



Commentary

Strengthening legal frameworks for vaccination: The experiences of Armenia, Georgia, and Moldova

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ABSTRACT

Background: Gavi, the Vaccine Alliance, delivers life-saving vaccines to children in the world's poorest countries and encourages countries to assume increasing ownership of their immunization programs as their economies grow. Vaccination legislation may promote country ownership and immunization program sustainability. However, despite establishment of vaccination laws as an indicator of national commitment to immunization through the Global Vaccine Action Plan, little is known about the content of vaccination legislation in low- and middle-income countries and the processes by which countries strengthen their legal frameworks. We describe the experiences of three countries supported by Gavi through its partnership with the Sabin Vaccine Institute— Armenia, Georgia, and Moldova—in strengthening their legal frameworks for vaccination as they transition from Gavi support.

Methods: Information presented comes from national legal documents and the 2017 European Regional Workshop on Immunization Legislation, in which legislators and health officials from Armenia, Georgia, and Moldova shared approaches to making immunization a national priority by strengthening legal frameworks. We outline each country's legislative framework, describe progress in modifying vaccination legislation, and present strategies developed by countries to continue strengthening the legal basis of their immunization programs.

Results: Armenia, Georgia, and Moldova have legal frameworks that guarantee immunization as a public good, define immunization calendars, and establish regulations for vaccine procurement and administration. Legislative priorities include modifications of regulations to optimize procurement (Armenia and Moldova), potential provisions to increase vaccination through incentives (Georgia) or requirements (Moldova, possibly Armenia), and new mechanisms to finance routine program costs (all three countries). Each country is employing a distinct approach to strengthen its legal framework.

Conclusion: These country experiences suggest that while legal approaches can promote country ownership, there is no standardized approach to vaccination legislation. A better understanding of the complex legal frameworks and their impact on supporting and sustaining progress in vaccination is needed.

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1. Introduction

A foundational principle of Global Vaccine Action Plan (GVAP)⁴ is that countries should assume full ownership of their national immunization programs (NIPs), where ownership means that countries finance programs with national funds and take primary responsibility for providing high-quality immunization services to all citizens [1,2]. Gavi, the Vaccine Alliance, was established to improve access to new and underused vaccines in the world's poorest countries. Since 2000, 73 low-income countries have relied on financial support from the organization to procure and deliver life-saving vaccines to over 500 million children [3]. Inherent in Gavi's design is the principle that as countries' economies improved, they would transition away from Gavi support. From 2016 to 2020, 20 countries will transition from Gavi support, with many others set to become self-financing over the following decade [4]. Along with other international partners, Gavi is assisting these countries in moving to independence and mitigating the challenges around transitions. In addition to addressing financial challenges, transitions to independence will benefit from clear understandings of country and partner responsibilities and the development of strategies to respond to threats to sustainability—e.g., the increased complexity of the vaccination schedule, rising vaccine costs, vaccine hesitancy, and increasing health system complexity—that were not as prominent at the start of Gavi's support.

Vaccination legislation—a comprehensive term that includes any legal document⁵ intended to secure or regulate NIPs—is a key component of national immunization policy and contributes to country ownership. Though neither sufficient nor necessary for the creation of sustainable programs, legislation is associated with increased national expenditures on vaccines and the development of independent, high-functioning NIPs [5,6]. For example, legislation helped Latin American and Caribbean (LAC) immunization programs move from dependence to country ownership and has been a valuable tool for other Gavi countries [2,5]. Along with the GVAP, regional action plans have identified the establishment of vaccination laws as an indicator of national commitment to immunization [7,8]. Despite these recommendations, there are few published studies about efforts of low- and middle-income countries to strengthen vaccination laws [2,5,6].

We describe the recent experiences of three countries supported by Gavi through its partnership with the Sabin Vaccine Institute—Armenia, Georgia, and Moldova—in strengthening their legal frameworks for vaccination while transitioning from Gavi support. We provide background on each country's health system, immunization program, and legal framework, describe challenges and progress in modifying vaccination legislation, and present strategies developed by national officials to strengthen the legal basis for their NIPs. We conclude by highlighting research gaps in the field of vaccination legislation and by sharing lessons learned for other countries seeking to improve their legal frameworks.

2. Methods

Information presented comes from a review of national legal documents and the European Regional Workshop on Immunization Legislation held in Tbilisi, Georgia in March 2017.

2.1. Review of legal documents and country background information

Three authors, DS, EP, and SPT, reviewed national documents on vaccination and legal documents pertinent to immunization in Armenia, Georgia, and Moldova. In addition to searching legal databases, we reviewed the bibliographies of government reports and Gavi appraisals to identify legislation. Current and former national officials from Armenia (HG), Georgia (EP), and Moldova (OD) performed literature searches in the native languages of these countries and confirmed that all pertinent legal documents had been identified and that the analysis was accurate. In Armenia, for example, the online database of legal documents and unified online database of draft laws and regulations were reviewed [9,10]. In select cases, we contacted officials who participated in the European Regional Workshop on Immunization Legislation (“the Workshop”, mentioned below) to resolve specific issues that arose during the data analysis and to provide updates on progress made following the Workshop.

We classified provisions in legal documents into one of three broad categories, each with subdivisions, using criteria established by Trumbo et al in a review of vaccination legislation from LAC [5]. Categories included declarative criteria (i.e., free vaccination, compulsory vaccination), financial criteria (i.e., budget line, tax exemptions, supply mechanism), and operational criteria (i.e., regulatory oversight, immunization schedule, enforceability, and existence of a national immunization technical advisory group [NITAG]) [5].

To better understand factors affecting vaccination policy in Armenia, Georgia, and Moldova, we researched each country's legal and governmental systems and reviewed reports from policy dialogues and briefings, Gavi joint appraisals, and immunization financing data trends. Based on this information, we created brief summaries of each country's health system and immunization program.

2.2. Workshop

In March 2017, Gavi and the Sabin Vaccine Institute sponsored a European Regional Workshop on Immunization Legislation in Tbilisi, Georgia to support the efforts of national legislators and health officials from Armenia, Georgia, and Moldova in strengthening their legal frameworks for vaccination [11]. Participants included 34 national officials from parliaments and the ministries of health of the aforementioned three countries, including 23 participants from Georgia, five from Moldova, and six from Armenia, as well as immunization experts from UNICEF, Gavi, the World Bank, and the U.S. Centers for Disease Control and Prevention. The Workshop's objectives were to identify important provisions of immunization legislation in each country, educate national officials on best practices to support legal frameworks, and create plans to strengthen the sustainability of NIPs through legislation [11].

During the Workshop, national officials participated in small-group activities to foster discussion of the importance of leadership and political will in strengthening and sustaining NIPs. Separately, teams of national officials, organized by country, identified challenges to the sustainability of their NIPs and developed plans to address these challenges. Plans included new or modified legal provisions to meet country goals and action items to achieve these legislative changes [11]. We outline below vignettes from the three

⁴ Global Vaccine Action Plan (GVAP); national immunization programs (NIPs); Latin American and Caribbean (LAC); National immunization technical advisory group (NITAG); out-of-pocket (OOP); Basic Benefits Package (BBP); Ministry of Health (MOH); State Health Agency (SHA); National Centers for Disease Control (NCDC); Universal healthcare (UHC); National Center for Disease Control and Public Health (NCDC); pneumococcal conjugate vaccine (PCV); Mandatory Health Insurance (MHI); National Health Insurance Company (NHIC); National Center of Public Health (NCPH); and Ministry of Education (MOE).

⁵ Legal documents include stand-alone vaccination laws, regulations, and executive decrees as well as public health, national healthcare, or educational laws with provisions on vaccines. The term “legal framework”, used elsewhere in the article, refers to all such documents that a country enacts to regulate its immunization program.

countries, including overviews of their legal frameworks, their challenges in immunization policymaking, and their ideas to strengthen program sustainability through legislation generated primarily by national officials, unless otherwise noted.

3. Country experience: Armenia

3.1. Context: Health system and national immunization program

In 1991, the collapse of the Soviet Union caused the decentralization and partial privatization of Armenia's healthcare system [12,13]. Facing high out-of-pocket (OOP) payments, patients struggled to access the health system [13]. In 1999, the government created a Basic Benefits Package (BBP) that gave vulnerable populations access to essential medical services [12]. Armenia has since expanded the BBP and primary care services, resulting in improved health outcomes [13].

The NIP, a component of the Ministry of Health (MOH), is supported by other MOH agencies, including the State Health Agency (SHA) and the National Centers for Disease Control (NCDC) (Table 1). The NCDC provides technical support, while the SHA ensures the appropriate use of funds allocated from the Ministry of Finance [13].

These funds cover vaccines and vaccine supplies. The country procures all routine vaccines through UNICEF and has substantially increased funding for vaccine purchases in the last decade [14]. In 2016, the government transitioned from Soviet era line-item budgeting to a program budgeting process with oversight from the Parliament where the NIP operates under time-bound, measurable performance indicators [14]. In 2018, the country began fully self-financing all vaccine purchases except IPV and HPV vaccines, which Gavi will continue to co-finance through 2019.

Table 1
Background information, Armenia, Georgia, and Moldova.

	Armenia	Georgia	Moldova
Country background			
Year of independence ¹	1991	1991	1991
Population, millions (2016) ²	2.9	3.7	3.6
Birth cohort, thousands (2017) ¹	38.2	51.9	41.2
Infant mortality rate, deaths <1 year per thousand (2015) ²	12.6	10.6	13.6
National Immunization Program indicators			
DPT3 coverage, % (2002) ³	94	87	97
DPT3 coverage, % (2016) ³	94	92	89
Number of antigens in national vaccination schedule ⁴	15	12	12
Financial indicators (all monetary amounts in USD)			
Gross national income per capita, Atlas method (2010) ²	3470	3000	1820
Gross national income per capita, Atlas method (2016) ²	3760	3810	2120
Total GAVI support since 2001 (millions) ¹	5.9	5.9	6.0
Total routine immunization expenditure per surviving infant (% supported with national funds) [2010] ⁴	24.52 (66%)	60.81 (64%)	31.37 (58%)
Total routine immunization expenditure per surviving infant (% supported with national funds) [2016] ⁴	80.43 (60%)	131.55 (89%)	29.9 (87%)

Sources:

¹ GAVI country fact sheets.

² World Bank <http://data.worldbank.org/>.

³ WHO Global Health Observatory <http://apps.who.int/gho/data/node.main.A827>.

⁴ WHO Joint Reporting Form [42].

3.2. Legal framework and challenges in immunization policy

Armenia does not have a vaccination law but its *Constitution* (1995, amended in 2005) and *Law on Medical Assistance and Services to the Population* (1996, last amended in 2018) guarantee the right to healthcare, including preventive services (Table 2) [15–17]. Using this framework, the government regulates immunization through ministerial decrees, sanitary norms, standard operating procedures, and procurement laws [14]. In 2016, Armenia passed *Government Decree #10*, endorsing a comprehensive plan for immunization that is intended to ensure the NIP's technical and financial sustainability [18].

Armenia's policy challenges include debates about mandatory versus recommended vaccination, the absence of legislation guaranteeing funds for routine program costs in addition to vaccine procurements costs (e.g., health worker trainings), and a procurement law that does not distinguish between unique aspects relevant to vaccine purchases in contrast to specifications for the procurement of other goods (i.e., the law has price criteria but does not mention vaccine quality or safety criteria). Furthermore, the NIP's budget only covers vaccines and vaccine-related materials, since external funds have traditionally covered trainings, communication activities, and other operational costs of the program.

During the Workshop, the Armenian delegation discussed strategies to pass a *Public Health Law* that contained key provisions on immunization. Since the Workshop, the MOH has drafted a comprehensive *Law on Healthcare* that, if passed, would replace the existing *Law on Medical Assistance and Services to the Population* [19]. The draft law includes a full chapter dedicated to public health and contains provisions that prioritize immunization, define the NIP's structure and responsibilities, and attempt to increase vaccine uptake (e.g., potential school-enrollment or opt-out requirements). In February 2018, the MOH circulated the concept of the draft law for discussion among stakeholders and approval by the government. It has not yet been introduced to Armenia's National Assembly [19].

3.3. Armenia: Ideas to strengthen program sustainability through legislation

Armenia has made considerable efforts to achieve its vision of protecting immunization from economic downturns, changes of government, and competing priorities [20]. Additionally, the change of government after the peaceful revolution of May 2018 has not affected the NIP [21–22]. Yet, challenges to sustainability remain, including lack of dedicated funding for routine costs, vaccine hesitancy, and procurement inefficiencies.

National officials are striving to make healthcare budgeting more efficient and cover new programmatic costs with streamlined expenditures. At the Workshop, Armenian participants discussed revising and reintroducing the *Public Health Law* to the National Assembly [11]. As mentioned, however, the MOH is now working on a broader health care law with a section on public health. At the Workshop, health officials and parliamentarians also discussed establishing a legal mechanism to use authorized but unspent procurement funds on operational priorities and modifying procurement legislation to improve future negotiating leverage, including multi-year tenders, long-term contracts, and quality instead of price-only criteria.

Armenia's NIP may also benefit from other regulatory approaches to maintain high coverage. National officials are considering transitioning from recommended to mandatory vaccination. However, officials are cognizant that efforts to improve coverage through a compulsory immunization policy could result in negative publicity and cause backlash among the growing number of Armenians refusing vaccination. Before enacting more

Table 2
Legal frameworks for vaccination: Armenia, Georgia, and Moldova.

Criteria ^a	Armenia	Georgia	Moldova
Legal Documents	Government Decree (#10, 2016); Sanitarian norms and rules for epi surveillance and vaccination organization; Law on Medical Assistance and Services to the Population (1996, last amended 2015)	Law on Health Care (1998); Public Health Law (2007); 0157 Decree of the MOH; and annual government orders on NIP	Law on Health Care (1995); Public Health Law (2009); 1113 Government Decree (2016)
Declarative criteria			
Free and universal provision of vaccines by the government for all	Yes	Yes	Yes
Vaccination as a free public good, guaranteed by the state	Yes	Yes	Yes
Specific line in the national budget for immunization program	No	No	No
Compulsory vaccination of all citizens	No (recommended)	Yes (though no mechanism for enforcement)	Yes (school-entry requirements for all vaccines in the national schedule)
Financial criteria			
Required line item in national budget for vaccine purchases	Yes	Yes	Yes
Guaranteed tax exemptions for the importation of vaccines, vaccine-related supplies, and cold chain materials	Vaccines procured from UNICEF SD are tax-exempt; other procurements are not	The Tax Law of Georgia exempts all medicines, including vaccines, from VAT taxes	Vaccines procured from UNICEF are tax-exempt; other procurements are not
Identification of specific procurements mechanism (e.g., UNICEF or WHO-prequalification) to guarantee safe, reliable supply	No	No	No
Procurement law permits multi-year tendering, long-term contracts, and advance payments	No	Yes	No
Operational criteria			
Established regulations on vaccination program to ensure safety and efficacy of vaccines	Yes	Yes	Yes
Required definition of a national immunization schedule	Yes	Yes	Yes
Enforceable sanctions for failing to comply with provisions of law (fines, restricted school entry, etc.)	No	No	School-entry requirements
National Immunization Technical Advisory Group	Yes	Yes	Yes
Opt-out policies	Yes	Yes	Yes
System insulating medical providers from litigation following real or adverse events associated with vaccination	No	No	No

^a Criteria have been adapted from Trumbo SP, Janusz CB, Jauregui B, et al. Vaccination legislation in Latin America and the Caribbean. *J Public Health Policy* 2013;34(1):82–99.

stringent legislation, the Armenian team intends to conduct public hearings and study other country experiences.

4. Country experience: Republic of Georgia

4.1. Context: Health system and national immunization program

Healthcare in Georgia radically changed following independence in 1991, moving from a centralized to a decentralized system. After failed early attempts to reform the health system, Georgia started to privatize healthcare facilities and, in 2013, established universal healthcare (UHC) [23]. Today, private companies provide most medical services, with financing from the government and OOP payments from patients [23,24].

Georgia's National Center for Disease Control and Public Health (NCDC), a component of the MOH, manages its NIP. Immunization services are integrated in primary care services of the UHC program and provided in private facilities [25]. Procurement is centralized, with most vaccines obtained through UNICEF [26]. With UNICEF's assistance, Georgia has strengthened its self-procurement capacity; in 2015, the country obtained hexavalent

vaccine from manufacturers at about one half of the market price [18,19]. Despite strong program performance, health officials report vaccine hesitancy, concerns about disparities in immunization rates, and the need to strengthen vaccine program infrastructure (e.g., improve surveillance systems) and program management (e.g., better monitoring and supervision activities) [25].

Both Parliament and the MOH strongly support immunization. In partnership with Sabin and with support from Gavi, national officials have overseen program financing and performance and revised legislation to promote country ownership. Like Armenia, Georgia is transitioning to program-based budgeting that will allow Parliament's Healthcare Committee to more closely monitor immunization-financing indicators. Funded through the NCDC, the NIP has a separate line in the national budget, and funding increased from \$2.5 million in 2014 to \$7.6 million in 2016 [25].

4.2. Legal framework and challenges in immunization policy

The Georgian *Public Health Law* (2007) requires the government to provide vaccines in the national schedule free of charge. Medical providers, in turn, are obligated to support vaccination [27].

According to the *Public Health Law*, all citizens should be vaccinated with immunizations in the national schedule, but exemption policies are quite liberal, allowing excusals for medical and religious reasons [27]. Recently, the government discussed policy options to increase vaccine uptake, including mandatory policies such as school-entry requirements. However, the MOE has argued that these requirements would decrease school attendance and be counterproductive.

Per the *Public Health Law*, ministerial decrees, and government orders, the country regulates vaccine safety, the immunization schedule, and a NITAG. Market-oriented reforms of the healthcare system have resulted in the liberalization of vaccine-related regulations and taxes. Through its tax laws and *Law on Public Procurement* (2006, last amended in 2014), Georgia facilitates importation and rapid clearance of vaccines through customs and has passed a procurement law that permits multi-year tendering, long-term contracts, and advance payments—all critical elements for effective vaccine procurement [26,28]. New vaccine introduction also requires updating relevant regulations; *Decree 0157* (2015), for example, added hexavalent vaccine to the national schedule.

To strengthen its legal framework, Georgian officials are interested in regulating or incentivizing private healthcare companies to offer higher quality vaccination services and to strengthen support for immunization. Ideas discussed during the Workshop included mandatory vaccinations for healthcare workers, protections for physicians in the event of post-vaccination reactions, and defining the responsibilities of schools in requesting immunization records as part of opt-out policies. Like other Gavi countries, Georgia recognizes the need to better estimate routine program costs and to ensure that funds are locally available and that budgets include the full costs of the NIP and not only vaccine procurement costs. The *Public Health Law* obliges local governments to operate immunization services [27]. Additionally, *Government Declaration #359* (2010) establishes requirements on service provision and accountability for medical providers [29].

4.3. Georgia: Ideas to strengthen program sustainability through legislation

In 2018, Georgia transitioned from Gavi support. Excluding support to introduce HPV vaccine, the NIP expects to finance all vaccine purchases [25]. Though challenges exist—e.g., vaccine hesitancy and rising healthcare expenditures—Georgia's legal framework has embedded medium- and long-term plans to protect immunization from budget cuts and competing priorities. Without external funding, national officials indicate that cost-effectiveness analyses, such as those done in advance of rotavirus and pneumococcal conjugate vaccine (PCV) introduction, will be critical to future decisions on new vaccine introduction [11]. Additionally, Georgia recognizes the need to strengthen its primary care system to ensure integrated services and immunization program sustainability.

At the Workshop, Georgian officials discussed three potential legal mechanisms to increase vaccine uptake: 1) Amending legislation to make the MOH and MOE responsible for implementing age-specific curricula on vaccination in elementary and secondary schools, 2) Providing children with additional vaccination opportunities at schools (possibly enforced via ministerial decree), and 3) Introducing new regulatory approaches to improve coordination between the MOH and private healthcare facilities and to focus on performance-based service delivery. Developing reporting indicators on service quality (e.g., cold chain function), motivating private facilities to meet vaccine uptake goals, and strengthening vaccine demand mechanisms are also under discussion.

5. Country experience: Republic of Moldova

5.1. Context: Health system and national immunization program

Following independence from the Soviet Union in 1991, Moldova transitioned to a market-based economy. Soon thereafter, health services contracted due to an economic depression, leaving patients to cover most of their healthcare costs [30,31]. To address this situation, Moldovan authorities began preparing the legislative basis to reorganize the health system based on Mandatory Health Insurance (MHI). Thus, Parliament approved the *Law on Mandatory Health Insurance* (1998) [32]. However, limited financial resources and lack of political will impeded the immediate implementation of the law, which only came into effect in 2004 following several adjustments to the bill [32].

Due to these reforms, Moldova's health system is now more accessible, with relatively higher rates of insurance coverage (87%) and lower OOPs [30,31]. As part of MHI, the government created a single purchasing agency for health-related goods and services, the National Health Insurance Company (NHIC). The NHIC pools public funds (central government contribution and payroll contributions, paid by employers, employees, and the self-employed) to purchase a standard and comprehensive package of services. For insured citizens, these services include almost all types of healthcare services, including medications and specialized outpatient and inpatient care. All citizens, regardless of insurance status, have access to emergency services, primary care, immunization, and other key public health interventions (e.g., HIV/AIDs and TB treatment).

The former National Center of Public Health (NCPH) (recently reorganized and renamed as National Agency of Public Health), a branch of the MOH, directs Moldova's NIP. The State, NHIC, and external partners provide funding for immunization, with small contributions from other national agencies for supplemental activities. The state budget does not contain a separate line for immunization, but the government has gradually increased funding for vaccine purchases. Moldova also recently passed *Government Decree 1113* (2016), which provides funding for the NIP from 2016 to 2020. In 2017, Moldova transitioned from Gavi support and began fully financing its NIP, excluding costs related to IPV and HPV introduction [33]. Notably, Parliament has regulatory oversight over the healthcare budget, and elected officials and health authorities collaborate closely on immunization.

5.2. Legal framework and challenges in immunization policy

Moldova's *Constitution* (1994) requires the State to provide a basic level of health protection to all citizens and is the foundation for the country's immunization policy [34]. Generally, Moldova has strong declarative and operational provisions for vaccination. In 2009, Parliament passed the *Law on State Surveillance of Public Health* that strengthened the NCPH's ability to monitor communicable diseases and made Moldova one of the few European nations requiring children to receive all vaccines in the national schedule to enroll in kindergarten and schools [35,36]. The MOE opposed the provision, arguing that it violated children's right to education. Ultimately, the Constitutional Court ruled the school-entry requirements to be legal, but many parents and some legislators remain wary of mandatory immunization [37].

Moldova's challenges in immunization policy relate to three main areas. The first is vaccine procurement. Due to its small population, the country has low purchasing power and has paid relatively high vaccine prices. To lower costs in advance of Gavi graduation, Moldova began purchasing routine vaccines through UNICEF, with estimated annual savings of \$250,000. However,

Moldova's *Law 131 on Public Procurement* (2015) restricts advance payments and multi-year procurement contracts, and national officials are now collaborating with UNICEF and other international organizations to address these issues [38].

Legislative changes are also needed to ensure sustainable funding of routine program costs. Though direct costs are known, indirect expenses (e.g., labor) are not fully determined and may be higher than expected. A study of 50 primary care facilities in Moldova estimated the average cost of a fully immunized child to be \$332, with 65% of expenditures for labor [39]. While the government is partially covering routine NIP costs to guarantee the universal right to immunization, additional mechanisms, such as a line in the NHIC's budget for vaccination, are needed for long-term program sustainability.

Finally, national officials indicated that anti-vaccination campaigns and distrust in the system, especially related to vaccine quality, have made parents skeptical of immunization mandates, with some reportedly creating false documents to bypass school-entry requirements. Physicians worry that they will not be protected against legal claims if children experience real or perceived adverse events following vaccination. Parliamentarians have discussed a program that protects medical providers from vaccine-related lawsuits as a potential solution to this problem.

5.3. Moldova: Ideas to strengthen program sustainability through legislation

Despite limited internal resources and freezing of some external financing following a major banking fraud scandal in 2015, Moldova has met Gavi co-financing requirements and assumed full responsibility for its NIP in 2017 [40]. Thanks to *Decree 1113*, the NIP has guaranteed funding through 2020, and national officials believe the country was well prepared for Gavi graduation.

Prior to the Sabin Workshop, Moldova had already strengthened its legal framework for immunization. To procure non-routine vaccines (e.g., influenza), Parliament modified legislation to allow the government to obtain vaccines with good manufacturing practice certification in lieu of WHO prequalification. At the Sabin Workshop, national officials proposed additional policies to bolster vaccination legislation, including a line for cold chain equipment in the NHIC budget and modifying regulations to allow multi-year contracts and advanced payments.

6. Discussion

Despite differences in health systems and immunization policies, the three countries featured here—Armenia, Georgia, and Moldova—face similar challenges in sustaining their health programs independent of donor support. In 2018, Armenia, Georgia, and Moldova will transition from Gavi support and assume ownership of their NIPs. Like many low- or middle-income countries, they have limited negotiating experience and, due to their relatively small markets, limited bargaining power with vaccine manufacturers and may therefore struggle to keep pace with rising prices [41]. Accordingly, legislative efforts in Armenia and Moldova have focused on modifying regulations to optimize procurement (e.g., adding provisions permitting multi-year contracts); Georgia's flexible procurement law may be a model for those countries. Similarly, countries will need to finance routine program costs traditionally covered by external partners, and a variety of solutions to this problem must be considered. In Moldova, legislation may obligate public health insurance agencies, in addition to the MOH, to ensure vaccine-related costs (e.g., the NHIC may cover cold chain expenses). However, greater

coordination between the health and financial sectors is needed, for which reason program-based budgeting may be helpful.

Independence from donor funding has also highlighted the need for improved advocacy and legislative adjustments to increase vaccine uptake. Examples include programmatic enhancements such as using performance indicators and electronic systems to better track data, incorporating immunization-related topics into school curricula, and forming an Eastern European network of parliamentarians to share approaches to support vaccination. Due to competing priorities and funding challenges, parliamentarians also recommended that the economic value of vaccination as an investment in health, not a cost, be stressed continuously.

The immunization landscape has changed significantly since Gavi's creation in 2000. The logistical and financial challenges of the advent of UHC in many countries, the integration of NIPs into complicated and costly health systems, and the emergence of anti-vaccination campaigns pose challenges to sustainability. From a policy perspective, the increasing complexity highlights the need for a greater understanding of existing legal frameworks. While there has not been a European or global evaluation of immunization legislation, a 2013 study in LAC showed that 92% of the Region's population lived in one of 27 of the 44 countries and territories that had passed vaccine legislation. Legal frameworks in LAC guaranteed immunization as a public good (i.e., free provisions vaccines provided by the government) (63%), specified the national schedule (78%), mandated immunization for citizens (96%), and provided specific indications for NIP financing (44%) [5].

Based on the experiences described here and Sabin's review of European legislation, legal frameworks in middle-income countries have changed in important ways. Many European nations, including Armenia, Georgia, and Moldova, consider a stand-alone vaccine law to be impractical either because immunization should be included in larger public health laws or because different agencies associated with NIPs—i.e., those in health, finance, procurement, and even education—must provide their own regulations on vaccination. For this effort to have a greater impact, there is a need for more sophisticated analyses of immunization legislation to serve as a baseline by which the impact of future legislation can be evaluated. The criteria of vaccination legislation proposed by Trumbo et al, though a useful starting point, should be amended to fully account for the ways that countries express their immunization policies. As an example, the criterion of “mandatory immunization” does not provide information on the specific vaccines mandated, the ease and process of obtaining exemptions, and other factors that may influence uptake or contribute to the effectiveness of the provision [5].

Several limitations should be highlighted. Vaccination legislation, by itself, does not guarantee country ownership, sustainable financing, or autonomous NIPs [2,5]. Both the literature and national officials in Armenia, Georgia, and Moldova indicate that ownership depends on financing, political commitment, evidence-based decision making, technical capacity building, and further strengthening NIPs in the context of strengthening UHC and primary care services, among other factors [2–4,9]. In addition, national officials must evaluate the applicability of potential legal provisions based on country political, social, and health factors. Debates about mandatory versus recommended immunization policies, a controversial subject throughout Europe, exemplify the point. Many countries consider mandatory vaccination an effective way of increasing or maintaining high vaccination coverage. However, others lack social and political acceptance for such policies and risk a backlash and potential erosion of existing coverage gains [36]. A final caveat pertains to ideas and policies considered at the 2017 European Regional Workshop on Immunization Legislation organized by Sabin. Because not all relevant legislative and health stakeholders from Armenia, Georgia, and Moldova attended the

meeting, these ideas should not be assumed to represent consensus opinions.

7. Conclusion

The experiences of Armenia, Georgia, and Moldova suggest that there is no standardized approach to vaccination legislation but that legal approaches can promote country ownership in the context of Gavi transition. As the immunization landscape evolves, countries may learn from each other, and a better understanding of the complex legal frameworks that impact vaccination is needed such that countries can tailor legislative provisions to their specific situations.

Declaration of interests

Silas P. Trumbo received a consultancy fee from the Sabin Vaccine Institute to analyze the legal frameworks for vaccination in Armenia, Georgia, and Moldova and to assist with the development of this manuscript. Otherwise, the authors declare they have no conflicts of interest.

Contributors

JLG and DS designed the study. BG oversees all project development and funding. SPT, DS, JLG, and EP helped to design and implement the European Regional Workshop on Immunization Legislation in Tbilisi, Georgia. OD and HG participated in the Sabin Workshop and helped to formulate ideas for strengthening legislation in their countries. DS, EP, and SPT reviewed national documents on immunization and legal documents pertinent to immunization in Armenia, Georgia, and Moldova. HG, OD, and EP validated the mapping of legal documents and, as necessary, conducted searches of legal documents in national databases in the native language of each country. SPT, DS, BGG, and JLG drafted the manuscript, with significant revisions and contributions from all authors. All authors reviewed the manuscript and approved the manuscript for submission. All authors attest they meet the ICMJE criteria for authorship.

Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.vaccine.2018.10.069>.

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