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Understanding Vaccine Policy Decision-Making in the Country of Georgia

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Abstract

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By Sarah K. Legare

The country of Georgia is in its final year of receiving aid from Gavi, the Vaccine Alliance, which has disbursed over five million dollars to the Georgian government to support its National Immunization Program since 2002. In addition to losing financial support, Georgia is expected to become more independent in its vaccine policy decision-making process in the future. This led to the creation of a National Immunization Technical Advisory Group in 2014 to advise policymakers on evidence-based vaccine policy decisions. This research documented the experiences of actors in Georgia's immunization system as they pertain to national vaccine decision-making during graduation from Gavi, as a formative step in understanding what is needed to ensure the country's successful graduation from Gavi's major financial and technical support. In June and July 2015, we conducted twenty-one semi-structured qualitative interviews in five regions and one autonomous republic in Georgia. Immunization stakeholders including national-level staff, Public Health Center staff, and vaccine providers responded to questions on policy-making processes, use of data, program administration and implementation. At the national level, respondents expressed that while immunization has been prioritized by the central government, there is a lack of national-level decision-making autonomy in that recommendations and research are initiated by external organizations. Within the National Immunization Program, a hierarchical approach to administration provides for a structured and functional system with well-defined roles and responsibilities. Understanding of the realities faced by regional and local staff in implementing the program differed between national-level staff and other respondents. Georgia's immunization system has been strengthened since the country gained independence in 1991 and still has opportunities to improve through increased initiative to produce and use data in policy making and giving more attention to locally relevant issues impacting program performance. Beginning in 2016, Gavi is conducting assessments of country readiness for graduation; quantitative surveys for regional health system staff and vaccination providers informed by the issues raised in this research would improve its understanding of National Immunization Program strengths and challenges.

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Chapter 1: Introduction

Introduction & Rationale

The country of Georgia, like most countries in the world, values immunizations as a key public health strategy for the prevention of disease [2]. When it was a part of the Soviet Union from 1921 until 1991, Georgia maintained its immunization program through supply and administration logistics based in Moscow. Upon gaining independence in 1991, Georgia was reliant on emergency aid for vaccines before re-establishing its National Immunization Program (NIP) in 1995 during comprehensive health reforms [3, 4]. Since 2002 Gavi, the Vaccine Alliance (Gavi) has provided key technical and financial support to the Georgian NIP. Due to economic growth, Georgia is now classified as a middle income country and, as of the end of 2015, no longer eligible to receive Gavi support [5]. The purpose of this thesis is to assess the environment for vaccine policy development and implementation in Georgia in its shifting economic and health environment.

Problem Statement

Globally, vaccination has proven to be one of the most cost-effective public health interventions [6, 7]. It has been used since the 7th century and has allowed us to control 14 vaccine-preventable diseases, including eradicating smallpox in 1980 and near-eradication of polio as of 2016 [8, 9]. Georgia has been polio-free since 2002 [10, 11]. Georgia has benefited from external support for its vaccination program throughout its time as an independent country from the Expanded Program on Immunization (EPI), the United Nations Children's Fund (UNICEF)/ United States Agency for International Development (USAID) Vaccine Independence Initiative (VII) since

1992, and Gavi since 2002 [3]. Its transition to the final self-funded phase of Gavi graduation in 2016 represents a major shift toward independent financing and administration of its vaccination program. While there will be technical support and resources available, such as access to vaccine tenders and in-country representatives from the World Health Organization (WHO) and UNICEF, programming and policy decisions will ultimately be the responsibility of country-level policymakers. To be successful, those decisions must be well-informed with global and locally relevant evidence. A properly functioning National Immunization Technical Advisory Group (NITAG), good communication and data reporting, along with political will are necessary for the transition to policy decision-making independence. Quantitative indicators gathered by state and international bodies are important to assess Georgia's readiness for this shift, but do not capture the nuances of the situation.

This thesis study examined the current climate of vaccine decision-making in Georgia through qualitative interviews with national-level and regional Public Health staff as well as healthcare providers to better understand current and upcoming challenges to graduation from Gavi support. Through analysis of this data, we can reinforce strengths and target strategies to address challenges in Georgia for a stronger and more self-sufficient immunization program as well as identify key weaknesses to address.

Purpose

The purpose of this research is to understand and describe the process of vaccine policy decision-making in the country of Georgia.

Research Question and Specific Aims

The key research question driving the study is:

What is the current process of vaccine policy decision-making in the country of Georgia?

This research has three specific aims: 1) to document the perspectives of vaccine policymakers, providers, and stakeholders in urban and rural areas; 2) to describe the current process of vaccine policymaking; 3) to facilitate understanding of strengths and challenges in Georgia's vaccine policymaking system.

Significance

There has been a global shift in the distribution of the world's poor and disease burden from low-income countries (LICs) to middle-income countries (MICs) since the 1990s, which has been accompanied by poor vaccine system performance in MICs [12-14]. The WHO-convened MIC Task Force analyzed the performance of all 103 MICs and used the framework of the WHO Global Vaccine Action Plan (GVAP); they found that 90% of global polio cases in 2014 and the majority of measles cases in 2013 came from MICs. Only 19 MICs have reached the GVAP target of reducing mortality of children under five by two thirds since 1990 and 38 still have DTP3 coverage below 90%, over half of which do not meet coverage equity goals. The overall trend in domestic healthcare spending for MICs also fell short of goals. At the end of 2013, 20% of MICs had not introduced any of the six new and underused vaccines identified as priorities by WHO (pneumococcal conjugate, human papillomavirus, injectable polio, Japanese encephalitis, and yellow fever vaccines). At the same time, only about 40% of MICs had NITAGs that met all WHO criteria. While the highest burden of vaccine-preventable disease (88% of annual cases), is

in Gavi-supported MICs, there are 63 MICs that are not a part of an international strategy nor do they have major donor support [12]. By 2020, the number of graduating Gavi countries is expected to reach 27, including large countries such as Nigeria, Indonesia, Vietnam, and the Democratic Republic of the Congo. These 27 countries have introduced between 1 and 8 vaccines each with Gavi support and face increases in per capita vaccine costs of between \$0.02 and \$1.03 during the accelerated phase of Gavi graduation. Georgia is between the extremes, having introduced 3 vaccines and increased its cost of vaccines \$0.13 per capita through accelerated graduation [15, 16]. A thorough understanding of the challenges that face these graduating countries is a key step in addressing them. In Georgia, quantitative indicators have been used to measure progress in the vaccine system via the WHO Joint Reporting Form (JRF) (Figure 1), but a qualitative assessment has not been undertaken to complement the indicator results [17].

A country-specific examination is important because individual situations and nuances within the vaccine system cannot be generalized from one country to another. Perceptions that are not captured in data reporting and differences in understanding that may go unnoticed without careful examination will be captured with this research. Vaccine program staff in Georgia interested in better

Figure 1: Summary of Indicators on the WHO Joint Reporting Form

WHO Joint Reporting Form Indicators

- Cases of suspect, tested, positive, and confirmed disease: diphtheria, measles, neonatal tetanus, total tetanus, pertussis, yellow fever, Japanese encephalitis, mumps, rubella, congenital rubella syndrome
- Current vaccine schedule, including vaccine source and price, quantity procured, and injection supplies
- Vaccination record system
- Routine and supplemental immunization coverage, school-based immunization, and reporting accuracy
- Recent and planned vaccination coverage surveys
- Multi-year plan for immunization presence and content, advisory mechanism for the national program
- Stock-outs, vaccine safety, program financing, influenza cases, vaccine hesitancy

understanding their challenges through the process of graduation from Gavi and developing strategies to meet them will benefit from these findings. Other MICs may also benefit through conducting their own research using some of the same methods.

Definition of Terms

AEFI: Adverse event following immunization

AMP: Agence de Médecine Preventive

BCG: bacille Calmette-Guerin vaccine against tuberculosis

BiH: Bosnia and Herzegovina

BMGF: Bill and Melinda Gates Foundation

CDC: United States Centers for Disease Control and Prevention

cMYP: comprehensive Multi-Year Plan for Immunization

DTP: Diphtheria Tetanus Pertussis vaccine

DTaP: Diphtheria Tetanus acellular Pertussis vaccine

DTP3: Third dose of Diphtheria Tetanus Pertussis vaccine

DTwP: Diphtheria Tetanus whole-cell Pertussis vaccine

EIDSS: Electronic Integrated Disease Surveillance System

EPI: Expanded Program on Immunization

ETAGE: European Technical Advisory Group of Experts on Immunization

EU: European Union

Gavi: Gavi, the Vaccine Alliance

GNI: Gross National Income

GVAP: Global Vaccine Action Plan

HepB: Hepatitis B vaccine

Hib: Haemophilus Influenza B vaccine

HPV: Human Papillomavirus vaccine

HSPIC: Georgia Health and Social Program Implementation Center

HSS: Health Systems Strengthening Support

ICC: Inter-agency Coordinating Committee

IPV: Inactivated Polio Vaccine

ISPH/TSMU: International School of Public Health/ Tbilisi State Medical University

ISS: Immunization Services Support

JRF: Joint Reporting Form

LIC: Low Income Country

LMIC: Lower Middle Income Country

MIC: Middle Income Country

MMR: Measles Mumps Rubella vaccine

MoLHSA: Ministry of Labor Health and Social Affairs

NCDC: National Center for Disease Control and Public Health

NIP: National Immunization Program

NITAG: National Immunization Technical Advisory Group

NRA: National Regulatory Authority

NVS: New and Underused Vaccine Support

OPV: Oral Polio Vaccine

PBF: Performance-Based Funding

PHC: Public Health Center

RIM: Regional Immunization Manager

Sabin: Sabin Vaccine Institute

SAGE: WHO Strategic Advisory Group of Experts on Immunization

SIVAC: Supporting Independent Immunization and Vaccine Advisory Committees

SSA: Social Service Agency

TT: Tetanus Toxoid

UMIC: Upper Middle Income Country

UN: United Nations

UNICEF: United Nations Children's Fund

USAID: United States Agency for International Development

V3P: Vaccine Product, Price, and Procurement web platform from WHO

Vaccine coverage: Estimated percent of people who have received a certain vaccine

VII: Vaccine Independence Initiative

VPD: Vaccine Preventable Disease

VRF: Vishnevskaya-Rostropovich Foundation

WHA: World Health Assembly

WHO: World Health Organization

Chapter 2: Literature Review

General description of Gavi, the Vaccine Alliance

Gavi, the Vaccine Alliance began in 2000 with goals to increase the availability of “new and underused vaccines” and to strengthen delivery systems in response to the shift in donations away from immunization-related priorities that happened in the 1990s [18]. At Gavi’s inception, the Vaccine Fund was started with a donation of \$750 million, to be distributed over five years, from the Bill and Melinda Gates Foundation (BMGF). Donations grew to \$1.1 billion by the end of 2001 with additional contributions from governments and foundations [19]. At the end of 2014, Gavi had \$8.9 billion in assets and has now committed over \$10 billion to eligible countries through 2020 [20].

Stakeholders from the public and private sectors, including governments, United Nations (UN) agencies, industry, and civil society, collaborate with Gavi. Through Gavi’s work, 500 million children have been vaccinated and an estimated seven million deaths have been prevented through over 300 vaccine introductions and vaccination campaigns in seventy-one countries [15]. Gavi renews its program and financial strategies every five years to update goals, targets, and priorities, and to determine which vaccines will be supported; the current strategy supports 11 vaccines. Each country’s performance is monitored based on twenty core indicators, outlined in Figure 1, as well as customized country-specific indicators, the majority of which are common to the WHO/UNICEF JRF. Countries send these performance indicators to WHO annually [18, 21].

To be eligible for support from Gavi, the most recent three-year average of a country’s Gross National Income (GNI), as reported by the World Bank [22], must be no greater than \$1,580.

Countries can apply for any or all of the three types of support available from Gavi: new and underused vaccine support (NVS), immunization services support (ISS), or health system strengthening support (HSS). HSS support is structured as a performance-based funding (PBF) approach [18]. Gavi also stipulates conditions for an application for each type of support. To apply for support to introduce a new vaccine, coverage of the third dose of diphtheria-tetanus-pertussis (DTP3) or a DTP-containing vaccine in the country must be at least 90%, with exceptions for the introduction WHO priority vaccines, and per capita GNI averaged over the last three years must not be above the \$1,580 Gavi eligibility threshold [22].

In addition to approval of support applications, Gavi's partnership with a country is contingent on the development of a comprehensive multiyear plan (cMYP) for immunization and the existence of an interagency coordination committee (ICC). The cMYP is designed to integrate Gavi support with a country's health system and develop priorities and includes plans for country cofinancing of vaccines and related program costs. ICCs are focused on coordination, support, and planning for the use of Gavi funds and NIP implementation; an ICC is a group of representatives from in-country government, civil society, as well as the WHO and UNICEF. Georgia established an ICC in 2000 at the beginning of its work with Gavi, comprising 11 representatives from the Ministry of Labour Health and Social Affairs of Georgia (MoLHSA), National Centers for Disease Control and Public Health (NCDC), WHO, UNICEF, and medical practice [20]. In partnership with Gavi, country officials are encouraged to propose their own solutions to improving vaccine delivery as opposed to being guided through solutions by Gavi staff and partners [18]. Once a country moves to the classification of Lower Middle Income

Country (LMIC) from Lower Income Country (LIC) by the World Bank, it begins a phased process of graduation from Gavi support [15].

Graduation from Gavi

When the World Bank no longer considers a Gavi-supported country as low income, the country enters a preparatory phase of graduation and its contribution toward vaccines begins an annual 15 percent increase. Gavi requires a minimum contribution of \$0.20 per dose of vaccine; this is the country's starting point for the graduation process. This annual increase continues until the country's per capita GNI meets or exceeds Gavi's eligibility threshold. Once a country's GNI reaches this threshold, it enters an accelerated graduation phase and has five years to begin fully financing vaccines. The annual increase in a country's required contribution during this accelerated phase depends on how long the country stayed in the previous preparatory phase and total immunization program costs. For an additional five years after graduation, countries may request to have their vaccine needs added to UNICEF vaccine purchasing agreements to allow access to lower vaccine prices. Gavi first introduced a graduation policy in 2009; the current graduation policy is new for Gavi as of 2015 and reflects changes, especially an averaging of GNI per capita over three years as opposed to using the most recent year's GNI, intended to help countries transitioning from Gavi support [15].

In 2015, Gavi updated its policies to address identified threats to vaccine program sustainability. These changes include averaging GNI over three years to balance rapid or inconsistent growth in any given year and two extra years of support if GNI has increased at least 20% in any one of the five years before the Gavi eligibility threshold is met. This protection is only triggered when

vaccine coverage is low, below 90% for the third dose of Diphtheria Pertussis Tetanus (DPT3) or DPT-containing vaccine. If the GNI increase is 30% or more in the same time period, the same two years of additional support are provided regardless of vaccine coverage. There are additional threats to sustainability that have not been accounted for in these policy changes: the size of the birth cohort and fertility rate, the percentage of the country's vaccine contribution when the eligibility threshold is met, and the waning of political will to support vaccine programs after Gavi support ends [15]. No countries have yet completed the Gavi graduation process as it exists now, so the impact of these threats is unknown. However, four countries, Albania, China, Bosnia and Herzegovina, and Turkmenistan lost eligibility for support before the implementation of the current graduation process; with the exception of China, all of these countries are in the WHO European region [18, 22].

In 2016, there are 54 countries eligible for support from Gavi. Since 2000, 74 countries have been Gavi-eligible and 71 of them have applied for and received support [15, 18]. Four countries ended their Gavi support due to an increase in GNI above the threshold when eligibility criteria were readjusted in 2007, four are set to graduate in 2016, and two new countries have become eligible for support since 2000. Eighteen countries, including Georgia, with a combined annual birth cohort of over six million, are expected to graduate from Gavi support by 2018 [23].

In 2011, the WHO developed a web platform, Vaccine Product, Price, and Procurement (V3P) and in June 2014 convened a Middle-Income Country (MIC) Task Force, comprising major partner organizations including Gavi to help MICs, including LMICs and Upper-Middle Income Countries (UMICs) maintain successful vaccine programs [12, 24]. V3P is based on the

identified challenge to MICs, especially those graduating from Gavi support, in accessing and understanding which vaccines are available on the market, how much they cost, and how to purchase them [25]. Georgia was one of the countries chosen for a pilot test of V3P to negotiate vaccine prices [12, 25, 26]. Georgia's experience helped shape the V3P platform, which is now live online and available for countries to use. With the benefit of five years of UNICEF vaccine prices after graduating from Gavi, Georgia will not immediately need to use V3P to negotiate its own vaccine prices. The MIC Task Force was formed after multiple requests and recommendations from the WHO's Strategic Advisory Group of Experts on immunization (SAGE) stemming from concern that most donor organizations were working in lower income countries and data showing that most vaccine-preventable deaths are in MICs, 63% of the global total [12, 27]. The MIC Task Force has a budget of \$20 million per year to review immunization system performance of MICs, better understand their needs and how they are being met, develop plans and frameworks to implement, monitor, and evaluate vaccine systems, and share information across immunization stakeholders working in MICs. While the MIC Task Force is currently focused on never-eligible Gavi countries, it is intended to support countries that have graduated from Gavi support in the future [12].

National Immunization Technical Advisory Groups

WHO has made several recommendations for all countries to establish National Immunization Technical Advisory Groups (NITAGs), and the call was strengthened at the 2012 World Health Assembly (WHA) with its GVAP as a part of the Decade of Vaccines, to take place from 2011 until 2020 [28]. The GVAP set forth a goal that every country should have a fully functional NITAG by 2020 [29]. NITAGs are intended to provide technical guidance to policymakers

through policy analysis and recommendations as well as advice on vaccination and monitoring strategy and data collection. They may also provide guidance to vaccine stakeholders not involved in policy formation, such as those responsible for program implementation including private institutions or government agencies [28, 30].

WHO has six basic criteria for NITAGs: they must have an administrative basis, establish formal terms of reference, implement a policy concerning conflicts of interest, meet at least once a year, meeting agendas and background information should be sent to members at least one week before meetings, and members should represent at least five areas of expertise [31]. WHO recommends that NITAGs include experts from areas including clinical medicine, epidemiology, infectious disease, microbiology, public health, immunology, vaccinology, immunization programming, and health systems and delivery [30]. A NITAG is officially formed via decree by the Ministry of Health. As of 2016, 124 countries have reported that they have a NITAG, 82 of which are fully functional, meeting all six WHO criteria. Since 2011, 17 new NITAGs have been established. Georgia formed a NITAG in late 2014, and the Georgian NITAG meets 3 of the 6 criteria, having not yet implemented a conflict of interest policy nor had the first NITAG meeting; their third unmet criterion is circulation of an agenda and background information to NITAG members one week prior to the meeting [31].

For countries like Georgia with new NITAGs or those in need of strengthening, the Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) initiative was formed in 2008. The SIVAC initiative is run by Agence de Médecine Préventive (AMP) and works in collaboration with WHO with a goal to increase NITAG functionality and decision-making

capacity through technical and financial support as well as training for NITAG members. Georgia has received support from AMP for its cost-effectiveness analysis of pneumococcal vaccine implementation, but has not received SIVAC support for its NITAG [31, 32].

Background on Georgia

Georgia has been an independent country since the fall of the Soviet Union in 1991. The country's government operated in an environment of overt corruption and was relatively ineffective until 2004 when the Rose Revolution, and subsequent elections, brought in a new government. Since then, there has been significant development, but market forces and land disputes with Russia have acted as barriers to economic and social progress. Its area is 43,300 square miles with 190 miles of coastline and shared borders with Armenia, Azerbaijan, Russia, and Turkey. The population in 2014 was 4.94 million with 1.1 million in the capital city of Tbilisi. The population is primarily Georgian (83.8%), Orthodox Christian (83.9%) and speak Georgian (71%) [33].

Table 1 shows health and development indicators for Georgia alongside the World Bank-defined region of Europe and Central Asia, other LMICs, and the world. Particularly striking is the difference between Georgia and other countries in physicians and nurses per capita, with the highest and lowest numbers in all categories, respectively. As shown in Table 2 and Figure 2, there are 9 regions in Georgia as well as two autonomous republics and a partially recognized state; the autonomous republic of Abkhazia and the partially recognized state of South Ossetia are under Russian control. Gas and oil is almost all imported, but hydropower is an increasing contributor to meeting energy needs. The economy is largely based on agricultural and mining

activity in addition to beverage and machinery production, and most trade is with neighboring countries [33].

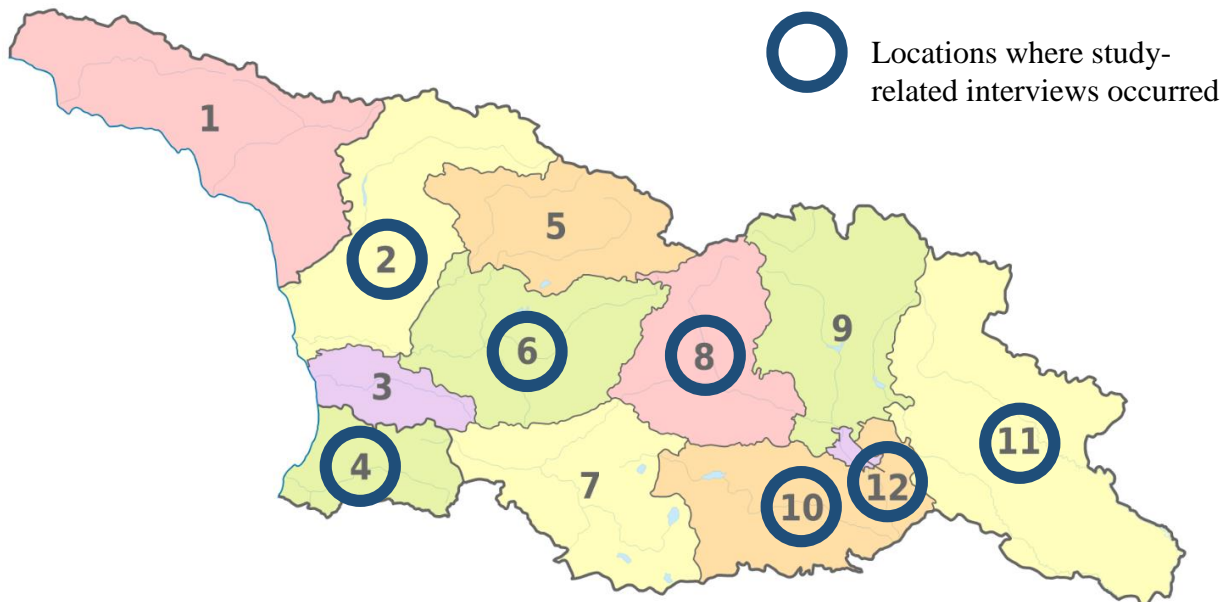
Table 1: Health and Economic Statistics of Georgia, the Europe and Central Asia Region, Lower-Middle Income Countries, and the World [34]

Indicator	Year	Georgia	Europe & Central Asia		LMICs	World
			Developing	All		
Gross National Income (per capita, USD)	2014	3,720	6,892	25,416	2,012	10,787
Gross National Product (per capita; PPP; constant 2011 international \$)	2014	7,233	13,501	27,651	5,752	14,287
Maternal Mortality Ratio (per 100,000 live births)	2015	36	25	16	253	216
Infant mortality rate (per 1,000 live births)	2015	10.6	17.8	9.7	40	31.7
Birth rate (per 1,000 people)	2013	13.3	16.1	12.4	23.4	19.4
Life expectancy for men (years)	2013	71	68.8	73.5	65.3	69.2
Life expectancy for women (years)	2013	78	76.4	80.3	68.8	73.3
Physicians (per 1,000 population)	2011	4.2	2.6	3.4	0.8	1.5
Nurses and midwives (per 1,000 population)	2011	0.2	5.9	7.5	1.7	3.2
Public health expenditure (% of GDP)	2013	2	3.8	7.1	1.6	6
Private health expenditure (% of GDP)	2013	7.4	2	2.4	2.7	4
Government education expenditure (% of GDP)	2012	2	no data			
Literacy Rate (%)	2010	99.7 (2013)	98.2	99	73.3	85.2
Poverty gap at \$1.90 a day (2011 PPP; %)	2012	5	0.6	no data	4.7	3.7

Table 2: Administrative Divisions of Georgia

Administrative Divisions (Shading indicates inclusion in this study)	Capitol City
1. Abkhazia	Sukhumi
2. Samegrelo-Zemo Svaneti	Zugdidi
3. Guria	Ozurgeti
4. Adjara	Batumi
5. Racha-Lechumi and Kvemo Svaneti	Ambrolauri
6. Imereti	Kutaisi
7. Samtskhe-Javakheti	Akhaltsikhe
8. Shida Kartli	Gori
9. Mtskheta-Mtianeti	Mtskheta
10. Kvemo Kartli	Rustavi
11. Kakheti	Telavi
12. Tbilisi	Tbilisi

Figure 2: Map of Georgia with Administrative Divisions [1]



Vaccine Purchase and Import

Vaccines are purchased with a combination of public and donor funds in Georgia. The Social Service Agency (SSA), part of the Georgia Health and Social Program Implementation Center (HSPIC) under the jurisdiction of MoLHSA, has been procuring the country's vaccines using state tenders since 2010 [2]. Prior to 2010, the Supply Division of UNICEF was responsible for procuring all vaccines to be used in public programs, whether they were purchased with country or donor funds [35]. Once vaccines are purchased, neither vaccination providers nor patients pay for them under the country's social insurance program [2].

The MoLHSA's Drug Agency functions as a National Regulatory Authority (NRA) and is responsible for vaccine import and documentation. Georgia does not manufacture any vaccines and imports only those that have been prequalified by the WHO. For these and any other vaccines previously registered in the European Union (EU) or United States, no further registration is required by Georgia [2]. Upon arrival in Georgia, vaccines are stored in a cold room at the Tbilisi airport and cleared by the Drug Agency and, if documentation has already been received, they are approved for transfer in three to four days to NCDC cold storage facilities in Tbilisi. National cold storage facilities in Georgia have a total capacity of 35,937 liters for +2 to +8 degrees Celsius, which is used to store all vaccines except oral polio until they are sent out to regional and district Public Health Centers (PHCs). Regional and district level storage facilities and an additional 1,463 liters of -20-degree storage are also used as needed. In total, there is enough storage space for all vaccines for the country necessary for a full year.

PHC staff submit quarterly vaccine orders with the NCDC, which works with the SSA to purchase them then deliver them to each PHC. Once PHCs receive vaccines, they are responsible for distributing vaccines to providers in their area and tracking vaccine temperature. Every immunization provider has refrigerators or cold boxes with freeze-watch indicators to transport and store vaccines after they collect them from PHCs. Anyone in custody of stored vaccines is required to keep a temperature log of cold storage temperatures with twice daily measurements [2].

Public funds are being used to finance an increasing share of the NIP, which rose from 58% to 77% between 2006 and 2014. This represents a cost increase from \$13 to \$61 per surviving infant [35]. The remainder of NIP costs are made up with donations from Gavi, UNICEF, the WHO, United States Centers for Disease Control and Prevention (CDC), and the Vishnevskaya-Rostropovich Foundation (VRF) [20]. Of these, the primary contributor is Gavi, which has been working in Georgia since 2002 and disbursed a total of \$5,107,873 over that time, shown by funding source from 2012 until 2018 in Table 3 and by type of Gavi support from 2000 through 2016 in Table 5 in the appendix.

Table 3: Annual vaccine support from Georgia and Gavi in USD, 2012-2018 (projected) [23]

Year	2012	2013	2014	2015	2016	2017	2018
Source							
Country-provided	239,941	299,000	571,500	824,000	1,229,000	1,448,500	1,710,000
Gavi-provided	650,500	545,500	904,500	974,500	369,500	250,000	0
TOTAL	890,441	844,500	1,476,000	1,798,500	1,598,500	1,698,500	1,710,000

Gavi's Role in Georgia and the Region

In WHO's European region, which includes 53 countries, Georgia is one of eight that have received support from Gavi. Others include neighboring Armenia and Azerbaijan as well as Kyrgyzstan, the Republic of Moldova, Tajikistan, Ukraine, and Uzbekistan, all former republics of the USSR [36]. Of these, Kyrgyzstan is in the preparatory transition phase, having surpassed the World Bank's \$1,045 GNI per capita threshold for LICs. Georgia, Armenia, Azerbaijan, Moldova, and Uzbekistan are in the accelerated transition phase in 2016, with an increase in GNI per capita above Gavi's \$1,580 threshold in the last five years; Ukraine is fully self-financed as of 2016, but still eligible for reduced vaccine pricing [15, 18]. In 2016, Tajikistan and Kyrgyzstan are the only countries in the region eligible to apply for Gavi support of new vaccines. When Gavi began in 2000, Albania, Bosnia and Herzegovina, and Turkmenistan were also eligible for support, but lost eligibility in 2007 when their per capita GNIs exceeded the then-\$1,000 Gavi threshold, which has since been increased to \$1,580 [22]. All of these countries have stayed above the eligibility threshold for Gavi, as outlined in Table 5 in the appendix.

In 2014, Gavi commissioned an external evaluation of its support from 2002 to 2011 to Bosnia and Herzegovina (BiH), which was conducted by the Curatio International Foundation. The evaluation was based on the broad areas of Gavi support for planning, implementation, and outcomes against criteria for relevance, efficiency, effectiveness, impact, and sustainability. Key recommendations of the evaluation were to 1) focus more on systemic coordination and decision-making than committees for administration of the vaccination program; 2) strengthen monitoring and evaluation both during the period of support from Gavi and after it has ended; 3) improve long-term financing plans so that they are predictable and sustainable; 4) support

countries in their vaccine procurement choices; and 5) work with partners to strengthen health systems. Gavi's current policies reflect their response to these recommendations. [37, 38].

The 2016—2020 Gavi strategy includes an emphasis on forming and strengthening ICCs and NITAGs to address the issue of decision-making and coordination. In 2011, Gavi began to require countries to report annually on six immunization outcome indicators to strengthen monitoring and evaluation. Following the conclusion of Gavi support, countries are encouraged to continue basic annual reviews and comprehensive assessments every five years to track the status of the immunization program. During the process of phasing out Gavi support, countries are now required to develop financial sustainability plans and may apply for graduation grants, which Georgia has done [5, 22]. NITAG members are expected to use this and other data to inform the country's choices of vaccines. As of 2016, Gavi has a policy to conduct comprehensive reviews of country readiness for graduation. Financial sustainability and graduation action planning helps further during the transition to independence. To work effectively with partners for health system strengthening, Gavi has adopted a more country-specific approach to fit the partners and context [37, 38].

Similar evaluations were not conducted in Albania or Turkmenistan, but both countries have been considered as successes following the conclusion of Gavi support. Albania introduced the pneumococcal vaccine on its own in 2011 and maintains a NITAG to inform vaccine decision-making [39]. In Turkmenistan, the government has increased its budget for the national vaccination program, which remains a political priority, through 2015[40]. However, Turkmenistan does not have a NITAG as of 2016 [31].

Significance of National Immunization Technical Advisory Groups to Graduation from Gavi

WHO's recommendation that every country in the world have a NITAG by 2020, evaluations of Gavi aid in countries that no longer receive it, such as BiH, and increasing awareness of the vaccine preventable disease (VPD) burden in middle-income countries have made evidence-based vaccine policy decision-making increasingly important. The evidence necessary to make policy decisions related to vaccines is complex and often context-specific. With an ICC, the agendas of stakeholders are represented because of the nature of the appointments and committee structure. The ICC is not designed as a decision-making body nor one that makes its own recommendations, rather it is meant to coordinate the efforts of Gavi and other bodies. Without the aid of Gavi, there is no coordinated mechanism to integrate knowledge of different subject matter areas relevant to immunization policies in a country. In Georgia, where the NCDC is the agency that implements the NIP, and the ICC represents stakeholders, no group of independent experts exists without the presence of a NITAG. For every country, but especially those transitioning away from a dependence on the prescribed and carefully administered technical and financial support, accessing, evaluating, and translating relevant data is an important and necessary part of policymaking.

Current National Immunization Program in Georgia

The NIP is implemented by the NCDC, under the oversight of the MoLHSA [2]. In Georgia, there are two parallel systems through which the population can access vaccines. The public system is implemented by the NCDC under the jurisdiction of the MoLHSA. Through this

system, all citizens can access the full course of WHO-recommended vaccines, with the exception of HPV, free of charge. Vaccines may also be purchased in the private sector if people choose not to access them through the public system. Vaccine providers are supplied with public vaccines; if a person wishes to receive privately available vaccines, the private providers may purchase them and administer them to a patient. There is no requirement for vaccination in the country, such as mandatory immunization for school entry [2].

Sustainability of Georgia's National Immunization Program

In 2014, NIP partners including WHO, WHO Europe, Gavi, UNICEF, and the Sabin Vaccine Institute conducted an NIP program assessment regarding Georgia's upcoming 2016 graduation from Gavi and sent an action plan to NCDC describing the activities needed following graduation. The NCDC received the action plan in June 2015, approximately one week before our interview with their representative, so we were not able to assess the impact of this action as NCDC had not yet begun to implement any of the listed activities. The program assessment found that the government's prioritization of vaccines and integrated electronic health management system, along with free vaccination, high vaccine coverage, functionality of the ICC, procurement of vaccines through UNICEF's services, and an evidence-based budgeting process were strengths. The projected steep increase in government cofinancing for the NIP through 2017, slow economic growth, operational costs, and the lack of a performance-based payment system for providers were identified as challenges.

Chapter 3: Methods

This study was designed as a case study using qualitative methods to conduct formative research to understand the perceptions and experiences of people working with the vaccine program in Georgia. Data consist of 21 semi-structured in-depth interviews with 26 people, including National-level staff members representing NCDC, CDC, WHO, ICC, and Parliament; Public Health Center staff including Regional Immunization Managers (RIMs), PHC Directors, and a cold chain nurse; and healthcare providers represented by practicing physicians and clinic directors. Three interviews were conducted with two respondents at once because of logistical constraints. In all cases, the respondents were in the same category, public health center staff for two interviews and providers for one. In the case of the providers, one of the respondents was the clinic director responsible for supervising the other respondent, a practicing physician. Sample size in each respondent category was based on a minimum target of six, based on the findings of Guest in 2006, then increased over a range of geographic and professional responsibilities until saturation was reached [41]. The minimum sample size and saturation were reached for all but National-level staff members of whom there are few in the country and who each have unique perspectives and information because of the nature of their appointments with different organizations.

Table 4: Interview Sites, Respondents, and their Positions

Site	National Staff	Public Health Center Staff			Providers		Total Respondents	Interviews
		Immuni- zation Manager	Public Health Center Director	Cold Chain Nurse	Practicing Physician	Clinic Director		
Batumi		1	1			2	4	3
Gori		1	2	1			4	4
Kutaisi			1		3	1	5	3
Mestia		1	1				2	1
Rural Adjara					2		2	1
Rustavi		1					1	1
Tbilisi	5						5	5
Telavi		1	2				3	3
TOTAL	5	5	7	1	5	3	26 Respondents	
		13			8			21 Interviews
								8 Sites

Data were collected in the national as well as regional capitals and nearby rural towns. Sites outside of Tbilisi were selected in consultation with the International School of Public Health of Tbilisi State Medical University (ISPH/TSMU) and program staff at USAID to capture varying geographic locations, accessibility, and local government environments. Sites included the regions of Tbilisi, Kakheti, Kvemo Kartli, Shida Kartli, Imereti, and Adjara, as shown in Table 2 and Figure 2. Respondents in these sites were contacted with the assistance of staff at the Vishnevskaya Rostropovich Foundation (VRF) and USAID. Within Tbilisi, respondents were recommended by staff at ISPH/TSMU, a coresearcher, Health Research Union, and CDC Georgia country office.

Data collection was conducted by the primary researcher as well as a coresearcher and two translators. The primary researcher conducted three interviews in English for respondents who

stated that they were comfortable in the language; the remaining eighteen interviews were conducted in Georgian by a coresearcher or in one case by the primary researcher with the assistance of a translator. Topics included the current immunization policy process, politics, disease seriousness and burden, factors contributing to vaccine choice, vaccine program history, strengths and weaknesses, vaccine procurement, financing, program implementation, research and evidence, future plans, and personal recommendations. This study was not considered to be human subjects research by the Institutional Review Boards of Emory University and HRU, therefore was exempt from their review. The interview guide is included in the appendix.

Researchers obtained verbal consent from all respondents to conduct and record interviews before beginning data collection. A handheld voice recorder was used to record each interview. Researchers transcribed recorded data in the language in which each interview was conducted, then Georgian interviews were translated into English by an independent translator. To check the quality of translations, a bilingual physician in Atlanta, Georgia listened to four (22%) of the Georgian interviews and compared them with the English transcripts. The fidelity of the translations was determined to be good. Subsequent sections were identified for correction and clarification based on the primary researcher's review of English transcripts; then areas of nine more interviews were spot-checked by the same bilingual physician. The primary researcher transcribed interviews conducted in English.

Data were entered into MaxQDA11 software for qualitative analysis (VERBI Software – Consult – Sozialforschung GmbH, Berlin, Germany) and coded using 19 inductive codes and analyzed using a Grounded Theory approach to allow key themes to arise from the data. Data were also

notated with memos and grouped according to the professional position of the respondent. In-depth descriptive and comparative analysis techniques were used to analyze key themes through stratifying by location and professional position. Additional subcodes were developed around key themes to explore components of each.

Chapter 4: Findings

Respondents were categorized into three groups: national staff, Public Health Center staff, and providers. Collectively, they focused on two broad themes relating to the vaccine system in Georgia: administration of the NIP, and its implementation.

Responses on National Immunization Program Administration from National Staff

In terms of NIP administration, national staff described the nature of the NIP as a government-approved program for the procurement, distribution, and administration of vaccines to Georgia's population. National respondents gave detailed descriptions of the structured protocols and activities encompassed by the NIP, including plans, targets, their justification, and roles and responsibilities of stakeholders. All national respondents commented on their perceptions of the roles of major vaccine system stakeholders. These responses are detailed below.

Role of NCDC

At the national level, the NCDC is understood as having most ownership over the NIP; it has technical and administrative staff dedicated to the immunization program who work closely with partners including WHO, UNICEF, ICC and the NITAG. Five of the eleven members of the ICC are NCDC employees. However, all vaccine initiatives and activities of the NCDC mentioned in interviews at the national level were either initiated or supported by an external organization rather than self-directed, reflecting a lack of autonomy in the NCDC. Once information and directives come from a partner organization, the NCDC initiates in-country procedures to implement programs and acquire administrative approval. For a vaccine-relevant policy to be

implemented, the NCDC must first gain approval from the MoLHSA and then Parliament. The NCDC is the body that brings initiatives to these policymakers as well as to the ICC and NITAG.

Role of NITAG

Of all interview respondents, only the NCDC, WHO, and ICC representatives knew that a NITAG had been created. The CDC representative was aware that formation of a NITAG was in process and that members were being trained. Each of the people aware of the NITAG's existence is either directly responsible for or impacted by the formation of the NITAG. They all clearly described the required structure and procedures for the NITAG according to WHO recommendations. All understood the NITAG as being under the MoLHSA and that it was formed by a Parliamentary decree. The ICC representative understood the NITAG's purpose as making recommendations on immunization issues. The NCDC perception of the NITAG's utility was to make decisions for NIP activities, vaccine introduction, and discussion on serious adverse events following immunization (AEFI). These respondents also described their perception of responsibilities for interaction with the NITAG. For the ICC, it was to provide information to the NITAG as needed, but any interaction with the NITAG had yet to occur. The NCDC described its responsibility to call upon the NITAG to meet as needed, but it did not currently have any situation that required the assistance of the NITAG. In the one NITAG meeting that had occurred, the upcoming change in vaccine schedule of the injectable poliomyelitis vaccine (IPV) was discussed, according to the NCDC. WHO is helping to facilitate the formation and functionality of the NITAG and described its role as supportive, to help ensure the increasing independence of the NITAG through training members and being available to provide technical assistance as needed. The WHO also identified the challenge of finding members in a small

country such as Georgia who do not have any conflict of interest according to the WHO regulations for NITAGs.

Role of Gavi

Gavi has supported the implementation of three vaccines during its partnership with Georgia: pneumococcal conjugate vaccine, rotavirus, and Haemophilus influenza B (Hib)-containing pentavalent vaccine (DTwP, Hepatitis B (HepB), Hib). In July of 2015, the Gavi support for the pentavalent vaccine in Georgia was removed and a hexavalent vaccine (DTaP, HepB, Hib, IPV) was supported in its place [42]. According to CDC, this change was made in response to Georgia's worries related to the source of the vaccines in conjunction with the upcoming switch from trivalent to bivalent oral polio vaccine (OPV) and an additional dose of injectable bivalent IPV being added to the schedule. This polio vaccine switch is scheduled to happen at the end of April 2016 worldwide [43]. A respondent from CDC reported that in the early stages of Hepatitis B vaccine introduction in Georgia, there was a case of AEFI that was attributed to the vaccine, which was manufactured in Korea. In 2008, a mass campaign for measles immunization was conducted in response to an outbreak using a vaccine from India; what were later discovered to be anxiety attacks were publicized by the media at the time as AEFI [44]. With these two cases of perceived AEFI involving vaccines sourced from Asia, NIP program staff decided to request Gavi to support the hexavalent vaccine, manufactured in Europe, instead of the pentavalent, for which European manufacturing had recently stopped [42]. The hexavalent vaccine also contains acellular pertussis vaccine rather than whole-cell pertussis vaccine, which the pentavalent vaccine contains. The WHO and SAGE have recommended that the consequences of adding acellular pertussis to the vaccine schedule be carefully considered because it has been associated

with lower effectiveness [45]. The European Technical Advisory Group of Experts on Immunization (ETAGE) has gone farther to recommend against the introduction of acellular pertussis in favor of the whole-cell vaccine [46]. The switch to hexavalent from pentavalent vaccine does provide an advantage because of the pending additional dose of IPV, but it is more expensive than hexavalent. However, Georgia secured the support of Gavi for this decision [42]. The Expanded Program on Immunization (EPI) prices in 2014 were \$18.65 per dose of hexavalent, compared with \$2.53 per 1-dose vial and \$1.95 per dose in a 10-dose vial of pentavalent vaccine. One dose of IPV was \$2.80 [47]. The addition of pneumococcal vaccine to the National schedule in 2014 added a stand-alone injection to the vaccine schedule; the CDC representative described increasing complexity of the vaccine schedule as a concern. Between the introduction of the pneumococcal and hexavalent vaccines, funding requirements were expected to double [48].

In addition to the publicly available vaccines in Georgia, which are free of charge, vaccines are available from private providers at a cost to the patient. According to the CDC respondent, it has been estimated that between 10% and 20% of children were already receiving the hexavalent vaccine through private providers, and preserving the integrity of the public vaccine program is a concern that was considered in the decision to request Gavi support for the hexavalent vaccine.

All National staff had a positive view of Gavi, which has assisted the NIP with major technical, training, and financial support for 13 years. The end of Gavi funding was also not viewed as an abrupt end to support as UNICEF and WHO representatives will remain in the country and continue to assist with vaccine pricing and technical support as needed after graduation.

Parliament, ICC, and NCDC representatives referenced the potential for future donor support. According to the Parliament representative, current negotiations were underway with Sabin regarding financial support for the NIP.

Role of CDC

CDC makes recommendations for immunization policy at the request of NCDC, most recently in 2014 for the introduction of IPV. CDC staff supply scientific literature to the NCDC on request. They have also worked with WHO and Gavi to evaluate the immunization system and provide funds for special activities such as \$84,300 for a measles supplemental vaccination campaign and \$5,107 for related injection supplies in 2013, as reported to Gavi in the most recent publicly available annual report [49].

Role of WHO

WHO prequalification of vaccines was valued by all categories of respondents; Georgia has a policy to import only vaccines with this classification [2]. The WHO also serves as the main provider of vaccine recommendations to the NIP related to the National vaccine schedule; it supports activities in the case of financial and technical resource shortages in Georgia and sponsors stakeholder meetings and trainings. In July 2015, WHO brought together vaccine program stakeholders from countries in the region to a meeting in Batumi, Georgia, to discuss upcoming 2016 changes in recommendations for polio vaccination. According to the WHO representative, it also sponsors the training and travel of Georgia's NITAG members to attend the meetings of previously established NITAGS to observe their operations.

Role of UNICEF

UNICEF is primarily responsible for purchasing and procurement of vaccines for the NIP and may provide information to inform policy decisions and conduct research prior to the implementation of a new vaccine or changed policy. In 2011, prior to Georgia's implementation of the rotavirus vaccine in 2012 and pneumococcal vaccine in 2014, as a precondition for them to be introduced, UNICEF conducted an Effective Vaccine Management Assessment at WHO's directive. They found that vaccine management procedures needed to be formally documented and that vaccine arrival and distribution needed to be more predictable [50]. There is an in-country representative for UNICEF who assists with vaccine-related as well as other initiatives through collaboration with NCDC. In 2013, UNICEF disbursed a total of \$43,834 for traditional vaccines (including bacille Calmette-Guerin (BCG), DTP, OPV or IPV, Measles Mumps Rubella (MMR), TT), injection supplies, and vaccination campaign costs [49].

Other Roles

Global initiatives and strategies, such as the global polio elimination strategy, reduction of mortality in children under 5 due to rotavirus as a part of the Millennium Development Goals (MDGs), also influenced the NIP. Tbilisi hospitals support the NIP via the sentinel surveillance system, and potential future support may come from Sabin pending current negotiations.

At the national level, there was an overall perspective of reliance on partner organizations for financial and technical support. To describe the operation of the NIP, one respondent stated, "The country executes the recommendations of international organizations and their expert opinions with the help of appropriate donors and budget." While country officers from partner

organizations including CDC, WHO, UNICEF, VRF, and Sabin will stay in Georgia postgraduation, program staff seem accustomed to receiving directives and funding from partner organizations, especially Gavi.

Responses Regarding National Immunization Program Administration from Public Health Center Staff

Role of Gavi

Awareness of Gavi's existence and understanding of its role in Georgia were highly variable among PHC staff. All PHC directors were unaware that Gavi support was ending in 2016 and each had a different idea of what support Gavi had been providing the country. One PHC director was unaware of the role that Gavi plays in Georgia, but described a decline in recent years in the availability of supplies such as forms and manuals needed by vaccine providers, as if a donor organization has already left the country. Another PHC director's awareness of Gavi was limited to knowledge that the pneumococcal vaccine had been added to the national schedule because of its support. A third PHC director was under the impression that UNICEF had stopped providing support and cited the success of the NIP after that point as an example of how it will succeed after Gavi support ends. This respondent also emphasized the need for careful program planning during the transition so that even if another donor organization does not start providing support in Gavi's stead, the government will be prepared to manage the NIP financially and logistically. Another PHC director used the comparison of the difficult situation during the beginning of Georgia's independence to one that is less dire now to support the idea that the NIP will be successful even after graduation from Gavi. This respondent was also under the impression that the NIP had functioned independently after emergency aid ended in the 1990s.

RIMs were all also unaware that Georgia was graduating from Gavi support and understood Gavi's role only as importing vaccines. One respondent expressed concern that the quality of vaccines may fall after the conclusion of Gavi support.

Role of Government

PHC directors described the Government as responsible for setting policy, but did not always specify who; when they did, the MoLHSA, Prime Minister, or Parliament was identified as making final decisions. One PHC director explained that MoLHSA and NCDC were the experts who decide which vaccines to import. Most PHC directors also understood NCDC as responsible for implementing the NIP and passing on information to them. Multiple PHC directors cited the government as responsible for financing the NIP, one of whom expressed frustration with the highly bureaucratic process of using state tenders to procure vaccines. Another emphasized that the NIP was a high priority for the government and that high vaccination coverage, above 95%, was important for entry into the EU, so the government would be motivated to maintain its support for the NIP. The most common idea about prioritization of immunization was that its effectiveness determined its priority, "Infectious diseases are a burden for the state and that determines their priority, also the effectiveness of immunization, it is the most effective intervention in the health care field, the most comprehensive and effective. That's... look, compare the treatment of one man to population-level [disease] prevention, you have no more infected people and they are no more burdens for the country, you have a healthy population." Two respondents stressed the importance of communication between the governments of countries in the region to share experiences and best practices. One PHC director described

universal insurance as one of the government's best actions, to relieve the worries of private citizens about paying for medical services.

RIMs described high-level government bodies, MoLHSA, and NCDC as part of a top-down hierarchical system that sends decrees for them to act on and sets policies that they are to comply with. Two RIMs described the Government as the body that funds the NIP, and one was unaware of and unconcerned with Government agencies, stating that, "No Government agencies are for doctors, we don't pay attention to the government."

Role of NCDC

PHC directors described how information about the NIP, documents, trainings, and vaccines come to them from the NCDC. Many of them explained that they are in daily communication with NCDC primarily via email, but telephone and Facebook were also cited as channels used to exchange information. When PHCs submit completed NCDC-supplied forms to NCDC with local epidemiologic data, the NCDC receives and analyzes it. One PHC director described NCDC as the body responsible for carrying out research on VPDs in Georgia, using an example of an investigation into meningitis caused by Hib in children under 5 prior to the addition of the Hib vaccine to the national schedule. The work was conducted between 2006 and 2010 then published in 2013 [51].

Similar interactions were described between RIMs and NCDC, with more emphasis on sending rather than receiving information. They described using an Electronic Integrated Disease Surveillance System (EIDSS) to register disease cases so that NCDC has access to the data

quickly and is able to compare data from different regions. Respondents explained that they are responsible for sending surveillance data to the NCDC, which then responds appropriately given AEFI or an outbreak. However, the connection between the information that RIMs send and policy decisions was not clear to respondents; when asked how the information sent to NCDC influences future policy, one respondent said, “I don’t know, we are just obliged to give information.”

Role of ICC

For both PHC directors and RIMs, awareness of the ICC was limited. Some respondents had heard of it, one described members as the head of the NCDC, the Minister of Health, and members of Parliament. Another PHC director explained when asked what the role of the ICC was, that “If [the ICC] establishes something important, the NCDC will notify us [at the PHC].”

Role of Public Health Centers

Most regional capitals where interviews were conducted had two public health offices: one that housed the PHC director and staff, and another vaccine office that housed the RIM, cold chain nurse, and contained cold storage for vaccines. However, in some cases these functions were combined in one multipurpose building. Whether vaccine offices or multipurpose buildings, these are where trainings and meetings with NCDC staff and vaccine providers take place.

Physicians practicing in the region are responsible to travel to the immunization office to pick up supplies at their own cost and attend trainings as needed. These trainings occur annually and with any change in policy or vaccine schedule and were simply described as an obligation by PHC staff.

Responses from Public Health Center staff and Physicians on National Immunization Program Implementation

Vaccine Supply

The NCDC brings vaccines to PHCs quarterly according to the order placed by staff in that office, but there are no regional vaccine warehouses, so PHC staff may have to come to Tbilisi to get vaccines if they run out. Vaccine ordering is based on historical quantities of vaccine used and administered by providers, tracked through paper and electronic records. Vaccine providers must come to regional public health centers to pick up vaccines at their own expense.

Respondents had varying perspectives on whether it is acceptable for providers to pay their own way on public transportation from their clinics to regional capitals to pick up vaccines. Providers are given a cold box with ice packs by their local PHC to transport vaccines. There are temperature monitors kept with vaccines at all times; each has an indicator to show if it has been exposed to temperatures above a safe level for vaccines, and providers log the temperature of vaccine cold storage twice daily. PHC staff reported taking extra efforts to ensure that physicians receive information on updated policies, by calling them or printing and delivering information sheets.

Multiple respondents explained the challenges involved with Georgia's current system that provides the choice to patients on where to get vaccinated and with which vaccines. There are no defined catchment areas for health centers in Georgia, and PHC staff as well as providers understand that patient perception of the quality of service, which is heavily influenced by trust in physicians, has an effect on vaccine coverage. Provider respondents reported that clinics in cities tend to see more patients—and they receive incentives based on the number of vaccines

they administer, so are happy to have these extra clients even if it causes problems with supply distribution. One physician explained that the coverage rates for health clinics located across the street from each other could vary by 20 or 30 percentage points if people trust one doctor over the other. In one city, the providers interviewed expressed that, rural health clinics provide low quality service despite buildings being renovated, so patients choose to come to cities to get vaccinated, “The state is dissatisfied all the time that their plans cannot be fulfilled, the coverage is not good. There are not vaccines, sometimes we run out of penta[valent vaccine], sometimes polio, no one can tell in advance how many children will be born in the year. This happens especially in villages, the situation there is such that [patients] try to come to cities, have you seen the polyclinics there? They have been renewed from the outside, but there are not qualified specialists or good conditions there. And if they can afford it, they come to cities and try to register here, that’s why we have an endless problem, we run out of vaccines and they have them left [in the villages], then they are redistributed,”

Communication

Some PHC staff felt as though the NCDC takes into consideration any feedback they receive from lower levels in the health system and appreciated frequent meetings and communication with NCDC. Generally, PHC staff and providers cited a good communication and feedback system for determining vaccine needs and supplying them as well as requesting and receiving support. A PHC director explained the communication system from the NCDC through the PHC to providers, “we receive information about immunization electronically from NCDC, immediately if there is something new then I send it to family doctors, rural doctors, to maternity homes, to everyone who is involved in the immunization program... no one stays without the

information, everyone has email, and if I know that they won't check it, then I invite them here, print and let them take it. I won't let it happen that someone says that he has not received it, or he didn't know. I print it and give it to them." Providers described a text messaging system that they use, administered by the NCDC, to remind patients to come in for vaccinations and that it works well. PHC staff and providers noted that there is not enough focus on local issues by National staff. Some respondents did not cite any areas for improvement in the NIP, and one PHC staff member would discuss challenges only after the recording device had been turned off.

Providers described that a great deal of their professional responsibilities related to vaccination involve communication with patients. They gave examples of clarifying misperceptions of when vaccination is needed, how safe it is, what the benefits are, and differences between private and publicly available vaccines. Providers described this responsibility as an important and necessary part of their jobs, but one that is time-consuming. Multiple providers suggested that this time could be reduced and the NIP improved as a whole through increased efforts to communicate with the public about vaccination through television, newspapers, or other means.

Resources

While all PHCs are equipped with computers and some level of internet connection, although it may not be reliable for more remote locations, rural health clinics may not have computers, internet, or vehicles, which are seen as a challenges that makes a properly functioning system more difficult to achieve. Cold chain resources were increased in the last five years, including refrigerators, temperature monitors, and cold boxes, and this has made vaccine supply and quality monitoring more reliable. Some providers and PHC staff are satisfied with the vaccine

system's resources while others have a lot of criticism, especially related to payment and salaries. Providers are paid a flat rate of 20 tetri, the current equivalent of about \$.09 per vaccination, which to everyone who commented on it, was too low. Any costs that providers incur through use of alcohol, cotton, or other supplies are not reimbursed. PHC staff and physicians also noted that salaries are low, especially for nondirectorial staff, and that it affected motivation to do their jobs well. One RIM cited a need for an understanding at the national level of local realities, "a lot of issues has been improved by this program, the only thing is more attention on local services. We are discriminated [against], don't you see the office we are sitting in? The system is good but people need improvement too."

Public Perception

The refusal to vaccinate was cited as a problem in some areas, but not others. Religious reasons, particularly among Azeri immigrants who are Jehovah's Witnesses, and perception of quality of both service and vaccines were noted as reasons that people refuse or delay vaccination, but the number has fallen. Trust in doctors and vaccinations has risen according to both PHC staff and providers, but vaccine hesitancy was cited as a problem at the national level, "We have problems with the public opinion because they, many of them, they don't like to vaccinate their child themselves. But during the outbreaks, it's... it's a problem." Media coverage and perceptions of quality have caused increases in vaccine refusals in the past. One PHC staff member believes that mitigating risks posed by those who choose not to get vaccinated should take place via integration of mandatory immunization into National legislation. Generally, PHC staff and providers cited that the population knows the benefits of vaccination, even to the point that they are willing to walk up to 10 km with a baby to receive them. There is a need for more

communication with the public. Trust and long relationships with doctors is important to keep vaccine coverage up.

Vaccine Quality

While some PHC staff understand that the national choice of which vaccines to import is based on WHO prequalification, others believe that it is based on decisions reached during meetings between MoLHSA and NCDC. Cases of real or perceived AEFI as with HepB vaccines shortly after their introduction and measles vaccines during the supplemental campaign carried out in response to the 2008 outbreak, still have an effect on vaccine choice for both the NIP and patients. As previously discussed, the ICC made a special request for Gavi support of the hexavalent vaccine as opposed to the pentavalent vaccine in part because of the origin of the vaccine, preferring European sources over Asian ones. There is a perception among some patients that privately available vaccines, which they must pay for, are a higher quality than government vaccines. Commercial vaccines are most commonly used in Tbilisi, but also in some rural or poor areas where people believe that they are better. Providers also noted that if a patient came to the clinic and requested a vaccine that was not available through the national system, human papillomavirus (HPV) vaccine or hexavalent, he or she would purchase it for that patient from a private supplier and administer it, charging for the cost of the vaccine and time.

Use of Data

Primary healthcare providers fill out NCDC-provided forms about the vaccinations they give and send them to PHCs, who summarize the data and report to the NCDC to inform the country's vaccine needs. Epidemiologic investigations are carried out following excess cases of vaccine-

preventable disease, and PHC staff reported that cases are examined very closely, including contact tracing. There is a new EIDSS system for electronic reporting, but it faces challenges related to internet reliability and the availability of computers, so PHCs are still using paper reporting protocols as necessary. One PHC director noted that EIDSS will show a balance of vaccine if a village doctor has not had internet because he or she would not be able to record how many vaccinations have been given, and the PHC will not anticipate a stock-out. A provider noted challenges related to the current system of vaccination record-keeping, “In educational institutions: schools, kindergartens, universities, people may be accepted and [the institution] won’t demand forms... but they may be interested if the vaccination was done. For example, if a child is gone 20 years and I don’t know whether he was vaccinated, I don’t keep this information... and he has not taken any information from [where he was vaccinated, the child] just says that he has been vaccinated.”

Chapter 5: Discussion

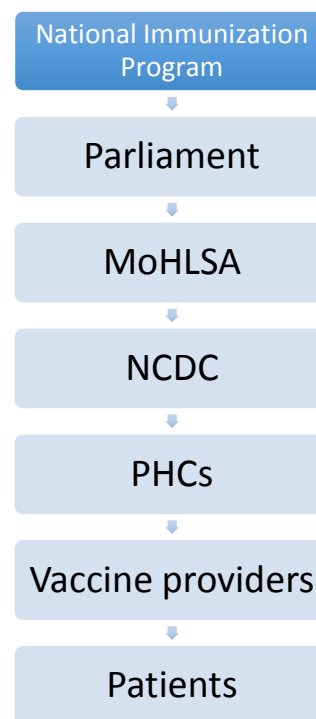
Throughout the process of graduation from Gavi support, the government of Georgia has been gradually taking on more responsibility for financing its NIP, but recommendations and the local data needed to make policy have largely been initiated by outside organizations. Not only the formation of a NITAG, but its effective functioning as the country's main source for evidence-informed recommendations, represents a major paradigm shift for NIP administrators and PHC staff. Through this process, Gavi and its partners are providing support via a graduation grant from Gavi, NIP assessment and program recommendations from WHO, UNICEF, Gavi, and Sabin, access to Gavi vaccine pricing for five years post-graduation and use of the V3P platform, the technical support from in-country representatives of WHO, UNICEF, CDC, Sabin, VRF, and others, as well as training for NITAG members by WHO.

Georgia's National government has prioritized immunization to date and interview respondents expressed a sense of confidence that the trend would continue. However, governmental officials did cite that they were seeking new financial donors for the immunization system, including Sabin. Parliamentary elections are scheduled for October 2016 and the Presidential election for 2018. As with any political election, there is no guarantee that the policies of Parliament will remain as they are in the current administration. This is a motivation for NIP program staff and the NITAG to present policy proposals that are as well documented as possible. Regional and local staff including at PHCs and providers will remain in their positions despite electoral results, which is reason for Georgia to invest in this level of the health system through training, efficient protocols and systems, and adequate salaries and facilities.

With decreased donor funding, immunization cost and cost-effectiveness are likely to become more of a determining factor in policy decisions. The cost-effectiveness study lead by an NCDC staff member to analyze the possibility of implementing pneumococcal vaccine is a case study in NIP's ability to generate and use local data [32]. However, the case of Georgia's choice of the more expensive hexavalent vaccine over WHO-recommended pentavalent vaccine because of concerns over the vaccines source country demonstrated the prioritization of public perception over cost and faith in WHO prequalification of vaccines. The real and perceived AEFI following HepB vaccine introduction and during a supplementary measles vaccination campaign in which Asian-sourced vaccines were involved are still understood to be a concern, but this concern was not expressed directly during interviews [44]. Now that Georgia has introduced the hexavalent vaccine into its schedule, it will be faced with the challenge to maintain funding for this more expensive vaccine after Gavi support comes to an end. The addition of hexavalent and pneumococcal vaccines together double funding requirements [48].

The top-down structure of the NIP, shown in Figure 3, was clear as respondents explained their job duties and interactions with actors above and below them. Professional roles were also well defined by forms and protocols. The NIP structure lends itself to a poor understanding of the duties of people who do not directly affect one's work. PHC staff did not know or care what higher-level government was doing, but they trusted that the NCDC would inform them of any important decisions. Daily communication

Figure 3: The top-down structure of Georgia's National Immunization Program, based on interview responses



between PHCs and the NCDC via email, phone, and Facebook was a part of this relationship. Providers and PHC staff also described regular communication involving reporting, distribution of vaccines, information, and trainings. Providers also explained their communication with patients, involving text message reminders for appointments or explanations of vaccine safety and reasons to vaccinate. PHC staff and providers were however only vaguely aware of Gavi and the ICC, with some confusion about the roles of each. Of 26 respondents, only the three directly involved in formation of the NITAG were aware that it existed.

Communication between adjacent tiers of the NIP is consistent according to respondents, but not beyond one level up or down. Even more, responses from people within a given level of the NIP, especially pertaining to understanding of policies, use of data, and perceptions of the system, were more similar to each other than those across levels or in a given geographic area. For topics pertaining to context such as the perceived prevalence of vaccine hesitancy or vaccination coverage, responses were clustered by geography. This shows that communication is specific to professional responsibilities and location; not all issues are apparent at the national level, which is where Gavi and its partners have concentrated their efforts on Georgia's graduation readiness. If Georgia's NITAG is going to be successful and NIP stakeholders at all levels informed of the NITAG's recommendations, communication between levels of the NIP should be improved.

When asked about strengths and challenges of the NIP, National staff tended to talk about funding, data, and high-level program logistics, while PHC staff and providers were concerned with salary, communications, surveillance and reporting. National staff referenced externally-initiated reports and analyses when identifying issues while PHC staff and providers said they

did not believe national staff were aware of the issues PHC staff and providers faced in their day-to-day responsibilities. It was not apparent from the interviews if National staff were aware of regional and local issues, but they were not mentioned in responses to interview or follow-up questions. Willingness to discuss specific operational challenges of the NIP and the detail with which these issues were discussed became apparent at regional and local levels.

PHC staff and providers raised issues involving distribution of vaccines, avoiding stock-outs, and the practicality of the current vaccination record-keeping system at the level of an individual patient. Without catchment zones for health facilities, patients are free to use any health clinic for vaccination and frequently travel to cities, which necessitates the redistribution of vaccines when one clinic runs out before expected and another does not use its stock. Travel to a health clinic other than the closest to one's home also creates complications for tracking vaccination coverage. The new EIDSS system, allowing for real-time data tracking, creates difficulties when internet service is not reliable in rural areas because PHCs cannot see the stock that is left at clinics; if an alternative form of inventory is not used, stock-outs may result. For individuals, verifying vaccination records is not enforced, and the availability of old records may be limited because of data retention policies. Other low- and middle-income countries that have implemented electronic disease surveillance systems have seen mixed results, with challenges attributed to lack of training and effective tools for data collection [52-55].

Both PHC staff and providers cited using their own resources to perform their job duties, and they expressed frustration about low salaries. Reimbursement for vaccination is low, and providers must pay their own way to PHCs to pick up vaccines. Respondents cited these

difficulties as hindrances to motivation and possible reasons why vaccination coverage is not higher in some areas. More remote PHCs also were not equipped with modern facilities or reliable technology in the form of computers and internet connection.

Because communication is weak across multiple tiers of the NIP, an assessment of NIP readiness for graduation may not capture the full spectrum of realities that exist in a country. Gavi and partners' 2016 initiative to begin graduation readiness assessments at the national level are at risk of missing regional- and locally-relevant issues that are likely to affect the NIP as a whole. Even before a country begins the process of graduation from Gavi, resources in the form of health system strengthening grants from Gavi may be available to ameliorate weaknesses that are better understood at the local level. Gavi HSS grants use a PBF model with funding driven by complete and accurate reporting as well as immunization outcomes, measured through Measles and DTP3 coverage. Gavi is also beginning country-level graduation assessments in 2016. These assessments of country performance are based on immunization coverage, reporting, and meetings with national-level NIP stakeholders, but no one at the regional or local level. With Gavi's transition toward customizing its graduation process to each country through individual graduation assessments, it should also be considering country context before graduation begins as well as regional and local operational issues that may not be evident in vaccine coverage reporting.

Limitations

Some of the interviews were short due to limited time of the respondents, and the content of the interview was sometimes thin; responses did not always delve deeply into the subject matter and context. Respondents interviewed in English were probed for further information where

superficial responses were given, as were respondents interviewed in Georgian if it was evident in the interviewer's translation that further information would inform the research. Through the process of translating interviews from Georgian to English, some meaning in responses may have been lost, but review of the interviews with a fully bilingual physician was conducted to limit the effects of translating data. The number of high-level officials is limited and saturation was not reached with this group.

Chapter 6: Conclusion and Recommendations

Gavi and its partners have made record-setting achievements in childhood vaccinations. As a part of their goal to strengthen health systems, Gavi may re-evaluate the methods it uses to assess the issues present in a country to capture those beyond the purview of national staff. A quantitative survey measuring communications, resources, public perceptions, vaccine supply, and the effectiveness of procedures before, during, in the graduation phase, and after the conclusion of Gavi support would be an effective way for Gavi to better understand and respond to locally relevant information.

For Georgia, such a survey would allow for the identification and recognition of issues such as PHC staff and provider employment satisfaction, vaccination record-keeping for patients and NIP reporting, successes from the past and remaining challenges. These issues threaten NIP sustainability; if they can be addressed before the conclusion of Gavi support when there will be an increased demand on the National health budget to support the NIP, they are more likely to be ameliorated. In the WHO European region, the six countries in the process of graduation or that have graduated this year are at a critical point for achieving and maintaining NIP sustainability; increasing the recognition of local challenges and successes that may not have risen to the National level is an opportunity to assist with sustainability and overall NIP functionality. For the two countries in the region still receiving Gavi aid, there is even more opportunity to adjust the ways in which NIPs are supported through HSS grants.

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Table 6: Gavi Support Provided to Countries in the WHO Europe Region

Country	2014 GNI per capita [34]	2015 Population [18]	2015 Birth Cohort [18]	2014 DTP3 coverage [18]	Gavi Commitments 2001-2020 [18]	Vaccines introduced with Gavi support [15]	First year of Gavi Support [18]	Final year of any Gavi funding [18, 23]	GNI Between \$1045 and \$1580 [34]	Phase of Graduation from Gavi [18]		
										Preparatory Transition	Accelerated transition	Fully Self-Financing
Armenia	\$4,020	3,017,355	39,140	93%	\$5,187,183	3	2001	2017	2004-2005			
Azerbaijan	\$7,590	9,753,858	193,366	94%	\$13,808,397	2	2001	2016	2005			
Georgia	\$3,720	3,999,420	53,994	91%	\$5,690,806	3	2002	2017	2004-2005			
Kyrgyzstan	\$1,250	5,939,928	153,977	96%	\$20,701,572		2001		2013-			
Republic of Moldova	\$2,560	4,068,797	42,915	90%	\$6,046,156	3	2002	2016	2006-2009			
Tajikistan	\$1,080	8,481,567	256,305	97%	\$25,888,181		2001		2014-			
Ukraine	\$3,560	44,821,612	484,392	76%*	\$3,544,463		2002	2008	2004-2005			
Uzbekistan	\$2,090	29,891,725	667,416	99%	\$79,461,353	4	2001	2018	2009-2011			
Bosnia and Herzegovina**	\$4,760	3,810,181	33,576	86%	\$2,260,595		2002	2011	1998-2000			
Albania**	\$4,450	2,896,596	39,526	99%	\$2,473,607		2001	2013	2000-2002			
Turkmenistan**	\$8,020	5,373,420	111,942	98%	\$1,233,659		2001	2006	2004-2005			

Understanding Vaccine Policy Decision-Making in Georgia

In-Depth Interview Guide

PURPOSE

Thank you for participating in this interview. Your responses will help us understand the decision-making process for vaccine policy in Georgia. I am a graduate student at Emory University in Atlanta, Georgia, United States studying global public health and infectious disease. My research counterpart Maia is a student of public health at the International School of Public Health in Tbilisi. We are interviewing Georgian officials involved with vaccine policy making as an independent research project. The interview will take approximately 60 minutes.

CONFIDENTIALITY

All information we collect will be confidential and your response will be de-identified; only the two members of our team will have access and read the transcript of this interview. Your responses will be anonymous; the interview will not ask for your name or any other identifying information. As previously mentioned, the interview is part of an independent research project. As such, your responses will be made anonymous, transcribed, compiled with other data we collect, analyzed, and finalized as a report or manuscript. Your participation is completely voluntary; you can choose to answer questions or not to; you may stop at any point if you no longer wish to participate. There is no risk or direct benefit to you for participating or leaving the interview before completion. There is, however, potential for greater benefit of a better understanding of the vaccine policy decision-making process in Georgia. In order to accurately transcribe your response, I would like to use a voice-recording device. Do I have your consent to do an audio recording of this interview? Do you have any questions or concerns about any aspects of the interview before we start? Thank you again for volunteering your time and thoughts for this interview.

Introductory Questions/ Characteristics and Responsibilities

What is your current position?

What are your responsibilities specifically related to vaccine policy?

What is your educational background?

Current Policy Process

What is your perception of the process for developing the vaccine policy agenda? (Probe: Who is involved?)

What information sources are used for policy making? (Probe: Which of those do you use? Where does the information come from? How are discrepancies in data from different sources addressed?)

What additional information would be helpful in making vaccine policy decisions? (Probe: Is that information available? If not, how could you get it?)

Disease and Disease Burden

How does the seriousness of a disease influence policy decisions?

How does the number of people affected by a disease influence policy decisions?

Alternative Prevention or Treatments

How do the current prevention or treatment methods for a disease influence policy decisions?

What are the criteria for choosing a vaccine? (Probe: What are the criteria for broad decisions? (E.g. decisions to recommend a vaccine) What are the criteria for specifics? (E.g. vaccine manufacturer, etc.))

How does population interest in a vaccine versus other prevention or treatments influence policy decisions?

Is there anything else that influences the decision to choose a vaccine?

History, Strengths, and Weaknesses

What are the strengths of the process?

How can the process be improved?

Procurement, Financing, and Implementation

How is budget involved in policy decisions?

How are logistical implementation considerations involved in vaccine decisions? (Probe: distribution, cold-chain, schedule, licensing)

How are recommendations disseminated to providers?

How are providers held accountable for following vaccine recommendations?

(Alternatively: How are vaccine recommendations enforced?)

Research and Evidence

How does previous experience with a vaccine influence policy decisions?

How does disease surveillance data influence policy decisions? (Probe: how do you view the quality of this data?)

How are monitoring and response to adverse vaccine events handled?

NITAGs and Future Plans

What are your thoughts on technical vaccine policy advisors (technical advisory group)? (Probe: How feasible is a functional technical advisory group in Georgia? What are the barriers?)

What changes do you expect in the vaccine policy-making process after the end of GAVI's commitment to aid in 2016?

Closing Questions

What are your recommendations for improving the vaccine policy-making process in Georgia?

Is there anything else involved in the vaccine decision-making process that we did not talk about?