CURATIO INTERNATIONAL FOUNDATION

Final Evaluation of Gavi Support to Albania

FINAL REPORT

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Table of Content

Acknowledgements iii
ABBREVIATIONS iv
Executive Summary 6
1. INTRODUCTION 16
1.1. Country Background 16
1.1.1. Health and Health Care System 16
1.1.2. Expended Program for Immunization 17
2. EVALUATION PURPOSE AND OBJECTIVES 19
2.1. Rationale 19
2.2. Evaluation Objectives 20
2.3. Scope of evaluation 20
3. EVALUATION METHODOLOGY 21
3.1. Evaluation Design 21
3.2. Evaluation Methods 24
3.3. Ethical Issues 25
3.4. Data Analysis 26
3.5. Quality Assurance 26
3.6. Evaluation Limitations 27
4. Evaluation Findings 28
4.1. Pre Gavi period (till 2001) 28
• Program Performance 28
• Collaboration and Partnership 28
• Political Support 28
• Financial Support 28
4.2. Gavi support period (from 2001 to 2014) 30
4.2.1. Overview of Gavi support to Albania 30
4.2.2. Planning 32
4.2.3. Implementation 35
4.3. Post Gavi support (from 2014-to present) 44
4.3.1. Programmatic sustainability 44
4.3.2. Financial sustainability 48
4.3.3. Positive and negative consequences of Gavi support 50
4.3.4. Main factors contributing to the achieved results 50
5. Lessons Learned 53
6. Conclusions 57
7. Recommendations 59
7.1. Recommendations to Gavi 59
7.2. Country Specific Recommendations 59
8. Annexes 61

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ABBREVIATIONS

ADs	Auto-disable syringes
APR	Annual Progress Report
ATAP	Access to Appropriate Pricing
CME	Continuous Medical Education
cMYP	Comprehensive Multi-Year Plan
DHS	Demographic and Health Survey
DPH	Directorate of Public Health
DPHD	District Public Health Directorates
DR	Desk Review
DPT	Diphtheria, Pertussis, Tetanus
EEFO	Earliest-Expiry-First-Out
EF	Evaluation Framework
EHSI	Epidemiology, Hygiene and Sanitary Inspectorate
EPI	Expended Program for Immunization
ET	Evaluation Team
EVM	Effective Vaccine Management
FSP	Financial Sustainability Plan
Gavi	Gavi, the Vaccine Alliance
GDP	Gross Domestic Product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GNI	Gross National Income
GI	Group Interviews
HII	Health Insurance Institute
HPV	Human Papilloma Virus Vaccine
ICC	Inter-agency Coordination Committee
IDI	In-Depth Interviews
IPH	Institute of Public Health
IPV	Inactivated Poliovirus Vaccine
IRC	Independent Review Committee
JRF	WHO-UNICEF Joint Reporting Forms on immunization
INS	Injection Safety Support
MICS	Multiple Indicator Cluster Survey
MR	Measles, Rubella
MMR	Measles, Mumps, Rubella
MoH	Ministry of Health
MoF	Ministry of Finance
MOU	Memorandum Of Understanding
MTEF	Mid-Term Expenditure Framework
NERC	National Ethical Review Committee
NIP	National Immunization Program
NITAG	National Immunization Technical Advisory Group
OECD	Organization for Economic Co-operation and Development
OOP	Out-of-Pocket Payment
OPV	Oral Poliovirus Vaccine

PAHO	Pan American Health Organization
PCV	Pneumococcal Conjugate Vaccine
PHC	Primary Health Care
PHR*plus*	Partners for Health Reform
RFP	Request For Proposal
SSI	Semi Structured Interviews
TWG	Technical Working Group
UNICEF	United Nations Children's Fund
VIG	Vaccine Introduction Grant
VPD	Vaccine Preventable Diseases
VVM	Vaccine Vial Monitor
WB	The World Bank
WHO	World Health Organization

Executive Summary

Introduction

Albania is a lower-middle-income country with a population of 2.89 million and a gross domestic product (GDP) per person of US$ 4,620 in 2014[1]. The transition from the closed communist regime to a liberal economy in Albania started in the early 1990s. In 1997, the country experienced a major political and economic collapse due to the failure of pyramid schemes, leading to a dramatic fall in GDP back down to the 1992 levels[2]. Albania began to recover economically in 1999, but was further affected by the Global Financial Crisis in 2008. Key socioeconomic challenges for Albania going forward include the early resumption of fiscal consolidation and strengthened public expenditure management, regulatory and institutional reform, the reduction of infrastructure deficits, and improving the effectiveness of social protection systems and key health services. Difficulties in the macroeconomic transition have affected the health status and financial protection of the Albanian population against the health care costs. While health outcomes are relatively strong by regional standards, the financial protection of households against high out-of-pocket payments (OOP) is weak, and the quality of care is a significant concern. Macroeconomic shifts, migration, urbanization and reforms within the health care system itself have put pressure on the country's immunization system.

The Institute of Public Health (IPH) coordinates and implements the National Immunization Program (NIP) in Albania. The NIP is responsible for the coordination, guidance, forecasting, planning and distributing of vaccines and injection supplies, as well as for monitoring, maintaining most of the cold chain and organizing immunization services in collaboration with National Health Insurance Fund.

The Directorate of Public Health (DPH) at the Ministry of Health (MoH) oversees public health district administration and the implementation of all public health programs in the country. The Albanian Health Insurance Fund (HIF) is responsible for the health care facilities providing immunization services and employs health care workers, including vaccinators. District Public Health Directorates (DPHD) use their epidemiologic services to provide methodological guidance and to monitor, supervise and assess the immunization services delivered by primary health care and maternity care facilities. They are also responsible for the planning and distribution of vaccines, surveillance of communicable diseases, epidemiological investigation of infectious diseases, outbreak response and other activities related to infectious diseases and immunization at the district level.

Overview of Gavi support to Albania

Gavi support to Albania started in 2001 through its support of the Hepatitis B monovalent (Hep B) vaccine, which ended in 2005. Injection Safety Support (INS) to the country was provided during 2004-2006. In 2005 Albania applied to Gavi for Hib monovalent support. Gavi approved the application in 2007; however, since the Hib mono vaccine was unavailable, the vaccine was not provided to the country. Albania instead requested liquid Pentavalent vaccine in 2008,

[1] World Bank at http://data.worldbank.org/country/albania. Accessed on August 2015

[2] World Bank Country Assistance Evaluation. 2000. http://www.oecd.org/countries/albania/35288421.pdf

which was introduced in 2009. The last shipment of Gavi supported Pentavalent vaccine took place in 2013.

Evaluation Approach and Methodology

This evaluation was commissioned by the Gavi Secretariat in accordance with Gavi the Vaccine Alliance's Evaluation Policy[3] to examine Gavi's support to Albania. Evaluations into the end of Gavi's support were performed in China in 2012[4] and in Bosnia-Herzegovina in 2014[5]. Albania represents the third country in which such an evaluation has been conducted.

The evaluation aimed to (i) assess the sustainability of programs previously supported by Gavi in Albania and their results, and (ii) identify factors contributing to the sustainability of these programs and their achievements.

The evaluation examined both the **financial** and **programmatic** sustainability of the immunization program through in-depth analysis of Albania's experience and program performance before, during, and after the completion of Gavi's time-limited, multi-year support to the country. The evaluation examined the types and quantity of Gavi support, and the plans and steps taken by the Government of Albania to replace Gavi funds after transition.

As requested in the evaluation's Request for Proposals, the evaluation findings were put in the context of evaluation results from the evaluation of Gavi support to Bosnia & Herzegovina (BiH), and the lessons learned and recommendations were derived based on the results of both evaluations.

The evaluation team implemented a mixed methods approach, using both quantitative and qualitative methods, including:

- *A desk review* of key documents pertaining to Gavi support to Albania, including project proposals, Annual Progress Reports (APR), official correspondence between Gavi and Albania governments, Interagency Coordination Committee (ICC) meeting minutes, comprehensive Multi-Year Plans (cMYP) and Financial Sustainability Plans (FSP), strategic health sector documents, policies and regulations.
- *Face-to-Face in-depth interviews* were used to collect qualitative information on a specific set of issues. In-depth interviews were conducted with key national and district level stakeholders and donor organizations/implementing partners. Phone/Skype interviews were conducted with Gavi stakeholders, specifically with the Gavi secretariat, and a former Gavi staff member involved in Albania programs from the beginning of Gavi support.
- *Site visits* were organized in sampled districts and facilities. A total of 7 PHC facilities in Shkodra, Fier and Tirana were visited.
- *Group Interviews (GIs)* were conducted with health providers (both doctors and nurses) to acquire more in depth perspective on specific evaluation questions.

[3] GAVI Alliance evaluation Policy, V2; reviewed by Gavi Evaluation advisory committee on January 2012; approved by Gavi Alliance Board; Effective from July, 2012.
[4] Abt Associates; Evaluation of GAVI-Government of China Hepatitis B vaccination program; December, 2012
[5] Curatio International Foundation; Final evaluation of GAVI Alliance's support to Bosnia and Herzegovina; July, 2014

– *Quantitative data* on immunization coverage rates, government annual budgets and expenditures, spending levels on vaccine procurement and vaccines doses procured was collected either during the site visits or from the latest available surveys.

Evaluation Findings and Conclusions

Before Gavi support (up to 2001)

- **In the early 1990s, the routine immunization program faced unstable government funding, disrupted cold chain equipment, challenges with safe injection practice and waste management, and outbreaks of Vaccine Preventable Diseases (VPDs)**. Albania had to use supplementary immunization activities, such as mass campaigns/catch-up activities, to maintain high vaccination coverage rates, particularly for measles and polio.

- **Immunization was a priority of the Albania health sector, however the immunization program mainly relied on donor support**. UNICEF, along with being a key country partner that rendered technical assistance and capacity building activities, also acted as the main donor for vaccines in this period. Good partnership and effective collaboration with the Government facilitated the quick recovery of Albania's immunization program from the crisis of early nineties and subsequent improvements in program performance.

Gavi Support period (from 2001 to 2014)

- **Programmatic and Financial Sustainability planning were key issues addressed by Gavi, despite the absence of a specific transition plan.** Even without having a transition plan**,** Gavi made important efforts to ensure financial and programmatic sustainability from the beginning of its engagement, through its requirements, communication and mandatory preconditions for initiating Gavi support. The financial and programmatic plans requested by Gavi and elaborated by the country (such as the FSP, detailed injection safety plan, cMYP, Hib vaccine introduction plan) facilitated transition planning from the outset. The financial planning exercise was extremely useful and contributed to a change in the EPI planning practice.

- **The Government committed to a gradual allocation of funds on traditional vaccines by signing an MOU with UNICEF in 2001 and establishing a separate line in the health sector budget for vaccine procurement.** This practice improved the vaccine budget's transparency and accountability and helped to safeguard government budget for vaccine procurement, including Gavi supported vaccines, once Gavi support ended.

- **Provided for almost 13 years since 2001, Gavi support was relevant to the country's needs and important for funding new and underused vaccines and injection safety in Albania**. The Hep B vaccine had already been introduced in Albania in 1995 with the support of the Rotary Club. However, following the country's political and economic collapse in 1997, Albania was unable to fund Hep B vaccinations once the support from Rotary Club ended in 1996. This resulted in a two-year interruption of the Hep B vaccination (1997-1998). While, after a partial economic recovery, the

Government was able to fully finance the cost of vaccines in 1999-2000, public funding for future years was not secured given the continuing economic fragility and the high budget deficit. Moreover, at that time there was no multiyear budget planning (e.g. Medium Term Expenditure Framework) in place to secure the Government's funds for vaccines in advance. Therefore, while it is unclear what would have happened to the sustainability of Hep B vaccination in Albania after the year 2000 without Gavi support, this support still appears to have been timely for Albania in sustaining stable funding for Hep B vaccinations. Gavi's multi-year support may have also helped to free the necessary public funds for the Government of Albania to introduce new vaccines independently (MMR in 2005 and PCV in 2011). Gavi support provided a critical contribution to the implementation of the National Injection Safety Plan. Gavi support to all programs (INS, Hep B, Penta) was based on thorough situation analyses, which were well documented and communicated to the national stakeholders (Ministry of Health and Interagency Coordination Committee members).

- **The coordination mechanism (ICC) established in line with Gavi's request ensured stakeholder coordination and evidence-based decision-making in Albania**. The ICC was instrumental in the coordination, strategic planning, problem solving and monitoring of program implementation. The Institute of Public Health (IPH) played a key role in the ICC's effective functioning. The expert immunization group, which had played the role of the National Immunization Technical Advisory Group (NITAG) since the ICC's inception, was fundamental in preparing evidence about the impact of the introduction of new vaccines. Coordinating meetings were participatory, involving all entities and institutions involved in immunization services as well as Gavi partners and other donors.

- **Collaboration and partnership with in-country partners were effective during Gavi support.** In-country partners (UNICEF, WHO, CDC, USAID, American Red Cross) played a crucial role both through directly involvement in the coordination of immunization activities and in direct support to the Program**.** UNICEF's contributions were extremely important to the long-term sustainability of the program**.** The practice of successfully taking over the financing for traditional vaccines previously funded by UNICEF helped the Government to properly plan and fulfill its commitment to fully fund Hep B/pentavalent vaccines once Gavi support ended.

- **Gavi's monitoring country performance during its support was evident and contributed to the improvements in the national immunization program.** Gavi's comments on discrepancies in factual data played a role in improving inconsistencies in demographic information, which was one of the big challenges in Albania, and facilitated the redesign of registration and reporting forms.

- **Financial arrangements for budget planning**, **negotiation and procurement** of vaccines were highly effective. The centralized model, combined with the use of UNICEF's procurement mechanism for purchasing of vaccines, allowed for the efficient use of Government funds.

- **Several programmatic adaptations were made during the Gavi support period.** As noted above, the Government introduced new vaccines into the national immunization

calendar with its own funds. It may be argued that Gavi support in financing Hep B and then pentavalent vaccine have freed up the public funds and helped the country to introduce MMR (2005) and IPV (2011) during the Gavi support period (2005). To reduce vaccine wastage rates, the EPI changed vaccine presentations from multiple to one or two dose vials. At the same time, in small districts with low numbers of infants, the NIP increased vaccine wastage in order to achieve high vaccination coverage.

- **Extensive trainings of healthcare workers** on new vaccines and injection safety were commenced to address key bottlenecks in the immunization program. The trainings were conducted prior to the introduction of vaccines, and were mostly financed through Gavi's Vaccine Introduction Grants (VIG).

Post Gavi period (2014-present)

- **The coordination mechanism established at the time of Gavi support continues to operate, although the frequency of the meetings has decreased.** During the Gavi support period, four ICC meeting were conducted, while since Gavi support ended only one or two coordinating meetings per year have been carried out. The expert immunization group formally assumed the title of NITAG in 2015 and continues to function effectively, preparing justifications and different scenarios for new vaccine introduction. Just recently, the Ministry of Health issued orders that clearly define the role of ICC and NITAG, their new composition and responsibilities. The ministerial order also outlines that the ICC should meet four times per year.

- **All Gavi supported activities have been continued**. The Hep B and pentavalent vaccines and Auto-Disable (AD) syringes are fully financed by the Government, and are safeguarded in the MoH budget. Albania did not experience a vaccine stock-out after Gavi support ended, unlike Bosnia & Herzegovina, where intermittent vaccine stock outs and shortages of medical supplies were observed.

- **Stable and high immunization coverage rates (> 95%) for all antigens included in the national immunization schedule have been sustained as of today at the national and district levels.** Only three districts out of 36 districts have relatively low coverage rates (92%-94%). This is explained by the high prevalence of the hard-to-reach population (mobile Roma population) in those districts. Albania does not have strong anti-vaccine movement in the country. There is trust in immunization programs and health professionals in general, but rumors are increasing and if not addressed timely, may present a challenge in future.

- **Achievements in safe injection have been sustained in Albania.** AD syringes are used throughout the country and safety boxes are available in all facilities. This is contrary to BiH, where injection safety practices were discontinued and irregularities in unsafe waste management practices were observed after Gavi support ended.

- **After Gavi support ended, Albania has continued to introduce new vaccines.** As mentioned above, in 2005 and 2011 MMR and PCV vaccines were introduced using Government funds. In 2014 Albania introduced the IPV vaccine without donor support. IPV replaced the OPV vaccine in the national immunization calendar. However, the planned Rota vaccine introduction was delayed until 2017 due to the lack of "sufficient

evidence" on its cost-effectiveness for the country and the absence of necessary funds. The introduction of new vaccines in post-Gavi period did not happen in Bosnia & Herzegovina, most likely due to weakening national coordination structures, the erosion of multiyear planning, the decentralization of vaccine procurement, abandonment of the UNICEF procurement mechanism and the lack of financial resources for the national immunization programs after Gavi support ended.

- **The budget planning mechanism used for vaccine procurement during the Gavi support period has been maintained and institutionalized**. A separate budget line in the MoH budget secures the budget for vaccine procurement and ensures financial sustainability for vaccines. The financial resources required for vaccines and injection supplies are also included in the Government's Mid-Term Expenditure Framework (MTEF). Although the stakeholders recognized FSP and cMYP to be very useful instruments, they are not fully utilized due to their "complexity". This may be related to underutilization of these tools and the fact that they were not adapted for institutionalization in the NIP planning process.

- **The use of the UNICEF procurement mechanism for purchasing all vaccines in the immunization schedule has been sustained**. This is a firm decision of the Government of Albania and has not been revisited. Albania, due to its small market, does not experience strong lobbying from drug-makers. This mechanism allows Albania to access favorable vaccine prices, albeit ones that are still three or four times higher than Gavi prices. Maintenance of vaccine supply through UNICEF SD may also allow Albania to access even lower prices in future, if Gavi will be successful in implementing all the recommendations in the Gavi's policy paper on support to Access to Appropriate Pricing (ATAP) that envision provision of access to price "as close to the Gavi price as possible" for non-Gavi lower-middle-income countries, which included Albania[6].

- **Other (non-vaccine) immunization related activities,** such as operational expenses for travel for vaccine collection and distribution from central to district levels, are fully funded by the government. However, sometimes expenses related to vaccine collection and distribution to health facilities are not reimbursed to health care providers. The government funds cold chain expenses, but there is no proper strategic approach to and funding for cold chain maintenance.

- **All the evidence at hand lead us to conclude that the achievements during the Gavi support period will be sustained, and improvements in the national immunization program in Albania will continue**. Both financing for immunization and programmatic management of immunization have become stronger since the initiation of Gavi support, and are likely to progress further as Gavi supported activities are fully integrated in the national policy and budget. However, Albania may need further support in improving the generation of evidence and long-term financial forecasting for the introduction of new vaccines (e.g. Rota).

[6] Gavi Support for Access to Appropriate Pricing (ATAP) for Gavi Graduated Countries. Report to the Board. 10-11 June 2015

Lessons Learned

The strong and high-level political support to immunization that existed in the pre-Gavi period, and was further demonstrated by the Government of Albania during and after Gavi support, was a critical factor in the overall success of the immunization program in the country. Strong and well-equipped National Immunization Program coordination was another critical factor that contributed to political support, and proved crucial in the continuation of activities. This underlines the importance of building strong and high level political support for national immunization programs through continuous engagement by Gavi and its partners in advocacy and policy dialogue with all relevant stakeholders at a national (and, if required, subnational) level from the very beginning of Gavi's program in a country, as it will most likely enhance program outcomes and significantly improve the sustainability prospects of Gavi's time-limited support.

Gavi support may play an important role even in countries with high political commitments to vaccination and strong immunization systems like Albania. It is likely that without Gavi support the country would have experienced problems in financing Hep B vaccination in the aftermath of the economic and political crisis (1997-2000), and may have had difficulties and delays in the independent introduction of new vaccines (MMR, PCV and IPV) at a later period, without the public funds "freed" as a result of continuing Gavi support to the Hep B and pentavalent vaccines. The support of Gavi and its partners was critical in (a) introducing long term planning practices for the immunization program; (b) building health providers' capacity in the proper use of the pentavalent vaccine; and (c) implementing the sustained injection safety policy nationwide.

Even in the absence of a specific transition plan, Gavi's requirements for eligible countries (the existence of a national coordination mechanism, a costed multi-year national immunization program) and its effective and continuous engagement throughout the implementation period have contributed to the improvement of the planning and implementation framework for the national immunization programs both in Albania and in BiH. The successful transition and sustainability of Gavi-supported programs require (a) a sustainable national coordination mechanism as observed in Albania, or a coordinated immunization planning mechanism in decentralized setting such as BiH; and (b) a strong national level agency responsible for the implementation, monitoring and expenditure tracking of the immunization program, as in Albania. Overall, the Albania case shows that a country can still perform well in terms of sustaining the immunization program without a special transition plan, if these key elements are in place. The BiH case indicates that transition without any transition plan may be challenging without sustaining the functional national coordination mechanism and a centralized planning for immunization programs.

The transition from Gavi support to full government financing of Gavi-supported vaccines occurred smoothly in both countries in the absence of a Gavi co-financing policy. This Gavi policy has a dual objective of contributing to the country ownership of vaccine financing and ensuring in-country financial sustainability. However, better financial sustainability prospects

for the immunization program were achieved in Albania compared to BiH[7], which may be related to the successful experience of similar co-financing arrangements that the Government of Albania had with UNICEF for routine vaccines**.** This arrangement, much like what is expected from Gavi's co-financing policy, has contributed to increased country ownership and financial sustainability by integrating immunization financing in the national budget process prior to Gavi's disengagement. The absence of a transition (graduation) policy and the transition planning opportunity has affected both countries, but to varying degrees**.**

The regulatory and logistical challenges in procurement and tendering for the purchase of safe, effective vaccine products at the lowest possible cost, are typical for many Gavi phase 2 countries[8]. If these challenges are not addressed during the early stages of transition, they may pose serious problems for national immunization programs, as demonstrated by the BiH case, where the inability to maintain centralized procurement mechanism and regulatory barriers in using UNICEF SD for vaccine procurement contributed to significantly higher vaccine prices compared to Albania and intermittent vaccine stock-outs.

Maintaining the use of UNICEF's procurement mechanism allows Albania to spend public funds more efficiently compared to BiH, and to have two to three times lower prices through the UNICEF SD. The experience of Albania and BiH shows that the countries that are currently transitioning to phase 3 may have difficulties in matching these prices through self-procurement or even through UNICEF's procurement mechanism after Gavi's disengagement. This realization prompted Gavi to seek commitments from manufacturers to provide Gavi prices to phase 3 countries, as stipulated in the revised Gavi Eligibility and Transition Policy[9] that came into effect from July 2015. Furthermore, Gavi has already negotiated continued low prices for phase 3 countries for the pentavalent, pneumococcal and rotavirus vaccines[10]. However, this arrangement will not apply to Albania, BiH, China or Turkmenistan, placing them in a disadvantageous position compared to the current phase 3 countries with similar income levels, simply because they became ineligible for Gavi support before the introduction of Gavi's Eligibility and Graduation policy. Our evaluation findings show that Albania and BiH are experiencing problems with rising vaccine prices and subsequent difficulties in the introduction of the new vaccines, and they may have benefited from access to Gavi prices for example for vaccines against Rotavirus and Human Papilloma Virus (HPV).

Both Albania and BiH experience problems in accounting and planning the full costs of the national immunization program. Use of the cMYP tool is not fully institutionalized in these countries. Both countries may benefit from the technical assistance initiated by Gavi through its partners (WHO) to address this issue and resolve financial sustainability problems.

The cases of Albania and BiH have showed that once Gavi support ends, the gains made from outside financial support and technical assistance from Gavi and its partners could suffer unless local advocacy efforts are intensified and national technical skills are strengthened. At present,

[7] Final Evaluation of GAVI Alliance's Support to Bosnia and Herzegovina. Curatio International Foundation. 2014

[8] Shen et al; The future of routine immunization in the developing world: challenges and opportunities. Glob Health Sci Pract December 1, 2014 vol. 2 no. 4 p. 381-394

[9] Gavi, the Vaccine Alliance Eligibility and Transition Policy, V2; Approved by Gavi Alliance Board, effective from July 2015

[10] Saxenian et al.; Overcoming challenges to sustainable immunization financing: early experiences from GAVI graduating countries. Health Policy Plan; February 8, 2014

most immunization-related technical support from international partner institutions is focused on Gavi countries, with little support for graduated and other middle-income countries that are ineligible for Gavi support, but still need such technical assistance and support.

Recommendations

Recommendations for Gavi

- The Gavi Secretariat independently and through its partners (UNICEF, WHO, the WB, CDC) needs to build strong, high- level political support for national immunization programs at the earliest stage of Gavi engagement with eligible countries. This can be achieved through advocacy and policy dialogue with all relevant stakeholders at national (and if required subnational) levels, and will most likely enhance program outcomes and significantly improve the sustainability prospects of Gavi's time-limited support.

- For successful transition and sustainability of Gavi-supported programs, transition planning should explicitly encompass support to the establishment of (a) a functional and sustainable national coordination mechanism; (b) a coordinated (if not centralized) immunization planning mechanism for countries with decentralized systems; (c) and a strong national level agency responsible for implementation, monitoring and expenditure tracking of the immunization program. These requirements need to be included in transition planning assessments and capacity building efforts initiated at the earliest possible stages of the transition.

- Gavi should try to provide Gavi prices for a time-limited period not only to "phase 3" countries, but also to other lower-middle-income countries like Albania and BiH that are no longer eligible or were never eligible for Gavi support, yet experience financial difficulties in introducing new and expensive vaccines, as recommended in the Gavi's ATAP policy paper for Gavi Phase 3 countries. Alternatively, or in parallel, Gavi and its partners should help small and medium sized countries to explore possibilities to establish innovative mechanisms, either through direct UNICEF agreements or other ways – such as the regional pooled mechanisms for vaccine procurement – to ensure more affordable prices for new vaccines, as articulated in WHO's SAGE Task Force Recommendations for Middle Income Country (MIC) Strategy[11].

- Gavi the Vaccine Alliance, WHO and UNICEF should consider refocusing their technical assistance efforts on unmet needs for immunization programs in phase 3 and other lower-middle-income countries that experience problems in the performance of their immunization programme. For example, both Albania and BiH may benefit from technical assistance aimed at strengthening national capacity in generating evidence for decision-making through analysis of costing and financing of routine immunization and new vaccine introduction (including the adaptation and institutionalization of cMYP tool), in the prevention of further growth in vaccine hesitancy and in the promotion of

[11] Sustainable Access to Vaccines in Middle-Income Countries (MICs): A Shared Partner Strategy. Report of the WHO-Convened MIC Task Force. March 2015

vaccine community demand. The experiences of the Pan American Health Organization (PAHO) and other international partners[12] in providing such support to non-Gavi MICs should be closely studied and, if possible, replicated in other regions, including Central and Eastern Europe.

Recommendations for Albania

- Although Albania has established a well-functioning procurement practice with UNICEF, the country can explore the possibility of new vaccine procurement through a regional pooling mechanism. Other small CEE/CIS countries, or Balkan neighbors such as BiH, Montenegro, Serbia, face similar problems. While developing a regional procurement mechanism may be a challenging task, Albania should regularly raise this issue with countries in the region. WHO/UNICEF could be active players in facilitating such discussions.
- In addition to vaccine budgets, Albania has to plan and mobilize adequate funding for recurrent costs such as cold chain maintenance, demand creation and community mobilization activities, to ensure the long-term sustainability of the immunization program. The full utilization and institutionalization of the adapted cMYP costing tool for planning purposes, may help to address this problem. The Government can apply to international partners (e.g. WHO) or mobilize internal resources to institutionalize the cMYP.

[12] Ibid

1. INTRODUCTION

1.1. Country Background

Albania is a lower-middle-income country with a population of 2.89 million and a gross domestic product (GDP) per person of US$ 4,620 in 2014[13]. The transition from the closed communist regime to a liberal economy in Albania started in the early 1990s. The country pursued major structural and economic reforms and pushed ahead with the establishment of democratic institutions. The country made significant progress up to the year 1997, when a major political and economic upheaval due to the failure of pyramid schemes led to a dramatic fall in GDP and severe inflation. Economic recovery started in 1999. Before the Global Financial Crisis in 2008, Albania was one of the fastest-growing economies in Europe, enjoying average annual real growth rates of 6%, accompanied by rapid reductions in poverty. However, after 2008 the average growth halved, further decreasing to 1.9% in 2014, while macroeconomic imbalances in the public and external sectors emerged. The pace of growth was also mirrored in poverty and unemployment rates: between 2002 and 2008, poverty in the country fell by half (to about 12.4%) but in 2012 it increased again to 14.3%.[14] Unemployment increased from 12.5% in 2008 to 16.9% in 2013, with youth unemployment reaching 26.9%. The economic structure has shifted from agriculture and industry to services and construction. Key socioeconomic challenges for Albania currently include the early resumption of fiscal consolidation and strengthened public expenditure management, regulatory and institutional reform, the reduction of infrastructure deficits, and improvement in the effectiveness of social protection systems and key health services.

1.1.1. Health and Health Care System

The difficulties of the macroeconomic transition have affected both the health status and financial protection of the Albanian population against health care costs. While health outcomes are relatively strong by regional standards, the financial protection of households against high out-of-pocket payments (OOP) is weak, and quality of care is a significant concern. Life expectancy at birth in Albania reached 74 years by 2012[15], which compares favorably with other countries in the region. Child health indicators suggest greater room for improvement. According to the 2008 Demographic and Health Survey (DHS), infant and neonatal mortality rates were 18 and 11 per 1,000 live births respectively, both of which are higher than comparable statistics for other countries in South-Eastern Europe, with steady improvements during the 1990s appearing to slow down more recently. Rates of ante and postnatal care are high, and maternal mortality is only slightly higher than the ECA regional average (21 versus 18 per 100,000 live births)[16]. Albania spends 6% of GDP on health care, 43% of which comes from the public sector. Public spending on health was only 2.6 percent of GDP in 2013, the lowest among countries in the region, equivalent only to Romania[17]. Out of pocket payments (OOP) are among the highest in the region, accounting for 55% of total expenditures on health. Albania

[13] World Bank at http://data.worldbank.org/country/albania. Accessed on August 2015
[14] Ibid
[15] WHO Country Profile at http://www.who.int/gho/countries/alb.pdf?ua=1 accessed on August 14, 2015
[16] World Bank Gender Statistics, 2013
[17] WHO Country Profile at http://www.who.int/gho/countries/alb.pdf?ua=1 accessed on August 14, 2015

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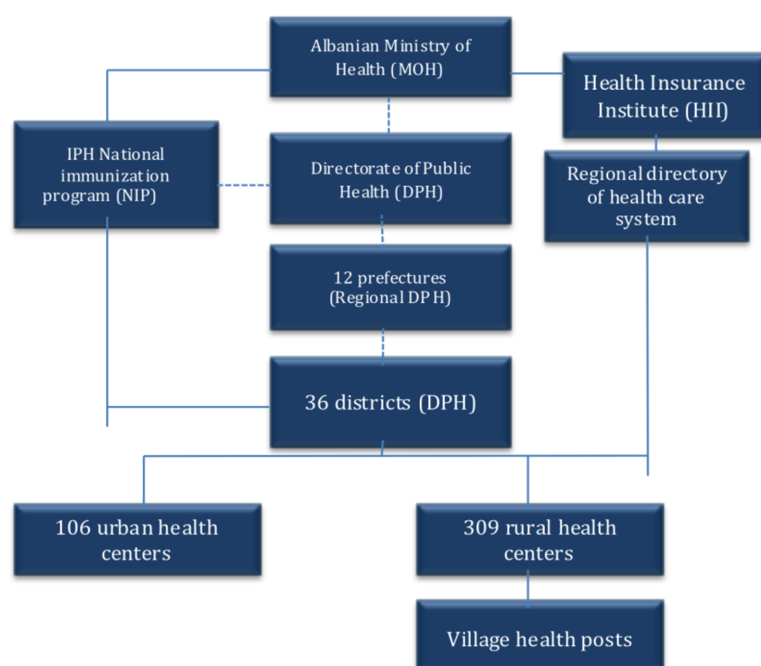
has one of the highest rates of catastrophic health expenditure in the region: 17% of Albanian households experienced catastrophic health expenditures (exceeding 10% of their incomes) in 2013[18]. In 2012, up to 6% of households were pushed into poverty as a result of health spending. High OOP expenditures and limited financial protection are due to several factors: only about 61% of the population (and half of the poorest quintile) is covered by social health insurance; the low quality of primary and secondary care in public settings leads many patients to seek care in tertiary hospitals or the private sector; drug prices are high, as are co-payments for drugs by the insured; drug shortages in public facilities often result in patients having to purchase from private pharmacies; and unofficial payments remain common (10% of total OOP), particularly in public hospitals[19]. The quality of medical care is highly variable across different providers, and contributes to sub-optimal health outcomes. The government, with support from international development partners (e.g. the World Bank), has initiated health reforms to address these gaps. However, improvements to Primary Health Care (PHC) service quality, hospital management and governance and health financing reform at the hospital level, were considered modest, while OOP expenditures for the poor increased. Further efforts are required to address the unfinished agenda in the health sector of Albania. Macroeconomic shifts, migration, urbanization and reforms within the health care system itself have put pressure on the country's immunization system[20].

1.1.2. Expended Program for Immunization

The Institute of Public Health (IPH) implements the National Immunization Program (NIP) in Albania. The NIP manages immunization services nationwide and is responsible for the forecasting, planning and distributing of vaccines and injection supplies, maintaining most of the cold chain and organizing supplementary immunizations.

Figure 1: Organizational Structure of the immunization System in Albania



The Directorate of Public Health (DPH) at the Ministry of Health (MoH) oversees public health district administration and the implementation of all public health programs in the country.

The Albanian Health Insurance Fund (HIF) is responsible for health care facilities and employs health care workers, including vaccinators.

[18] World Bank Project Appraisal Document. 2015
[19] Ibid
[20] PATH, WHO, OPTIMIZE Albania report, 2013

District Public Health Directorates (DPHD) with their epidemiologic services provide methodological guidance, monitoring, supervision and assessment of the immunization services delivered by primary health care and maternity care facilities. They are also responsible for the planning and distribution of vaccines in their district, the surveillance of communicable diseases, epidemiological investigation of infectious diseases, outbreak response, and other activities related to infectious diseases at the district level.

Primary health care centers offer immunization services at the point of care. Vaccination is provided through a wide network of 2,282 baby and child services in urban health centers (including maternity hospitals) and in health posts in rural areas. Consultant pediatricians and family doctors are responsible for immunization services in urban and rural areas respectively.

An ongoing health sector reform process in Albania has led to the consolidation of the 36-district administrative system into 12 prefecture (regional) administrations.

2. EVALUATION PURPOSE AND OBJECTIVES

2.1. Rationale

In 2000-2006, all countries with less than or equal to US$1,000 Gross National Income (GNI) per capita (based on 1998 World Bank data) were eligible to apply for Gavi support. 74 countries were initially eligible for Gavi support. From 2007 to 2010, country eligibility was based on World Bank GNI per capita data for 2003. The eligibility threshold was maintained at the initial level of US$ 1,000. The updated GNI data meant that four countries (Albania, China, Bosnia & Herzegovina, and Turkmenistan) surpassed the threshold, while another one (Kiribati) dropped below it. At this time, they became ineligible to apply for new support, although Gavi continued to meet any existing multi-year commitments. At that time there were no formal or explicit procedures to guide countries to transition from eligibility to ineligibility. Country co-financing came into effect in 2007. However, Gavi's Co-Financing Policy[21], which entered into force in 2008, was not explicitly linked to transition from Gavi support.

The paper presented to the Gavi Alliance Board in November 2009 on graduation/transition from Gavi support noted three main difficulties for countries posed by the absence of transition procedures: i) uncertainty over when eligibility may be updated and what graduation would entail, making planning for graduation difficult, if not possible; ii) the abrupt end of Gavi support; and iii) the considerably higher and more unpredictable prices graduating countries face for some vaccines, particularly newer vaccines.

In 2009 the Gavi board approved a new eligibility policy with GNI per capita threshold of US$1,500, which came into effect in January 2011.

The Graduation Policy that was approved in 2009 and entered into force in January 2011[22] eliminated many uncertainties over eligibility and removed, or at least mitigated, difficulties in planning for graduation. This has enabled the countries to prepare for the completion of Gavi support and make arrangements for covering the higher costs of immunization programs (e.g. due to expensiveness of vaccines, particularly newer ones). With this Graduation Policy at hand, countries in the graduation process become ineligible to apply for new support, although they were still able to obtain Gavi support through existing multi-year commitments[23]. Thus the Graduation Policy, along with the Co-Financing Policy, has cushioned the transition from Gavi support to self-financing.

In June 2015, the Gavi board approved a new Gavi Eligibility and Transition Policy[24] (ETP). The new policy sets out the criteria, processes and procedures that determine which countries are eligible and when to apply for and receive different forms of Gavi support as they transition along a continuum of economic development to the point that all Gavi support ends. This policy also defines three groups of countries and transition procedures: a "Phase 1 Country" is Gavi eligible country whose GNI per capita is above the low-income country threshold, and whose

[21] GAVI Alliance Evaluation Policy V.1, effective from June 2008.
[22] GAVI Alliance graduation policy; Version 1.0, November 18, effective from January, 2011
[23] Final Notes, GAVI Alliance Board Meeting, 17-18 November 2009, http://www.gavialliance.org/about/governance/gavi-board/minutes/2009/
[24] Ibid[9]

average GNI per capita of the previous three years is equal to or below the eligibility threshold. A "Phase 2 Country" is one whose three-year average GNI per capita is above the eligibility threshold and for whom Gavi support is decreasing, in accordance with the transition procedures. A "Phase 3 Country" no longer receives Gavi support and is fully financing Gavi vaccines itself, with access to UNICEF tenders for vaccines issued on behalf of Gavi countries for a time-limited period[25]. The policy has been effective since 1 July 2015.

As mentioned above, Albania has surpassed the Gavi eligibility threshold and became an ineligible country before Gavi's transition policy came into effect. Albania did not experience a transition phase similar to current Gavi phase II countries. Therefore, it was crucial to evaluate how Albania managed the transition away from Gavi's support and what the impact was of this transition on the sustainability of the national immunization program. This evaluation provides additional evidence that will guide other countries currently transitioning from Gavi support.

2.2. Evaluation Objectives

This evaluation was commissioned by the Gavi Secretariat in order to conduct a final evaluation of Gavi's support to Albania. Evaluations into the end of Gavi's support were performed in China in 2012[26] and in Bosnia-Herzegovina in 2014[27]. Albania represents the third transitioned country in which such an evaluation has been conducted.

The evaluation aimed to (i) assess the sustainability of programs previously supported by Gavi in Albania and their results; and (ii) identify factors contributing to the sustainability of these programs and their achievements.

2.3. Scope of evaluation

The evaluation examined both the **financial** and **programmatic** sustainability of immunization program through in-depth analysis of Albania's experience and program performance before, during, and after the completion of Gavi's time-limited, multi-year support to the country. The evaluation examined the types and quantity of Gavi support and the plans and steps taken by the Government of Albania to replace Gavi funds after transition.

[25] Gavi Eligibility and Transition Policy; version 2.0; June, 2015;
[26] Abt Associates; Evaluation of GAVI-Government of China Hepatitis B vaccination program; December, 2012
[27] Curatio International Foundation; Final evaluation of GAVI Alliance's support to Bosnia and Herzegovina; July, 2014

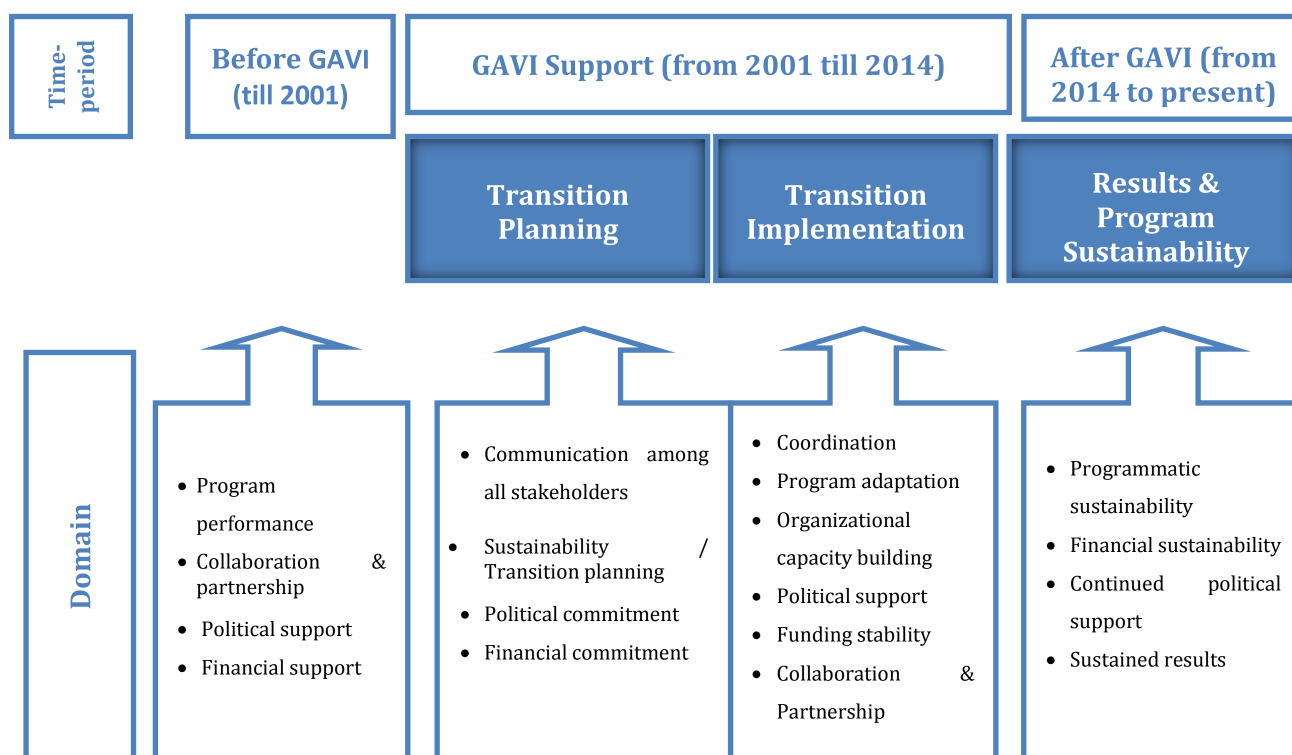
3. EVALUATION METHODOLOGY

3.1. Evaluation Design

The overall evaluation design is a holistic retrospective single case study. The evaluation team used mixed method approach, which combines the qualitative and quantitative components described later in the report, to achieve the evaluation objectives and to respond to the specific evaluation questions as specified in the Request for Proposals (RFP) [28] for this evaluation.

As stated in the RFP, the Gavi support to Albania has been evaluated along three time-periods: pre-Gavi support, period of Gavi support (planning and implementation) and post-Gavi support (results & program sustainability). The overall evaluation framework is presented in Figure 2.

Figure 2: Evaluation Framework



[28] Request for proposal (RFP)-FEGSA28052015, Final Evaluation of Gavi support to Albania

The Pre-Gavi period (up to 2001) was evaluated by looking at the a) immunization program performance; b) collaboration & partnership; and c) political and financial support.

Program performance was measured by the coverage rates of traditional vaccines such as DPT-3 under 1 year and Measles-1 under 2 years.

Collaboration & Partnership was evaluated by looking at the donor landscape and support to immunization related activities prior to Gavi, such as vaccine supply, health management information system (HMIS), disease surveillance, cold chain and injection safety.

Political and Financial support was measured by looking at to what extent the Immunization Program was prioritized in the policy documents, and to what extent the government fulfilled its commitment to the program.

The Gavi support period (2001 – 2014) was evaluated via two dimensions: transition planning and the transition implementation process.

Transition planning was assessed by investigating whether: i) stakeholders were informed and cognizant of the implications of the completion of Gavi's time-limited support; ii) transition (sustainability) plan was developed by the country and was integrated into national health system planning; iii) adequate political and financial commitments were made.

Transition implementation was evaluated by looking at to what extent: a) the transition process was coordinated; b) the activities were implemented according to the transition (sustainability) plan to ensure the sustainability of Gavi support; and c) the transition implementation was efficient and effective.

The efficiency of transition implementation was evaluated by assessing if procured vaccines & supplies were achieved in a cost efficient manner. ***The effectiveness*** of transition implementation was measured by examining whether the planned key objectives/targets were achieved and by evaluating the major factors that influenced the achievement or non-achievement of the objectives.

The Post-Gavi period (2014 – present) was evaluated by examining the political support, funding stability, the functionality of systems-structures (ICC, NITAG), the continuity of Gavi supported programs, the sustainability of the results achieved during the Gavi support period and their impact.

Programmatic sustainability was assessed by using the WHO's health systems building blocks framework[29]:

- Governance and leadership - institutional arrangements, enabling legal environment, regulatory system, evidence based policy development and planning for immunization programs and the degree of their integration into general health care governance; the accountability structures and engagement with the community and media, including the role of media in covering the transition and graduation process; ownership and level of engagement of various stakeholders; and community acceptability of immunization measures.

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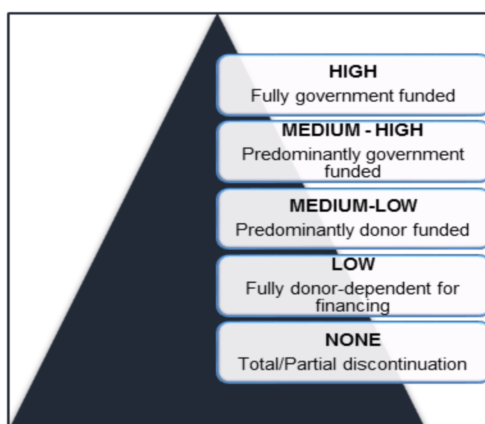
[29] The WHO Health Systems Framework; http://www.wpro.who.int/health_services/health_systems_framework/en/

- Service delivery - analyzing i) access to services, or whether the services are directly and permanently accessible with no undue barriers of cost, language, culture, or geography; ii) coverage, or whether delivery is designed so that all in a defined target population are covered; iii) whether services are of high quality, (i.e. they are effective, safe, centered on the patient's needs and given in a timely fashion); iv) whether the local area health service networks are actively coordinated; and finally v) whether services are well managed so as to achieve the core elements described above with a minimum wastage of resources. Managers are allocated the necessary authority to achieve the planned objectives and are held accountable for overall performance and results.
- Human resources – examining whether an adequate number of skilled health are workforce available and motivated to deliver quality services;
- Availability of vaccines and consumables – evaluating procurement, supply management and logistical practices.
- Information system – assessing immunization information and surveillance system operations, data quality, analysis and data utilization for policy/management capabilities.

Financial sustainability takes into account the concept of self-sufficiency and is defined "*as the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunization performance*".[30] Sustainability is further broken down into five levels, which are described in Figure 3 below. This categorization incorporates the concept of self-sufficiency and differentiates between levels of government and donor support. To assess the relative sustainability, the variable that measures financial sustainability at five levels is created as shown in Figure 3 below.

Figure 3: Levels of Financial Sustainability[31]



To construct this variable, the data were collected on the sources of funding used to procure vaccines, syringes and safety boxes in each year after Gavi support ended. The evaluation team relied predominantly on the EPI manager's reports, but also verified their responses in interviews with MoH, UNICEF, WHO as well as other stakeholders.

The team analyzed the factors associated with the level of financial sustainability across all the domains to determine which factors were most influential in achieving certain level of financial sustainability.

The evaluation also explores the ***intended and unintended effects*** of Gavi support on country health systems. This includes documenting the positive implications and challenges involved in introducing or broadening the use of new vaccines and injection safety practices, for example the effect Gavi support had in achieving financial sustainability for overall immunization programs and not just for vaccines supported by Gavi.

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[30] Gavi Co-financing policy, Version No 2.0. June 2015
[31] Source: Final Evaluation of Gavi Support to Bosnia & Herzegovina. 2014

The evaluation matrix used for this evaluation is presented in Annex 1

3.2. Evaluation Methods

The study team used a mixed methods approach to ensure the comprehensiveness and validity of the data obtained. These methods included: 1) document review; 2) qualitative research methods: face-to-face in-depth interviews with the key national, district and international stakeholders; 3) group interviews with health providers (physicians and nurses); and 4) secondary quantitative data analysis.

Document review

A review of existing documents was a major part of the evaluation. The desk review was undertaken with the help of NVivo® software. The evaluation team consulted with the Gavi secretariat and in-country stakeholders and obtained a comprehensive list of the relevant documents. Annex 3 lists all the documents reviewed. The list was augmented during site visits, where the evaluation team collected additional relevant documents. The data collected through the review of the documents informed: i) key stakeholder mapping; ii) the design of the evaluation framework and evaluation tools; and also iii) allowed for the identification of information gaps and any additional documents/research/reports that needed to be collected during the data collection phase.

In-depth interviews

Face-to-face in-depth interviews were used to collect qualitative information on a specific set of issues. In-depth interviews were conducted with the key national and district level stakeholders and donor organizations/implementing partners who were closely involved in the design of Gavi supported programs, who were responsible for Gavi supported program management, coordination and/or implementation, and who were knowledgeable about programs' financial management. See Annex 4 List of Interviewed Stakeholders. In-depth interviews were conducted using semi-structured interview guides with questions tailored to the specific individuals interviewed (see Annex 6 In-Depth Interview Guide).

Phone/Skype interviews were conducted with Gavi stakeholders, specifically with the Gavi secretariat, and a former Gavi staff member involved in the Albania programs from the beginning of Gavi support. Interviews conducted with the key stakeholders were an important source of evidence for many of the evaluation questions. The objectives were twofold: i) to solicit stakeholders' views on the key evaluation questions; and ii) to gather data and additional evidence to supports analysis.

Site Visits

Site visits were organized in sampled districts and facilities. Initially, the Evaluation Team intended to select the districts based on immunization coverage rates. However, the immunization statistics obtained during the preparatory stage demonstrated stable, high coverage rates (>92%) in all districts. Therefore, the districts were selected to capture the geographical diversity of the country and the existence of "hard-to-reach" population. These included one district in the North (Shkodra), one district in the South (Fier) inhabited by the Roma population, and the Tirana district. Health care facilities in each sampled district were selected randomly. Three health care facilities were sampled in Tirana (one rural and two urban), and two facilities (one urban and one rural) in Shkodra and Fier. In total, 7 PHC facilities were visited.

Group Interviews

Group Interviews (GIs) were conducted with health providers to acquire more in depth perspective on specific evaluation questions. GIs were organized in each sampled district. The GIs were conducted by two people: an international consultant and a local consultant who provided interpreter services during the discussion.

GIs with service providers included both doctors and nurses. The purpose of the GIs with providers was to evaluate the perspectives of doctor and nurses on the performance of the immunization program, existing challenges and achievements. The evaluation team conducted one GI in each selected site; in total, 7 GIs were carried out using the **Group Interview Guides in** Annex **7.** GIs with health providers were conducted without presence of their supervisors to avoid biased responses.

GIs with beneficiaries were not possible due to the absence of National Ethical Review Committee (NERC) clearance. Since the old NERC was dissolved in spring 2015 and a new committee has not yet been established, the evaluation team was not able to obtain such clearance.

Quantitative Data

Most of the quantitative data was gathered through document reviews. The evaluation team collected data on immunization coverage rates for different antigens included in the national immunization calendars, data on wastage rates, expenditures on vaccines and injection supplies.

3.3. Ethical Issues

UNEG Ethical Guidelines[32] guided the entire evaluation process. The evaluation team ensured impartiality and consistency in presenting the findings and results of the evaluation through the collection of diverse perspectives on the subject of this evaluation.

The evaluation process followed all the initially proposed methodologies with the exception of Group Interviews with program beneficiaries. As a form of "human subjects research," GIs with direct beneficiaries required NERC clearance. The evaluation team was not able to obtain official clearance before the data collection, as well as while in field because there was no functioning NERC in the country at the time of the evaluation.

Before beginning the interviews, the evaluation team obtained verbal consent from all respondents. As an introduction, respondents were provided with background information about the evaluation and its purpose. Key informants were interviewed face to face without the presence of other individuals; their identities were not revealed and their statements were not attributed to a source. The duration of the interview was tailored to the respondents' availability. All the interviews were tape-recorded and participants were assured of their privacy and confidentiality protection. All respondents were provided with the contact information of both the local counterparts and members of the evaluation team, in case further questions or concerns arose after the data collection period.

[32] UNEG Ethical Guidelines for Evaluation, UNEG, 2008, http://www.unevaluation.org/search/index.jsp?q=ethical+guidelines

3.4. Data Analysis

Qualitative data analysis entailed documentation, conceptualization, coding, and categorizing, as well as examining relationships using NVivo® software package. A "framework analysis" approach[33] was used to analyze the qualitative data obtained through the variety of the data collection methods described above. The information derived from each of the sources of qualitative and quantitative data used at every stage of the study were triangulated within and between the data sets, with the aim of identifying common understandings of the experiences of the issues in focus, as well as differences of opinion between various stakeholders. Following triangulation, the data sets were used to develop specific analyses, such as timelines summarizing the chronology of Gavi program implementation, descriptions of particular processes used in the design or implementation of the programs and the roles of various stakeholders in these processes.

3.5. Quality Assurance

The following techniques were used during the evaluation to assure the quality of findings and recommendations: (a) respondent validation, which involved cross checking interim and final evaluation findings with key informant respondents; and (b) triangulation of data: different sources of data were used, where possible, to draw valid conclusions about the major themes of the evaluation and produce a more complete understanding of the evaluation questions.

To account for the data quality and assess the strength of our conclusions we used the "robustness scoring" approach[34], using four scores (A to D) in this process. Score assignment depended on two criteria: a) the extent to which qualitative and/or quantitative evidence generated from different sources pointed to the same conclusion; and b) the quality of individual data and/or source of evidence.

Table 1 shows how the "robustness score" was assigned.

Table 1 Robustness Ranking for Evaluation Findings

Ranking	Description
A	The finding is consistently supported by the full range of evidence sources, including quantitative analysis and qualitative evidence (*i.e.*, there is very good triangulation); and/ or the evidence source(s) is/are of relatively high quality and reliable to draw a conclusion (*e.g.,* there are no major data quality or reliability issues).
B	There is a good degree of triangulation across evidence, but there is less or 'less good' quality evidence available. Alternatively, there is limited triangulation and not very good quality evidence, but at least two different sources of evidence are present.
C	Limited triangulation, and/ or only one evidence source that is not regarded as being of a good quality.
D	There is no triangulation and/ or evidence is limited to a single source and is relatively weak; or the quality of supporting data/ information for that evidence source is incomplete or unreliable.

[33] Thomas D.R; *A General Inductive Approach for Analyzing Qualitative Evaluation Data*. American Journal of Evaluation, 2006 27: 237
[34] GAVI Second Evaluation Report; CEPA LLP. 2010; p.27

3.6. Evaluation Limitations

The evaluation faced the following limitations, which impeded the data collection process and affected the findings of the evaluation:

- Due to the length of the Gavi support period, which lasted almost 13 years, some key individuals involved in program planning and implementation have moved to different offices and/or countries and were not readily available for interviews. Nevertheless, the evaluation team used various means (Skype calls, network references, etc.) to access these individuals and obtain their informed feedback;
- Another limitation emerged due to the long recall periods, with some individuals facing challenges remembering events that took place several years earlier;
- The evaluation team was not able to gain access to certain documents, such as some ICC meeting minutes, communication letters;
- The small sample size (3 out of 36 districts) selected due to the time and financial limitations means that generalization of the evaluation findings from site visits should be done with caution.

4. Evaluation Findings

4.1. Pre Gavi period (till 2001)

Domains

- Program Performance
- Collaboration and Partnership
- Political Support
- Financial Support

Until the dramatic socio-economic changes in the early 1990's, Albania was self-sufficient in terms of vaccines. It began production of vaccines against most major Vaccine Preventable Diseases (VPDs) in the late 1950s (Diphtheria and Tetanus toxoids in 1959, DT in 1962, Pertussis in 1965, DPT and BCG in 1971, and Measles in 1976). The OPV vaccine was regularly imported after 1961. However, local manufacturing of bio-products was discontinued in 1991 after WHO expressed concerns regarding quality standards. Since then UNICEF covered almost all the vaccine needs of EPI.[35]

The National Immunization Schedule in the pre-Gavi support period is presented below in Table 2.

Table 2: National Immunization Schedule till 2001

At Birth	2 month	4 month	6 months	12 months	2 years	5 years	6 years	14 years	18-19 years
BCG									
HepB	HepB		HepB						
	DTP	DTP	DTP		DTP				
	OPV	OPV	OPV		OPV		OPV		
				MR		MR			
							DT		
								Td	Td

Albania inherited a strong immunization system from the communism period with high coverage rates. Civil unrest after the political changes in 1990 and the Kosovo crisis resulted in extensive damage to health care infrastructure and in the disruption of essential services, including immunization. About 30% of heath staff abandoned their positions with higher rates in the south regions of the country.[36] During the early 1990s mass campaigns were mainly used to fill gaps in routine immunization coverage for Measles and Polio. Measles outbreaks in 1989-1990 and a polio epidemic in 1996 with 138 cases, 16 of which proved fatal, revealed the limitations of the immunization program - particularly deficiencies in the cold chain. The Government recognized the magnitude of the problem, and, in 1993, passed a Law "On preventing and combating communicable disease" (No. 7761) to strengthen immunization measures. With extensive support provided by the donor organizations, mainly by UNICEF, the government invested in infrastructure and in the improvement of the immunization coverage rates, which have been over 90% for almost all vaccines since 1995 (see Table 3).

[35] Ministry of Health, National plan of action for immunization for 2001-2005

[36] Nuri, B. In: Tragakes, E., ed. Heath care systems in transition: Albania. Copenhagen, European Observatory on Health Care Systems, 2002: 4(6).

Table 3: Immunization coverage rates (%) 1995-2000. WHO-UNICEF estimates.

	1995	1996	1997	1998	1999	2000
BCG	97	94	94	87	93	93
DTP-1	98	98	99	99	98	98
DTP-3	97	98	99	96	97	97
HepB-3	88	96	97	94	96	96
MCV-1	91	92	95	89	85	95
Pol-3	98	99	99	97	97	97

Source: WHO-UNICEF estimates

In 1994-95, the Hepatitis B vaccine for immunization of newborns was introduced into the national immunization calendar with the financial support of the Italian Rotary Club. However, following the country's political and economic collapse in 1997, Albania was unable to fund Hep B vaccinations once the support from Rotary Club ended in 1996. This resulted in a two-year interruption of the Hep B vaccination (1997-1998). While, after a partial economic recovery, the Government was able to fully finance the cost of vaccines in 1999-2000, public funding for future years was not secured given the continuing economic fragility and the high budget deficit. Moreover, at that time there was no multiyear budget planning (e.g. Medium Term Expenditure Framework) in place to secure the Government's funds for vaccines in advance. Since Government remained committed to continuing the Hepatitis B vaccination, and in light of uncertainty about what would happen after 2000 with Hep B vaccination given the limited public funds available, the Government applied to Gavi for Hep B vaccine support in 2000.

Until 1995 only glass sterilizable syringes were used, with the exception of disposable single-use syringes for the Hep B vaccine. In 1996, disposable syringes were introduced for all injection practices, and became universally used countrywide by 1999. Auto-disable syringes (ADs) for childhood immunization were introduced in 1996. The exclusive use of ADs for immunization started in the late 2000 with MR campaign of children 1 -14 years old. First UNICEF, and later on the Albanian Government, secured an uninterrupted provision of ADs. [37]

There were deficiencies with regard to safe disposal of injection supplies. Despite the regular and uninterrupted supply with safety boxes by UNICEF, they were not universally used. No collection procedures existed and there were no written guidelines for used injection equipment disposal. Filled boxes were most often discarded in the general waste, despite that district PHCs were recommended to burn them in pits and bury the residuals. In 2000, a National Policy for Injection Safety was developed in Albania.[38]

Summary of findings for the pre-Gavi period (until 2001)

Domain	Findings	Robustness Ranking	
Program Performance	Despite the challenges with disrupted infrastructure (cold chain equipment) and unstable government funding, the	A	Findings are substantiated through document review and supported by qualitative

[37] Ministry of Health, Institute of Pubic Health. (2003) Plan of Action to improve Immunization Injection Safety and Safe Disposal of Injection Equipment in Albania 2003-2007

[38] Ibid **Error! Bookmark not defined.**

	immunization program maintained high coverage rates with extensive donor contributions and using mass catch up campaigns. Disposable syringes were universally used, however, no safe disposal policy was observed.		information
Collaboration and Partnership	The program mainly relied on donors' support. Good partnership and effective collaboration with donors and the Government was a prerequisite for quick recovery from the crises and improved program performance.	A	Findings are substantiated through documentary review and supported by qualitative information.
Political and Financial Support	Immunization remained a priority of the health sector, although financial commitment was low due to the economic problems.	A	Findings are substantiated through documentary review and supported by qualitative information.

4.2. Gavi support period (from 2001 to 2014)

4.2.1. Overview of Gavi support to Albania

Gavi support to Albania started in 2001 with the support of the Hepatitis B monovalent vaccine, which ended in 2005. Injection Safety Support (INS) to the country was provided during 2004-2006. In 2005 Albania applied for Hib monovalent support. Gavi approved the application in 2007, although the HiB monovalent vaccine was never supplied, because it was unavailable. Instead, Albania requested liquid Pentavalent vaccine in 2008, which was introduced with Gavi support in 2009. The last shipment of Gavi supported Pentavalent vaccine took place in 2013. A Summary of Gavi support to Albania is provided in Table 4, while key points of Gavi support period are presented in Table 5. More details on the main developments during 2001-2013, as deduced from the document review, are summarized and presented in the Annex 2.

Table 4: Summary of Gavi support[39]

	Disbursements 2001-2013 (US$)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Hep B	$403,392													
INS	$110, 377													
NVS - Penta	$1,707,271													
Vaccine Introduction Grant	$300,000													
Total	**$2,521,040**													

[39] http://www.gavi.org/country/albania/

Table 5: Key points of Gavi support

Year	KEY POINTS
2000	• Government of Albania applied for Hep B vaccine support to Gavi in August 2000.
2001	• Albania was approved for Hep B vaccine support in May 2001. (***Gavi decision letter GAVI/01/153/clm, 17 August, 2001)*** • Albania received new vaccine introduction grant of US $100,000 from Gavi in 2001 (***APR, 2003)*** • Albania applied for INS to Gavi.
2002	• On May 2002, the GAVI board did not approve Albania's application for INS. The application missed a sufficiently detailed plan related to the Safety of Injection for Expanded Program on Immunization (***APR, 2002; IRC on APR for 2001, January, 2003)*** • New INS application together with INS plan for 2003-2007 was resubmitted in August 2002 (***Albania INS proposal, 2002)***
2003	• In May 2003 IRC approved Albania's INS proposal with clarification. (***IRC decision letter GAVI/03/087/jd, 14 July, 2003)*** • On September 22, 2003 Gavi informed MoH of Albania that the clarifications provided by Albania were satisfactory, and the country was granted support for INS. ***(Gavi decision letter GAVI/03/132/jd, 22 September, 2003)***
2005	• In October Albania applied for Hib monovalent support to Gavi ***(APR 2005)*** • Gavi support for Hep B vaccine ended
2006	• Albania's proposal for the Hib vaccine introduction was approved by Gavi IRC in November, 2006. ***(17 th IRC proposal review 22-27 November, 2006, (Gavi decision letter GAVI/07/023/ire/hb, 15 February, 2007)*** • Hepatitis B vaccine support from Gavi ended in 2006 ***(APR 2007)*** • INS support ended in 2006 (***IRC Report on APR for 2006)***
2007	• Due to the unavailability of Hib mono vaccine, in consultation of UNICEF supply division Albania planned to introduce the Pentavalent vaccine instead ***(APR 2007)***. • Albania received a new vaccine introduction grant of US $100,000 from Gavi in August 2007
2008	• The IRC approves the change in presentation from Hib mono to DTP-HepB-Hib
2009	• Albania received Pentavalent introduction grant at US $100,000 from Gavi in January, 2009 • Pentavalent vaccine was introduced in March, 2009
2013	• Gavi support for Pentavalent vaccine ended

4.2.2. Planning

In this section we examine to what extent the processes and support put in place by Gavi addressed financial and programmatic sustainability. We also describe the relevance and effectiveness of Gavi support planning by assessing whether it complied with Gavi requirements and if all Gavi supported programs were relevant to the country's needs

Key Evaluation Questions

- To what extent were there processes or support put in place by Gavi to address both financial and programmatic sustainability?
- To what extent did Albania prepare and plan for the transition away from Gavi support?

When Gavi support to Albania began, countries applying for Gavi support were required: i) to establish an operational Interagency Coordinating Committee (ICC) for immunization, and ii) to develop a Financial Sustainability Plan (FSP) – a document assessing the key financing challenges facing the national immunization program within the broader health-financing context. Initially, all countries receiving Gavi support were required to submit an FSP in their second year of support. In 2006, the FSP was replaced by a comprehensive Multi Year Plan (cMYP) for Immunization.

In response to the Gavi requirement, the Government of Albania established an Interagency Coordinating Committee (ICC) in the year 2000 to ensure stakeholder coordination, evidence-based decision-making and smooth implementation of the immunization program. Prior to that, the ministerial committee, which had been functional since 1990s, have been coordinating immunization activities in the country. The ICC was established based on the existing committee. In 2003, a Technical Working Group of experts (TWG) (which had played the role of the National Immunization Technical Advisory Group) under the IPH was established to provide and present evidence-based arguments to ICC on the introduction of new vaccines, their effectiveness and impact.

The first immunization planning exercise for the country, the National Plan of Action for Immunization, covered the period 2001-2005 and was developed with UNICEF / WHO technical assistance. The plan responded to the country needs, was coherent with Gavi's goals and considered partners' recommendations derived from the immunization program assessments.[40,41] The national plan aimed at a) achieving and maintaining >90% immunization coverage for all antigens (DTP, Hep B, BCG, Polio, Measles) at all administrative levels; b) introducing new vaccines (Mumps and Hib vaccines) into the national immunization calendar; c) strengthening epidemiological surveillance and monitoring of EPI targeted diseases; d) maintaining an effective cold chain system; e) reducing vaccine wastage rates; f) ensuring immunization safety and safe injection practices; g) strengthening EPI management and coordination; and h) strengthening political commitment to EPI.

Later, in line with Gavi's request for strengthened sustainability planning, Albania developed an FSP for 2004-2013 and a cMYP for 2009-2013. Both plans were developed using the external technical assistance of Gavi partners (WHO and UNICEF) with the aim of

"... Long term thinking was absent at that times, we were preoccupied with filling existing gaps ...."

Quote from the Government representative

[40] National EPI Coverage Survey, MoH, IPH, UNICEF, WHO, November 1999
[41] Rapid Assessment of Cold Chain, IPH, UNICEF, June, 2000

creating national capacity as well. However, that aspiration appears to have been not entirely successful. Almost all the interviewed stakeholders mentioned that the financial planning exercise was extremely useful and contributed to changes in the EPI planning practice. However, according to the key informants, due to the "complexity of the costing tool" used for the development of the cMYP and the absence of follow-up external technical assistance in institutionalizing multi-year financial and programmatic planning for immunization, this exercise was not repeated. The existing FSP and cMYP documents have not been updated since then.

> *"… The process of the development of FSP was very useful for us…we started to think more strategically…."*
>
> *Quote from the Government representative*

In 2000, the Government of Albania applied for Gavi support for financial assistance with Hep B and Hib vaccines. **Gavi did not have co-financing or eligibility and transition policies at the time of the country application.** However, country stakeholders were aware of the time-limited nature of Gavi support. The Government requested full 100% financing of both vaccines during the following five years (2001-2005)[42] in light of the economic and budget uncertainties faced by the country at that time and gradually increasing financial obligations to cover routine vaccine procurement funded by UNICEF until the year 2005.

Gavi did not approve the application for the Hib vaccine and requested more justification for its introduction. Only the application for the Hep B vaccine was approved. As stated earlier, the Hep B vaccine for newborns was introduced in 1995 in Albania with the Rotary Club financial support. Although Government fully financed Hep B vaccines in 1999-2000, funds were not secured in the budget to ensure an uninterrupted supply of the vaccine in the following years. Moreover, the country had already experienced an interruption in Heb B vaccination in 1997 and 1998 due to the lack of public funds. Therefore, Albania used the opportunity to receive funds from Gavi to ensure the guaranteed and uninterrupted supply of Hep B vaccine for the next five years. Albania received Gavi support, which was crucial considering the high prevalence of Hep B among Albanian population.[43] As mentioned above, it was planned that the Government would fully take over Hep B vaccine procurement in the year 2006. This commitment was later reflected in the FSP for 2004-2013. Gavi encouraged Albania's intention to allocate domestic resources for the hepatitis B vaccine procurement after 2006.[44]

No specific transition plan was developed for the transition of responsibilities for Gavi supported vaccines. **However, the development of FSP, CMYP, the injection safety plan, Hib vaccine introduction plan helped to adequately plan the transition process.** In addition, according to stakeholders, the practice of successfully taking over the financing for traditional vaccines previously funded by UNICEF helped the Government to properly plan and fulfill its commitment to fully fund Hep B/pentavalent vaccines once Gavi support ended**.** The Government strictly adhered to the terms of the agreement with UNICEF, thus demonstrating its strong ability to plan and gradually take over responsibility for vaccine funding.[45]

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[42] The Government of Albania, proposal for support of Hep B vaccine

[43] Resuli B. et al. Epidemiology of hepatitis B virus infection in Albania. *World J Gastroenterol*. 2009 Feb 21; 15(7): 849–852.

[44] IRC Report on APR for 2003

[45] Ibid [58]

In 2001, the Government of Albania also applied to Gavi for INS support. The Gavi board did not approve Albania's application due to the missing national injection safety plan for EPI. To fulfill the Injection Safety application requirements, the country was requested to develop a detailed plan of action for Injection Safety and Waste Disposal Management.[46] A new INS application, together with INS plan for 2003-2007, was resubmitted in August 2002. In May 2003, Gavi's Independent Review Committee (IRC) approved Albania's INS proposal with clarification. IRC requested the ICC to provide a letter of assurance that Gavi support for injection safety would not replace current funding by the Government or partners[47]. After receiving the requested clarification, Gavi approved Albania's INS proposal in 2003 (see Annex 2).

In 2005, Albania re-applied to Gavi for Hib monovalent support and received conditional approval, with a request to elaborate a detailed Hib vaccine introduction plan and evidence of the cold chain storage capacity at various levels of the health services to accommodate the vaccine volumes requested[48].

Gavi always maintained direct communication with the MoH and IPH. In general, the respondents considered Gavi's role in providing feedback very valuable and practical in facilitating improvements in planning and program performance.

The absence of a Gavi graduation policy may have affected the country's ability to adequately plan for the introduction of new vaccines. According to key informants, up until the adoption of the Gavi graduation policy in 2009, Albania was counting on future Gavi assistance for new vaccines (such as PCV and Rotavirus vaccines), while the introduction of Rota vaccine with Gavi support was planned for 2014. According to stakeholder information, in 2010 the MoH received formal notification of the country's graduation from Gavi support (although evaluation team was not able to identify documentary evidence of this communication). This information was shared with other stakeholders at an ICC meeting. The news about country transition from Gavi support was not unexpected. However, while Albania still managed to introduce PCV using the public funds, this had implications on the timing of the Rotavirus vaccine introduction. According to the Gavi 2009 graduation policy, Albania became ineligible to apply to Gavi for Rota support, but Gavi support for pentavalent vaccine was continued. Due to the lack of Government funds, the independent introduction of the Rota vaccine at much higher (four to five times) prices than Gavi prices was shifted after 2017.

Summary of findings on the planning

Evaluation questions	Findings	Robustness Ranking	
To what extent were processes or support put in place by Gavi to address both financial and programmatic sustainability?	Gavi made *adequate* efforts to assure financial and programmatic sustainability from the beginning of support through their requirements, communication and mandatory preconditions for initiating Gavi support. In all instances Gavi support was *relevant* to country needs, *realistic* and *critical* for funding new and underused vaccine introduction and injection safety in Albania. Gavi support was based on thorough situation analyses, *well documented* and *communicated.*	A	Findings have been substantiated through a review of communication between Gavi and Albania, and supported by qualitative data and document review.

[46] Gavi decision letter GAVI/02/128/jd, June, 2008
[47] IRC decision letter GAVI/03/087/jd, 14 July, 2003
[48] IRC Meeting October 31/November 8, 2005

To what extent did Albania prepare and plan for the transition away from Gavi support?	No specific transition plan was developed. However, all financial and programmatic plans requested by Gavi and elaborated by the country (such as FSP, cMYP, detailed injection safety plan, Hib vaccine introduction plan) were *highly adequate* and facilitated transition planning from the beginning of Gavi support, even in the absence of a specific transition plan. The successful experience of transition from UNICEF's support for routine vaccines contributed to Albania's preparedness to transition away from Gavi support. However, the absence of graduation policy and thus timely forewarning of graduation may have affected the country's ability to introduce new vaccines, both in terms of planning and allocating necessary resources (for Rota).	A	Findings have been substantiated through a review of communication between Gavi and Albania and supported by qualitative information.

4.2.3. Implementation

Evaluation Questions

- To what extent were the activities of the sustainability plan (if one was developed) effectively and efficiently implemented?
- What activities took place in the absence of a sustainability plan, if one was not developed?

In this section we evaluate the effectiveness and efficiency of transition implementation by looking at the extent to which transition processes were coordinated, Government financial commitments fulfilled and whether activities were implemented according to the plan. The period covers the period 2001-2013. **The ICC was instrumental in strategic planning, problem solving, coordination and monitoring of program implementation throughout the Gavi support period**. The ICC was the main coordination mechanism in the country for immunization activities. During different periods the ICC was chaired by the Minister of Health or the Deputy Minister of Health, which underlines the importance of the Immunization program for Albania. Other members of the ICC were representatives of the different departments of the MoH, including budgeting and planning, the Ministry of Finance (MoF), the Health Insurance Institute, partner agencies and other donors, NGOs and field experts. The IPH served as a secretariat for the ICC, preparing the agenda and discussion topics for the meetings. A technical group of experts was formed to prepare scientific justifications for proposed changes to the immunization policy, such as introduction of new vaccine, calendar changes, etc. On average, four meetings were organized per year. Almost all the interviewed respondents recalled their active involvement in the work of the ICC. The IPH played a key role in the effective functioning of the Committee, according to respondents. A review of the ICC meeting minutes proved that the Committee was participatory; the meetings were used for discussing existing program challenges and making appropriate decisions based on justifications prepared by the technical group. The ICC organizers always tried to ensure the presence of financial officers from the MoH and the MoF when EPI financial aspects were discussed. This practice supported the government's financial commitment to the EPI and, most likely, facilitated the program's financial sustainability.

"... We had to be well prepared for the ICC meetings as the members always required strong arguments for our proposals ..."

".. if the financial people were not able to attend the critical meetings were postponed ..."

Quotes from the IPH representative

"... ICC was a functional body. Decisions were always made based on evidence prepared by the IPH. ... We were supplied by the meeting minutes afterwards. ICC was not formed to satisfy Gavi requirement..."

Quote from ICC representative

Development partners played important role both in direct involvement in the coordination of

"... We strictly decided to use UNICEF procurement mechanism as it was most cost-efficient way of vaccine procurement ..."

Quotes from Government representative

immunization activities and in direct support to the Program. Among the main partners were UNICEF, WHO and USAID. **The role of UNICEF and its contributions were extremely important to long term sustainability**. UNICEF continued basic vaccine support according its agreement with the Government and made significant investments to upgrading the cold chain. It also supported the country in communication and advocacy activities and in immunization activities for the hard-to reach Roma population. WHO provided technical support to strengthen EPI with a focus on surveillance of VPDs, laboratory capacity, and advocacy during the European immunization Weeks. WHO also financed EPI managers' participation in the regional workshops. The World Bank grant conditions for health system reform were linked to the government commitment to allocate funds for EPI, which according to the stakeholders was an additional powerful motivation for the Government to fulfill its obligations in financing the new vaccines after Gavi support ended. The USAID funded Partners for Health Reform (PHR*plus*) project provided technical assistance to the government of Albania from 2001 to 2005 in the design and implementation of a sub-set of its health sector reform strategy, focused on strengthening the PHC sector. **Primary health care reforms have acknowledged immunization services as one of the most important tasks for PHC providers**. The project assisted the MoH in defining the basic package of PHC, which included immunization as a key component. A set of indicators was developed, including Immunization coverage, to track performance of PHC providers. The indicators were later used in the performance based payment scheme for the PHC centers. PHC funding was formed by 80-85% fixed budget and 15%-20% performance based reimbursement, of which 5-10% was a "quality bonus" depending on the accomplishment of 9 output and outcome indicators. Quarterly reporting of indicators (including immunization coverage rate) was required. If the bonus criteria were fulfilled, incentives were paid twice a year as an add-on to salaries. This model was piloted by USAID and scaled-up nationally after 2007[49]. CSOs involved in the immunization activities are the Albanian Red Cross, the Roma Center for a Contemporaneous Vision and the Albanian Infectious Diseases Association. Representatives of the CSOs are members of the ICC. The Albanian Red Cross was involved in immunization campaigns in 1990s and in 2000. The main activities are related to social mobilization during mass campaigns and during work with special groups (e.g. women of childbearing age). The Roma Center for a Contemporaneous Vision is involved when outreach to mobile Roma population is needed, such as monitoring visits, delivery of communication messages, etc. The Albanian Infectious Diseases Association is an active member of the ICC, participating mainly in the technical discussions.

The UNICEF procurement mechanism has been used from the beginning of UNICEF support to the country. This mechanism was used for all vaccines and injection supplies included in the national immunization calendar. Using this "most cost-efficient mechanism" to procure vaccines remained the Government's firm decision throughout the Gavi assistance period, and was not revisited despite some lobbying from commercial manufacturers. Respondents also mentioned that Albania, due to its small market, is not of big interest to manufacturers and so did not experience strong pressure from lobbyists.

[49] Albania Health Sector Assessment for an evidence based decision making in light of the new country strategy 2014-2017 of the Swiss Cooperation with Albania; 2012.

Gavi's monitoring of country performance during Gavi support was evident and has contributed to the immunization program improvements. Gavi/IRC performed a thorough analysis of the APRs and communicated decisions on funding, recommended further improvements and guided Albania on necessary steps and interventions. Gavi support was beneficial to strengthen the capacity of EPI officers at the national and sub-national levels. During the initial phase, low in-country capacity and experience in international reporting made the preparation of APRs challenging for the national EPI staff. The quality of APRs was relatively poor, which gradually improved based on Gavi feedback. According to stakeholders, **Gavi comments on discrepancies in factual data played a role in improving inconsistencies in demographic information, which was one of the big challenges** in Albania. Due to high rates of migration and internal mobility of the population, data from the national statistics and health facilities differed, leading to a distortion of coverage rates.[50] To address the problem, along with other actions, the IPH redesigned immunization registration and reporting forms by separating the mobile population data.

> *"The country should provide better estimation of the demographic information. It is unacceptable that different figures are presented with each version of the report. The committee requires clarifications from the country"*
>
> *Quote from Gavi Monitoring and Assessment report. 20 January 2002*

In 2011, the MoH in collaboration with the Optimize project (PATH/WHO) funded by the Bill and Melinda Gates Foundation developed a registry-based immunization information system in one of the pilot regions (Shkodra). The automated system allows the vaccination status of individual children to be tracked, accurate coverage rates to be calculated and vaccine stocks to be managed. The national scale-up of this model is still pending due to the lack of financial resources.

Immunization coverage rates were maintained at high levels (see Table 6). A Demographic Health Survey (DHS) conducted in 2008 validated coverage rates with 97% for DTP and MMR-1 coverage.

Table 6: National level immunization coverage rates (%) for 2001-2013 years, WHO-UNICEF estimates

Vaccine	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
BCG	93	94	95	97	98	97	98	99	97	99	97	96	99
DTP-1	97	98	97	98	99	98	98	99	99	99	99	99	99
DTP-3	97	98	97	97	98	97	98	99/97*	98	99	99	99	99
HepB-3	96	96	97	99	98	98	98	99	98	99	99	99	99
HepB-BD	98	99	98	99	99	99	98	98	98	99	97	97	99
Hib-3	–	–	–	–	–	–	–	–	98	99	99	99	99
MCV-1/MMR-1	95	96	93	96	97	95	97	98/97 *	97	99	99	98	99
MCV-2/MMR-2	90	93	93	96	97	94	95	98	98	98	99	99	99
PCV-3	–	–	–	–	–	–	–	–	–	–	99	99	99
Pol-3	97	98	97	98	97	97	99	99	98	99	99	99	99

Source: WHO-UNICEF Estimates
* DHS data

Immunization coverage rates were maintained at above 95% at the sub-national (district) level as well. Coverage rates for DTP-3 and Hep B-3 by districts for the period of 2000-2014 are presented in Annex 5.

[50] APR for 2005

To reduce vaccine wastage rates, Albania changed vaccine presentations from multiple to one or two dose vials. Since the introduction of the Pentavalent vaccine, DTP was used only for booster dose at 2 years of age. In 2010 the DTP vaccine wastage rate decreased from 25% to 20%, but since 2011 it has increased again, reaching 30% in 2012. According to the EPI manager, there are lots of small districts with a low number of children in Albania; therefore, **EPI decided to allow for an increased wastage rate in order to reach high vaccination coverage.** Vaccine presentations and wastage rates for each vaccine for the period 2005-2013 are shown in Table 7.

Table 7: Vaccines, presentations and wastage rates (%) for 2005-2013[51]

Vaccine	2005	2006	2007	2008	2009	2010	2011	2012	2013
BCG (20)	70	70	70	70	70	70	70	70	70
DTP (10)	25	25	25	25	25	20	25	30	30
TT (10)	25	25	25	25	25	20	20	20	20
DT (10)	25	25	25	25	25	25	25	25	25
TD (10)	25	25	25	25	25	25	25	25	25
OPV (10)	35	35	35	35	35	35	35	35	35
MMR (10)	30	30	30	25					
Hep B (10)	10	10	20	20	20				
MMR (1)				5	5	5	5	5	5
DTP-Hep B-Hib (1)					5	5	5	5	5
Hep B (1)						5	5	5	5
PCV7 (1)						5			
PCV10 (2)							5	5	5

Source: IPH

Gavi funds helped Albania to strengthen its human resource capacity. Gavi's new vaccine introduction grants were used to train health care personnel involved in immunization activities. A cascade of trainings for health care workers (family doctors, pediatricians, nurses) was provided on different topics (safe injection, cold chain, vaccine management, etc.), using the training of trainers' approach. The trainings were most extensive prior to the introduction of new vaccines. Although it was challenging for the interviewed health care providers to remember concrete topics or years when they received trainings due to recall bias, it was obvious from the interviews that continuous capacity building took place.

Progress had been made in the area of safe injection. In 2000, no written guidelines existed for sharp waste disposal, and filled safety boxes were discarded in the general waste.[52] In 2002 a national policy for injection safety and safe disposal of injection safety was developed and approved by the Minister of Health. In 2013 the Government of Albania adopted a new policy that regulates waste disposal in accordance with the National Waste legislation[53]. This law repealed Law # 9010 dated 13.2.2003 "On environmental management of solid waste" and Law # 9537 dated 18.5.2006 "On hazardous waste management"[54]. An Assessment of Immunization Quality and Safety conducted in October 2006 by WHO identified that 100% of facilities used AD and/or disposable syringes. For immunization activities safety boxes were used in 81% of cases, which limited the risk identified to the

[51] Data on vaccine wastage rates before 2005 was not available
[52] Injection safety plan for 2003-2007
[53] Law No 10463, dated 22.09.2011 "On integrated waste management, amended by Law no 156, dated 10.10.2013.
[54] http://scp.eionet.europa.eu/facts/factsheets_waste/2011_edition/2014/albania2014

community.[55] The latest (2010-2011) APRs mention that safety boxes were used for sharp disposal throughout the country. The problem with waste disposal still existed during the Gavi support period: most of the districts had contracts with private companies to manage waste, but in rural areas open burning was still used. All targets set in the injection safety plan for 2003-2007 were met in a timely manner (Table 8).

Table 8: Safe Injection targets

Indicators	Target year	Targets	Achievements
Proportion of health facilities provided with ADs	2004	100%	100%
Proportion of health facilities provided with reconstitution disposable syringes	2004	100%	100%
Proportion of health facilities with one month stock of ADs	2004	100%	100%
Proportion of health facilities with one month stock of reconstitution disposable syringes	2004	100%	100%
Source: Injection Safety Plan for 2003-2007			

The relatively weak vaccine management capacity observed in the first years of Gavi support was gradually strengthened. The latest Effective Vaccine Management (EVM) assessment conducted in 2012 highlights the following strengths of the management system: a) a very low risk of vaccine damage due to correct storage or distribution; b) sufficient storage capacity; c) dedicated and knowledgeable staff; d) adopted WHO policies (Vaccine Vial Monitor (VVM) use, Earliest-Expiry-First-Out (EEFO) principle, use of shake test); and e) the availability of vaccine management guidelines throughout the system[56].

Respondents reported regular supervision and monitoring of immunization programs during the implementation of Gavi support and beyond. The evaluation team was not able to obtain written supervision reports and feedback dated back to the Gavi support period at the visited health facilities, however the APRs reported utilization of Gavi financial support (new vaccine introduction grant) for supervisory visits.

> "Supervisory visits were conducted by the district health directorate in every month …"
>
> *Quote from health care facility representative*

Several programmatic changes were introduced during the Gavi support period. The national immunization calendar has been changed three times during Gavi support period. The Government introduced the Mumps vaccine into national calendar in 2005 by replacing MR with the MMR vaccine. The introduction of the MMR vaccine was fully financed by the government. No longer a Gavi eligible country, in 2011 Albania introduced the PCV vaccine (PCV 10) at its own expense at substantially higher price than for the Gavi eligible countries (16 USD per dose compared to 3.5 USD per dose for Gavi), making it a success story for the Gavi model of financial sustainability that was introduced in 2006 with Gavi's Co-financing policy. This model implied that as a result of developing FSPs and cMYPs, countries supported by Gavi should be able to introduce new vaccines with their own resources, once

[55] Immunization Quality and Safety Assessment report, WHO, 2006
[56] Republic of Albania EVM assessment report; 2-21 December, 2012

they become ineligible for Gavi support[57]. All changes made in the national immunization schedule during the Gavi supported period are presented below.

Table 9: National immunization schedule till January 2009

At Birth	2 month	4 month	6 months	12 months	2 years	5 years	6 years	14 years	18-19 years
BCG									
HepB	HepB		HepB						
	DTP	DTP	DTP		DTP				
	OPV	OPV	OPV		OPV		OPV		
				MMR		MMR			
							DT		
								Td	Td

** Highlighted are Gavi supported vaccines*

Table 10: National immunization schedule January 2009-January 2011

At Birth	2 months	4 months	6 months	12 months	2 years	5 years	6 years	14 years	18-19 years
BCG									
HepB-0									
	Penta	Penta	Penta						
	OPV	OPV	OPV		OPV		OPV		
					DTP				
				MMR		MMR			
							DT		
								Td	Td

** Highlighted are Gavi supported vaccines*

Table 11: National immunization schedule January 2011-2014*

At Birth	2 months	4 months	6 months	12 months	2 years	5 years	6 years	14 years	18-19 years
BCG									
HepB-0									
	Penta	Penta	Penta						
	OPV	OPV	OPV		OPV		OPV		
	PCV	PCV	PCV						
					DTP				
				MMR		MMR			
							DT		
								Td	Td

** Highlighted are Gavi supported vaccines*

[57] http://www.gavi.org/about/gavis-business-model/country-commitment-to-co-financing/

The Government of Albania managed to fulfill the financial commitments that it had taken at the initial stage. Gavi's partner (UNICEF) played an important role in this process.

In 2001 an agreement was reached between the Government of Albania and UNICEF on the assistance in stabilizing the EPI vaccine (not supported by Gavi) supply to the country. Through a phased-out vaccine procurement process, UNICEF was supposed to pay for 100% of the country's need for EPI vaccines in the first year and gradually decreasing shares of the annual vaccine supply thereafter, while the government would phase-in with an ever-increasing contribution (doubling the percentage every year), reaching 100% self-reliance in EPI-vaccine procurement in 2006.[58]

" .. there were many priorities in health, therefore to avoid surprises it was important that we safeguarded the vaccine budget line, which required significant effort from our side …"

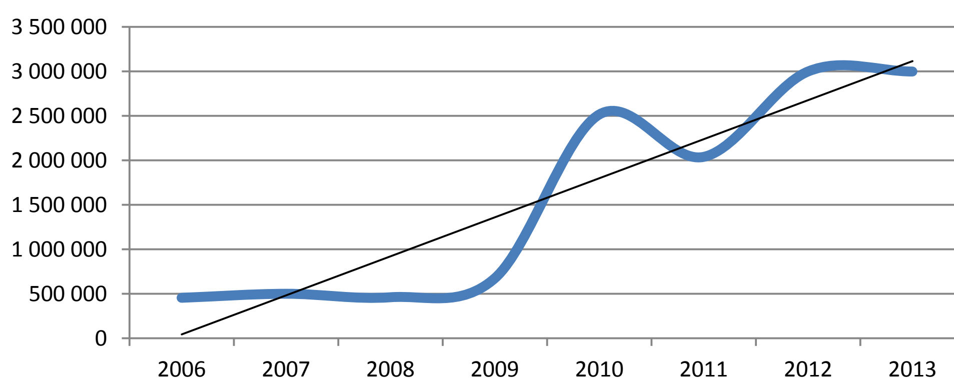
Quote from government representative

As soon as the Government signed an MOU with UNICEF, a separate budget line under the MoH budget was created safeguarding government funds for vaccines. This was preceded by extensive work by the MoH with the MoF to ensure that the budget for vaccine procurement would be secured and increased year-to-year. The budget for vaccines and injection supplies was also included in the Government's Mid-Term Expenditure Framework (MTEF) ensuring predictable financing for vaccine procurement, eventually including the vaccines supported by Gavi.

The IPH projected vaccine costs for every three years and submitted them to the MoH. The budget was negotiated between the MOH and the MoF annually. When the MoH approved the annual budget for vaccines and injection supplies, the money was transferred from the MoH account to the IPH account earmarked for vaccine and injection supply purchasing. Almost all the interviewed stakeholders confirmed that there were no shortages in vaccines and injection supplies during the Gavi support period. This practice continues to the present.

Government expenditure on vaccines and injection supplies for the period of 2006-2013 is provided in Figure 4 below[59].

Figure 4: Government expenditures on vaccines and injection supplies ($US)



Source: MoH of Albania 2015

[58] Financial sustainability plan of the national immunization program, Albania, July, 2004
[59] Source: IPH financial department

In addition to fulfilling the financial commitment on vaccine procurement defined in the cMYP, the government made significant investments in upgrading cold chain equipment in 2008 and in 2013.

Although no specific transition plan for transitioning from Gavi support was developed in Albania, the FSP for 2004-2013 was used to ensure programmatic and financial sustainability of the immunization program. All objectives defined by the FSP were achieved (See Table 12).

Table 12: Objectives of the FSP

Objectives	Status
Achieving and maintaining 90% or higher vaccination coverage rates for each EPI antigen at all administrative units;	Achieved
Introducing new antigens, specifically Mumps and Hib vaccines;	Achieved
Developing and implementing immunization policies;	Achieved
Improving and maintaining effective cold chain system;	Achieved
Reducing vaccine wastage rates to operationally possible levels;	Achieved
Introducing presentation mix analysis for the vaccines supplies to ensure most efficient vaccine prices and combinations;	Achieved
Strengthening political commitment to EPI;	Achieved
Strengthening management and coordination of the EPI;	Achieved
Ensuring immunization safety and safe injection practices during immunization.	Achieved

During Gavi support, Albania attained and maintained high coverage, introduced new vaccines, decreased the vaccine wastage rate, revised national policies, addressed cold chain issues and improved vaccine management.

Summary of findings on the implementation

Evaluation Questions	Findings	Robustness Ranking	
To what extent were the activities of the sustainability plan (if one was developed) effectively and efficiently implemented?	Gavi support was implemented *highly effectively and efficiently*. The main coordinating body in the country (ICC) was influential in coordinating and implementing the activities. Existing program challenges were *adequately* addressed and improved; Gavi funds were used for strengthening local human resource capacity, vaccine management capacity etc. Collaboration and partnership with in-country partners were ongoing and in-country partners played a crucial role in the effective implementation of the program.	A	Findings are substantiated through documentary review and widely corroborated the key informants data
What activities took place in the absence of a sustainability plan, if one was not developed?	Although no specific transition plan was developed, the FSP was used to ensure the programmatic and financial sustainability of Gavi support. Financial arrangements for budget planning, negotiation and procurement of vaccines were highly effective. The centralized model and use of the UNICEF procurement mechanism for purchasing	A	Findings are substantiated through a documentary review and widely corroborated by key informants data.

	vaccines and access to Gavi prices for Gavi supported vaccines during Gavi support period allowed the *efficient* use of the Government funds.		

4.3. Post Gavi support (from 2014-to present)

This section of the report examines programmatic and financial sustainability of Albania's immunization program, after Gavi support ended. Specifically, it evaluates extent to which Albania managed to replace Gavi support and maintained, expended or improved effective immunization systems after Gavi's time-limited support. The section covers the period since 2014.

Key evaluation Questions

- To what extent have the relevant activities related to 'Gavi support' been continued?
- To what extent have the systems and structures functioning or developed at the time of Gavi support, such as coordination by the ICC / NRAs / NITAG, technical support from partners, procurement from UNICEF and information sharing, continued to function effectively?
- To what extent have the results of Gavi supported programs been sustained, expanded or improved since the conclusion of Gavi's time-limited support?
- What are the main factors explaining the achieved results (positive or negative)?
- Have new vaccines been introduced in Albania since the conclusion of Gavi support?

4.3.1. Programmatic sustainability

Governance and leadership: **the ICC as a coordination mechanism for immunization program has been maintained as a decision making body, despite the decreased frequency of the ICC meetings.** The frequency of ICC meetings was reduced to once or twice per year. Almost all the interviewed stakeholders mentioned that the ICC was more effective during the Gavi support period than it is today. In 2015, only one ICC meeting was held, while during Gavi support three or four ICC meetings were usually organized in the same period. On the other hand, evidence exists that the ICC continues to function as a decision-making body for important alterations to immunization programs. In 2014, the ICC met to discuss programmatic adaptations related to IPV introduction. Interviewed stakeholders reported that, to make a firm decision on the replacement of OPV with IPV, the ICC applied the same practice that was used before the introduction of the Pentavalent vaccine during Gavi support. The IPH prepared alternative scenarios evaluating the budget implication of IPV introduction and presented them to the ICC, after which a decision in favor of the replacement was adopted. However, the evaluation team was not able to review the minutes from this meeting. The minutes from the last ICC meeting, conducted in April 2015, shows that issues related to Rotavirus vaccine introduction were discussed. ICC requested NITAG to provide more solid evidence on the benefits of the Rotavirus vaccine introduction and its budgetary implications to make final decision and delayed the vaccine introduction after 2017.

Two MoH orders have been issued since Gavi's disengagement in order to improve the effectiveness of the ICC in April 2015. Ministerial order #187, 2015, defines a new structure for the ICC, its composition and frequency of meetings. The deputy minister of health is the chair of the ICC, while representatives of different departments from the MoH and professional associations are members of the committee. The IPH continues to fulfill the secretariat function for the ICC. The order also highlights that the ICC should work with different NGOs and in-country partners, effectively assigning advocacy functions to this body. The order also stipulates that ICC meetings should be conducted at least four times per year.

MoH order #186, 2015, establishes a National Immunization Technical Advisory Group (NITAG) and defines its new composition, functions and responsibilities. According to the order, NITAG was established to advise the ICC, the IPH and the MoH on: a) new vaccines, their efficiency, security and side effects; b) changes to be introduced in the national immunization schedule; and c) the best methods to monitor the impact of the

" .. Immunization program always was a high priority in Albania …"
"… Our health care workers are dedicated to their work…it is our culture…".

Quote from Government representative

immunization program. NITAG should also be active in communicating and providing correct and updated information on vaccines and immunization to the public and professionals.

Access to the Gavi supported vaccines ensured – Vaccines supported by Gavi (Hep B and Pentavalent) are included in the mandatory immunization calendar and fully financed by the government.

Immunization coverage rates – Albania still maintains high immunization coverage rates (> 95%) for all antigens included in the national immunization calendar (BCG, Hep B, Polio, Measles, Diphtheria, Tetanus, Hib, PCV) in the post Gavi period. National level coverage rates for HepB-3, Hib-3, DTP-3 and MCV-1 for the last five years are presented in **Figure 5.**

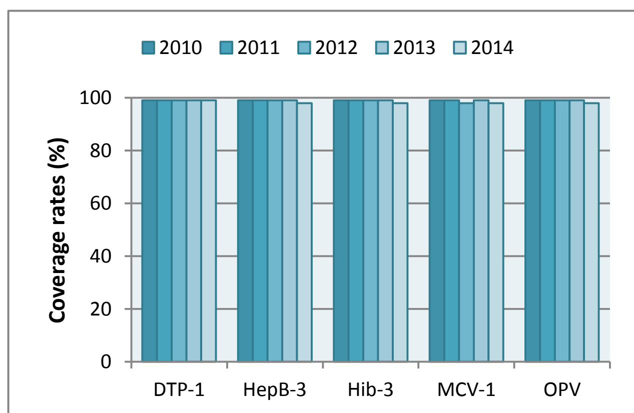
High coverage rates (>92%) are also sustained at the sub-national/district levels (Annex 5). As observed during the site visits, the coverage level drops to 70% for Roma communities in Albania, which are concentrated in particular districts. Some Roma are integrated into the resident population; however, somewhere between 30,000 and 120,000 Roma are mobile and live in temporary houses, in poor living conditions, have low levels of education and high prevalence of criminal behavior.[60] Vaccination of these groups is done through campaigns twice a year. The IPH developed special procedures for reporting and vaccine forecasting for this subpopulation that allow the separate calculation of the coverage rates for the general and the mobile Roma population.

" There are several reasons why children of mobile Roma communities are not vaccinated, they are not registered, mothers are not educated enough to know importance of immunization, there could be stigmatizing attitude towards Roma, it is also cultural factor…. Government and UNICEF is taking steps to solve the problems, but still challenges exist."

Quote from Roma CSO representative

Almost all interviewed stakeholders mentioned that Albania's long history of maintaining high immunization coverage rates has created the desire to sustain coverage rates at the same level currently. As stated by the respondents, the following factors contribute to this: a) strong political support to the immunization program in Albania; b) a strong coordinating body in IPH; c) an historically strong immunization system; d) few cases of refusals from parents, due to the high level of trust in vaccination and doctors; e) individual leaders and strong program management from the IPH side; and f) health care personnel (doctors and nurses) dedicated to immunization.

Figure 5: Immunization coverage rates for 2009-2014



Achievements in Effective Vaccine management system have been sustained in the post-Gavi period. Vaccine delivery and distribution is done in a timely manner in Albania. Over the last years, Albania has not experienced a stock-out in vaccines or other vaccination supplies. The National Central Cold Store under the IPH receives vaccines twice per year. Vaccines are distributed

[60] Osmanaj E. Roma Community in Albania before and After the period of Communism. *European Scientific Journal*. February 2013. Vol 9. No_5:1857– 7881

from the central cold store every three months to the district cold stores located in the district health directorates. District health directorates distribute vaccines to the health care facilities on a monthly basis. In rural vaccination posts, vaccines are distributed through the commune health centers. In most cases, service providers collect the vaccine from the district store, using cold boxes with cool-packs. PHC personnel use their private vehicles or public transportation to collect the vaccines from the district stores and are not reimbursed for this activity.

The central cold store at the IPH comprises 4 walk-in cold rooms, 2 freezers and 2 ice-lined refrigerators. Fridge-tags and freeze-tags are used to monitor the temperature in cold rooms and refrigerators. The temperature is checked and recorded manually twice per day, including weekends, by the cold chain manager and/or technician. At the district level, the cold chain equipment usually includes 2 or more ice-lined refrigerators and 1 more freezer. The cold chain equipment at the Commune Health Centre is composed of 1 refrigerator that is either ice-lined or Liebher type and equipped with fridge-tags and freeze-tags; temperatures are manually recorded twice a day[56]. Cold chain expenses are funded by the government but there is no proper strategic approach and funding for maintenance.

In 2013 and 2014 the Government of Albania invested significantly in the cold chain. Old equipment was replaced with new ones in those health facilities that had such needs. In all the visited facilities, functional refrigerators, cold boxes and vaccine stocks were observed.

Albania has sustained safe injection practices after transition from Gavi support. Injection supply and safety boxes are available throughout the country, and only AD syringes are used for vaccination. The evaluation team observed AD syringes and safety boxes in all the visited facilities. However, the problem with waste disposal still exists in Albania. Contracting out waste management services to public/private companies is widely applied in urban facilities, but in rural areas open burning is still used.

New vaccines have been introduced after Gavi support. As mentioned above, the government of Albania started to introduce new vaccines into the national immunization schedule with its own funds when Gavi still supported the country (MMR in 2005, PCV in 2011). This practice has been sustained after Gavi phased out. Albania introduced the IPV vaccine at its own expense in 2014. IPV replaced the OPV vaccine, and only one dose of OPV is provided to the children at 10 months (see Table 11)

In 2014, the IPH carried out a cost effectiveness analysis of rotavirus vaccination to generate evidence to support the introduction of the Rota vaccine in Albania. The exercise was supported by the ProVac International Working Group (IWG), with contributions from the WHO Regional Office in Europe, the US CDC, the Agence de Medicine Preventive, PATH and the London School of Hygiene and Tropical Medicine. This was the second such study after the 2006 Hib cost-effectiveness analysis; however, the 2014 study was completely led by the country.[61] As mentioned above, the evidence did not support a policy decision to introduce the vaccine at a given time, as introducing the vaccine was not found to be cost effective when rotavirus cases and deaths were based on plausible minimum estimates,[62] considering the prices for Rota accessible to Albania.

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[61] Ahmeti A, et al. Cost-effectiveness of rotavirus vaccination in Albania. Vaccine (2015), http://dx.doi.org/10.1016/j.vaccine.2014.12.075
[62] Ibid 61

There are also discussions about introducing the HPV vaccine in Albania. However, in light of limited Government funds and the high prices of HPV vaccine, this is not planned in the next three years. The HPV vaccine would be considered after the Rotavirus vaccine is introduced.

Table 13: National immunization schedule since January 2014

At Birth	2 months	4 months	6 months	10 months	12 months	2 years	5 years	6 years	14 years	18-19 years
BCG										
HepB-0										
	Penta	Penta	Penta							
	IPV	IPV	OPV			IPV		IPV		
	PCV	PCV		PCV						
						DTP				
					MMR		MMR			
								DT		
									Td	Td

Source: the Institute of Public Health, 2015

Highlighted are Gavi supported vaccines

The Albanian health system does not have a shortage of primary care doctors and nurses in urban or rural areas that could threaten the provision of immunization services. Trainings on immunization topics (injection safety, new vaccines, etc.) are still provided to build the capacity of health workers. Almost all the interviewed nurses and pediatricians mentioned that trainings on vaccination issues are conducted regularly. Trainings are organized either by the IPH or district health directorates. The costs for organizing the trainings are mainly covered from the IPH budget with some support from UNICEF. Physicians and vaccinators travel to district health directorates to attend the trainings that are free of charge, but they usually cover their own travel expenses. All the interviewed health care providers recall the trainings conducted before the introduction of the PCV and IPV vaccines.

The Continuous Medical Education (CME) system does not specify compulsory modules for primary care doctors; the requirement is to accumulate at least 50% of mandatory credits during the four-year term from specialty courses without further specification. Although Immunization courses are not mandatory, they are licensed through the CME system and offer credits for the participants.

The technical and management capacity of EPI staff at the national level is considered to be high by national stakeholders. Along with their solid technical background, they are committed to their work and are led by strong advocates of the Immunization Program. As mentioned by a number of stakeholders, the head of the EPI at the IPH is an influential opinion leader who involves and motivates others and pushes the immunization agenda ahead.

The results based financing for achieving the immunization targets is continued. However, according to the interviewed PHC providers, the financial motivation created by these payments is not a decisive factor for providers to vigorously implement the immunization program. Rather, they perceive carrying out the tasks related to this program as their primary obligation for the population in their care.

The scope and volume of the partners' (WHO and UNICEF) technical assistance to the immunization program in Albania has significantly declined after Gavi support. Immunization is

not one of the priority areas of WHO's and UNICEF's country programs for Albania. The evaluation team was not able to identify evidence of capacity building efforts in immunization supported by the international partners after the year 2013. Key informants also confirmed that partners did not prioritize immunization after Gavi's disengagement. For example, UNICEF SD continues to play an important role in procuring vaccines for reasonable prices for the country but has little interaction otherwise on immunization issues. Another example includes the discontinuation of support for the national scale up of the electronic immunization information management system, which was piloted with the help of the Optimize Project (WHO/PAHO) during Gavi support (2011).

4.3.2. Financial sustainability

The Government of Albania managed to fully fund all programs supported by Gavi in the post-Gavi period, thus ensuring high financial sustainability prospects for the country's immunization program. Key informants noted the smooth transition from Gavi support to local funding for the procurement of vaccines and injection supply. The Government knew in advance about the ending of Gavi funding and ensured the allocation of adequate funding into the budget. Currently all vaccines, including vaccines supported by Gavi, are fully financed by the Government. Moreover, budget planning for vaccines and injection supplies is well established and institutionalized within the national budget cycle. To secure vaccine procurement and ensure financial sustainability of the immunization program, there is a separate budget line for vaccines in the MoH budget. In addition, the financial resources required for vaccines and injection supplies are included in the Government's Mid-Term Expenditure Framework (MTEF). In 2016-2018, the projected budget for vaccines and injection supplies included in the MTEF equals to 350,000,000 Lek or 2,868, 860$ US per year[63]. As mentioned above, the financial resources required for the Rotavirus vaccine are not included in the MTEF, as no decision has been made when the Rotavirus vaccine should be introduced.

Although the budget for vaccines and injection supplies has been secured in Albania, the budget for other immunization related activities (non-vaccine costs) appears to be insufficient. Government officials do not recognize all the costs of the immunization program. The budget for operational expenses, such as vaccine collection and distribution and cold chain maintenance costs, is insufficient. Cold chain maintenance is the responsibility of health centers in Albania. All the visited facility managers mentioned that they do not have specific budget for cold chain maintenance and that expenses related to cold chain maintenance are covered from the facility budget for running expenses. In some cases, the facilities request support from the regional/district health directorates.

While the three-year budget planning practice is well established in Albania, it should be noted that the Comprehensive Multi-year planning (cMYP) tool is not utilized for this purpose. As stated above by the IPH staff, the "cMYP-costing tool is a very complex tool" and it is not utilized in practice; only some parts of the costing tool are used from time to time. Gavi and its partners (WHO and UNICEF) have not provided any additional training or mentoring on the institutionalization of the cMYP tool since cMYP was developed in 2008.

> "We do not use whole tool of cMYP for estimating funding needs. This tool is too complex, but we use some worksheets…. "
>
> *Quote from IPH representative*

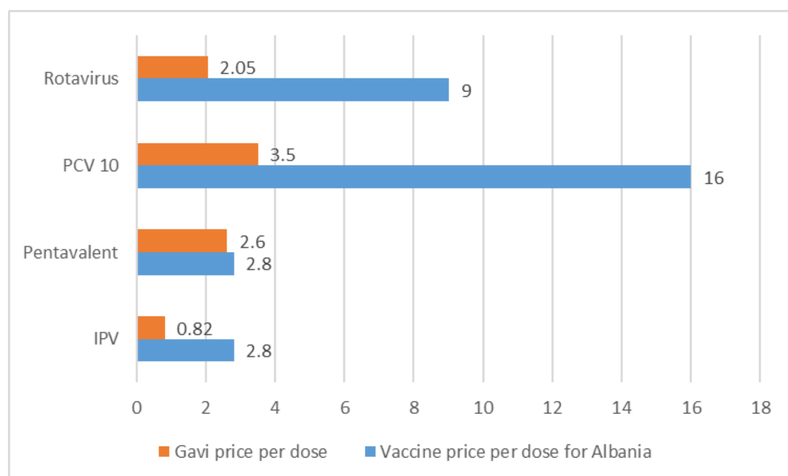
[63] Source: MoH, budgeting department

The UNICEF procurement mechanism for vaccines and injection supplies has been sustained in Albania. All vaccines, including Gavi-supported vaccines (Hep B and pentavalent) as well as those introduced by the Government (MMR, PCV, IPV), are procured through UNICEF. All stakeholders stated that this decision was made from the beginning of Gavi support and that Albania is not going to change vaccine procurement mechanism, since it is the most cost-efficient way and the quality of vaccines is guaranteed. UNICEF procurement mechanism is also used for purchasing cold chain equipment; in addition, out of EPI program Anti Retro Viral (ARV) drugs are procured through this mechanism. Policymakers acknowledge that if Albania was to shift to local procurement, its small market size would lead to a shortage in vaccine supplies, as has happened in other countries in the region. Albania would consider the regional procurement mechanism that has been discussed by those countries, but no final agreement has been reached yet.

Despite the use of the UNICEF procurement mechanism, the country is now paying 3-4 times more for vaccines previously supported by Gavi (with the exception of pentavalent vaccine, which is provided by UNICEF at prices on par with Gavi prices), as the vaccine prices for Gavi countries are no longer accessible for Albania (see Figure 6). This has led to financial difficulties and delays in the introduction of new vaccines. In the post-Gavi period, the country planned to replace the pentavalent vaccine with the hexavalent vaccine, although, according to key informants, this was not achieved due to the government's lack of financial resources to afford this particular vaccine formulation[64]. The introduction of the Rotavirus vaccine was planned from 2014, but was delayed due to insufficient Government funds. The ICC has requested more justification to embark on this initiative. At present the financial resources required for its introduction have not yet been secured in MTEF, but it is still on the EPI agenda after 2017. According to our estimates, the full cost of introducing these new vaccines (Hexavalent and Rotavirus) may significantly increase national immunization program costs from the current level of 1.6% to an estimated 1.9% of Albania's health sector budget. High prices and unaffordability are also cited by national stakeholders as barriers to the introduction of another vaccine (HPV) from Gavi's portfolio. On the other hand, despite the high price, the introduction of PCV and IPV vaccines was fully financed by the Government of Albania, as their introduction was considered cost-effective by the national authorities.

[64] It should be noted that IPV containing hexavalent vaccine is not offered by UNICEF as there is no WHO prequalified hexavalent vaccine available in the market at the moment. Thus Albania attempted to resort to international self-procurement, but failed to find a reasonable price. Many countries in the region experienced the same issue.

Figure 6: Comparison of prices (in US$) for the selected Gavi supported vaccines for Albania and Gavi eligible countries (2014-2015)



Source: UNICEF SD 2015

4.3.3. Positive and negative consequences of Gavi support

Based on the evaluation findings the, following positive consequences were observed:

- The establishment of the ICC promoted evidence-based decision making in Albania;
- Gavi's efforts to mobilize partners' financial and technical resources generated collaborative responsibility for the immunization program, and also built knowledge;
- Gavi support facilitated strong collaboration between the IPH and the Health Insurance Institute in planning and implementing the immunization program;
- Gavi support stimulated the introduction of improved planning and budgeting practices in vaccine procurement. The development of the financial sustainability plan contributed to a change in EPI's planning and forecasting practice;
- The Independent Review Committee (IRC)'s feedback on proposals submitted by Albania facilitated improvements in the planning exercise;
- Gavi's comments on discrepancies in factual data reported in APRs stimulated the redesign of immunization registration and reporting forms by separating mobile population data. Therefore, Gavi played a role in improving inconsistencies in demographic information, which had been one of the big challenges in Albania.

All stakeholders mentioned that there were no unintended negative effects from Gavi's time-limited support; nor could the evaluation team identify any from the document review.

4.3.4. Main factors contributing to the achieved results

While we were not able to establish direct attribution, based on the responses to the previous evaluation questions, the evaluation team identified the following key factors that may have determined the achieved results:

> " Based on Gavi's request, a financial plan for immunization was developed with the assistance of international partners…"
>
> "….Gavi helped to change our planning and forecasting practice.."
>
> *Quotes from government representative*

National:

- Albanian inherited of a strong Immunization System;
- Strong political support to the EPI in Albania;

- The IPH's strong managerial capacity, individual leaders and dedicated health care providers;
- The experience of co-financing and phasing out accumulated by the Government of Albania under the UNICEF-supported routine vaccination program.

Gavi and partners

- Gavi requirements that served as a catalyst for the introduction of effective mechanisms for the long term planning and management of immunization;
- Vaccine introduction grants that were critical in building human resource capacity for new vaccine introduction;
- Support and guidance provided by Gavi throughout the implementation period; and
- Strong and continuous support from partners during Gavi support.

Summary of findings on sustainability

Evaluation Questions	Findings	Robustness Ranking	
To what extent have the relevant activities related to 'Gavi support' been continued?	All Gavi supported activities are *fully* continued: Hep B and pentavalent vaccines, as well injection supply, are fully financed by the Government.	A	Findings are substantiated by documentary, quantitative and qualitative data.
To what extent have the systems and structures functioning or developed at the time of Gavi support continued to function effectively?	The coordination mechanism established at the time of Gavi support continues to operate, although the frequency of meetings decreased and the Government has to take additional measures to address the functionality of this structure.	A	Findings substantiated by triangulation of documentary and key informant data.
	NITAG continues to *fully* function, and prepares justifications and different scenarios for new vaccine introduction. After Gavi support ended, a new composition of the technical group was established.	A	Findings substantiated by triangulation of documentary and key informant data.
	The UNICEF procurement mechanism is used to purchase all vaccines included in the immunization schedule	A	Findings substantiated by triangulation of documentary and key informant data.
	Technical assistance from Gavi partners for the immunization program and its various aspects has diminished, if not disappeared, after Gavi's disengagement, while unmet needs remain (e.g. for institutionalization of the cMYP).	B	Findings based on documentary review and an interview with one key informant.
To what extent have the results (both outcomes and impact) of Gavi supported programmes been sustained, expanded or improved since the conclusion of Gavi's time-limited support?	High immunization coverage rates have been sustained at the national and district levels.	A	Findings are based on the analysis of available administrative quantitative data and qualitative information.
	Achievements in Safe injection are sustained: AD syringes are used throughout the country, and safety boxes are available in all facilities. Albania managed to replace the cold chain throughout the country after Gavi support ended.	A	Findings are substantiated by documentary, quantitative and qualitative information.
	Effective vaccine management system is sustained. The country has not experienced a vaccine stock-out.	A	Findings are substantiated by documentary and qualitative information.
	Overall, the financial sustainability prospects for Gavi supported activities are high, as the	A	Findings are substantiated by documentary and qualitative

	Government of Albania has managed to fully fund these activities through the public funds (without external donor support).		information.
	There is inadequate funding for immunization related operational expenses (vaccine collection and distribution, cold chain maintenance).	C	Findings are substantiated only by qualitative data in the absence of available quantitative information.
	The cMYP tool is not utilized in practice, which may affect the Government's ability to conduct long-term immunization planning and fully capture immunization program costs.	A	Findings are substantiated by documentary and qualitative information.
What are the main factors explaining the achieved results (positive or negative)?	Multiple factors can explain the achieved results: - Albanian inherited a strong Immunization System - Gavi requirements that served as a catalyst for the introduction of effective mechanisms for immunization long term planning and management; - Support and guidance provided by Gavi; - Strong and continuous support from partners during the Gavi support period; - Strong political support to the EPI in Albania; - The IPH's strong managerial capacity, individual leaders and dedicated health care providers; - Vaccine introduction grants that were critical in building human resource capacity for new vaccine introduction.	A	Findings substantiated by the triangulation of documentary and key informant data.
What have been the main unintended positive and/or negative effects of the time-limited nature of Gavi support and its conclusion?	Establishing the ICC promoted an evidence based decision making process in Albania;	A	Findings are substantiated by documentary and qualitative information.
	Gavi support stimulated the introduction of planning and budgeting practices for vaccine procurement; The development of financial sustainability plans contributed to changes in EPI planning and forecasting practice;	C	Findings are substantiated only by qualitative information.
	Gavi's comments on discrepancies in factual data reported in APRs stimulated the redesign of immunization registration and reporting forms;	A	Findings are substantiated by documentary and qualitative information.
Have new vaccines been introduced in Albania since the conclusion of Gavi support?	Albania introduced MMR, PCV with its own expenses during the Gavi support period, and IPV vaccine after Gavi support ended.	A	Findings are based on a review of immunization schedules.

5. Lessons Learned

This section presents the lessons learned in response to the last two evaluation questions. The lessons learned are based on the current evaluation findings and are contextualized against the findings from the final evaluation of Gavi support to Bosnia & Herzegovina, as requested by the RFP.

Key evaluation Questions

- What are the key lessons learned from Gavi's support and the conclusion of this support in Albania?
- To what extent could Gavi utilise these lessons and experiences (from both Albania and Bosnia-Herzegovina) to strengthen its approach to graduation and transition going forward? What are some key recommendations you would make to the Gavi Alliance and to other countries in process of transitioning away from Gavi support now and in the future?

Strong, high-level political support to immunization existed in the pre-Gavi period, and was further demonstrated by the Government of Albania during and after Gavi support. This was a critical factor in the overall success of the immunization program in the country. This support ensured that the Gavi-supported immunization objectives were fully integrated in the national policy and budget, thus assuring a seamless transition from Gavi support to full domestic financing of the vaccines and AD syringes previously procured through Gavi funds. Conversely, weak political support in BiH for the national immunization programs at the national level, and varying degrees of support at the subnational (entity) level, has likely contributed to the relatively unfavorable programmatic and sustainability prospects in that country. The importance of political support – in creating a favorable environment for integrating immunization goals in national policies, legal frameworks and budgets – was also identified as a key determinant for programmatic and financial sustainability by the recent assessments and evaluations conducted for Gavi transitioning countries[65,66]. Therefore, building strong, high level political support for national immunization programs through continuous advocacy and policy dialogue with all relevant stakeholders at national (and if required subnational) level from the very beginning of a Gavi program will most likely enhance program outcomes and significantly improve the sustainability prospects of Gavi's time-limited support.

Gavi support may play an important role even in countries with a high level of political commitment to vaccination and strong immunization systems like Albania. It is likely that, without Gavi support, the country would have experienced problems in financing Hep B vaccinations in the aftermath of its economic and political crisis in 1997-2000, and may have had difficulties and delays in independently introducing new vaccines (MMR, PCV and IPV) at a later period without the public funds "freed" by continuous Gavi support to the Hep B and pentavalent vaccines. Gavi and its partners' support was critical in (a) introducing long term planning practices for the immunization program; (b) building health providers' capacity in proper use of pentavalent vaccine; and (c) nationwide implementation of the injection safety policy.

GAVI support intended to contribute to strengthening the Government's capacity to develop policies and strategies and to enhance planning and management capabilities for immunization services**. Gavi requirements** for eligible countries (existence of a national coordination mechanism, a costed multi-

[65] Saxenian et al. Overcoming challenges to sustainable immunization financing: early experiences from GAVI graduating countries. Health Policy Plan. February 8, 2014

[66] GAVI Alliance Co-Financing Policy Evaluation. Norwegian Institute of Public Health. 2014

year national immunization program) and **Gavi's effective and continuous engagement throughout the implementation period** contributed to improvements in planning and implementation framework for the national immunization programs both in Albania and in BiH. They also most likely ensured stakeholder coordination at national (Albania) and subnational (BiH) levels, provided traction for evidence based decision-making and contributed to country ownership of the Gavi-supported immunization program goals. These improvements to the structure and effectiveness of immunization planning and implementation/management were sustained after Gavi's disengagement from Albania, as the functional national coordination mechanism, the relatively long term centralized planning framework (three years through the MTEF mechanism), and the strong implementation agency (the IPH) were retained. By contrast in BiH, national immunization programs were negatively affected by several factors, including: the diminished role of the national coordination mechanism; the deterioration of central planning for the immunization programs; and the absence of a strong implementing agency at the national level (like the IPH in Albania) responsible for strategic planning, problem solving, oversight function in relation to expenditure tracking or programme review. Problems caused, included the discontinuation of safe injection policies and the periodic vaccine stock-outs after Gavi support ended. Thus, the Albania and BiH cases highlight the importance of (a) a sustainable national coordination mechanism and a coordinated (if not centralized) immunization planning mechanism; and (b) a strong, national level agency responsible for implementing, monitoring and expenditure tracking of the immunization program, to ensure the successful transition and sustainability of Gavi-supported programs. We think that this lesson is also relevant for other Gavi phase II countries and may be taken into account during transition planning.

The transition from Gavi support to full Government financing of Gavi-supported vaccines occurred smoothly in both countries in the absence of Gavi's co-financing policy. This Gavi policy has a dual objective of contributing to country ownership of vaccine financing and in-country financial sustainability**.** However, the fact that Albania has better financial sustainability prospects for the immunization program than BiH[67] may be related to the similar co-financing arrangements between the Government of Albania and UNICEF for routine vaccines (i.e. those not supported by Gavi)**.** This arrangement, much like what is expected from Gavi's co-financing policy, contributed to increased country ownership and financial sustainability by planning for and integrating immunization financing for all vaccines (including Gavi supported vaccines, once Gavi support ended) in the national budget process prior Gavi's disengagement. Thus case of Albania, like most of the countries currently transitioning to phase 3[68], may support the continuous application of Gavi's co-financing policy.

The absence of a Gavi transition (graduation) policy and the Gavi transition planning opportunity has affected both countries, but to varying degrees. While Albania experienced uncertainties related to the availability of further Gavi support for new vaccine introduction (IPV and Rota), it still managed to introduce one out of two new vaccines (IPV) with its own resources. However, the transition was more problematic for BiH as it shifted to a decentralized procurement mechanism for vaccines, and as a result experienced interruptions in vaccine supply and much higher prices (5-20 times higher than UNICEF) for vaccines than Albania. The transition planning assessment routinely conducted in currently transitioning countries would have revealed this procurement capacity challenge and alerted the government and the international partners – most likely prompting remedial

[67] Final Evaluation of GAVI Alliance's Support to Bosnia and Herzegovina. Curatio International Foundation. 2014
[68] GAVI Alliance Co-Financing Policy Evaluation. Norwegian Institute of Public Health. 2014

actions prior to the transition to self-procurement. Challenges in procurement planning, tendering and handling are typical for many of the transitioning countries. A few currently transitioning countries have attempted to procure vaccines themselves (e.g. Georgia, Azerbaijan and Moldova), and they have all experienced significant difficulties[69]. If these challenges are not addressed during the early stages of transition, they may pose serious problems for national immunization programs, as demonstrated by the BiH case.

Maintaining use of the UNICEF procurement mechanism allows Albania to spend public funds more efficiently than BiH and to have lower prices through the UNICEF SD. However, even these lower vaccine prices are still 3-4 times higher than Gavi prices, which appears to have contributed to the delays in introducing new vaccines in the country. The situation is understandably worse in BiH, which experiences even higher vaccine prices. Unlike Albania, BiH has been unable to introduce any new vaccines since Gavi's disengagement. It is also unclear whether new vaccines will become available for the BiH population in the near future. GAVI through UNICEF is able to negotiate extremely low prices due both to its large market and the organization's excellent credit rating. The experience of Albania and BiH shows that the currently graduating countries may be unable to match these prices through self-procurement or even through the UNICEF procurement mechanism after Gavi's disengagement. This realization has already prompted Gavi to seek commitments from manufacturers to provide Gavi prices to graduates, or "phase 3" countries as stipulated in the revised Gavi Eligibility and Transition Policy that will come into effect from the year 2016. Gavi has also already negotiated continued low prices for graduated countries for pentavalent, pneumococcal and rotavirus vaccines[70]. However, this arrangement will not apply to Albania, BiH, China or Turkmenistan, as Gavi support to these four countries has already ended, placing them in a disadvantageous position compared to current phase 3 countries with similar income levels, simply because they became ineligible to Gavi support before the introduction of Gavi's Eligibility and Graduation policy. Our evaluation findings show that Albania and BiH are experiencing problems with rising vaccine prices and subsequent difficulties in the introduction of the new vaccines, and they may have benefited from access to Gavi prices for at least the new vaccines.

In addition to vaccine budgets, the Government has to mobilize adequate funding for recurrent costs, such as cold chain maintenance, demand creation and community mobilization activities, to ensure the long-term sustainability of the immunization program. In order to do so, decision makers have to be aware of the full costs of the immunization program, which for example may be achieved by using the cMYP tool fully. The problem of accounting and planning the full costs of the national immunization program is present in both Albania and BiH. The full utilization of cMYP tool is not institutionalized in these countries. Thus, both countries may benefit from the technical assistance initiated by Gavi through its partners (WHO) to address this issue and improve financial sustainability.

The evaluation findings show that the technical support from WHO, UNICEF, the World Bank, USAID and other development partners, was pivotal for sound immunization planning in both Albania and BiH during Gavi support. Both countries, like the currently transitioning countries, have benefited from inter-country exchanges, knowledge sharing workshops and regular visits by senior

[69] Ibid

[70] Saxenian et al. Overcoming challenges to sustainable immunization financing: early experiences from GAVI graduating countries. Health Policy Plan. February 8, 2014

officials from Gavi, WHO, UNICEF etc., raising the political profile of immunization. The international partners' focus has shifted from immunization once Gavi support ended in Albania and BiH. The cases of Albania and BiH have showed that once GAVI support ends, the gains made from such visibility and outside financial support and technical assistance could suffer, unless local advocacy efforts are intensified and national technical skills are strengthened. At present, most immunization-related technical support from international partner institutions is focused on Gavi countries, with little support for graduated and other middle-income countries that are ineligible for Gavi support, like Albania and BiH, but still require technical assistance and political support. Latin America is an important exception. The Pan American Health Organization (PAHO) backs immunization advocacy efforts and provides technical assistance for large numbers of middle-income countries on that continent. Its ProVac initiative helps to strengthen countries' technical capacity to make evidence-based decisions about new vaccine introductions. Similar efforts could be initiated by Gavi through WHO and/or UNICEF in other regions, including the CEE/CIS region which encompasses both Albania, BiH and several currently transitioning countries.

6. Conclusions

During early 1990s the immunization program managed to respond to emergency needs, and mass campaigns were used to fill the gaps in immunization coverage. The immunization program had unstable government funding, disrupted cold chain equipment, and challenges in safe injection practice and waste management. Nevertheless, the immunization program maintained high vaccination coverage rates. UNICEF was the main donor in the field of immunization. Good partnership and effective collaboration with the Government facilitated the quick recovery of Albania's immunization program from the crisis and improved program performance.

Programmatic and Financial Sustainability planning were key issues addressed by Gavi through the eligibility requirements fulfilled by the country, including financial and programmatic plans (FSP, detailed injection safety plan, cMYP, Hib vaccine introduction plan), which facilitated transition planning from the beginning of Gavi support. The financial planning exercise was extremely useful and contributed to changes in EPI planning practice.

Gavi support was relevant to Albania's needs and important for funding new (Pentavalent) and underused (Hepatitis B) vaccines and injection safety in Albania. Without Gavi support sustainable and uninterrupted financing for Hep B/pentavalent vaccines may not have been ensured at the time of its initiation. Gavi support for all programs was based on thorough situation analyses, which were well documented and communicated to the national stakeholders and in-country partners.

The coordination mechanism (ICC) established in line with Gavi's request ensured stakeholder coordination and evidence-based decision-making in Albania. The ICC was instrumental in coordination, strategic planning, problem solving and monitoring of program implementation. The Institute of Public Health (IPH) played a key role in ensuring that the ICC functioned effectively. The Technical Working Group's/NITAG's role was fundamental in preparing evidence about the impact of new vaccine introduction. Coordination meetings were participatory; all entities and institutions involved in immunization services as well as Gavi partners and other donors were actively involved.

Collaboration and partnership with in-country partners (WHO, UNICEF) was effective. In-country partners played a crucial role both in direct involvement in the coordination of immunization activities or in direct support to the Program**.** UNICEF's contributions were extremely important to the long term sustainability of the program**.** The practice of gradual increase of government allocations for traditional vaccines, which was part of the UNICEF agreement, helped the Government to successfully manage the transition process from Gavi Hep B support and fulfil its commitment. The Government strictly adhered to the terms of the agreement, thus demonstrating a strong ability to gradually take over the financing responsibility.

Gavi's monitoring of country performance during its support was evident. Gavi's comments on discrepancies in factual data played a role in improving inconsistencies in demographic information, which had been one of the big challenges in Albania, and facilitated the redesign of registration and reporting forms. Financial arrangements for budget planning, negotiation and procurement of vaccines were highly effective through the UNICEF procurement mechanism. Before new vaccines were introduced, healthcare workers received extensive training to address key bottlenecks in new vaccine introduction and injection safety, mostly financed through Gavi's Vaccine Introduction Grant.

The coordination mechanism established during Gavi's support continues to operate, although the frequency of the meetings has decreased. During the Gavi support period, four ICC meetings were

conducted, while after Gavi support ended only one or two coordination meetings per year are carried out. NITAG continues to function effectively, preparing justifications and different scenarios for new vaccine introduction. Recent Ministerial Orders clearly define the role of the ICC and NITAG, their new composition and responsibilities. A Ministerial Order also outlines that ICC should meet four times per year.

All Gavi supported activities have continued. The pentavalent vaccine, which includes the Hep B vaccine and AD syringes, is fully financed by the Government. The budget for those activities have been safeguarded in the MoH budget. Albania did not experience a vaccine stock-out after Gavi support ended, contrary to BiH where intermittent vaccine stock outs and shortages of medical supplies were observed.

Stable and high immunization coverage rates (> 95%) have been sustained at the national as well district level. There is a general trust towards health professionals and the immunization program. Achievements in the implementation of the safe injection policy have also been sustained in Albania**.** This is contrary to BIH, where injection safety practices were discontinued and irregularities in unsafe waste management practices were observed after Gavi's support ended.

Unlike BiH, Albania was able to introduce new vaccines during and after Gavi support. In 2005 and 2011, the MMR and PCV vaccines were introduced by the Government funds. In 2014, Albania introduced the IPV vaccine without donor support. IPV replaced the OPV vaccine in the national immunization calendar. The introduction of new vaccines in the post Gavi period did not happen in BiH.

The budget planning mechanism for vaccine procurement that was used during Gavi support has been maintained and institutionalized. The financial resources required for vaccines and injection supplies are also included in the Government's Mid-Term Expenditure Framework (MTEF). Although the stakeholders recognized FSP and cMYP tools to be very useful, they are not fully utilized due to their "complexity", which may be related to the lack of the national institutional capacity in using these tools. Other (non-vaccine) immunization related activities, such as operational expenses for travel for vaccine collection and distribution, and cold chain maintenance expenses, are insufficiently funded.

In contrast with BiH, the use of the UNICEF procurement mechanism to purchase all vaccines included in the immunization schedule has been sustained in Albania.

In summary, all the evidence at hand lead us to conclude that the achievements during the Gavi support period will most likely be sustained in the coming few years, and improvements in the national immunization program in Albania will continue. Both financing for immunization and programmatic management of immunization have become stronger since the initiation of Gavi support and are likely to progress further as Gavi supported activities are fully integrated in the national policy and budget.

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7. Recommendations

The recommendations are based on the current evaluation findings. However, some of the recommendations are derived from a synthesis of the results of this evaluation and the results of the BiH evaluation, which was also conducted by Curatio International Foundation.

7.1. Recommendations to Gavi

- The Gavi secretariat, independently and through its partners (WHO and UNICEF), should build strong, high level political support for national immunization programs at the earliest stage of Gavi engagement with eligible countries. This can be achieved through advocacy and policy dialogue with all relevant stakeholders at the national (and if required, subnational) level, and will most likely enhance program outcomes and significantly improve the sustainability prospects of Gavi's time-limited support.

- For successful transition and sustainability of Gavi-supported programs, transition planning should explicitly encompass support to the establishment of (a) a functional and sustainable national coordination mechanism; (b) a coordinated (if not centralized) immunization planning mechanism for countries with decentralized system; (c) a strong, national level agency responsible for implementation, monitoring and expenditure tracking of the immunization program. These requirements should be included in the transition planning assessments and capacity building efforts, and should be initiated at the earliest possible stages of transition.

- Gavi should try to provide Gavi prices for a time-limited period, not only to the "phase 3" countries, but also to other lower-middle-income countries like Albania and BiH that are no longer eligible or were never eligible for Gavi support, but experience financial difficulties in introducing new and expensive vaccines, as recommended in the Gavi policy paper on support to Access to Appropriate Pricing (ATAP) for Gavi Phase 3 countries. Alternatively, or in parallel, Gavi and its partners should help small and medium sized countries to establish regional pooled mechanisms for vaccine procurement to ensure more affordable prices for new vaccines, as articulated in WHO's SAGE Task Force Recommendations for Middle Income Country (MIC) Strategy.

- Gavi the Vaccine Alliance, WHO and UNICEF should consider refocusing their technical assistance efforts on unmet needs for immunization programs in graduated and other lower-middle-income countries that experience problems in their immunization programs. For example, both Albania and BiH may benefit from technical assistance that strengthens their capacity to generate evidence for decision making through analysis of costing and financing of routine immunization and new vaccine introduction (including the adaptation and institutionalization of the cMYP tool), in prevention of further growth in vaccine hesitancy and promotion of vaccine community demand. The experience of PAHO and other international partners in providing such support to non-Gavi MICs should be closely studied and, if possible, replicated in other regions, including Central and Eastern Europe.

7.2. Country Specific Recommendations

- Albania can explore the possibility of new vaccine procurement through the regional pooling mechanism. Other small CEE/CIS countries, or Balkan neighbors such as BiH, Montenegro, Serbia, face similar problems. While developing a regional procurement mechanism may be a challenging task, Albania should regularly discuss this issue with countries in the region. UNICEF/WHO could be active players in facilitating such discussions.

- In addition to vaccine budgets, Albania should plan and mobilize adequate funding for recurrent costs, such as cold chain maintenance, demand creation and community mobilization activities, to ensure the long term sustainability of its immunization program. The full utilization of the cMYP costing tool for planning purposes may help to address this problem. The Government can apply to international partners (e.g. WHO) or mobilize internal resources to institutionalize the cMYP.

8. Annexes

Annex 1: **Evaluation Matrix**

Evaluation Questions	Judgment Criteria/Indicator	Methods	Document Source
PLANNING			
EQ1. To what extent were there processes or support put in place by GAVI to address both financial and programmatic sustainability?	Judgment on the **adequacy** of the process or support based on the responses to the sub question 1.1. (*highly adequate; adequate; not adequate*) separately for programmatic and financial sustainability.	Qualitative information collected through: • Document Review (DR); • In-Depth Interviews (IDI);	Country proposals, GAVI management letters, IRC proposal reviews,
1.1. To what extent were these relevant, realistic, well-documented and well communicated?	Judgment on (a) **relevance** (*yes/no*); (b) **realistic** (*yes/no*); (c) **well-documented** (*yes/no*); (d) **well-communicated** (*yes/no*)		
EQ2. To what extent did Albania prepare and plan for the transition away from GAVI support?	Judgment on the **adequacy** of the planning based on the responses to the sub questions 2.1.-2.4 (*highly adequate; adequate; not adequate*).	• DR; • IDI;	Country proposals, the national development and health care strategies, Country Medium Term Expenditure Frameworks, Budget Plans; Relevant Ministerial Decrees, GAVI management letters, IRC proposal reviews.
2.1. To what extent was the planning put in place by the country relevant, feasible (considering socio-economic and political context) and coordinated?	Judgment on (a) **relevance** (*yes/no*); (b) **feasibility** (*yes/no*); (c) **coordination** of the country planning		
2.2. To what extent was the planning put in place comprehensive (covering both financial and programmatic aspects) and institutionalized (integrated into the health system planning)?	Judgment on (a) **comprehensiveness** (*yes/no*) and (b) **institutionalization** (*yes/no*); of the country planning		
2.2.1. What were the main financial arrangements put in place to ensure sustainability?	Evidence and description of the financial arrangements		
2.2.2 What were the main programmatic arrangements put in place to ensure sustainability?	Evidence and description of the programmatic arrangements		
2.2.3 To what extent did GAVI support these efforts?	Judgment on the **level of support** (*high/medium/low*) for planning		
2.3. To what extent were stakeholders informed and cognizant of the implications of the conclusion of GAVI's time-limited support?	Judgment on how informed and cognizant were stakeholders (*well /somewhat/not*)		
2.3.1. Did the stakeholders clearly understand timeline and necessary steps for transition?	Judgment on the level of understanding (yes/no)		

2.4. To what extent was the implementation plan for transition detailed to ensure its effective implementation?	*Judgment on the level of detail of the plan (sufficiently/not)*		
IMPLEMENTATION			
EQ3. To what extent were the activities of the sustainability plan (if one was developed) effectively and efficiently implemented?	Judgment on **effectiveness** of the implementation of the sustainability plan (*highly/somewhat/not*) based on the evaluation sub questions 3.1, 3.2, 3.3, 3.4 Judgment on **efficiency** of the implementation of the sustainability plan (*highly/somewhat/not*) based on the cost of procured vaccines and the evaluation sub questions 3.4 and 3.5	Qualitative information collected through: • DR; • IDI; • Group Interviews (GI) Quantities data on vaccines prices	Country proposals, the national development and health care strategies, Country Medium Term Expenditure Frameworks, Budget Plans; Budget Execution Reports, NIP reports, Relevant Ministerial Decrees, GAVI management letters, IRC proposal reviews.
3.1. What were the main challenges and how were they addressed?	Evidence and description of the challenges (if any)		
3.2. What were the main programmatic arrangements put in place to ensure effective implementation of transition plan?	Evidence and description of the **arrangements** according to the WHO health system building blocks		
3.3. To what extent achievements or challenges of the transition process were regularly monitored?	Judgment on the **regularity** of monitoring *Regularly/somewhat/not*		
3.4. To what extent the time-period for transition was feasible and attainable?	Judgment on the **feasibility (***yes/no***)** and **attainability (***yes/no***)** of the transition time-period		
3.5. Was implementation of transition plan on time and according to schedule?	Judgment whether the implementation was **according to schedule** (*yes/no*)		
3.6. What adaptations were made to the program during transition period?	Evidence and description of adaptations		
3.7. To what extent did GAVI support these efforts?	Evidence and description of GAVI support		
3.8. What was the role of partners during transition plan implementation?	Evidence and description of the role (roles) of partners		
EQ4. What activities took place in the absence of a sustainability plan, if one was not developed?	Description of the relevant activities		
4.1. How were these activities coordinated? How were they initiated?	Description of how the activities were initiated and the coordination arrangements,		
4.2. What was the role of partners supporting the country after the end of GAVI support?	Evidence and description of the role (roles) of partners		
4.3. Which stakeholders should have been involved in the transition process, but were not involved?	List of stakeholders and justification of their involvement		
4.4. What have been the consequences of the lack of a plan?	Description of consequences (if any)		
RESULTS			
EQ5. To what extent have the relevant activities related to 'GAVI support',	Judgment on the extent to which the GAVI	Qualitative	MOH documents, NIP

such as delivery of vaccines, injection safety procedures, addressing inequities, surveillance and monitoring, been continued?	supported activities have continued (*fully/partially/not*)	information collected through: • DR; • IDI; • GI	reports
EQ6. To what extent have the systems and structures functioning or developed at the time of GAVI support, such as coordination by the ICC / NRAs / NITAG, technical support from partners, procurement from UNICEF and information sharing, continued to function effectively?	Judgment on the extent to which the respective activities have continued (*fully/partially/not*) and function properly (*yes/partially/no*)	Qualitative information collected through: • DR; • IDI	MOH documents, NIP reports, ICC meeting minutes
EQ7. To what extent GAVI political engagement changed throughout grant implementation and how it affected program implementation?	Description of changes and their effect on the program implementation (If any)	Qualitative information collected through: • IDI	
EQ8. To what extent have the results (both outcomes and impact) of GAVI supported programs been sustained, expanded or improved since the conclusion of GAVI's time-limited support?	Judgment on whether the results were sustained (*yes/no*); expanded (*yes/no*) and/or improved (*yes/no*) in accordance with the assessment of the programmatic and financial sustainability described above and based also on sub questions 8.1. and 8.2.	Qualitative information collected through: • DR; • IDI; • GI	Health sector documents, NIP reports, APRs, evaluation reports on immunization
8.1. What are the ongoing challenges Albania faces for sustainability of its immunization program? What are the facilitating factors?	Description of the challenges and facilitating factors		
8.2. What adaptations were made to the immunization program following the conclusion of GAVI support? What was the possible impact on intended outcomes (particularly coverage, safety, financial sustainability etc.) of these adaptations? What was the decision-making process around these adaptations?	Description of the (a) **adaptations**; (b) their possible **impact** and (c) the **decision-making** process		
EQ9. What are the main factors explaining the achieved results (positive or negative)?	Judgment on the main factors	Qualitative information collected through: • DR; • IDI	EPI reviews, evaluation reports on immunization
EQ10. What have been the main unintended positive or negative effects of the time-limited nature of GAVI support and its conclusion?	Evidence and description of the main unintended positive and negative effects	Qualitative information collected through: • DR; • IDI	evaluation reports on immunization
EQ11. Have new vaccines been introduced in Albania since the conclusion of GAVI support?	Evidence of the new vaccine introduction (*yes/no*)	Qualitative information	Health sector documents, NIP reports

11.1. f so, what are the financing and procurement arrangements and the prices being paid for these vaccines?	Description of the arrangements and prices	collected through: • DR; • IDI	
11.2. Which stakeholder initiated introduction of the new vaccine?	Description of the stakeholder		
11.3. If no new vaccines are introduced what are the main barriers to new vaccine introduction?	Description of barriers (if any)		
EQ12. Did the GAVI support incorporate adequate exit strategies and capacity development measures to ensure sustainability of the results over time?	Judgment on adequacy of the exit strategies (if any) (*highly/somewhat/not*)	Qualitative information collected through: • DR; • IDI	GAVI management letters, IRC proposal reviews.

Annex 2: Key points during the Gavi support

Year	KEY POINTS
2000	• The Interagency Coordinating Committee on immunization (ICC) was established on July 17, 2000. • The Government of Albania applied for Hep B vaccine support to Gavi in August 2000.
2001	• Albania was approved for Hep B vaccine support in May 2001. The estimated total value of support for 2001-2002 was US $140,000. (***Gavi decision letter GAVI/01/153/clm, 17 August, 2001)***. • Albania received a new vaccine introduction grant of US $100,000 from Gavi in 2001 (***APR, 2003)***. • Albania applied to Gavi for INS.
2002	• Albania received 339,000 doses of Hep B vaccine in three shipments during 2002 (***IRC on APR for 2001, January, 2003)***. • On May 2002, the GAVI board didn't approve Albania's application for INS. The application missed a sufficient detailed plan related to the Safety of Injection for Expanded Program on Immunization (***APR, 2002; IRC on APR for 2001, January, 2003)***. • On June 28, 2002 Gavi sent a decision letter to the MoH informing about the Board's decision about the country's INS proposal, and requested resubmission of the INS proposal. *"Albania is urged to provide a detailed plan of action on injection safety and waste disposal management, according to the current GAVI guidelines."* ***(Gavi decision letter GAVI/02/128/jd, June, 2008)*** • A new INS application, together with an INS plan for 2003-2007, was resubmitted in August 2002 (***Albania INS proposal, 2002)***.
2003	• In March 2003 Albania was requested to provide clarifications about increased targets of infants immunized with Hep B in 2003. • In May 2003 the IRC approved Albania's INS proposal with a clarification. The IRC requested ICC to provide a letter of assurance that GAVI support for injection safety would not replace current funding by the Government or partners (***IRC decision letter GAVI/03/087/jd, 14 July, 2003)***. • On September 22, 2003 Gavi's decision letter was sent to the MoH of Albania informing that the clarifications provided by Albania were satisfactory, and that the country has been granted support for INS. The total funds committed for 3 years was at US $ 92,000. ***(Gavi decision letter GAVI/03/132/jd, 22 September, 2003)***
2004	• The IRC congratulated Albania on its achievements in injection safety improvement. Almost all targets were reached: 100% of health facilities were provided with AD syringes and adequate quantity of safety boxes. However, due to the lack of funding 20% of health facilities were not provided with incinerators. • The IRC recommended the country to collaborate with ICC and local partners in order to accelerate the process of **FSP preparation** and submission. • The IRC approved the revised number of surviving infants and DTP, HepB and injection safety support targets for 2004-onward. • The IRC strongly encouraged the country to work in close collaboration with local partners to improve the immunization reporting system, in order to ensure the reliability of coverage figures.

	• The IRC congratulates the country on its demonstrated intention to allocate domestic resources for hepatitis B vaccine procurement from 2006. (***IRC Report on APR for 2003)***. • Gavi committed US $103,000 for three years for INS ***(Gavi decision letter GAVI/04/120/jd, July 30, 2004)***. • An FSP was prepared in July 2004.
2005	• The FSP was reviewed by the IRC in 2005 and accepted with only minor corrections being recommended. • In October Albania applied for Hib monovalent support to Gavi ***(APR 2005)***. • Albania received conditional approval. Gavi requested Albania to provide a) a detailed Plan of Introduction for the Hib vaccine including strategies, targets, activities, indicators and timelines; and b) evidence of cold chain storage capacity at the various levels of the health services to accommodate the vaccine requested. ***(IRC Meeting October 31/November 8, 2005)***. • Gavi support for Hep B vaccine ended.
2006	• Albania responded to Gavi's request regarding to Hib vaccine support proposal in June 2006 ***(APR 2005)***. • The IRC reviewed the resubmitted proposal for the Hib vaccine support and gave conditional approval, requesting Albania to a) correct inconsistencies in population figures, numbers of births and numbers of surviving infants; and b) develop a detailed Plan of Introduction for the requested Hib vaccine. ***(16 th IRC proposal review 26 June-5 July, 2006)***. • A Detailed Plan of Hib vaccine introduction was prepared and approved by ICC ***(APR 2006)***. • The IRC approved Albania's proposal for Hib vaccine introduction in November, 2006. The estimated total value of support for 2008-2012 was US $ 2,305,000 ***(17th IRC proposal review 22-27 November, 2006, Gavi decision letter GAVI/07/023/ire/hb, 15 February, 2007)***. • Hepatitis B vaccine support from Gavi ended in 2006 ***(APR 2007)***. • INS support ended in 2006 (***IRC Report on APR for 2006)***.
2007	• Due to the unavailability of Hib mono vaccine, Albania, in consultation with UNICEF's supply division, decided to introduce the Pentavalent vaccine instead ***(APR 2007)***. • Albania received a new vaccine introduction grant of US $100,000 from Gavi in August 2007, which, according to the document review, was not utilized. • Effective Vaccine Store Management (EVSM) was conducted in May, 2007.
2008	• The IRC approves the change in presentation from Hib mono to DTP-HepB-Hib.
2009	• Albania received a Pentavalent introduction grant at US $100,000 from Gavi in January, 2009. • The Pentavalent vaccine was introduced in March, 2009
2011	• The PCV vaccine was introduced into the national immunization calendar in 2011. The expenses were covered by the Government ***(APR 2011)***.
2013	• Gavi support for Pentavalent vaccine ended.

Annex 3: List of documents reviewed

N	Document	Language
1	GAVI Alliance country eligibility policy, effective from January 2011	English
2	GAVI Alliance graduation policy, effective from January, 2011	English
3	Gavi Eligibility and Transition Policy, effective from July 2015	English
4	Evaluation of GAVI-Government of China Hepatitis B Vaccination Program, Abt Associates, December, 2012	English
5	Management Response – Evaluation of GAVI-Government of China Hepatitis B Vaccination Program	English
6	Final Evaluation of Gavi support to Bosnia and Herzegovina, Curatio International Foundation, July, 2014	English
7	Gavi, the Vaccine Alliance; Response to the “Final evaluation of Gavi support to Bosnia and Herzegovina;” December, 2014	English
8	Albania proposal for Hepatitis B vaccine support with clarifications, August, 2000	English
9	Albania proposal for Injection Safety Support (INS), 2002	English
10	Albania Injection Safety Support action plan for 2003-2007	English
11	Albania proposal for Hib vaccine support	English
12	Albania National Plan of action for Immunization for 2001-2005	English
13	Albania Financial Sustainability Plan for 2004-2013	English
14	Annual Progress Report (APR) for 2001	English
15	Annual Progress Report (APR) for 2002	English
16	Annual Progress Report (APR) for 2003	English
17	Annual Progress Report (APR) for 2004	English
18	Annual Progress Report (APR) for 2005	English
19	Annual Progress Report (APR) for 2006	English
20	Annual Progress Report (APR) for 2007	English
21	Annual Progress Report (APR) for 2008	English
22	Annual Progress Report (APR) for 2009	English
23	Annual Progress Report (APR) for 2010	English
24	Annual Progress Report (APR) for 2011	English
25	Gavi Monitoring and Assessment report on 2001 year, January 20, 2003	English
26	Gavi decision letter on Albania’s proposal for INS support, GAVI/02/128/jd, 28 June, 2002	English
27	IRC report on Albania’s APR for 2002; GAVI/03/029/jj	English
28	Gavi decision letter on Albania’s proposal for INS support, GAVI/03/087/jd, 14 July, 2003	English
29	IRC report on APR for 2003, 23 June, 2004	English
30	Gavi letter on Albania’s APR for 2003, GAVI/04/120/jj, 30 July, 2004	English
31	IRC meeting, Geneva, 31 Ocober-3 November, 2005	English
32	IRC 16th proposal review, Geneva, 26 June-5 July, 2006	English
33	IRC 16th proposal review, Appendix B, Geneva, 26 June-5 July, 2006	English
34	IRC 17th proposal review, Geneva, 22 -27 November, 2006	English
35	IRC report on APR for 2006, September, 2007	English
36	Gavi letter on Albania’s APR for 2006, GAVI/07/422/aba/rl, 14 December, 2007	English
37	Gavi letter on Albania’s APR for 2007, GAVI/08/237/sc 8 September, 2008	English
38	IRC report on Albania’s APR for 2007, June, 2008	English

39	IRC report on Albania's APR for 2010, July, 2011	English
40	IRC report on Albania's APR for 2011,	
41	OPTIMIZE, Information systems and technologies for tomorrow; Albania pilots an immunization information system	English
42	OPTIMIZE, Information systems and technologies for tomorrow; Albania report, 2013	English
43	Erida Nelaj, Mirela Lika, Silva Bino, Evaluation of Albanian Immunization Program with Hepatitis B vaccine, research article, Albanian j. agric. sci. 2013; 12 (2): 315-319	English
44	PHRplus; Primary Health Care reform in Albania: A pilot project to provide evidence for health policy, 2005	English
45	Health Care Systems in Transition (HiT), Albania, 2002	English
46	Albania Financial Sustainability Plan for 2004-2013	English
47	Albania comprehensive Multi- Year Plan for immunization for 2009-2014	English
48	Effective Vaccine Store Management Assessment for the National Store report, 2007	English
49	Monitoring of the Primary Health Care System in Albania, research study, 2014	English
50	Financing Agreement between Albania and International Development Association, Health System Modernization Project, April, 2006	English
51	PAD Health System Modernization Project, 2006	English
52	WHO, EVM Assessment report, 2012	English
53	Albania Ministry of Health, WHO, Integrated Assessment of Immunization quality and Safety, October, 2006	English
54	Order of the Minister of health # 187 on Establishment of ICC, April, 2015	Albanian
55	Order of the Minister of health # 186 on Establishment of National Immunization Technical Advisory Group, April, 2015	Albanian
56	Albania health Sector Assessment, Swiss Cooperation with Albania, 2012	English
57	National EPI Coverage Survey, MoH, IPH, UNICEF, WHO, November 1999	English
58	Rapid Assessment of Cold Chain, IPH, UNICEF, June, 2000	English
59	Osmanaj E. Roma Community in Albania before and After the period of Communism. European Scientific Journal. February 2013. Vol 9. No_5:1857– 7881	English
60	Resuli B. et al. Epidemiology of hepatitis B virus infection in Albania. World J Gastroenterol. 2009 Feb 21; 15(7): 849–852.	English

Annex 4. List of Stakeholders Interviewed

Stakeholder type	Organization	Position
Government	Ministry of Health	Deputy Minister
		Former Deputy Minister
		Budget and planning office, Senior officer
		Director of Mother and Child Health
		Family Planning Office
	Institute of Public Health	Director
		Epidemiology and Infectious Disease Control Department, Head
		NITAG, Chair
		EPI Manager
		EPI officers
		Budget and Planning Department, Director
	Ministry of Finance	Health Budget Officer
	Health Insurance Institute	Director of Primary Care
	National Center for Continuous Education	Director
Academia	Catholic University, Faculty of Medicine, Tirana	Former EPI manager
	Tirana University, Faculty of Medicine	Department of Infectious Diseases
CSO	Albanian pediatric association	Group of experts on immunization
	Albanian Red Cross	Senior Health officer
	Roma Center for a contemporaneous vision	Senior Health officer
International partners	UNICEF Albania	Senior heath officer
	WHO Albania	Senior heath officer
	USAID Albania	Senior heath officer
	The World Bank	Senior heath officer
	Swiss Embassy	National program officer
Subnational	Regional Public Health Directorate	Director; Epidemiologist
	District Public Health Directorate in Tirana, Shkodra and Fier	Director; Epidemiologist, Cold Chain manager
Providers	Primary health care facility (urban health center, rural health center providers)	Family doctors, vaccinators nurses involved in immunization (Tirana, Skodra, Fier)

Annex 5. District level immunization coverage rates (%) for DTP3 and Hep B 3 vaccines for 2000-2014

Districts	2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	2010	2011	2012	2013	2014
	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	Penta	Penta	Penta	Penta	Penta	Penta
BERAT	97.8	99.3	97.2	98.6	98.2	98.9	100.0	100.0	98.8	99.1	97.2	98.0	98.3	98.1	99.8	99.3	97.6	98.3	98.7	99.2	99.4	98.0	97.8	98.6
BULQIZE	98.7	100.0	100.0	99.4	99.4	99.9	99.5	99.5	99.3	100.0	100.0	100.0	100.0	98.5	100.0	100.0	96.8	96.8	99.1	100.0	100.0	100.0	100.0	100.0
DELVINE	100.0	100.0	100.0	98.9	98.3	100.0	100.0	100.0	98.0	96.3	98.5	97.8	96.8	100.0	100.0	99.1	100.0	100.0	100.0	100.0	99.0	100.0	100.0	100.0
DEVOLL	100.0	98.2	99.2	98.9	99.6	100.0	100.0	100.0	99.0	98.3	97.6	97.6	98.4	98.4	97.8	97.8	93.2	93.2	98.6	97.9	100.0	100.0	100.0	100.0
DIBER	96.7	94.3	99.3	99.5	99.3	99.3	98.6	98.9	99.3	99.3	99.2	99.4	99.1	92.7	99.6	99.6	99.4	99.4	98.7	99.7	99.9	100.0	100.0	100.0
DURRES	99.0	99.7	99.4	99.3	100.0	100.0	100.0	100.0	99.0	99.0	98.7	98.9	98.7	99.4	99.5	99.5	100.0	100.0	99.1	100.0	99.9	100.0	99.9	100.0
ELBASAN	98.2	97.4	99.0	99.1	98.8	98.4	97.2	100.0	98.9	99.1	98.4	98.0	97.4	97.3	99.5	99.3	99.0	99.0	99.3	98.6	99.3	98.5	98.3	97.0
FIER	97.6	97.3	99.0	98.2	99.4	99.4	99.0	99.0	99.3	99.2	99.5	99.5	98.8	99.0	98.8	98.8	96.5	96.5	99.1	97.0	98.4	94.4	98.2	100.0
GJIROKASTER	95.7	95.5	95.3	97.0	98.1	96.9	98.6	98.6	97.0	98.7	98.0	98.8	79.9	84.8	94.2	94.2	98.5	98.8	99.6	100.0	95.9	98.2	97.6	100.0
GRAMSH	99.9	100.0	100.0	100.0	100.0	100.0	100.0	100.0	97.7	99.2	98.1	97.8	99.5	94.9	98.6	98.6	99.7	99.7	100.0	100.0	100.0	100.0	99.7	99.4
HAS	92.3	92.4	93.1	93.5	99.1	99.1	93.6	100.0	96.6	96.6	97.9	97.9	96.0	96.0	98.5	98.5	98.8	98.8	99.1	98.3	98.4	99.1	99.5	100.0
KAVAJE	96.8	97.9	98.7	98.8	98.4	98.7	97.8	98.3	98.8	98.9	100.0	100.0	95.3	100.0	100.0	98.3	99.3	99.4	99.7	99.9	100.0	100.0	100.0	95.1
KOLONJE	97.3	95.0	100.0	98.8	99.3	99.3	96.4	96.4	95.4	95.4	98.4	98.4	98.2	98.2	95.8	95.8	100.0	100.0	99.0	100.0	96.6	100.0	100.0	98.7
KORCE	99.5	99.8	98.9	99.1	98.1	96.3	93.8	99.4	93.1	97.3	93.5	96.6	94.4	91.8	100.0	94.5	99.9	94.3	99.1	99.0	98.9	98.7	98.8	98.2
KRUJE	94.4	84.1	95.4	88.1	95.5	93.5	93.9	92.5	97.8	95.5	97.6	96.1	97.8	97.8	97.9	85.6	98.5	96.9	99.2	99.5	99.3	99.6	99.6	100.0
KUCOVE	95.2	90.4	98.1	98.2	97.6	98.9	98.9	96.7	100.0	100.0	99.7	99.7	99.4	98.6	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.2
KUKES	96.3	90.1	99.5	88.9	99.6	99.9	97.9	99.6	99.4	99.7	100.0	99.9	100.0	98.6	99.8	92.7	99.7	99.7	99.5	100.0	100.0	100.0	100.0	100.0
KURBIN	100.0	100.0	100.0	100.0	100.0	100.6	90.3	90.2	98.1	96.6	99.3	99.1	89.1	91.2	99.1	99.1	99.5	99.5	99.8	100.0	99.0	99.3	99.4	100.0
LEZHE	97.8	97.0	93.0	90.4	93.2	90.2	90.3	92.4	96.8	98.1	96.6	96.3	84.4	90.8	99.1	96.1	99.7	99.7	99.2	99.9	99.5	99.9	99.9	95.7
LIBRAZHD	99.3	98.9	98.4	97.5	99.9	99.6	99.0	99.0	99.8	99.8	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.1	100.0	100.0	100.0	100.0	98.9
LUSHNJE	97.1	94.7	97.5	99.8	95.9	96.9	95.9	99.1	98.4	99.2	98.2	99.1	90.8	99.2	91.0	89.6	96.7	94.5	99.5	98.0	98.3	98.8	98.0	100.0
M.MADHE	97.6	86.4	95.4	96.5	93.1	90.7	100.0	100.0	98.3	99.0	99.1	99.1	96.4	89.5	99.2	91.0	99.5	99.0	100.0	100.0	99.7	100.0	100.0	100.0
MALLAKASTER	96.7	96.7	97.7	97.7	100.0	99.1	100.0	100.0	99.1	99.1	98.8	98.8	98.7	98.7	99.8	99.8	100.0	100.0	99.7	99.7	99.4	99.1	99.4	92.8
MAT	97.1	98.1	96.1	94.7	95.9	96.4	97.8	97.8	99.9	99.9	99.9	99.6	99.4	100.0	99.3	99.3	100.0	100.0	99.2	100.0	100.0	100.0	100.0	95.5
MIRDITE	94.9	100.0	92.4	100.0	97.5	100.0	95.6	100.0	98.9	99.2	98.5	98.5	99.3	100.0	98.9	99.2	100.0	100.0	99.0	100.0	100.0	100.0	100.0	100.0
PEQIN	99.3	100.0	98.6	98.4	97.0	99.4	98.0	96.0	98.8	98.8	99.0	99.0	98.9	98.9	100.0	100.0	100.0	100.0	99.6	99.4	100.0	99.3	98.3	99.9

Districts	2000		2001		2002		2003		2004		2005		2006		2007		2008		2009	2010	2011	2012	2013	2014
	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	DTP3	HepB 3	Penta	Penta	Penta	Penta	Penta	Penta
PERMET	98.1	98.6	99.1	98.9	100.0	100.0	100.0	93.1	96.5	97.5	96.1	97.0	96.7	94.3	83.5	83.5	98.3	98.3	99.2	100.0	100.0	100.0	100.0	94.0
POGRADEC	96.0	98.8	100.0	97.5	98.1	98.9	99.4	98.3	99.6	98.9	97.2	97.8	98.6	97.5	98.2	98.4	98.5	98.5	99.6	99.6	99.5	97.9	97.0	100.0
PUKE	99.1	99.2	97.3	99.5	99.8	99.7	100.0	100.0	99.8	99.8	99.6	99.6	96.3	97.7	100.0	90.9	98.9	98.9	99.5	99.5	100.0	100.0	100.0	94.0
SARANDE	96.2	96.0	95.8	95.8	99.5	98.7	100.0	98.7	98.7	99.1	99.0	99.1	93.3	99.5	99.3	100.0	99.5	97.9	98.5	94.5	91.2	94.7	98.5	99.6
SHKODER	89.7	91.5	90.4	88.1	94.1	91.9	92.1	92.1	98.4	99.5	99.4	99.1	97.8	100.0	97.5	99.4	99.6	99.8	99.1	98.3	95.7	98.0	98.2	100.0
SKRAPAR	91.0	90.6	97.6	98.2	97.9	96.6	96.8	96.8	98.4	97.6	100.0	100.0	99.5	100.0	100.0	100.0	100.0	100.0	98.8	100.0	100.0	100.0	100.0	99.4
TEPELENE	98.9	98.4	100.0	98.7	97.3	98.7	97.1	98.4	98.1	98.4	97.6	98.2	97.1	98.0	98.5	98.5	98.3	98.3	100.0	98.2	96.8	96.6	100.0	100.0
TIRANE	100.0	100.0	98.6	98.1	97.6	98.0	99.0	94.3	95.9	96.4	98.5	98.7	98.4	97.9	98.7	98.7	99.3	99.3	98.3	99.5	99.4	99.3	99.1	96.4
TROPOJE	63.3	97.1	98.1	96.8	96.5	95.4	93.4	93.4	96.9	96.9	97.1	94.4	99.5	99.5	100.0	100.0	98.3	98.3	98.5	100.0	100.0	99.1	98.9	98.6
VLORE	97.9	96.6	96.9	92.9	95.4	96.3	95.7	97.8	98.7	98.2	96.6	96.9	99.6	98.6	98.1	98.5	99.5	98.5	99.1	99.1	99.5	99.9	98.0	98.2
ALBANIA	97.5	97.8	97.7	98.2	97.8	95.9	97.3	94.4	98.2	98.3	98.4	98.5	97.2	97.6	98.4	97.5	99.0	98.7	97.8	99.2	99.1	98.9	99.0	98.5

Annex 6. In Depth Interview Guides

Question	MOH	IPH	Partners (UNICEF, WHO, USAID	HII	Regional director of health	District PHD	CSOs
Before Gavi							
Please describe major successes and challenges of the EPI before GAVI support (end of 1990s)? (*probe about* vaccine supply, HMIS, cold chain, injection safety, disease surveillance, communication).		X	X		X	X	X
UNICEF was major partner supporting EPI during 1990s, Italia Rotary Club supported with HepB introduction in 1995, please describe if other donors supported the program till 2001? What was the role of the WHO?	X	X	X				
Gavi support (pre transition)							
How was the decision for GAVI support to Albania made? What evidence was used? Why Albania applied to HepB support when the vaccine was already financed by the Government?	X	X	X				
In 2003 the first FSP was developed for 2004-2013 in line with the national Immunization Program. Which stakeholders were involved in the process of FSP development? How legally empowered was the FSP? What is your perspective on how realistic it was and how much buy-in there was for the plan? When the plan was last updated (*probe about* 2006 update for Hib proposal)? Who was primary user of the plan? What were the main advantages/ disadvantages of having a plan? Any examples of its practical application. Did Albania prepare cMYP? If yes when developed, when last updated.	X	X	X				
How the Government and other actors ensure that sufficient financial resources were available? Please clarify whether the financial commitment of the Government was reflected in the Government's multi-year financial plan (MTEF)?	X	X	X	X			

Question	MOH	IPH	Partners (UNICEF, WHO, USAID	HII	Regional director of health	District PHD	CSOs
What were the main challenges of the program during Gavi support period and how they were addressed? (*prompt about* poor quality data, high wastage rates, injection safety, hard-to-reach population e.g. Roma, migration)?	X	X	X		X	X	
How effective was the coordination? What was the role of ICC? What was the role of Gavi in coordination process? How useful were comments /recommendations from Gavi? What was the role of partners (UNICEF, other partners) in coordination?	X	X	X				X
Did the country comply with the Gavi proposed schedule of co-financing? If not what was the reason, how it was addressed?	X	X	X				
What was the role of Gavi to encourage the Government to allocate sufficient resources during and after completion of Gavi support? The role of other partners? From your perspective, what could have been improved in this process?	X	X	X				
UNICEF procurement mechanism was used for procurement of all vaccines, including vaccines not supported by Gavi. Why such decision was made? How the country dealt with the lobby of pharmaceutical companies or other groups to use non-UNICEF procurement mechanism?	X	X	X				
Gavi support (Transition period -Planning)							
When did you hear that Albania became no longer eligible for Gavi support? Who did you hear from? How well this was communicated to the country? Please describe this process, who /which agency played a role to clarify Gavi new policy of graduation to the country?	X	X	X				X
How transition planning was put in place? (*prompt about* development of specific transition plan, update of Financial-sustainability plan/ cMYP in line with country graduating status,	X	X	X	X			X

Question	MOH	IPH	Partners (UNICEF, WHO, USAID	HII	Regional director of health	District PHD	CSOs
any other arrangements) Did the (transition) plan cover both financial and programmatic aspects?							
What were the main concerns or risks identified during the transition period? Which aspects were the least concern about?	X	X	X				X
How the process was coordinated, what was the role of partners? Which stakeholders should have been involved in the process, but were not involved?	X	X	X				
Did the Government and other partners clearly understand timeline and necessary steps for transition?	X	X	X				X
Implementation							
What adaptations were made to the immunization program following Albania became graduating country? Did this affect programmatic aspects (introduction of new vaccines, safe injection support, cold chain upgrade, technical support, etc.) If programmatic adaptions were made did they had any impact on outcomes (particularly coverage, safety, financial sustainability etc.)? What was the decision-making process around these adaptations?	X	X	X		X	X	X
Was the transition period set by Gavi sufficient to ensure implementation of planned activities? If not what would be the most appropriate time-period for full transition?	X	X	X				X
As the plan (FSP) was implemented, were the actual expenditures in line with expectations and plans? If not, why not?	X	X	X				
Results (post Gavi)							
From your perspective how the systems and structures function after end of Gavi support? *Probe about* service delivery; vaccine availability and logistical management; safe injection practices;	X	X	X	X	X	X	X

Question	MOH	IPH	Partners (UNICEF, WHO, USAID	HII	Regional director of health	District PHD	CSOs
waste management; strategies to reach hard-to-reach population?							
Please clarify if ICC is still functioning? If yes, how frequently ICC meetings are conducting? What is the current role of ICC?	X	X	X				X
Please clarify if NITAG/Technical Group of Experts under the IPH is still functioning?	X	X	X				X
What is the role of partners supporting the country after the end of GAVI support?	X	X	X				
How EPI targets been sustained after completion of Gavi support, specifically on the coverage rates, wastage rates, injection safety practice, surveillance of VPDs (AFP, Congenital rubella syndrome)?	X	X	X		X	X	
What are the ongoing challenges Albania faces for sustaining achievements of its immunization program? What are the facilitating factors?	X	X	X	X	X	X	X
What adaptations were made to the immunization program following the conclusion of GAVI support? What was the possible impact on intended outcomes (particularly coverage, safety, financial sustainability etc.) of these adaptations? What was the decision-making process around these adaptations?	X	X	X	X	X	X	X
Does the country still continue the same procurement practice (UNICEF procurement mechanism)? If not, why?	X	X	X				
Did the country make vaccine cost analyses to make decision about most cost-effective way of procurement of vaccines? Does the country have capacity to develop/update the cMYP without external support?	X	X	X				
What type of syringes does the country currently procure? (*probe about* AD syringes, disposable syringes).	X	X			X	X	

Question	MOH	IPH	Partners (UNICEF, WHO, USAID	HII	Regional director of health	District PHD	CSOs
During last 3-4 years (2012-2015) did the country experience stock-outs of vaccines and AD syringes? If yes, what was the reason?							
What have been the main unintended positive or negative effects of the time-limited nature of GAVI support and its conclusion?	X	X	X				X
Albania introduced Pneumococcal vaccine in 2011 without Gavi support. Please describe which stakeholders initiated the process, advocated for the new vaccine introduction? Where justifications prepared? If yes who contributed to this process?	X	X	X				X
Are the expenses for PCV (including consumables) fully covered by the Government? Is UNICEF procurement mechanism used for PCV procurement? If not why and what are prices paid for these vaccine?	X	X	X				
What where main barriers with the introduction of PCV and how they were dealt?	X	X	X		X	X	X
Rotavirus Cost-effectiveness study has been conducted in Albania recently, please describe who (which partner) advocate for this Rota vaccine introduction, who (which partner) contributed to the cost-effectiveness study? Where the justifications presented to the Government and if yes what was the decision made?	X	X	X				
If the decision is to introduce the Rota vaccine in the schedule, are the costs included in the MTEF, is the cMYP renewed? Which procurement mechanism will be used?	X	X	X				
If the decision is to introduce the Rota vaccine in the schedule, are relevant programmatic arrangements made?	X	X	X				
If the decision is not to introduce / postpone the introduction what are argumentations from the Government?	X	X	X				
How the Government and other actors ensure that sufficient	X	X	X	X			

Question	MOH	IPH	Partners (UNICEF, WHO, USAID	HII	Regional director of health	District PHD	CSOs
financial resources are available after Gavi support? Please clarify whether the financial commitment of the Government are reflected in the Government's multi-year financial plan (MTEF)?							
In the future how do you think Albania will handle introduction of new vaccines? (*prompt about* increasing Government financial allocations)	X	X	X		X	X	X
Did the GAVI support incorporate adequate exit strategies and capacity development measures to ensure sustainability of the results over time?	X	X	X				

Annex 7. GROUP INTERVIEW GUIDES

Guide Group interview with health care providers

Group Interview Participants Primary Heath care doctors primarily responsible for childhood immunization services.

Introduction prompt: Thank you for agreeing to speak with us today. We have been contracted by Gavi Alliance to carry out the final evaluation of GAVI's support to Albania. GAVI support started in 2001, when GAVI provided a Vaccine Introduction Grant and Hepatitis B monovalent vaccine. GAVI then began supporting Injection Safety program. Pentavalent vaccine was also provided by GAVI from 2009.

- Could you please describe your responsibilities and relation to the immunization program, how long you have been working in this field.?

- When was the last training on immunization that you received? What was the topic? How many staff (proportion from of PHC doctors and nurses) from your facility was trained? Did it cover all the questions about when and how to administer the vaccine, potential adverse events?

- How do you get your vaccines and syringes for immunization? Do you use AD syringe or disposable syringe? Are there still challenges with injection safety in your facility? How the situation has changes during last 3 years? What are areas that need improvement?

- During the last 3 years, did you ever experience stock outs of vaccines, and supplies (AD syringes, safety boxes)? How long did it last, how frequently it happens? What explanation did you receive from Immunization managers?

- Are there challenges with the cold chain? How the situation has changed during last 3 years? What are areas that need improvement?

- Are there challenges with coverage rates? What has changed over the last 3 years to encourage/maintain high (or improve) vaccine coverage rates? Especially hard to reach population?

- Are there challenges with HIS?

- Are there still challenges with funding for immunization?

- Were on-the-job trainings on immunization practice carried out in your facilities? If yes who provided, how often, is it useful?

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