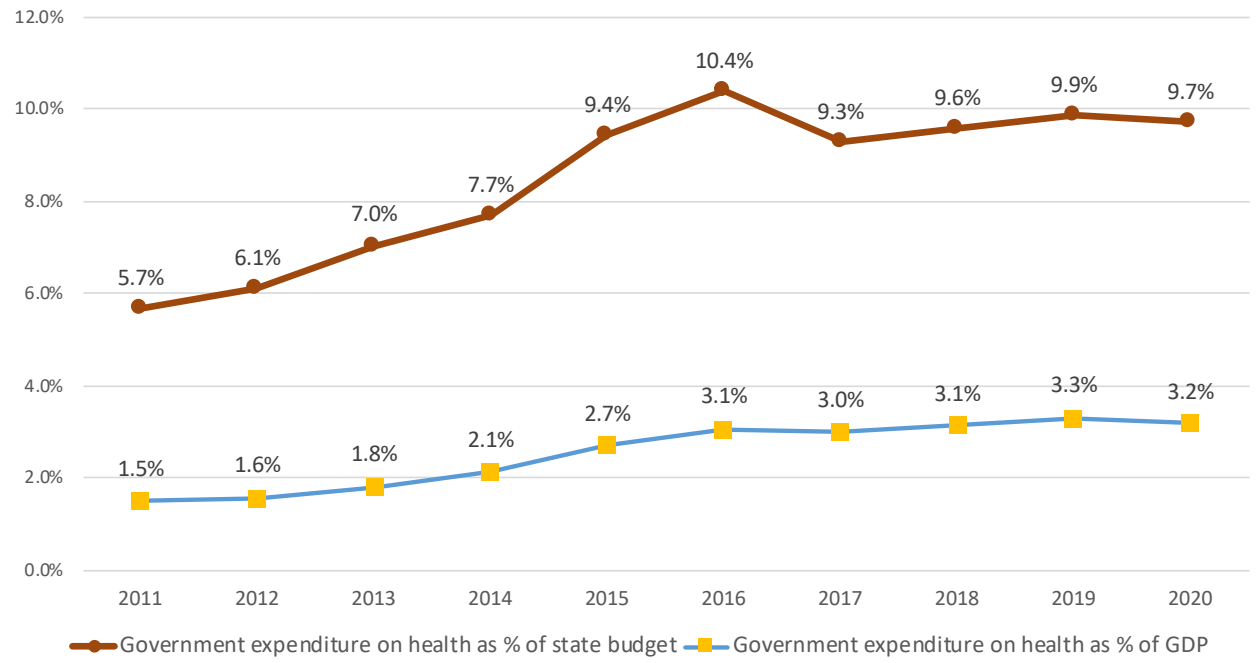
[2] Georgia developed three multi-year plans: 2007-2010, 2012-2016, 2017-2021.

Financial Sustainability

Georgia transitioned from Gavi support in 2018, having fulfilled its co-financing responsibilities since the start of Gavi co-financing arrangements in 2009.[3] The country was briefly considered in default in 2010 due to a miscommunication on the modality of procurement of co-financed doses. However, the issue was quickly resolved, and Georgia received and maintained good performer status (Gavi, 2015).

Economic growth is a necessary step before a country can feasibly take over donor-funded responsibilities, and Georgia has performed well in this area during the last decade. In the pre-COVID era (2010-2019), the 5-year average annual growth of Gross Domestic Product (GDP) per capita ranged from 3.8%-5.3%. In 2020, the COVID-19 pandemic adversely impacted the economy, resulting in negative GDP (-6.0%).[4] In addition to macroeconomic parameters, the **political will of the government to fund the health sector** is critical in making progress towards transition. The Georgian Government's allocations to health increased significantly from 2013 following the introduction of the UHC program. During 2012-2016, state budget allocations for health increased more than 2.5 times, from a low base of 1.6% to 3.1% of GDP.[5] Despite an economic shock in 2015 that resulted in the local currency depreciating by 42% against the USD, the Government maintained increased financing for health.

Figure 1 Government allocations on health, 2001-2020



The UHC program receives the highest priority in the health budget, consuming about 70% of the Government's total health allocations. The NIP is one of the state health programs approved annually by the Government. The NIP budget covers costs for routine immunization vaccines and injection supply, which constitutes more than 70% of the total program budget; vaccines and other pharmaceuticals for epidemiological indication (rabies, tetanus); influenza vaccine and service costs (from 2014); cold chain support; and communication and information system support (from 2020). However, the NIP budget is not the only governmental fund spent on immunization. Under the UHC Program, routine immunization service costs

[3] Since 2008, countries applying to Gavi for New Vaccine Support have had to co-finance a portion of the vaccine cost.

[4] World Bank data. https://data.worldbank.org/

[5] Ministry of Finance of Georgia. (2020). State Budget Performance Reports 2010-2020. Retrieved from https://www.mof.ge/en/4565;

are integrated into the consolidated budget for PHC services. NIP management costs, such as EPI unit staff costs, are part of the NCDC institutional budget, while personnel costs for immunization supervision at the municipal level are covered by municipal budgets.

One of the **critical shortcomings of immunization financing in Georgia** is that governmental sources for communication and information system support is very limited, and capacity building activities and operational costs for supportive supervision are not included. Currently these needs are externally supported and there is a risk that the hand-over of capacity building activities (trainings and supportive supervision) by the Government will frustrate development efforts. The allowances paid from partner-supported programs are standardized and aligned between donors; however, Government rates are disproportionally small and below the actual costs of meals and accommodation, thus disincentivizing personnel to provide similar activities with Government funding. Since 2017, Government funds have been allocated to cold chain strengthening, with the biggest investments in 2019.

Table 1 shows the progressive trend of NIP financing. There was a sharp increase in 2015, which was largely associated with procurement of the Hexavalent vaccine. In 2021, the increase is associated with the procurement of the Tetravalent[6], HPV, and Influenza vaccines[7].

Table 1: Government financing of NIP, 2011-2021 (1000 Georgian Lari (GeL) or 1000 USD)

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021[8]
								Fully self-financing			
NIP budget Gel	4,520	4,940	5,430	4,431	11,174	16,206	17,927	21,803	22,556	24,130	33,239
annual change %		9%	21%	-26%	152%	45%	11%	22%	3%	7%	38%
NIP budget USD [9]	2,681	2,976	3,265	2,510	4,922	6,847	7,146	8,602	8,001	7,760	10,029
annual change %		11%	21%	-30%	96%	39%	4%	20%	-7%	-3%	29%

Currently Georgia benefits from Gavi negotiated prices for Gavi supported vaccines that are procured through the UNICEF Supply Division (Rotavirus, PCV, and HPV). According to the conditions of this arrangement, Georgia is able to pay the same price that was paid in their final year of Gavi support for ten years post-transition (WHO, 2017).

Future budgetary projections for the NIP are reflected in the Medium-Term Expenditure Framework (MTEF), a multiyear planning instrument, which is a prerequisite for sustainable program financing in the long run.

In the context of the coronavirus crisis, it is critical that the pattern of increasing allocations to the NIP continues. So far, Georgia has managed to sustain this achievement.

However, transition should be understood within a broader macro-fiscal and political economy context. Also, transition obligations for other donors, such as Global Fund supported HIV and TB programs in Georgia, put additional pressure on the sector and requires more in-depth exploration and analysis.

[6] Children vaccinated with the hexavalent vaccine with the first three doses are offered a tetravalent vaccine for booster doses at 18 month and 5 years of age.

[7] The cost of the influenza vaccine constitutes 12% of the 2021 approved budget.

[8] The 2021 approved budget excludes covid-19 vaccine administration budget

[9] USD/GeL exchange rate - average for the period. Source: National Statistics Office of Georgia.

Vaccine Procurement

Georgia is leveraging the opportunity to purchase vaccines through a pooled mechanism, and as such, procures all routine immunization vaccines (except Hexavalent vaccine) through the UNICEF Supply Division. This procurement arrangement became possible following legislative amendments in 2006. Since 2011, the NCDC has been responsible for the procurement of vaccines.

Prior to 2015, vaccine stock-outs were reported and were attributed to improper planning and forecasting in earlier years, a reliance on UNICEF supplies, and global supply constraints (Pentavalent in 2015). UNICEF contributed significantly to national capacity strengthening by engaging NCDC specialists in capacity building workshops, joint learning forums, and other capacity building modalities. A comprehensive assessment of the vaccine procurement system in 2016 found the system performance to be 'good', with a total score of 86%. It also found vaccine forecasting and budgeting to be well planned, and the procurement process to be open, transparent, and efficient. High-level advocacy for vaccine procurement has resulted in the simplification of customs clearance procedures for vaccines and the removal of value-added tax (VAT) on vaccines.

Procurement legislation also allows for multiyear contracting and other procurement practices that have been introduced to improve flexibility and transparency including an e-platform for online participation and accountability, international access to the procurement database, and acceptance of international electronic tender documentation in English (LNCT, 2019; UNICEF Georgia & NCDC, 2016).

The challenges with vaccine procurement relate to market authorization. About 50% of the vaccines used in the national calendar are not registered in Georgia. WHO prequalified drugs and vaccines do not fall under the "recognized regime"[10] which allows for simplified registration. On the other hand, due to a small market size, manufacturers are not interested in vaccine registration in Georgia. As a solution, the Government uses one-time waivers each time unregistered vaccine procurement is carried out. Although this practice is well established and smooth, there is an understanding that the practice should eventually be replaced by regulatory changes in order to remove this barrier.

Georgia has a collaborative agreement with the WHO on drugs but not on vaccines, which also precludes simplified registration. Current legislation does not allow for joint procurement with other countries or purchasing from more than one supplier. Joint procurement requires the harmonization of regulations between the countries in question, and thus implementing significant changes to the legislation would be too challenging at this stage. The capabilities of the local National Regulatory Agency (NRA) also need strengthening. The current function of the NRA is limited to market authorization. WHO, in the frame of the Gavi transition grant, and other partners, have invested in NRA capacity building over the years; however, several institutional changes over the last decade led to high turnover of qualified staff, which has contributed to weak NRA capacity, particularly in post-market surveillance.

In 2015, Georgia decided to introduce the Hexavalent vaccine. The combination of smart regulations and procurement processes allowed Georgia to access competitive prices (less than half the average commercial market price) for high-quality vaccines and negotiate a two-year contract with the manufacturer, despite being such a small market.

[10] Law of Georgia on Drugs and Pharmaceutical activities, 2009 approves registration rules allowing two types of registration: national registration and recognition regime. The latter is applicable to pharmaceutical products already registered in the specific list of countries established by the Government decree.

Programmatic Sustainability

New Vaccine Introduction

Decisions on the introduction of new vaccines in Georgia are taken by the ICC, which is chaired by the Minister of Health. The ICC was established in 2000 and is represented by different sectors, including the Ministry of Health (MoH), which has a central role, Ministry of Finance (MoF), and partners. Final decision-making is preceded by deliberations between key decision-makers at the MoH, NCDC, and other experts. Prior to the establishment of the National Immunization Technical Advisory Group (NITAG) in 2014, policy recommendations on new vaccines were developed by the NCDC. Since 2014, the national vaccine decision-making function has been strengthened with the NITAG providing evidence-based technical advice to the MoH and ICC. Local disease burden data are given priority for policy decisions; however, where local data were not available for some vaccines (e.g., Hib), the best available data was used. For the Rotavirus and PCV vaccines, local sentinel surveillance data and WHO disease burden estimates were used. Since economic considerations were also important for the MoH decision-makers, particularly just prior to Rota and PCV introductions between 2010-2011, disease burden data were supported by economic evaluations and budgetary saving estimations. Political processes, such as the Parliamentary elections in 2012, and related structural changes delayed the Rota and PCV introductions by one year, but this delay did not impact the achievement of meeting co-financing obligations.

In 2015, Georgia prioritized the inclusion of the Inactivated Polio Vaccine (IPV) in the immunization calendar, in line with recommendations from the Polio Eradication and Endgame Strategic Plan 2013-2018.[11] The NITAG advised introduction of the Hexavalent vaccine, in place of a multi-dose IPV vaccine, for several reasons: the avoidance of additional injections, high level of trust towards the vaccine in the private sector, and avoidance of a global supply shortage (LNCT, 2019). The introduction was preceded by consultations with Gavi and WHO/Europe on the possible implications of this switch to the program, considering that Gavi could not provide support and a pooled procurement mechanism was not possible since Hexavalent vaccines were not listed in WHO's prequalified products (Gavi, 2014). However, under the leadership of the Minister of Heath and the NCDC Director, the position of key Georgian stakeholders was firm. The NCDC, with support from the WHO, researched the market and leveraged available information to analyze price acceptability. Access to global market price data was crucial in negotiations with the manufacturer, resulting in prices comparable to larger markets. Nevertheless, the budgetary implications were significant, doubling the NIP budget. 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.

The decision-making process to introduce the HPV vaccine lasted two years and was triggered by the burden of cervical cancer in the country. The affordability of the HPV vaccine through Gavi support was crucial in the final decision. Georgia used this last window of opportunity and applied for HPV support (CIF & LNCT, 2021).

The role of international partners, particularly WHO/Europe and UNICEF, was crucial in supporting the MoH/ICC, NITAG, and other national stakeholders with scientific proof of the efficacy and safety of the vaccines and sharing the experience of other countries.

In 2013, partners consulted Georgia about its potential interest in switching to PCV-13 presentation, but the decision was made to maintain PCV-10, at least until full graduation from Gavi support. In 2021, Georgia opted

[11] 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/

to switch to PCV-13. This decision was triggered by the COVID-19 pandemic, which made clear the need to prevent respiratory illnesses in the adult population. In 2020, PCV-13 vaccines were purchased and provided to the elderly population. In early 2021, the MoH renewed this discussion with the NCDC, and the vaccines were procured. The PCV-13 vaccine will be expanded to the child population beginning in October 2021.

Program Performance

In the early 2000s, immunization coverage rates started to improve after a dramatic drop in the 1990s. The coverage rates reached 70-90% for traditional vaccines, however these results were subject to scrutiny 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). By 2011, DTP-3 coverage improved, reaching over 90%. At this time, official country and WHO/UNICEF estimates became aligned, and the program was considered a strong performer by WHO/UNICEF (Gavi, 2013, 2015).

To respond to **data quality issues**, the immunization information system was reformed between 2003-2005 with support from USAID. A software tool known as "Geovac" was developed to track a range of indicators on a routine basis and improve the accuracy and reliability of data at subnational and national levels. Geovac, with further modifications, was used until the next generation system became fully operational (Government of Georgia, 2016).

Data quality issues, in connection with the health system and other external factors, emerged during the development of Geovac. There was a significant difference between the number of live births (based on the civil registry) and the number of surviving infants (registered by health facilities) that could not be explained by infant mortality. The main reasons for the data issues were poor linkages between maternity and primary care services due to a broken patronage system, an improper census of the child population, particularly in urban areas, and migration of the rural population (Government of Georgia, 2016). The situation became more complicated by impacts from health system reforms, including the free choice of family doctors regardless of geographic catchment areas and a primary care payment mechanism which created low interest among service providers to improve program performance (Gavi, 2015; Paatashvili, 2018).

The problem with the denominator was gradually solved by the **introduction of a new Immunization Management Electronic Module** (IMEM) in 2014 with support from UNICEF. IMEM was built around citizens national IDs, allowing individual vaccination profiles, tracking of vaccine administration (historical and ongoing), and registering adverse events. Most importantly, it made possible access to real-time information on reliable coverage rates. Data quality on surviving infants (denominator) remained a challenge until 2016 but was resolved following the integration of IMEM with the birth registry[12]. IMEM has gradually expanded and strengthened its capacities, including the addition of an SMS notification function and a software application. Most notably, IMEM was modified for COVID-19 vaccination registration and reporting in 2021.

Additional updates for IMEM were planned in 2020 as part of the Gavi post-transition grant, with a focus on capacity strengthening activities centered around data analysis and real-time decision-making at national and subnational levels. However, the COVID-19 pandemic required the mobilization of resources to modify the system to respond to COVID-19 vaccination needs, therefore funding for subnational capacity strengthening activities was reduced in the budget.

[12] The birth registry system was created in parallel to the government setting up 30 different E-health modules to improve governmental oversight of state subsidized health programs and to increase transparency of financing.

Further updates to IMEM, as well as maintenance and continuous capacity strengthening activities, are one of the areas that should be fully taken over by the Government in the future. IMEM, which was housed at the NCDC together with the EPI unit, is in a transition phase. Based on recent structural changes, all health information management systems will be moved to a newly established agency for digital health. It is not clear how shifting the ownership will impact the coordination between IMEM and the EPI unit.

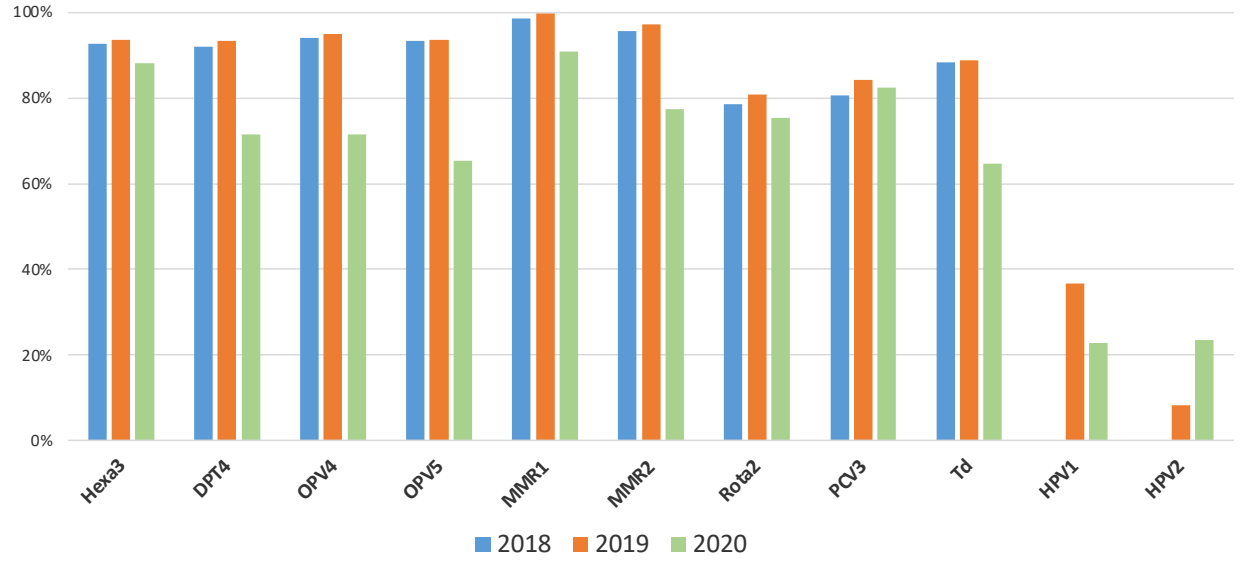
In order to increase vaccine uptake, Georgia introduced a **mandatory immunization** policy in early 2019. The legislation defined a list of mandatory vaccines required prior to enrollment in school and kindergarten. No penalties or sanctions were imposed for non-compliance. Policy discussions were taken up by the Parliamentary Health and Social Issues Committee, with active participation from the MoH, Ministry of Education, NCDC, partners (like Sabin institute), and other stakeholders. The process was supported by a review of other country experiences commissioned by the Parliamentary Committee. During intersectoral working group meetings, various policy options, such as restrictions to education and child-care facilities and other health care benefits, were discussed; however, no enforcement measures were introduced, as stakeholders believed they would be counterproductive. In addition to childhood immunization, mandatory vaccination was introduced for health care professionals and school and kindergarten teachers through subsequent regulatory changes.

One year after the introduction of the mandatory policy, no significant changes were observed in immunization coverage (2019). Although there was a 1% increase in MCV-2 coverage, similar improvements were observed in MCV-1 among 12-24 months old children – a target group not affected by the mandatory policy. Since the mandatory policy coincided with a measles outbreak and accelerated vaccination of target groups, causality is difficult to determine. It was not possible to identify any further impacts of this policy, as 2020 coverage rates were negatively affected by the COVID-19 pandemic.

Georgia's NIP remains a strong performing program in the EURO region with an historically well-maintained cold chain network and monitoring and surveillance system. While coverage against most antigens is above 90%, suboptimal coverage rates are noted both with traditional and new vaccines. In 2018, coverage of the 3rd dose of DTP containing (Hexavalent) vaccine was 93% (in 13 districts - below 90%), but uptake of Rotavirus and PCV-3 was lagging behind with 79% and 81% accordingly. In 2019, there was a slight increase in some coverage rates (with Hexa3 reaching 93% and MMR-1 reaching 100%).

The COVID-19 pandemic affected NIP performance in 2020. Although routine immunization services remained available and accessible from the start of the pandemic, mobility restrictions in the spring and fall of 2020 created an access barrier for the population. In addition, fear of contracting the disease in health facilities also negatively affected coverage rates. Parents were mainly concerned with completing the first series of vaccinations, and were less concerned with booster doses, resulting in deteriorated coverage rates. Since schooling was conducted online in large urban areas, the mandatory immunization mechanism was not enforced in 2020. The HPV vaccine, which was introduced in Georgia in 2019, was also not supported by communication campaigns due to the COVID pandemic. As a result, HPV coverage reached very low levels. Another adverse effect the COVID-19 pandemic had on the immunization program was the diversion of human resources at national and subnational levels to COVID-19 vaccination.

Graph 3 Georgia Immunization coverage, 2018-2020



The reasons behind unsatisfactory immunization coverage rates are complex and comprise demand and supply side factors. **On the demand side**, health care providers, who represent the most trusted source of information for the population, have not adequately addressed vaccine safety and quality concerns that are mainly influenced by misinformation on social media. **On the supply side**, there is inadequate knowledge of current EPI norms and standards. Moreover, many primary care providers lack communication skills and do not have a conducive working environment (in terms of time and incentives) for adequate communication. In addition, there is a knowledge gap among various specialty doctors regarding contraindications and vaccine safety (UNICEF Georgia, 2016). Finally, the country lacks effective, organized measures to monitor and address vaccine hesitancy movements. This became particularly prominent during the COVID-19 vaccination roll-out. **Weak regulatory arrangements between private care providers and the public health system** create additional challenges for monitoring and supervision. Current practice is based on personal connections between epidemiologists and service providers, which is not sustainable in the long-term. In addition, private service providers in primary care are less interested in promoting preventive services, particularly given limited time resources (Paatashvili, 2018).

The low motivation of primary health care workers has been identified as one of the barriers to strengthening immunization program performance. Performance incentives for service providers has been explored since 2012 (Gavi, 2015; Government of Georgia, 2011, 2016; Sabin Vaccine Institute, 2017), but PHC reforms over the last decade have not yet resulted in any changes to provider payment schemes.

Capacity Building

Each new vaccine introduction was preceded by extensive training on the respective disease burden, vaccine characteristics, eligibility and schedule, vaccine handling, immunization safety, AEFI, immunization management information systems (MIS), including IMEM administration, and caretaker communication. Training participants were assessed through pre- and post-tests. Prior to vaccination roll-out, refresher trainings were conducted with primary care and public health staff. In 2019-2020, major efforts were made to enhance communication skills for health professionals, through trainings, materials, and on-the-job assistance.

Supportive supervision activities were of the utmost importance for joint problem solving, creating confidence among service providers, and ultimately improving performance.

There is a risk to maintaining, developing, and passing knowledge to new generations of health professionals, as immunization principles are not adequately integrated into the formal medical education system at the pre-service, postgraduate, or professional development levels. In fact, continuing medical education was suspended between 2006-2018. In response to this gap, the Gavi transition plan (2019-2020) envisioned the development of immunization modules for medical education curricula targeting doctors and nurses; however due to the COVID-19 pandemic, this activity was postponed to 2021.[13]

Capacity building activities involved participation in knowledge sharing forums, regional workshops, and site visits, and were mainly targeted to national level EPI staff, financial and procurement focal persons, NITAG members, and key decision-makers. The role of Gavi and its partners (WHO, UNICEF) in this area was critical. Since Georgia has been a member country of the Learning Network for Countries in Transition (LNCT) since 2017, focal persons from the MoH, NCDC, and MoF benefited from the network's learning products and peer learning exchanges, particularly around vaccine hesitancy and vaccine procurement in the post-transition period. Peer learning and capacity development opportunities, access to technical resources, and engagement with partner organizations through LNCT enabled the application of new knowledge and approaches in routine work, as well as process streamlining.

As mentioned earlier, the NITAG plays an important role in recommending policy decisions to the MoH. NITAG members are not paid, and the EPI unit provides secretariat support. There are no resources available for support staff in the areas of evidence collection and synthesis. Although there is no expectation that the NITAG in Georgia will carry out systematic reviews and rapid evidence reviews, interpretation and contextualization are needed to support and advance the immunization agenda. Currently the NITAG is involved in the development of COVID-19 vaccination policy advice, which has also created additional challenges to its operations.

Conclusion

Below is a summary of factors that contributed to Georgia's successful transition from Gavi support, and potential risks to sustaining and expanding the health gains achieved to date. One of the limitations of this case study is that it was not analyzed in the context of a multi-transition landscape or related political economy factors.

Enabling Factors in Georgia's Successful Transition

- ***A conducive economic environment and political will to prioritize health:***
    - Georgia performed well in the pre-COVID era; GDP growth showed a favorable trend, creating the fiscal space for sustainable financing
    - The prioritization of health by the government (increasing public allocations to health) created increased budgetary space for investments in immunization
- ***Political commitment and collaborative partnership:***
    - Traditionally, the immunization program in Georgia has received high political commitment, ensuring sustainable funding, particularly for vaccine procurement
    - Strong ICC with effective intersectoral collaboration and a functional NITAG were instrumental in immunization related policy decisions
    - Involvement of multiple stakeholders, including the MoF, in discussions of transition issues helped build political commitment prior to transition

[13] As of September 2021, seven modules have been developed and the process in underway to incorporate them in the curricula.

- Dedication from immunization champions, including strong support from high level decision-makers at the MoH and the Parliament of Georgia, was key in driving the immunization agenda forward

- ***Partners' role in the effective transfer of responsibilities and capacities:***
  - Although the challenges of transition and the importance of early preparedness have recently received considerable attention among development partners, the approach to Gavi transition already included early assessment and clear communication with the Government on accomplishments and commitments, which were critical for the smooth transition of financial obligations
  - Repeated joint assessments with the involvement of national stakeholders helped create a spirit of joint action and increase Government ownership in the transition process
  - Securing access to affordable vaccine prices for specific vaccines post Gavi support is an important precondition for sustainable financing
  - Gavi assistance, with the involvement of partners, provided a broad range of technical capacities including planning, forecasting, market intelligence, and procurement skills. In order to maintain this gain, it is important to sustain these capacities through refresher activities, advocacy, and exposure to learning/experience sharing platforms
  - Partners played an important role in providing evidence, skills, and tools for advocacy activities on increased allocations and negotiations with the MoF for the introduction of new vaccines
- ***Programmatic sustainability:***
  - Sufficiently strong health system to ensure equitable coverage with immunization services
  - Strong institutional capacities in procurement and public financial management
  - Introduction of Immunization Electronic Management System, which removed data discrepancy between the civil registry and health information systems
  - Gavi investments in immunization service providers and public health personnel capacity building played a critical role in improving program performance

Potential Risks to Georgia's Financial and Programmatic Sustainability

- ***Sustaining and improving immunization coverage rates:***
  - The existing immunization finance scheme, which is integrated in per-capita payments for PHC, does not create incentives for performance improvement; without changes in payment methods, there is limited potential for coverage improvement, particularly in urban settings
  - Weak interpersonal communication skills of health care providers contribute to caregivers' mistrust and misconceptions on immunization
  - Inadequate response towards vaccine hesitancy, particularly towards newly introduced vaccines
  - Existing regulatory framework does not create a conducive environment for monitoring and supportive supervision of private providers, who are key players in service delivery in Georgia
  - Disruptions caused by the COVID-19 pandemic require additional programmatic efforts to catch-up missed immunizations
- ***Insufficient Government financing of other components of NIP:***
  - Communication, monitoring, supervision, and information system support is still largely funded from external sources; there is risk that Government financing may not cover the full need when external support ends

    - There is a risk of disincentivizing NIP personnel following transition of certain components to Government funding due to disproportionally small government rates
    - Advancing the immunization agenda requires NITAG work to be supported with adequate resources
- ***Vaccine procurement, post-market surveillance:***
    - Currently Georgia benefits from Gavi negotiated freeze prices for vaccines; once this condition expires, Georgia will procure vaccines at market prices, which will require a significant increase in government allocations. Such forecasting has not yet been carried out
    - Although there is experience of successful price negotiation with manufacturers, Georgia faces a risk of paying high vaccine prices due to its small market size
    - Vaccine safety surveillance functions remains weak at the NRA
- ***Sustained Human Resource capacities:***
    - The lack of institutionalization of good immunization management practices in pre-service, post-graduation, and continuous education systems creates a risk to sustained knowledge among healthcare workers

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