CURATIO INTERNATIONAL FOUNDATION

20 Years of Challenging Transition

FINAL EVALUATION OF GAVI ALLIANCE'S SUPPORT TO BOSNIA AND HERZEGOVINA

FINAL EVALUATION REPORT

July 31, 2014

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Map of Bosnia and Herzegovina[1]

[1] The map presented in this document does not imply the expression of any opinion whatsoever on the part of GAVI and CIF or its partners concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitations of its frontiers or boundaries.

ABBREVIATIONS

AD	Auto-Disable
AEFI	Adverse Events Following Immunization
APR	Annual Progress Report
AVC	Anti Vaccine Campaign
BCG	The bacille Calmette-Guérin vaccine
BD	Brcko District
BiH	Bosnia and Herzegovina
CDC	Centers for Disease Control/Atlanta
cMYP	Comprehensive Multi-Year Plan
OECD/DAC	Organization for Economic Cooperation and Development/Development Assistance Committee
DTP	Diphtheria, Tetanus, and Pertussis vaccine
DTPa-IPV-Hib	Combined diphtheria-tetanus-acellular pertussis-inactivated poliovirus and Haemophilus influenzae type b vaccine
EPI	Expanded Program on Immunization
ET	Evaluation Team
EU	European Union
FBiH	Federation of Bosnia and Herzegovina
FGD	Focus Group Discussion
FSP	Financial Sustainability Plan
GAVI	Global Alliance for Vaccines and Immunization
GDP	Gross Domestic Product
GNI	Gross National Income
HD	Health Department
HepB	Hepatitis B
Hib	Haemophilus influenzae type B
HIF	Health Insurance Fund
ICC	Interagency Coordination Committee
INS	GAVI Injection Safety Support
IRC	Independent Review Committee
ISS	Immunization Services Support
KAP	Knowledge, Attitudes and Practice survey
M&E	Monitoring and Evaluation
MICS	Multiple Indicator Cluster Survey
MMR	Measles, Mumps, Rubella Vaccine
MoCA	Ministry of Civil Affairs
MoH	Ministry of Health
MoHSW	Ministry of Health and Social Welfare
MYSP	Multi-Year Strategic Plan
NGO	Non-governmental organization
NVS	New and underused vaccine support
OPV	Oral Polio Vaccine
PHC	Primary Health Care

PHI	Public Health Institute
RAT	Rapid Assessment
RFP	Request for Proposals
RS	Republika Srpska
TB	Tuberculosis
TV	Television
UNFPA	United Nations Population Fund
UNICEF	The United Nations Children's Fund
UNICEF SD	Supply Division of the United Nations Children's Fund
VMA	Vaccine Management Assessment
VPD	Vaccine Preventable Diseases
WB	The World Bank
WHO	World Health Organization

EXECUTIVE SUMMARY

INTRODUCTION

Bosnia and Herzegovina (BiH) is a transition economy state in Eastern Europe, consisting of two entities (the Federation of Bosnia and Herzegovina (FBiH), Republika Srpska (RS)) and the independently administered Brcko District (BD). Its economy relies heavily on the export of metals, as well as on remittances and foreign aid. A highly decentralized government creates challenges for economic policy coordination and reform, while bureaucratic barriers and a segmented market discourage foreign investments. BiH experienced a difficult civil war during the 1990s. After restoring peace, outputs, including health services, recovered slowly.

Decision-making in the BiH health system is decentralized to the entities and the BD, and in FBiH these powers are further devolved to the local (cantonal) level. According to the March 2003 Law on Ministries, the Ministry of Civil Affairs (MoCA) of BiH is in charge of the coordination of health issues at the state level.

Over the past several years, both entities have initiated wide-ranging reforms in the health sector aimed at increasing financing, strengthening delivery systems and improving quality of care. However, key health system challenges – such as inequalities in access, institutional fragmentation, shortage of medical personnel, and financial sustainability – contribute to the ongoing need for external financial and technical assistance.

During BiH's post-war recovery, the country required external assistance to improve the national immunization programmes and introduce new vaccines. The Global Alliance for Vaccines and Immunization's (GAVI) support to BiH was launched in 2002 with the Vaccine Introduction Grant for the Hepatitis B (HepB) monovalent vaccine. The support ended in 2011 with the last shipments of the GAVI supported Haemophilus influenzae type B (HiB) monovalent vaccine. GAVI also supported the introduction of Injection Safety policies in BiH. Over the years, GAVI's support amounted to a total of US$2.27 million.

GAVI's graduation policy did not exist at the time that BiH funding ended. Therefore, BiH did not experience a graduation phase similar to current Phase III GAVI graduating countries. GAVI support to BiH concluded when the time-limited multi-year period for which support had been approved came to an end in 2011. How BiH managed the transition away from GAVI's support and what the impact was of this transition on the sustainability of the national immunization programme has not been evaluated yet. This evaluation assesses the financial and programmatic sustainability of GAVI-supported immunization activities through an in-depth analysis of BiH's experience and the immunization programmes' performance before, during and after the completion of GAVI's time-limited support to the country. The recommendations and lessons learned from the evaluation are expected to inform possible future amendments to the GAVI's Graduation Policy.

The primary audiences for this evaluation consist of the GAVI Alliance Secretariat, the GAVI Board and its Programme and Policy Committee. The results will also benefit the country itself, especially the MoCA Health Department (HD), Ministries of Health of each entity and other partners and organizations interested in sustainability of outcomes and impact of their involvement in health sector and especially in the immunization programmes in BiH.

APPROACH AND METHODOLOGY

GAVI's support to BiH was evaluated along three evaluation focus areas: **planning** (pre-GAVI support)**, implementation** (support received during GAVI period) and **outcomes** (post-GAVI support). Additionally, evidence related to each of the focus areas was assessed against five Organization for Economic Cooperation and Development/Development Assistance Committee (OECD/DAC) evaluation criteria: **relevance, efficiency, effectiveness, impact/results, and sustainability,** with greatest emphasis on sustainability.

Efficiency of GAVI implementation was evaluated by assessing whether selected qualitative and quantitative outputs were achieved in a cost-effective and timely manner. **Effectiveness** was measured by examining whether the planned key objectives/targets were achieved and by identifying major factors that either promoted or hindered achievement. The **outcomes** of GAVI support and its sustainability have been analysed by assessing **programmatic and financial sustainability**, as requested by the evaluation Request for Proposals (RFP). **Programmatic sustainability** was defined broadly as the sustainability of key immunization program dimensions and the World Health Organization (WHO) Health System building blocks, not restricted only to the areas directly supported by GAVI. The evaluation of **financial sustainability** took into account the concept of self-sufficiency and was defined as the extent to which the GAVI support was sustained through the resources of the country itself rather than those of external partners.

The evaluation team (ET) organized *site visits* to collect data from the lower administrative levels in a sample of primary health care (PHC) facilities/health centres and public health institutions in RS, FBiH and the BD. The team implemented a mixed methods approach, using both quantitative and qualitative methods, including:

- *A desk review* of key documents pertaining the GAVI support to BiH, including project proposals, Annual Progress Reports (APR), official correspondence between GAVI and BiH governments, Interagency Coordination Committee (ICC) meeting minutes, Multi-year Strategic Immunization and Financial Sustainability Plans (FSP), the health sectors' strategic documents, policies and regulations.

- *Key informant in-depth interviews* were conducted during site visits with three types of respondents: (1) members of the ICC and senior representatives of the BiH governments; (2) representatives of the ministries of health, immunization mangers, health facility managers and providers; (3) key informants able to provide "interview based evidence" for facts and details pertaining to the evaluation subject. Most of the interviews were performed face-to-face using semi-structured in-depth interview guides. A couple of Skype/phone interviews were conducted with respondents[2] who were not available for face-to-face interviews, but played instrumental roles in the GAVI program implementation.

- *Quantitative data* was collected either during site visits, through a formal request process to the relevant authorities, or from the latest available surveys. The data collected included immunization coverage rates, government annual budgets and expenditures, spending levels on vaccine procurement and vaccines doses procured, vaccine unit prices, cold chain inventory and vaccine wastage reports. Information on UNICEF vaccine unit prices as well as local currency foreign exchange rates for

[2] GAVI Secretariat and UNICEF

the respective years were obtained from the official web sources and used for comparative analysis with the entity level unit prices.

Both quantitative and qualitative data were analysed to assess evaluation focus areas using the afore-mentioned evaluation criteria. Qualitative findings were triangulated across the key informants, and compared with desk review findings. The available data were used to develop specific analyses, such as timelines summarizing the chronology of GAVI programmes implementation, descriptions of particular processes used in the design or implementation of the programmes; stakeholder analyses of actor positions on specific features of the design and implementation at specific time, and possible factors contributing to the positive/negative outcomes of GAVI support.

FINDINGS AND CONCLUSIONS

RELEVANCE AND EFFECTIVENESS OF PLANNING

GAVI support was relevant to country needs and essential for funding the strengthened immunization programmes during the early stages of the support. Introduction of new vaccines and the promulgation of the injection safety policy in BiH was in accordance with internationally accepted guidelines and based on thorough, well-documented, and transparent situation analysis.

BiH complied with all the preconditions for GAVI support in a timely manner. More specifically, the ICC was established to ensure stakeholder coordination and evidence-based decision-making for smooth implementation of the immunization programme.

Planning for the transition away from GAVI support was initiated from the very beginning. A Multi-Year Strategic Plan for Immunization (MYSP)[3] was developed jointly by all entities with external partners' technical support and is an example of effective planning. To ensure the sustainability of the immunization program, in 2005, BiH developed the FSP[4]. The FSP alongside with the MYSP served as the Government's planning tool for the transition away from GAVI support.

EFFECTIVENESS AND EFFICIENCY OF GAVI IMPLEMENTATION

Implementation objectives and programmatic targets were partially met. For example, the coverage targets were achieved or surpassed for Haemophilus influenzae type b (Hib) monovalent vaccine (97%) and HepB 1st dose at the national (97%) and the subnational levels (95%), however coverage rates for HepB 3rd dose failed to achieve targets at both the national (88% compared to the target of >95%) and the subnational (86% vs. >90%) levels. BiH failed to achieve 100% availability of auto-disable (AD) syringes and safety boxes at vaccination posts as well as maintaining dropout rates for HepB below 8%.

The majority of activities planned under the MYSP for Immunization and FSP were implemented.

- **Immunization schedules for GAVI supported HepB vaccine were harmonized** in the entities and the BD, though the broader immunization schedules maintained some differences in the entities and the BD. Hib schedule was standardised in FBiH and RS (2, 4, 18 months) while the BD introduced the third dose of Hib at 6 month.

[3] BiH Multy Year Strategic Plan for immunization, BiH, 2001
[4] BiH Financial Sustainability Plan, v. 1.23 ICC

- **The ICC was instrumental in the coordination and monitoring of implementation, however suffered certain limitations in performing these functions**, specifically related to its role in strategic planning, problem solving, and its oversight function in relation to expenditure tracking or programme review.

- **Extensive training of healthcare workers on the new vaccines and injection safety were commenced prior to the vaccines introduction, however uneven coverage of health personnel with trainings was reported.** The post-vaccine introduction evaluation found health care workers' knowledge regarding use and advantages of new vaccines and practice of consulting parents on the benefits of immunization acceptable. However, health personnel's knowledge of injection safety and waste management was insufficient,[5] resulting in under-performance of injective safety practices during GAVI program implementation. The same study reports that over 90% of respondents felt that they needed additional training on the advancements in the development of new vaccines, 55% on the risks associated with vaccination.

- **Substantial efforts were put in place by governments and partners (UNICEF/WHO) for public education and awareness raising, but measures for mitigation of negative anti vaccine campaign (AVC) influence on immunization coverage lacked regularity and carried an ad hoc character**. Advocacy, social mobilization and communication plans were developed and campaigns implemented prior to and after new vaccine introduction, but lacked regularity. Most evaluation respondents strongly believed that AVCs negatively affected and continue to affect immunization coverage. However, data from 2011 shows only a small proportion of the patient and provider population affected by this[6].

- **Delays in vaccine and GAVI Injection Safety Support (INS) delivery** were reported during the implementation mostly due to customs related issue, though they did not affect achievement of the programmatic objectives.

- **Initial weaknesses in vaccine management capacity were gradually strengthened and significantly improved** in response to Vaccine Management Assessment[7] (VMA) recommendations. Specifically, BiH strengthened the capacity of Public Health Institutes (PHIs) and improved cold chain and procurement procedures at all levels in the system.

- **Immunisation surveillance system was improved through standardized reporting, but challenges remain.** According to the Post-Introduction Evaluation of New Vaccines in BiH[8], challenges in the aggregation and communication of health facility data prevail. The challenges of reporting system were highlighted in the 2011 APR, but no hard evidence was obtained that Governments and/or GAVI took specific steps to address them.

- **Injection safety and waste management practices require improvements to which both GAVI and BiH could have contributed.** The APR for 2011 reports absence of a country level Injection Safety Policy, as well as only 60% of immunization service

[5] Knowledge, attitude and practice survey on routine immunisation, new vaccines and public confidence in the health care system and interventions in Bosnia and Herzegovina, UNICEF, 2011
[6] Ibid 5
[7] Vaccine Management Assessment in BiH, WHO, 2006
[8] Post Introduction Evaluation of New Vaccines in Bosnia and Herzegovina, WHO Bosnia, WHO EURO, CDC, 2009

providers having access to injection safety equipment. Gaps in health personnel capacity were confirmed through recent Knowledge, Attitude, and Practice (KAP) surveys.[9] While GAVI's INS support ended in 2008, the country still had stock of injection safety materials available for use in 2011. Underutilization of INS equipment was also evident during our site visits.

- **The entity level policies for immunization waste disposal were not completely implemented during the GAVI support.** The post-introduction evaluation of new vaccines[10] reported disposal of syringes and needles with the regular city waste in some cantons of FBiH and RS regions. Although problems were adequately reflected in the APRs, BiH has not proposed strategic actions for their resolution.

- **BiH gradually improved annual GAVI progress reporting practice and quality, though room for further improvement remained even during implementation**. Close to the end of GAVI support BiH managed to improve timely submission of the APRs to GAVI, though completeness of reports remained a challenge. The main problems frequently cited in GAVI letters were absence of i) reporting on progress against financial and programmatic indicators; ii) reports to be signed by the Minister of Health and endorsed by the members of the ICC; and iii) ICC minutes to be attached.

- **GAVI's annual monitoring of BiH performance during implementation was evident, though the timeliness of GAVI secretariat's response desired improvement.** Observed delays and inconsistencies in GAVI's responses to BiH left entities insufficient time to adjust budgets. While GAVI strictly requested regular reporting on the progress of indicators, its delays allowed BiH to postpone recording its progress towards immunization targets until the next reporting period. This practice resulted in missing the opportunity to timely advice country on corrective measures when targets were underachieved. Data quality concerns have not been adequately addressed and highlighted in the GAVI Independent Review Committee (IRC) reports and Decision Letters.

- **Although GAVI support for implementation and system-related bottlenecks were well documented and reported by BiH, hard evidence on mitigation measures is lacking**. GAVI followed up on key programmatic and/or implementation weaknesses and challenges reported and managed to mobilize timely support through its partners. However, more consistent follow up on further implementation of planned measures would have been beneficial allowing provision of timely advice on corrective measures to the country. Close to the end of GAVI support, BiH managed to improve timely submission of the APRs to GAVI, though the completeness of reports remained a challenge. Annual monitoring of the country performance from GAVI during implementation was evident, however timeliness of GAVI secretariat's response desired improvement.

Certain evidence of efficiency gains during the GAVI support exists. Specifically:

- **The roles of financial agents** for funding the immunization programmes were defined, revisions were introduced in the public procurement law enabling

[9] Ibid 5
[10] ibid 8

procurement of vaccines through UNICEF Supply Department (SD), and, as a result, some efficiency gains from vaccine procurement were achieved.

- **GAVI mobilized development partner support –** GAVI support made available to BiH was limited only to new vaccine introduction grant and provision of vaccines and injection safety supplies. Other development partners also played important roles, both by being directly involved in the project management and oversight, and/or by supporting localized projects. WHO and UNICEF, in particular, were key participants in the ICC and provided substantial technical and financial support to BiH's immunization programmes.

OUTCOMES AND CONTRIBUTION TO SUSTAINABILITY

A coordination mechanism was maintained even after GAVI's funding ended, but currently holds fewer responsibilities than its ICC predecessor and demonstrates operational weaknesses – Since the end of the GAVI support, selected functions of the ICC, specifically coordination of the partners and compilation of the reports for international reporting, were handed over to the MoCA HD. Although the coordination function is maintained for the immunization programme, the effectiveness of its operations is inadequate mainly due to its weak functional powers and limited human resources.

Access to new vaccines is currently ensured, but intermittent vaccine stock-outs and shortages of medical supplies persist. With GAVI support, new vaccines are included in the mandatory immunization calendar of both entities and the BD. These are provided free of charge to target groups. Periodic vaccine stock-outs and shortages of medical supplies are observed in the post-GAVI period due to the lengthy and complicated procurement process. Availability of buffer stocks allowed the governments to ensure continuity of immunization program and have not yet compromised targets.

Cold chain equipment and its maintenance and management are deteriorating due to inadequate public funding for maintenance and replacement of ageing cold chain equipment.

Immunization programme management structures continue to operate, but serious weaknesses are observed in supervision, monitoring and evaluation functions. Observed irregularity and poor quality of immunization program supervision in BiH indicates that supervision is not seen as a learning process and a way to improve the programme achievements. It is still perceived as an activity for controlling staff that could lead to disciplinary measures. Supervision thus remains an administrative function of senior public service employees over their subordinates.

Despite certain improvements after GAVI support, country information systems demonstrate deficiencies. The current information systems in the two entities and the BD do not provide adequate data to estimate vaccine coverage and drop-out rates, due to problems with both numerator and denominator assessments.

Injection safety practices are discontinued and irregularities in unsafe waste management practices were observed. BiH failed to fully endorse the Injection Safety Policy.[11,12] The

[11] National Policy Document for Injection Safety and Safe Disposal In Bosnia – Herzegovina, April 2005

[12] National Plan of Action (2006-2010) to Improve Immunization injection safety and safe disposal in BiH, April 2005

majority of the visited facilities in both entities and the BD discontinued procurement of AD syringes and safety boxes. Single use syringes are used, ensuring injection safety for beneficiaries. Health personnel, as observed by the evaluation team during the visits to selected health facilities, do not follow injection safety practices thus creating risk to personnel. Supervisory mechanisms for monitoring injection safety are largely absent at PHI and facility level. Most health facilities in BiH lack incinerators and needle cutters for safe destruction of syringes and needles and untreated waste is discharged into an uncontrolled, non-engineered open dump, which does not protect the local environment.

The immunization systems have continued exposure to the boarder health systems challenges in the country, including shortage of medical personnel, low pay and lack of motivation, high turnover and absence of effective continuous professional development system. Sustainable routine immunization services are dependent, over the long term, on sustainable health services and systems, and, if not adequately addressed, will possibly contribute to the deterioration of immunization services in future.

Attempts to introduce new vaccines are constrained by the scarcity of financial resources and the financial sustainability for vaccine procurement is at risk. Specifically:

- **The transition from GAVI support to domestic funding for vaccine procurement was smooth.** The key informants unanimously noted smooth transition from GAVI support to local funding for the vaccine procurement. The entity governments knew in advance about the conclusion of GAVI funding and ensured allocation of domestic resources for the procurement of vaccines. Transition planning was supported by PHIs in both entities and the BD. PHIs prepared forecasts for required vaccines, while the procurement was handled by the respective institutions/organizations.
- **Countrywide planning and budgeting mechanisms for immunization programmes, created during the GAVI support, were crippled upon the completion of GAVI support**. The latter occurred mainly due to administrative-territorial arrangement and due to political specificity of the country and should not be viewed as unintended negative outcome of the GAVI support.
- **Financing of vaccine procurement is sustained, though it can face substantial risks due to a small market, fragmented procurement, low competition, and high vaccine prices**. The failure in the procurement tenders for Pentavalent vaccine in BiH during the last year was caused by inability of companies to supply markets in BiH with adequate quantities of vaccines. Although BiH can assure the administration of the Pentavalent vaccine until mid-2015 using their buffer stock, the strategy for the way forward is not yet formulated. Since GAVI support ended, BiH is exposed to the open market, where vaccine prices are substantially higher relative to GAVI/UNICEF prices, and has to shoulder a high financial burden. The price comparison analysis performed by the ET, reveals that prices paid by BiH were 5-20 times higher than UNICEF/GAVI prices. Higher vaccine prices mean fewer resources for other health priorities, especially non-vaccine immunization services. The unpredictability of future vaccine prices for BiH market imposes further limits on purchasing ability, thus calling for urgency to rethink vaccine procurement strategies and arrangements. Fragility of the global vaccine market[13], including for Pentavalent vaccines[14], raises the risk of vaccine shortages in coming years in BIH. The Government lacks well formulated strategy to cope with possible shortage of Pentavalent vaccines.

[13] Innovations and Access: Vaccine Supply Updates. December 2012. UNICEF Supply Division
[14] Global Vaccine Action Plan. Monitoring, Evaluation & Accountability. Secretariat Annual Report 2013.

Non-vaccine immunization services are largely underfunded. The majority of public sector PHC facility managers interviewed complained about underfunding of the PHC sector, thus limiting health facilities' ability to perform outreach activities for improving immunization coverage, to purchase consumables and safety boxes, to maintain and/or to replace cold chain equipment, to fund staff training, etc.

Inadequate financing undermines the roles of PHIs at all levels and raises risks for effectiveness and sustainability of immunization programs. Poor financing of the PHIs in both entities and the BD was cited by all PHIs visited. Annual budgets are limited to cover only labour costs and communal expenses, while no funding is made available for supervision, enhancement of surveillance, and reporting functions, health worker training, and public education and awareness raising etc.

SUMMARY CONCLUSIONS

GAVI support was relevant and timely for BiH's needs and essential for funding and strengthening immunization programmes during the early stages of the support. The introduction of new vaccines and injection safety in BiH was in accordance with the internationally accepted guidelines and based on thorough, well-documented, and transparent situation analysis. The majority of activities planned under the MYSP for Immunization and the FSP were implemented, though some of the programmatic targets were not fully met and the effectiveness of implementation varied across the MYSP and FSP objectives. Overall, the transition from GAVI support to domestic funding of immunization programmes was smooth. The majority of GAVI supported activities continued, even after GAVI funding ended, except of injection safety policy implementation. While sustained financing for the GAVI supported programmes are ensured in the immediate post GAVI period, issues with long-term programmatic and financial sustainability pose serious concerns.

LESSONS LEARNED

- The strong focus on country ownership to achieve results has proven effective. Country ownership should continue to be the starting point GAVI's support effectiveness. The ICC coordination mechanism, required by GAVI in all eligible countries, proved its benefits even in countries like BiH, with fragile and weak political and governance structures. The challenge is to put the country genuinely in charge, to listen, adjust priorities, and measure results.

- Mobilizing long-term donor funds has enabled the GAVI Alliance to make multi-year funding commitments to BiH up to 2011, aligned to the country's own plans. This has given BiH a confidence to introduce new vaccines and sufficient time to plan for financial transition to domestic resources.

- In the absence of a well-formulated transition policy, BiH experienced the conclusion of GAVI funding without benefitting from a thorough assessment of country readiness for sustaining results and self-sufficiency. The phase out of GAVI's support should be systematic and its efforts should facilitate graduation with pre-determined financial and technical benchmarks. Furthermore, GAVI should maintain political support to assure financing of products and programmes continue after graduation.

- Through its innovative approach to develop tools and policies, GAVI supported BIH's financial planning for routine immunization and for new vaccine introduction. This process generated more focus on immunization costs and financing and contributed to a greater understanding of the financial implications when introducing new vaccines within government's and politicians.

- After the end of GAVI's support, the BiH entity governments made policy decisions based on selecting the lowest available vaccine price, without having full understanding of what market prices were and how they may affect overall long-term programme costs and sustainability. The price increases after the end of GAVI funding further strains limited public funding for immunization and significantly increases sustainability risks. Moreover, such developments will impede and delay the introduction of additional new vaccines in the national schedules.

- In order to sustain its achievements and maximize the potential impact of vaccine introductions in the Phase II countries, the GAVI Alliance will need to focus on strengthening national immunization systems and improving coverage to reach the most disadvantaged and underserved children. This will entail increasing GAVI's investments in health systems strengthening, better tailoring these investments to country-specific needs, and ensuring that plans for implementing the investments are designed in such a way that they focus on achieving immunization-specific outcomes. BiH's experience clearly demonstrates GAVI's value added in organizing partner's support especially for those countries that do not access Health System Strengthening grant and or Immunization Service Support from GAVI.

- Weaknesses identified in GAVI's monitoring of country performance resulted in missed opportunities to timely address challenges faced and calls for enhanced grant management tools for monitoring, tracking issues and identifying risks and requires face to face monitoring visits during and after GAVI support.

- GAVI and partners could have addressed the weak implementation of Injection Safety policies, however there was no evidence of GAVI and/or partner reaction and follow-up on these important issues. GAVI could have been instrumental in requesting country governments to formulate time bound mitigation strategic plans, should it been more attentive to the problems reported in APRs. Furthermore, GAVI could have mobilized partner support for enhancement of injection safety policy implementation in BiH as well as for regular monitoring of government's follow-up actions.

RECOMMENDATIONS

COUNTRY-SPECIFIC RECOMMENDATIONS

Strengthen local coordination mechanism for the immunization programmes in BiH. Coordination meetings have to serve as a platform for discussion of immunization programme and system challenges and for building consensus between constituencies on integration of remedial actions in the broader health sector reform agenda.

Restore the practice of multi-year planning of the immunization programmes - in order to ensure further sustainability and effectiveness of the immunization programmes, an

excellent precedent of developing state level MYSP and budgeting of immunization services practiced during GAVI support, has to be given a priority again.

Revisit vaccine procurement choices – in light of the vaccine procurement problems related to market fragmentation, low competition and high vaccine prices, alternative procurement options, including state level procurement framework contracts, should be explored to ensure sustainment of vaccine availability for the population. Alternatively, BiH can also explore the possibility of vaccine procurement through UNICEF SD, though this option may be shorthanded for some forms of new vaccines introduced by the country. Furthermore, BiH is not the only country in the region facing challenges with vaccine procurement. Small Balkan countries, such as Montenegro, Moldova, face similar problems. While developing regional procurement mechanism is labour and time-consuming exercise, BiH has to regularly raise this issue and actively discuss with the neighbouring countries. UNICEF/WHO could be active players in facilitating such discussions.

Enhance the supervision of immunization services and strengthen immunization information systems in order to address such weaknesses as lack of financial resources for the supervision and reporting, absence of adequate and uniform supervision guidelines, procedures and reporting forms. PHIs in both entities and the BD are advised to elaborate entity level strategies for follow up and reaching out underserved target groups.

Prioritise funding for cold chain and logistics – to eliminate problems related to the out-dated and broken cold chain equipment and their maintenance. BiH is advised to continue periodic assessment of cold chain equipment needs and to replace broken equipment not worth repairing. As country experiences scarcity of trained technicians, one alternative option could be to contract out maintenance services. Financing for cold chain and logistics must also be given priority.

GAVI and partners could have addressed weak implementation of Injection Safety policies, however there was no evidence of GAVI and/or partner reaction and follow-up on these important issues. GAVI could have been instrumental in requesting the Governments to formulate time bound mitigation strategic plans should it been more attentive to the problems reported in APRs. Furthermore, GAVI could have mobilized partner support for enhancement of injection safety policy implementation in BiH as well as for regular monitoring of government's follow-up actions.

Develop and implement state level comprehensive and effective public communication strategy for the immunization programmes – to counter the rise of a strong anti-vaccine sentiment negatively influencing the vaccination decisions of parents and health workers.

Develop and implement strategy for hard to reach population - Further efforts must be made to provide services in hard-to-reach communities, restore trust between minorities and health providers and adapt communications to achieve this. Immunization of migrant children has to be a priority for both entities and the BD through a collaborative and innovative approach.

RECOMMENDATIONS TO GAVI

Enhance country coordination mechanism - In an era of more pluralistic and complex health systems, such as in BiH, it will be increasingly important for immunization planners to link to

a wider coordination system that is inclusive of the health sector, regulatory authorities, civil society and private sector interests. Managing through systems, rather than being over-reliant on committees, may broaden participation in implementation and, in doing so, expand the reach of immunization and maternal and child health care services in GAVI eligible countries.

Improve monitoring and evaluation of GAVI supported national programmes during and after GAVI support – through (1) shifting way from reliance on coverage and population data and consider alternative forms of application and performance requirements, such as the coverage consistency and an equity dimension; (2) enforcing utilization of regular data quality audit practice especially for Immunization Services Support (ISS) non-applicant countries during GAVI support with measures to ensure the sustainability of the data quality audit practice after the transition; (3) Establishing country level monitoring system and procedures to respond to country-level problems quickly, helping through leveraging partnerships or direct technical assistance to under-performer countries and (4) harmonizing country progress reporting and GAVI's response due dates with the country budget cycle.

Increase the predictability and sustainability of long-term financing for national immunization programmes – The case of BiH can possibly serve as a model example for GAVI graduating countries. Achievement of "graduated country" status alone may not ensure financial sustainability of immunization programmes in middle-income countries. In order to increase the predictability and sustainability of immunization programmes in these countries GAVI is advised to institutionalize long-term graduation-planning exercise that addresses vaccine procurement policies and practices, market intelligence (forecasted prices, expected entry of new suppliers and vaccine products, etc.), national regulatory capacity, and immunization technical advisory bodies and their effective functioning. Furthermore, GAVI should consider the development of pooled procurement mechanism for the graduated countries. In doing so, GAVI can learn from PAHO's Revolving Fund experience of providing tiered pricing thus allowing graduated countries to procure vaccines at the middle market price after graduation. Pooled procurement mechanism will increase country bargaining power vis-a-vis pharmaceutical firms and suppliers.

Assist countries to make efficient procurement choices - While strengthening of public procurement system is beyond GAVI responsibilities, procurement issues should be considered as a key priority and addressed in partnership with other donors/partners (WHO, World Bank (WB)) working on public administration reform and public procurement systems. The assessment of public procurement system and actions directed towards enhancement of procurement system capacity should be adequately reflected in FSPs and implementation closely monitored during GAVI support. Phase out of GAVI's support should be systematic and efforts towards this end should concentrate on government commitments towards country ownership and self-sustainability and should facilitate graduation with pre-determined financial and technical benchmarks. One measure that would help is advising these countries to procure from UNICEF SD or to proceed with regional pooled procurement options, as applicable.

Join forces with partners and other donors for health systems strengthening - In view of financial and technical resource constrains revealed by the GAVI HSS evaluation in 2009[15], GAVI is advised to join forces with partners and other donors in order to increase and deepen focus on health system strengthening aspects (e.g. for health sector coordination,

[15] GAVI Health System Strengthening Support Evaluation, HLSP, 2009

procurement supply management, immunization information system strengthening and/or for human resources development).

CHAPTER 1: INTRODUCTION

This chapter provides brief information about Bosnia and Herzegovina's (BiH) political and governance structure, economic challenges, and key issues identified in the health sector that may potentially affect the sustainability of the immunization programme. Furthermore, it also offers a short description of GAVI support to the country.

1.1 COUNTRY BACKGROUND

BiH, one of the sovereign republics that used to be part of the former Yugoslavia, is located in the western part of the Balkan Peninsula and covers an area of 51,129 km^2. It shares international borders with Croatia to the north, south and west, and with Serbia and Montenegro to the east.

The peace agreement of 1995, signaling the end of hostilities that started in 1992, resulted in BiH having two administrative entities – the FBiH and the RS. Since 2000, the BD has been independently administered as a unique administrative unit of local government under the sovereignty of BiH. The Governments of the FBiH and the RS are each responsible for internal affairs, environmental, economic, social and health sector policies, justice and taxation. This implies that BiH practically has three health care systems. Canton governments (in the FBiH) deal with health (through ten cantonal health ministries), education, culture, housing, public services, local land use and social welfare expenditure.

The Council of Ministers of BiH has exclusive responsibility for foreign policy, defense, customs policy, monetary policy, immigration and asylum policies, air traffic control, and payment of international financial obligations, inter-entity transport, and communications and law enforcement. According to the Law on Ministries from March 2003, the MoCA of BiH is in charge of the coordination of health issues at the state level.

Bosnia has a transitional economy with limited market reforms. The economy relies heavily on the export of metals, as well as on remittances and foreign aid. A highly decentralized government creates challenges for economic policy coordination and reform, while bureaucratic barriers and a segmented market discourage foreign investments. The war in BiH caused production to plummet by 80% from 1992 to 1995 and unemployment to soar[16]. After restoring peace, output recovered slowly since 2002 when Gross Domestic Product (GDP) growth exceeded 5% per year. However, the country experienced a decline in GDP of nearly 3% in 2009 reflecting on local effects of the global economic crisis and Gross National Income (GNI) per capita has stagnated since at around 4,600-4,740current US$[17].

[16] CIA, World Factbook, USA, 2005

17 The World Bank Data. GNI per capita, Atlas Method.
http://data.worldbank.org/indicator/NY.GNP.PCAP.CD/countries/BA?display=default

1.2 KEY ISSUES IN HEALTH SECTOR

According to the Constitution of the BiH, the health sector is under the complete responsibility of the entities. The health care system was restored after the devastating war: the health infrastructure was rebuilt, the insurance system was re-established and population access to health services was improved. Over the past several years, both entities have initiated wide-ranging reforms in the health sector aimed at increasing sectoral efficiency, strengthening financial sustainability, and improving quality of care. However, weaknesses still remain in efficiency, equity, and quality of services, calling for deeper reforms. The major issues in the health sector include:

The high burden of disease – The leading cause of morbidity and mortality are non-communicable diseases. About 50% of deaths are attributable to cardiovascular diseases and about 20% to cancer[18]. The ageing population and unhealthy lifestyles associated with smoking, diet, alcohol, and drug abuse are the main contributors to the current epidemiological burden. Human Immunodeficiency Virus - HIV, sexually transmitted infections and tuberculosis (TB) remain high priority despite successes against communicable diseases in the past. Road accidents and injuries (intentional and unintentional) are rising and also contributing significantly to the death toll.

The restoration of routine immunization in post- war BiH, with the support from GAVI and other development partners, resulted in higher immunization coverage rates and the decline of vaccine preventable diseases (VPDs).

Inequality in access to health care – Health authorities in BiH face growing challenges with inequality in access to health care. With 14% of the population living below the national poverty line and a nationally reported unemployment rate of 31% (2012),[19] much of the population remains uncovered by health insurance (17–35% in different parts of the country)[20]. A rural-urban gap and health insurance benefits that are not portable across the cantonal boundaries within the FBiH further contribute to geographical inequality in access to health care. Marginalized populations, such as the Roma, have the poorest health status and the most barriers to health care access, despite some efforts to ameliorate their situation.[21]

Financial sustainability – The financial sustainability of the health system is uncertain. BiH's total health expenditure was 10.9% of GDP in 2011[22], generally higher than the average for central and Eastern European countries. However, it is unclear whether this relatively high level of health spending will be maintained in the long term, especially if macroeconomic conditions remain stagnant. About 60% of total health expenditure is paid from government sources, while the remaining 40% are household, private, out-of-pocket expenditures.[23] Nevertheless, a general perception prevails within the sector, that insufficient financing is available for a health sector where services are considered of poor quality.

[18] Agency for Statistics of Bosnia and Herzegovina. 2013. http://www.bhas.ba/index.php?option=com_publikacija&id=1&lang=en&Itemid

19 Country Cooperation Strategy at a Glance, WHO, 2013, http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_bih_en.pdf

[20] Ibid 19

21 Special Report on the status of Roma in Bosnia and Herzegovina. Institution of Human Rights Ombudsman in Bosnia and Herzegovina. 2013

[22] Public Expenditure and Institutional Review, World Bank, 2012

[23] Ibid 22

High fragmentation – The highly fragmented nature of the health systems in BiH represents one of the causes underlying the high costs and poor performance[24]. The Dayton Peace Accords stipulated that the entities should be responsible for health regulation, organization, financing and service delivery. In FBiH, the responsibility for health services has been further delegated to the cantons, so FBiH health sector includes the FBiH Ministry of Health (MoH), the 10 cantonal MoH's, the Federal Solidarity Health Insurance Fund (HIF), the 10 cantonal HIFs, and 11 institutes of Public Health. The RS health system is centralized at the entity level, so responsibility is shared only between the Ministry of Health and Social Welfare (MoHSW) of RS, a single HIF and a single PHI. The BD also has a department of health and a single PHI. As a result, BH has 13 MoH's, HIFs and PHIs, which has led to substantial duplication and inefficiency.

Fragmentation of responsibility for health care in FBiH results in inefficient operation of the health system. The WB Public Health Expenditure and Institutional review[25] displays variation of public per capita health expenditures between the entities. FBiH spend approximately double the amount of per capita than RS, even though RS substantially increased public health spending recently.

Albeit health sectors in the two entities differ, the spending difference suggests that significant inefficiency must exist in FBiH since health outcomes in the two entities are comparable. The health spending in the RS appears to be more efficient, probably as a result of the introduction of the service delivery and health financing reforms, while health spending across FBiH cantons varies greatly, resulting in less than optimal spending on primary care[26]. PHC expenditures are approximately twice as high in Herzegovina-Neretva and West Herzegovina as they are in Una-Sana and Posavina cantons[27]. The BD substantially increased health budget over the course of the last three years, mainly allocating budget to capital investments.

The current reform agenda revolves around issues related to broadening the contribution base for premium collection, strengthening the pooling function of financial resources and using effective resource allocation mechanisms. These actions may not lead to financial sustainability unless efficiency problems are addressed as well.

Limited institutional capacity compounded by institutional fragmentation hampers health care reform implementation. The overall administration of the government health sector has a lot of duplication. System-wide decisions are difficult to make because responsibilities and authority between local and central levels are not clearly delineated, particularly in FBiH, which also has an additional cantonal, level. Consequently, consistent state level planning, policy development and coordination are constrained by institutional and human capacity weaknesses.

Inefficient service delivery – Technical assessments[28] of both entities' health care systems point to inadequate mix of primary, secondary and tertiary care facilities, shortages of key materials and equipment, and uneven knowledge of evidence-based protocols. There is neither excess nor shortage of hospital services. The problem mostly relates to the composition and quality of services at hospital level, which are deemed poor. In the past decade, the number of hospital beds has slightly declined from 3.7 to 3.3 per 1000

[24] Ibid 22
[25] Ibid22
[26] Ibid 22
[27] Ibid 22
[28] Project Appraisal Report, The World Bank Report No. 25672, 2005

population, one of the lowest bed/population ratios in the Southeastern Europe region and half of the European Union (EU) country average. However, both the average hospital admission and hospital occupancy rates are relatively low. The underlying problem is that decentralization has led to an excessive fragmentation of the government health sector, resulting in duplication within the service delivery system and missed opportunities for economies of scale.

The low quality of services provided at the primary health care level and the lack of coordination among health professionals result in too large number of cases being referred to higher levels of care and treated at unnecessary high costs[29]. In addition, basic health services are still mainly delivered based on age, gender or disease in sub-specialized dispensaries, which is not the most efficient way to use available resources.

BiH has tested the family medicine model on a large scale. This model has proven to be acceptable to both primary level professionals and population. Nonetheless, provision of immunization services remains a function of the paediatric units at PHC facilities.

Currently, the BiH governments are discussing further steps for enhancing the family medicine system. The option of transferring the supervision of infants and immunization services from paediatricians to family medicine practitioners is high on the political agenda, but interaction between family medicine and the public health service in the field of immunization has not yet been discussed in detail. On one hand, paediatricians and facility managers vastly oppose the proposed reforms, as that transfer of immunization services is perceived to negatively affect immunization programme effectiveness. On the other hand, family physicians feel unconfident to take care of children under one year old.

Shortage of medical personnel and lack of motivation is evident, especially at the PHC level and has been named by key informants as one of the major problems faced by health providers in both entities and the BD.

At PHC facilities (Dom Zdravljas), paediatricians and immunization nurses are responsible for immunization. Children are not immunized without paediatrician's clearance. However, due to a shortage of paediatricians at the PHC facilities, the paediatricians from nearby hospitals are part-time contractors at the PHC clinics.

> "The biggest challenge is shortage of medical personnel. Due to close proximity to Croatia and better reimbursement of doctors and nurses in Croatia, many moved or work across the border still living in our Canton. In some areas there is absence of personnel and health facilities try to outsource services. They contract part-time doctors which is the most cost-efficient solution in this situation"
>
> "My hard work is not appreciated. There is no salary increase, no other type of reward".
>
> *Quote from Key Informants*

Planning for the production of a new generation of physicians graduating from the medical education system is not based on actual needs of the sector and the quality of the education does not ensure production of qualified personnel.

The constitutional decentralization even limits governments to retain and reward health personnel. For example, attempts of FBiH to increase health worker salaries with the help of sector collective agreement were impeded by a constitutional court ruling. As a result, salaries vary between cantons due to differences in available financial resources, as well as

[29] Ibid 28

to the fact that, constitutionally, cantons are granted decision-making power on budgets and salaries.

A salary increase introduced in RS and the BD around 2012, was insufficient for salaries to catch up to those of neighbouring countries. Consequently, low-paid health workers migrate to neighbouring countries and BiH faces human resource shortages. Furthermore, there is no effective mechanism to influence health worker performance in BiH. The few salary increase decisions that could be made were not based on individual performance of health workers, but rather an increase per position depending on the type of the health facility. Regardless of the problems related to low pay and the absence of performance-based motivation mechanisms, the ET observed high dedication of health personnel to immunization services.

> "I am happy how my staff works, however I regret that I cannot reward them to increase their motivation"….
>
> *Quote from Key Informant*

Health information system – The health information system is weak and does not provide the high-quality information needed for evidence-based policy-making. Health managers do not have easy access to the management information system, further limiting their management capabilities[30]. Furthermore, a central health information system – capturing information from RS, FBiH, and the BD – does not exist, which challenges central level planning and coordination of health care policies.

The sustainability of immunization services is dependent, over the long term, on efficient and sustainable health services and systems. The current health sector challenges call for significant adjustments to ensure that the system is able to cope with imminent demographic and epidemiological changes and growing population expectations, as well as to sustain the successes achieved thus far.

1.3 GAVI SUPPORT TO BOSNIA & HERZEGOVINA

GAVI graduation and sustainability concepts

Increased and sustained allocation of national resources to immunization is a strategic objective for GAVI, which contributes to achieving the organization's Strategic Goal SG3 – "Increase the predictability of global financing and improve sustainability of national financing for immunization".

In GAVI Phase I (2000 to 2006), the GNI per capita eligibility threshold was US$ 1,000 (based on 1998 WB data). Seventy-four countries were initially eligible for GAVI support. In GAVI Phase II (2007 to 2010), country eligibility was based on the WB 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. This reduced the number of countries eligible to apply for new support from GAVI in phase II to 72. At this time, they became ineligible to apply for new support, though GAVI continued to meet any existing multi-year commitments for support. As such, until adoption of this policy, there were no formal or explicit procedures to guide countries as transitioned from eligibility to ineligibility, although any prior approved multi-year commitments were respected. During this period, there was no support or policy to assist countries when their initially

[30] An upgrade of health information system in the RS is underway that is expected to significantly improve evidence informed policy making in the republic, including for the immunization programme

approved time-limited support came to an end. Country co-financing did come into effect in 2007. However, there was no explicit link in the policy to graduation from GAVI support.

The paper presented to the GAVI Alliance Board in November 2009 on graduation from GAVI support noted that this lack of a clearly defined policy, *"has created uncertainty for, and potentially inhibited decision-making by, GAVI-eligible countries".* The Board paper also noted the following three main difficulties for countries due to the absence of graduation 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; iii) The considerably higher and more unpredictable prices graduating countries face for some vaccines, particularly newer vaccines.

A revised eligibility and graduation policy were approved in 2009, with an effective start date of January 2011. The GAVI Alliance Graduation Policy is applicable to all Phase III (from 2011 to 2015) eligible countries, as is the eligibility policy, which sets a threshold that is adjusted annually for inflation. For 2013, countries are eligible for GAVI support if their GNI is less than or equal to U$1,550. As such, 17 countries have surpassed the threshold and are classified as graduating. These 17 countries cannot apply for new GAVI support and experience a linear ramp-up of their co-financing contributions, as per GAVI's Co-Financing Policy.

GAVI support to Bosnia & Herzegovina

At the launch of GAVI support during 2002, BiH was rebuilding its health infrastructure weakened by the civil war. Routine immunization coverage had fallen during the war and according to WHO/UNICEF estimates DTP3 coverage was 55% in 1995, which increased to 80% in 2002[31].

In 2002, GAVI provided BiH with a Vaccine Introduction Grant in advance of GAVI's support for the HepB monovalent vaccine starting in 2003. GAVI then began supporting the monovalent Hib lyophilized vaccine provision, with the first introduction grant given to RS in 2007. And final GAVI supported vaccines were shipped to BiH in 2011. A summary of GAVI's support to BiH is provided below in Table 1.

Table 1: History of GAVI Support:

	YEARS[32]	APPROVED (USD)	DISBURSED (USD)[33]
Hep B mono	2003	70,000	70,000
	2004	25,962	25,962
	2005	31,218	31,218
	2006	44,011	44,011
	2007	53,129	53,129
	2008	33,449	36,796
	2009	1,563	1,563
	SUB TOTAL	**259,332**	**262,679**
Hib mono	2007	415,532	415,532

[31] These coverage estimates represent national coverage estimates (BiH actually consists of two entities: FBiH and RS, as well as of the BD, as a unique administrative unit of local government under the sovereignty of BiH.)
[32] Year refers to the year of shipment or disbursement of funds from GAVI to country
[33] Although reflected in dollar amounts, when disbursements relate to a vaccine, such as Hepatitis B monovalent vaccine, these equate to the total number of doses provided.

	2008	345,000	346,675
	2009	367,000	367,233
	2010	375,500	361,976
	2011	369,500	368,357
	SUB TOTAL	**1,872,532**	**1,859,773**
Injection Safety Support (INS)	2006	24,221	24,221
	2007	15,207	15,207
	2008	13,702	13,702
	SUB TOTAL	**53,130**	**53,130**
Vaccine Introduction Grant	2002	100,000	100,000
	SUB TOTAL	**100,000**	**100,000**
GRAND TOTAL		**2,275,583**	**2,275,583**

BiH did not experience a graduation phase similar to current Phase III GAVI countries and transitioned before GAVI's graduation policy was enacted. GAVI support to BiH concluded when the time-limited multi-year period for which support had been approved came to an end in 2011. Through the 2011 APR, BiH made GAVI aware that sustainability was an issue and expressed concerns about vaccine prices[34]. Another challenge identified by BiH through its annual reporting to GAVI was the AVC in the country. Several stories about possible adverse events following vaccination received large media attention. This subsequently caused disruption to the routine programme implementation and negatively impacted demand for immunization.

How BiH managed the transition away from GAVI's support and how this transition impacted the sustainability of the national immunization programme has not been studied before.

[34] APR 2011

CHAPTER 2: EVALUATION PURPOSE, OBJECTIVE AND METHODOLOGY

2.1 RATIONALE

This evaluation was commissioned by the GAVI Alliance Secretariat in accordance with the GAVI Alliance Evaluation Policy, which calls for the conduct of a final evaluation where GAVI Alliance support has ended. BiH will therefore represent the second graduated country in which an evaluation is conducted following the conclusion of GAVI's time-limited support to the country. The first comparable evaluation was conducted in China[35]. This evaluation provides lessons learned about graduation and sustainability of the GAVI programmes in BiH and in that contributes to future design and implementation of GAVI support to other countries.

The evaluation intends to:

- Generate and document experiences related to BiH prior to GAVI support, during the implementation of GAVI supported-programmes, and in the transition away from GAVI support , and
- Based on lessons learned develop recommendations that could inform possible amendment to the GAVI's Graduation Policy for going forward.

2.2 EVALUATION OBJECTIVES

The GAVI Secretariat commissioned this evaluation with the objective of expanding its knowledge about graduating countries. This evaluation provides lessons learned about graduation and sustainability of the GAVI programmes in BiH and contributes to future design and implementation of GAVI support to other countries.

Therefore, this evaluation aims to:

- **Assess the sustainability** of the programmes previously supported by the GAVI in BiH and their results after time limited GAVI support ended;
- **Identify factors contributing to the sustainability** of these programmes and their achievements.

The primary audiences for this evaluation are the GAVI Alliance Secretariat, the GAVI Board and its Programme and Policy Committee. The results will also benefit the country itself, especially the Ministry of Civil Affairs (MoCA) Health Department (HD), Ministries of Health of each entity and other partners and organizations interested in sustainability of outcomes and impact of their involvement in health sector and especially in the immunization programme in BiH.

2.3 EVALUATION SCOPE, GEOGRAPHICAL COVERAGE & PHASES

[35] Abt. Associates Inc. Evaluation of GAVI-Government of China Hepatitis B Vaccination Program. Bethesda, MD. December 2012

According to the GAVI-issued RFP (ANNEX 7: RFP) the evaluation assessed support received from GAVI and examined both, **financial and programmatic sustainability** through an in-depth analysis of the BiH's experiences and performance of the immunization programmes **before, during, and after** the conclusion of GAVI's time-limited multi-year support to the country. The evaluation examined the types and quantity of the GAVI support and plans and steps taken by the authorities for replacing GAVI funds after transition across all entities in FBiH, RS and the BD.

The evaluation was carried out in two phases: 1) the inception phase (preparation) and 2) the core evaluation phase (data collection; analysis; and report writing). The inception phase was conducted in February 2014 and resulted in delivery of the inception phase report to GAVI containing a detailed methodology for the evaluation. The core evaluation phase – which included country visit, data collection, analysis, and report writing, was conducted during April – May 2014. The final evaluation report incorporates comments received from key stakeholders.

2.4 EVALUATION FRAMEWORK

For achieving evaluation objectives, the evaluation framework (ANNEX 4: EVALUATION FRAMEWORK) has been developed, was guided by the evaluation Terms of Reference provisions on evaluation focus areas, criteria and questions.

Consequently, GAVI's support to BiH was evaluated along three-evaluation focus areas: **planning** (pre GAVI support), **implementation** (period of GAVI support), and **outcomes** (post-GAVI support) assessed against five OECD/DAC evaluation criteria: **relevance, efficiency, effectiveness, impact/results and** sustainability, with greatest emphasis on sustainability (see

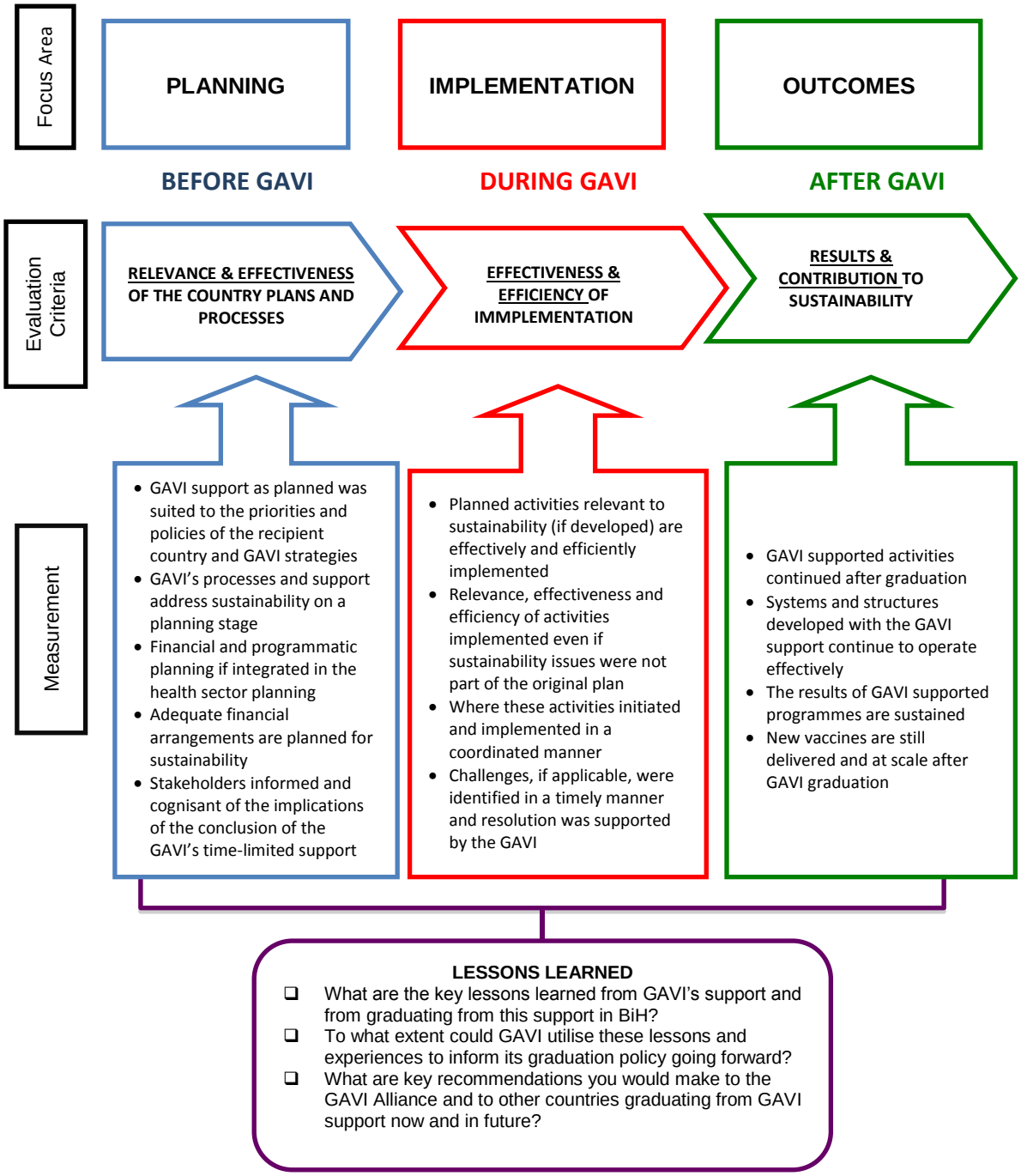
Figure 1, below).

The **planning** focus area examined **relevance and effectiveness** of the country plans and planning processes.

- **Relevance** was established by assessing whether: i) GAVI support as planned was suited to the priorities and policies of the recipient country and GAVI strategies; ii) GAVI's processes and support addressed sustainability on a planning stage; iii) adequate financial arrangements were planned for sustainability; and iv) stakeholders were informed and cognizant of the implications of the conclusion of the GAVI's time-limited support.
- **Effectiveness** of planning was established by evaluating whether financial and programmatic planning process was aligned with the overall health planning, was inclusive and properly organized and the resulting plans were evidence-informed and have set attainable objectives.

The **implementation** focus area concerned the implementation process of the GAVI supported programmes and planned sustainability measures by assessing their **effectiveness** and **efficiency** in achieving immediate programmatic and financial objectives and targets.

Figure 1: Evaluation Framework



- **Efficiency of implementation** was evaluated by assessing if selected qualitative and quantitative outputs were achieved in a cost-effective and timely manner.
- **Effectiveness of implementation** was measured by examining whether the planned key objectives/targets were achieved and the factors that influenced achievement of these objectives or lack thereof.

The **outcomes** of GAVI support were analysed by assessing **programmatic and financial sustainability**, as requested by the evaluation Terms of Reference.

Programmatic sustainability was defined broadly as the sustainability of key immunization program dimensions not restricted only to the areas directly supported by GAVI. The WHO Health System Building Blocks guided the assessment of programmatic sustainability. More specifically, **programmatic sustainability** was assessed by examining:

i) Governance, leadership, and accountability: the existing institutional arrangements, the enabling legal environment, the regulatory system and whether evidence-based policy development and planning for immunization programmes were usual practice; accountability structures and Expanded Program on Immunization' (EPI) manager's engagement with the community and media, including the role of media in covering the transition and graduation process;

ii) Service delivery: the availability of immunization services and access to services, management and service quality;

iii) Human resources: whether adequate number of skilled health workforce is available and motivated to deliver quality immunization services;

iv) Availability of vaccines and consumables: whether procurement, supply management and cold chain logistical practices are adequate to assure uninterrupted supply of vaccines, syringes and injection safety supplies;

v) Surveillance and information system: whether the surveillance system functions well, and whether surveillance and immunization information systems generate quality data, which is used in analysis and for policy formulation and management decisions.

The evaluation of **financial sustainability** took into account the concept of self-sufficiency and was defined as the extent to which the GAVI support was sustained through the resources of the country itself rather than external partners.

2.5 EVALUATION METHODS

A team comprised of two Curatio International Foundation health systems experts, a consultant from the Johns Hopkins University School of Public Health, and counterparts from Partnerships in Health, a local non-governmental organization (NGO) in BiH, carried out the evaluation jointly.

The ET used mixed methods to ensure comprehensiveness and validity of the data. These methods included literature review, qualitative research methods and quantitative data analysis.

DESK REVIEW – A review of existing documents was a major part of the evaluation. The ET consulted with and obtained necessary documents from GAVI Alliance and through web search during the inception phase (ANNEX 1: LIST OF DOCUMENTS REVIEWED). The list of documents reviewed was augmented during site visits, where the ET collected additional relevant documents. Data collected through this exercise informed: i) mapping of key stakeholders; ii) the design of the Evaluation Framework (ANNEX 4: EVALUATION FRAMEWORK) and evaluation tools/questions; as well as iii) the identification of information gaps and need for additional documents/research/reports to be collected during the data collection phase. The information obtained during the desk review was registered in the "Desk Review Database" and informed drafting of the relevant sections of final evaluation report.

QUALITATIVE RESEARCH METHODS – In-depth interviews were used to collect qualitative information on topics related to each evaluation criteria. Interviews conducted with key informant stakeholders were an important source of evidence for many of the evaluation

questions and their objectives were twofold: i) to solicit stakeholders' views on the key evaluation questions, and ii) to gather data and additional evidence to supports analysis.

Interviews included questions about the decision-making process, planning and effectiveness of implementation of GAVI-supported program elements (i.e. new vaccines – HepB and Hib; injection safety) leading to a country's replacement or lack of replacement of the GAVI support; the extent to which the intermediate and final results were achieved and sustained, from both the programmatic and the financing aspect; whether GAVI's support contributed to the strengthening of health system; the extent to which GAVI support was replaced with the government and/or donor/private funding in each year after graduation from GAVI's support; and how GAVI support may have impacted the broader health sector in BiH.

Prior to visiting key informants, interview guides were developed based on the EF, ensuring the systematic coverage of all questions and issues. The interview topics were selected based on the evaluation questions, but grouped and targeted according to the stakeholder, organization, or individual to be interviewed (ANNEX 6: IN-DEPTH INTERVIEW GUIDE). The ET members took detailed notes during the interviews and coordinated with local partners to ensure that questions were thoroughly asked and answered, and well-understood through translation.

While Focus Group Discussions (FGDs) with health providers were originally planned, these could not be carried out due to the few numbers and limited availability of medical personnel and PHI respondents at visited sites. In such instances, individual or group interviews were conducted with selected stakeholders, using the same interview guides. FGDs with the beneficiaries were not possible due to the lack of local Ethical Review Committee clearance.

QUANTITATIVE DATA – The majority of quantitative data was obtained from the health authorities in both entities and the BD; however collection of the required data from RS was problematic. Specifically, the evaluation team collected data on immunization coverage rates for different antigens, including in the immunization calendar for each entity, as well as data on procured doses of vaccine and expenditures for the period of 2011-2013. The quantitative analysis relied on publicly available data, as well as data provided by the GAVI secretariat, to ascertain performance of the programmes before, during, and after GAVI support.

2.6 QUALITY ASSURANCE

The following techniques were used during the evaluation to assure the quality of the data collection, analysis, and interpretation:

- Respondent validation: interim findings were cross-checked with the key informant respondents throughout the data collection period;
- Triangulation of data: different sources of data were used, where possible, to draw valid conclusions about the major themes of the evaluation and to produce a more complete understanding of the evaluation questions;

Inevitably, the quality of the data obtained for the evaluation varied from site to site. Therefore, to account for the data quality and to assess the strength of our conclusions, the ET followed the "robustness scoring" approach for each finding used by the Second GAVI

evaluation Report[36]. The Table 2 below displays a detailed description of "robustness score" assignment. Assignment of the score depends on two criteria: a) the extent to which the qualitative and/or quantitative evidence generated from the different sources point to the same conclusion and b) the quality of the individual data and/or source of evidence (e.g., as determined by sample size, reliability/ completeness of data, etc.).

Table 2: 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.

2.7 DATA COLLECTION

The evaluation team visited BiH between April 3 – 18, 2014. The appointments for data collection, as well as translation from the local languages into English were arranged through local counterparts at Partnerships in Health. A list of people met by the ET can be found in Annex 2 (ANNEX 2: LIST OF PEOPLE MET). For each meeting, one or more of the ET members facilitated the discussion, based on the interview guides described above. The interviews took place in the language preferred by participants – although, generally, the local language was used. Local partners facilitated translation and, where possible, assisted with note taking. The ET members prepared a detailed set of notes from all interviews, which was verified by local partners to ensure completeness and accuracy.

The ET identified key informants for three types of in-depth interviews:

- **Top-level interviews** – conducted with the members of the ICC (and/or alternatives) or with other senior representatives from the government. For these interviews the evaluation team focused on questions related to i) policy formulation, content and its relevance to achieving ownership and sustainability objectives; ii) implementation issues at GAVI Secretariat and in-country follow up.
- **Subject-specific interviews** – conducted with the officials/representatives of the MOH, immunization managers, facility managers, etc. and focused on particular aspects of the evaluation, such as policy impact on national processes, intended and unintended consequences.
- **Facts finding/data interviews** – conducted with individuals with more in-depth knowledge of the explored issues, identified through the "snowballing" technique as a result of the top-level and subject-specific interviews, e.g. GAVI secretariat and individuals previously involved in the programme implementation.

[36] GAVI second evaluation report, CEPA LLP in association Applied Strategies, 2013

Skype/phone interviews were conducted with a couple of respondents[37] who played instrumental roles in the GAVI programme implementation, but were not available for face-to-face interview.

Country specific quantitative data was collected either during the site visits or through a formal request process to the MoH in each entity and the BD. The ET attempted to collect data on immunization coverage rates, government annual budgets and expenditures, spending levels on vaccine procurement and vaccines doses procured, vaccine unit prices, cold chain inventory and vaccine wastage reports. The timeframe for data collection, included the last three years, 2011 – 2013, after GAVI support ended. Furthermore, information on UNICEF vaccine unit prices as well as foreign exchange rates of BiH local currency by respective years were obtained from the official web sources and used for the comparative analysis with the entity level unit prices.

Site visits to collect quantitative and qualitative data from the lower administrative levels were organized in sampled primary health care facilities/health centres and public health institutions in RS, FBiH and the BD. In RS and FBiH, two municipalities with a Primary Health Centres (Dom Zdravljas) PHC were randomly selected. One health centre was selected in the BD. The list of selected cantons/municipalities and facilities that were visited for data collection is presented in Table 3 below.

Table 3: Sampling/Selection of institutions for site visits

	FBiH	RS	BD
Central	Federal MoH	MoHSW	Department of Health, and Other Services
	2 Cantonal Ministries of Health in **Posavski** and **Hercegbosanski**		
	Federal Public Health Institute	Public Health Institute of the Republic of Srpska	
Cantonal/regional level	2 cantonal Public Health Institutes in **Posavski** and **Hercegbosanski**	2 regional centers of Public Health Institute of RS (in **Foča** and **Trebinje)**	
Local (vaccination services)	2 Community-Health Centers (dom zdravlja) in **Posavski** and 2 Community-Health Centers (dom zdravlja) in **Hercegbosanski**	2 Community-Health Centers (dom zdravlja) in **Foča** and 2 Community-Health Centers (dom zdravlja) in **Trebinje**	1 Health Center

2.7 ETHICAL CONSIDERATIONS

UNEG Ethical Guidelines[38] guided the entire evaluation process. The ET ensured impartiality and consistence in presenting findings and results of the evaluation through the collection of diverse perspectives on the subject of this evaluation.

The evaluation process followed all initially proposed methodologies except FGDs with direct careers/parents of beneficiaries. Being considered "human subjects research," the

[37] GAVI Secretariat and UNICEF
[38] UNEG Ethical Guidelines for Evaluation, UNEG, 2008, http://www.unevaluation.org/search/index.jsp?q=ethical+guidelines

FGDs with direct beneficiaries required local Ethical Review Committee clearance. The ET applied all possible ways to obtain official clearance before data collection, as well as while in field. As clearance was not granted in a timely fashion, FGDs with mothers/parents of a child were not conducted.

Before beginning the interview discussions, ET obtained verbal consent from all respondents. As an introduction, respondents were provided with background information about the evaluation and its purpose. The duration of the interview was tailored to the respondents' availability. None of the interviews were tape-recorded and participants were assured of their privacy and confidentiality protection. All respondents were provided with contact information of both the local counterparts and members of the ET, in case further questions or concerns would arise after the data collection period.

2.8 DATA ANALYSIS

Both quantitative and qualitative data were used to assess evaluation domains and criteria. Findings based on qualitative data were triangulated across the key informants, and compared with the available documentary evidence before drawing conclusions and formulating recommendations.

Qualitative data analysis: The team compiled the detailed notes taken during interviews, as well as the additional documents that were collected during the fieldwork. Interim team discussions about key emerging findings took place during the fieldwork. Data analysis proceeded with a thorough review of all key documents and identification of the main themes for each of the evaluation criteria proposed in the RFP for this evaluation. Two individuals separately analysed interview notes and conducted document review. The findings emerging from the interviews and documents were compared and, where discrepancies were found, a third ET member was requested to look at these issues. Based on the feedback from a third team member findings were summarized, themes and detailed findings were again crosschecked across the respondents to ensure consistency. All ET members, including the local partners, reviewed the findings resulting from this process.

Following triangulation, the data sets were used to develop specific analyses, such as timelines summarizing the chronology of GAVI programmes implementation, descriptions of particular processes used in the design or implementation of the programmes and stakeholder analyses of actor positions on specific features of the design and implementation at specific time. Where multiple data sources were available, the ET did not identify discrepancies in the data that was collected.

Quantitative data analysis: Quantitative data was difficult to obtain, especially in RS. Although we submitted data requests through official channels, as advised by respondents and local counterparts, the requested data had not yet been received at the time of the data analysis and report writing. Nevertheless, the team collected available data on the annual budget expenditure on vaccines, the number of doses procured, immunization coverage. The team also obtained information on UNICEF vaccine unit prices, as well as foreign exchange rates of the BiH local currency by respective years from the official web sources and used for comparative analysis with the entity level unit prices. In addition, the ET used immunization coverage data from the latest Multiple Indicator Cluster Surveys (MICS) as well as performed a media search in order to identify any trends in immunization related publications, particularly related to the anti-vaccine movement.

The Microsoft Excel spreadsheets were used to analyse trends in coverage rates, budget expenditure on vaccine procurement and vaccine unit prices. Quantitative information

derived from different sources were always compared and at every stage of the study the data was triangulated within and between the data sets with the aim of identifying common understandings of issues in focus, as well as to ensure data quality.

2.9 EVALUATION LIMITATIONS

The evaluation findings presented are based on compiling and analysing many different sources of information (both current and past) in a short period of time. Some analyses that were originally proposed could not be implemented due to time constraints and/or data/information gaps. Therefore key limitations of this evaluation include:

- The collection of quantitative data was a challenge, especially in RS, due to the need to submit formal data requests to various bureaucratic structures, which was not met during the timeframe for this evaluation. The ET could not obtain quantitative data from RS other than immunization coverage data, which limited analysis of vaccine unit prices and financial allocations for vaccine procurement in RS.
- The documented sources detailing GAVI support, especially during its early years and related to planning, coordination and implementation was only limited to the APRs and IRC reports and decision letters. And while these reports did identify key challenges, responses to these challenges were not reflected in the subsequent reports.
- Recall bias could not be completely avoided, particularly due to the long recall period (almost 10 years). Subsequently small discrepancies in timing of events are inevitable, although in most cases the ET was able to triangulate data from different sources and establish a high degree of reliability.
- In some instances individual interviews were not possible; therefore group interviews were pursued as an alternative. The group interviews might have inhibited individuals from expressing their true opinions about the immunization system. However, because group interviews contribute to about 10% of all qualitative data, the ET is certain that this change in approaches did not introduce significant bias in the evaluation findings.
- The local, entity-level Ethical Review Committee clearances for interviews or focus group discussions with parents were not possible to obtain in a timely fashion, preventing the team from collecting data from the beneficiaries and assessing their attitudes towards immunization in general, access barriers, and perceived quality of care.

CHAPTER 3: EVALUATION FINDINGS

3.1 RELEVANCE AND EFFECTIVENESS OF PLANNING

In this section, the relevance and effectiveness of planning for GAVI support, reflecting the pre-GAVI period, is examined by assessing: the extent to which BiH effectively planned and complied with GAVI's policies and strategies; whether all GAVI supported applications were relevant to country context and epidemiological situation; and whether the governments demonstrated effective planning for GAVI support implementation.

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 were these relevant, realistic, well documented and well communicated?
- To what extent did BiH prepare and plan for the transition away from GAVI support?

Countries applying for GAVI's support, as per GAVI's policies, are requested: i) to have an operational Interagency Coordinating Committee (ICC) as GAVI requires ICC signatures on applications for new and underused vaccine support (NVS), ISS and injection safety support (INS) applications and APRs; and ii) to develop a FSP - a document that assesses the key financing challenges facing the national immunization programme within the broader health-financing context. The FSP describes a government's approach to mobilizing and effectively using financial resources to support medium- and long-term programme objectives. Previously, all countries receiving GAVI support were required to submit a FSP in their second year of GAVI support. In an attempt to reduce the planning and application requirements on countries and to build on existing national processes, the FSP elements were transitioned into the comprehensive multi-year plan (cMYP) guidelines in late 2006.

In order to qualify for GAVI's support BiH with GAVI and partner support complied with all requirements in a timely manner. Process and timeline of BiH and GAVI interactions are schematically provided in the Table 4 below.

Table 4: Key milestones of BiH and GAVI interaction

YEAR	Milestones
2000	✧ ICC instituted ✧ EPI Review Completed ✧ HepB proposal submitted
2001	✧ MYSP adopted ✧ GAVI Invitation letter for HepB received ✧ BiH HepB proposal submitted ✧ GAVI pre-approval conditional letter received ✧ HepB Action Plan developed
2002	✧ Cold Chain Storage capacity assessment completed ✧ HepB Proposal resubmitted ✧ GAVI approval for HepB received ✧ GAVI Vaccine Introduction Grant approved
2003	✧ EPI Management Review conduced ✧ Health worker trainings initiated in RS and the BD ✧ HepB vaccines received for the BD and RS
2004	✧ HepB vaccines received for FBiH, RS, BD ✧ INS assessment carried out ✧ INS plan developed ✧ INS application submitted to GAVI ✧ Hib RAT completed
2005	✧ GAVI approval of INS ✧ Communication Plan developed

	✧ Reporting forms standardized ✧ MIS installed in FBiH ✧ Public Procurement law amended allowing procurement through UNICEF SD ✧ Hib proposal submitted ✧ GAVI comments on Hib proposal received ✧ FSP developed
2006	✧ Revised Hib proposal submitted ✧ GAVI approval of Hib proposal ✧ VMA conducted in FBiH
2007	✧ BiH starts to gradually take over vaccine procurement
2009	✧ GAVI support for HepB ended ✧ GAVI Vaccine Introduction fund ended ✧ INS support ended
2011	✧ GAVI Hib support ended

The ICC was established to ensure stakeholder coordination and evidence-based decision making and the smooth implementation of the immunization programmes. The ICC was established as a stand-alone committee in October 2000, chaired by the MOH Ministers on a rotation basis. The Ministry of Foreign Affairs, EPI managers from both FBiH and RS, UNICEF, and WHO, represented the ICC. UNICEF played instrumental role in establishment of the ICC and provided secretarial support up to 2008. The ICC was meeting on a quarterly basis.

Main functions identified for the ICC were:
- Approving annual plans, monitoring of the progress, and defining corrective actions as needed to meet operational immunization coverage and disease reduction targets,
- Ensuring safe immunization practices and vaccine wastage reduction;
- Performing periodic field assessments of implementation progress of basic strategies and activities of the Multi-year Plan such as safe immunization practices, wastage reduction, cold chain effectiveness, adequacy of recording and reporting of VPD, immunization coverage and adverse events following immunization;
- Discussing financing of the EPI and mobilize resources for important needs.
- Discussing feasibility of supplementary vaccination during epidemic upsurges of VPDs and mobilize resources for implementation of outbreak control measures.

The MYSP for Immunization[39] was developed jointly by all entities and is an example of effective planning – The MYSP for the years 2002-2006 was prepared jointly by the Federal MoH, the MoHSW of the RS and the BD Department of Health, with the technical assistance of UNICEF and WHO/EURO, and approved by the BiH Interagency Coordinating Committee in February 2001. The MYSP was largely informed by the immunization cluster surveys carried out with UNICEF's support (1996, 1998, 1999 and 2000) and findings of the UNICEF/WHO supported Expended Programme of Immunization.

The MYSP for immunization was regarded as the means through which BiH would fully restore its Immunization Programmes, and would be able to sustain effective control of traditional VPD and also to reduce community burden of HepB and invasive Hib infections. Four key strategies were set by the plan: i) Setting standardized common policies, guidelines and schedules for immunization services in BiH; ii) Achieving and maintaining >95% coverage through quality and safe routine immunization in all geo-administrative units and communities of BiH; iii) Strengthening disease surveillance; and iv) Enhancement of monitoring, evaluation and supervision on performance of the Multi-year Plan activities.

The MYSP 2002-2006, which guided the implementation of EPI in BiH, was fully consistent with GAVI goals. The plan addressed all the diseases against which the WHO/EURO

[39] BiH Multy Year Strategic Plan for immunization, BiH, 2001

recommends universal immunization. It set disease elimination goals for Poliomyelitis, Diphtheria and Neonatal Tetanus and disease reduction targets for Measles, Mumps, Rubella (MMR), Pertussis, Viral HepB, Tetanus and disseminated forms of TB in children. The Plan also envisaged assessing the Hib burden and the introduction of universal immunization. The budget of MYSP covered the costs of purchase of vaccines at UNICEF prices, purchase of immunization-related materials, such as AD syringes, safe disposal boxes, cold chain and freight, as well as capacity building of health workface, though the budget lacked the indication on possible source of funding.

To insure sustainability of the immunization program, BiH developed the FSP[40], which was approved by the ICC in 2004 and submitted to GAVI in January 2005. The FSP identified three priority elements of the financial sustainability of immunization program in both entities of BiH. These elements were to ensure that i) responsibilities for the financing of the national immunization program are clearly defined in the legislation and enforced; ii) vaccines are procured at the lowest cost (close to UNICEF rates) and iii) the vaccination schedule is revised primarily on the basis of cost-benefit analysis. The FSP, alongside with the MYSP, served as the Government's planning tool for the transition away from GAVI support.

Relevance of new vaccine introduction was established through epidemiological evidence generated at the country level. The decisions were adopted through an inclusive process and in accordance to the international guidance. Decision on introduction of **HepB** was based on WHO/EURO recommendations and the experience of other European countries with intermediate and low endemicity of HepB (Italy, Germany, Spain, Greece etc.). The MYSP identified control of HepB as one of the eleven strategic objectives of the EPI.

On September 6, 2001, during a meeting with the epidemiologists, paediatricians and official representatives of the FBiH, the RS and the BD a consensus was reached to initiate the hepatitis B immunization programme at birth (in 12 hours), and to complete the 3-dose schedule by the time the child is 6 months old[41]. Policy-makers from both entities and the BD reached a consensus that the maintenance of high immunization coverage of every next birth cohort at each geo-administrative level of BiH is the most effective immunization strategy for reaching the final goal of reducing chronic HVB infection morbidity and mortality. Ministerial Decrees of both entities formalized this decision.

The HepB Universal Immunization Action Plan 2002-2006 was developed in 2001, aiming to create five immune birth cohorts and to pave the way to HepB low endemicity in BiH through sustained immunization. The plan provided detailed, time bound actions planned for implementation. However, the plan did not address the government's financial plan for sustaining the HBV vaccination and Injection Safety practices, and, instead, relied on MYSP forecasts. Based on the findings of the Immunization Programme review in June 2003, BiH initiated major changes in programme management concomitant with preparations for the introduction of neonatal HepB vaccination and a new optimized vaccination schedule as described in Annual Reports to GAVI for 2003 and 2004.

In 2002 the MoH in FBiH addressed the emerging priority of combating **Hib** invasive disease by pilot use of Hib vaccine in a four-dose schedule (2, 4, 6 and 18 months of age). The MoH, being advised by the Independent Expert Group on Immunization in the entity, considered revisiting of four-dose Hib schedule and decided that the Immunization schedule that will be

[40] Ibid
[41] ICC meeting minutes

introduced in May 2004 should include Hib vaccine in a three dose schedule (2, 4 and 18 months), following the so called Nordic schedule with a delayed third dose to obtain better long term protection.

A Hib Rapid Assessment (RAT)[42] was conducted in July 2004 and showed that the disease burden in BiH (Hib meningitis incidence 14.8 –27.2 / 100 000 in children below 5 years of age) was high enough to justify vaccine introduction. The ICC reached an unanimous decision in terms of financing and procurement of Hib vaccine, and suggested to the MoH of FBiH to finish the pilot project on Hib immunization in FBiH – and to find a mechanism for continuous provision of Hib vaccine, which is an important measure of protection of children against severe, life-threatening infections, caused by Haemophilus influenza type B. Pursuant to the results of the Hib RAT assessment RS also decided to apply for GAVI support to be able to introduce Hib vaccine.

The injection Safety Assessment[43], carried out in 2004, largely informed GAVI's support to immunization Injection Safety improvements. The ICC meeting in September 2004, agreed on the implementation of an injection safety assessment with the support from WHO. The objectives of this assessment were to identify and quantify issues and priorities regarding the safety of injection for immunization. The specific recommendations, according to the results of the assessment prioritized three areas of interventions: i) To reinforce behavioural changes among health care workers and staff involved in injection safety and safe disposal; ii) To ensure adequate supply and distribution of injection equipment including AD syringes, safety boxes and vaccines; and iii) To ensure the safe collection and disposal of injection equipment. Consequently, based on these recommendations, the BiH National Injection Safety National Policy document[44] and National Plan of Action to Improve Immunization injection safety and safe disposal in BiH[45] were developed. The proposal for injection safety alongside with the introduction of Hib was submitted for GAVI approval in 2005.

The National Injection Safety Policy Document set national standards for acceptable injection equipment; defined procedures for the disposal and destruction of used injection equipment; addressed issues of on-the-job health worker (physician, nurses and managers) trainings and the integration of training modules in the curriculum of the pre-service medical and nursing education; as well as management and supervision of health workforce in applying injection safety practices and public awareness raising. The policy document was later followed by the implementation plan; however the ET was not able to obtain any information from key informants and/or official documents, which addressed budgetary needs for policy implementation.

In all instances, GAVI's financial support was critical and relevant for the introduction of new vaccines and support of injections safety strategies. According to the key informants, sufficient funds were not available in BiH's health sector budgets to finance the introduction of new vaccines. This finding is partially corroborated by the WHO estimates on the health sector budgets showing that in 2001 per capita public expenditures on health for BiH (201 PPP$) were less than one third of the 2011 level (632 PPP$) when GAVI support ended[46].Thus GAVI support was highly relevant, timely and key for improving the country's immunization programmes.

[42] Hib Rapid Assessment, WHO, 2004
[43] BiH Injection Safety Assessment, WHO/Euro, 2005
[44] Ibid 11
[45] Ibid 12
[46] European health for all database (HFA-DB), April 2014, accessed on June 28, 2014

GAVI displayed important efforts to assure financial and programmatic sustainability, as demonstrated by the following factors:

- The invitation letter for submission of application for HepB was sent to the Ministers of Health of both entities in April 2001. The entities worked together to submit a single application to GAVI.
- GAVI imposed conditions related to enhanced financial and programmatic sustainability. In December 2001, GAVI provided IRC letter reflecting pre-approval conditions and requesting development of the HepB introduction plan and government's proposal on financial sustainability.
- The information about capacity and quality of the cold chain was given a priority focus at the approval of HiB proposal and assurances requested from BiH. In 2005 BiH applied for introduction of Hib vaccine and received conditional approval. The IRC letter to the government specified two conditions: i) Revision of the proposal to assure that GAVI funding does not replace government funding and ii) Clarification on whether the cold chain deficiencies have been addressed and whether the cold chain has sufficient capacity to introduce the new vaccine and include cold chain indicators in the plan of action. At the request of GAVI, BiH with assistance from WHO in 2003 conducted assessment of cold chain to assure sustainability and quality of vaccine supply, as well as performed detailed cold chain capacity assessment and provided requested clarifications in the proposal which was resubmitted for GAVI funding.
- GAVI did not approve the initial 2000 BiH proposal for Immunization Injection Safety,. In order to qualify for injection safety support, GAVI advised the country to re-submit its proposal to include a plan for injection safety, as well as to specify what has been achieved from the MYSP plan.

GAVI Decision Letter, 10 December 2001

In order for the country to qualify for approval for the provision of HepB vaccine GAVI imposed the following conditions:
Condition 1: To develop the HepB introduction plan with particular regard to: providing more details on cold chain storage capacity**;** confirmation that GAVI funding will not replace government funding for the current HepB vaccine, and how funds thereby saved will be used for immunization purposes**;** justifications for the proposed schedule of HepB vaccinations **and** information regarding lessons learned from past experience with HepB vaccine (cold chain storage capacity) reconcile figures in tables in the HepB introduction plan;

Condition 2: To provide strategic directions towards financial sustainability and complete tables (for 5 years) in Annex 1 (sources of funds, and unmet needs).

SUMMARY OF FINDINGS ON RELEVANCE AND EFFECTIVENESS OF PLANNING

EVALUATION QUESTION	FINDINGS	ROBUSTNESS RANKING	
To what extent were there processes or support put in place by GAVI to address both financial and programmatic sustainability?	Programmatic and financial sustainability were key issues addressed by GAVI during the proposal development and negotiations and were embodied in the mandatory preconditions for initiating the GAVI support.	A	Findings are substantiated through review of communication between GAVI and BiH and supported by qualitative data and document review
To what extent were these relevant, realistic, well documented and well communicated?	GAVI support was relevant to country needs and essential for funding the strengthened immunization programmes during the early stages of the support. Introduction of new vaccines and injection safety in BiH was realistic and in accordance with internationally accepted guidelines and based on thorough situation analysis well documented and communicated to country stakeholders	A	Findings are substantiated through documentary review and supported by qualitative data
To what extent did BiH prepare and plan for the transition away from GAVI support?	Planning for the transition away from GAVI support was initiated from the very beginning through supporting uniform approach for immunization planning between entities, imposing the development of the FSP, the injection safety plan and cold chain capacity assessment as preconditions for GAVI support.	A	Findings are substantiated through review of communication between GAVI and BiH and supported by qualitative data

3.2 EFFECTIVENESS AND EFFICIENCY OF IMPLEMENTATION

This section mostly assesses effectiveness and efficiency of GAVI support implementation.

EFFECTIVENESS OF IMPLEMENTATION

ICC institutional arrangements changed during implementation and demonstrated limited coordination and implementation capacity – According to the March 2003 BiH Law on Ministries, the MoCA of BiH has assumed restricted coordination function of health issues at the state level. Consequently, in 2008 the immunization coordination function became the responsibility of MoCA, Ministries of Health at FBiH, RS and the BD, PHIs, UNICEF and WHO, represented the ICC.

KEY EVALUATION QUESTIONS

- To what extent were the activities of the sustainability plan (if one was developed) effectively and efficiently implemented?
  - What were the main challenges and how were they addressed?
  - To what extent did GAVI support these efforts?

In its initial iteration, at the beginning of GAVI, the ICC was instrumental in i) bringing together both entities and in preparation of applications for GAVI support; ii) building consensus around introduction of new vaccines and integration into the entities' immunization calendars; iii) assisting the entities to jointly identify resources needed to achieve immunization programme's goals; iv) periodically monitoring implementation of GAVI support and produced reports.

In most cases, respondents reported that the ICC essentially operated for GAVI endorsement processes and for information dissemination. What was commonly absent from key stakeholder interviews was any sense that the ICC was functioning in any strategic planning, problem solving or analytic way (with some exceptions as described above). There was very little evidence that the ICC was consistently and effectively addressing the core issues of coordination and resource gap analysis. Furthermore, the ET was unable to verify that the ICC had any oversight function in relation to expenditure tracking or programme review, aside from APRs). The reasons commonly provided by the key respondents for weak coordination function of the ICC were:

- Governance constraints primarily arising from the political-administrative system of the country and negatively affected state level decision making, policy/strategy development and follow-up actions; and
- Structural constraints due to the under-representation by the key constituencies (private sector and civil society).

The immunization schedule for HepB was harmonized in all three entities, though EPI schedules differ in entities (ANNEX 3: IMMUNIZATION SCHEDULES) **–** Annually, the Order on "the Programme of Mandatory Immunization" was issued in both entities and the BD. Since 2005, annual orders were carefully revised proposing new schedule, reducing list of contraindications, clarifying obligations on reporting of AEFI, and a new policy of open vials.

Healthcare workers were trained prior to new vaccine introduction to address one of the key immunization programmes' bottlenecks – According to the FSP, the weak human resource capacity has been identified as one of the key challenges for the sustainability of the immunization program in BiH. In response, the FSP proposed, development of the

human resource-training plan and training of all (100%) of health workers. The APRs regularly reported on the number of training sessions conducted, the topics covered, and the number of health workers trained. However, training coverage rates differed by type of training and health worker and the geographic coverage remained largely unknown.

According to key respondents, healthcare workers were trained on the new vaccines prior to introduction and reported satisfaction with the quality of training they received. Educational materials were developed and provided to health professionals.

Training activities in both entities were mainly financed through GAVI support (US$ 100,000), while the government of the BD financed the training of their health personnel abroad, for example in Croatia, from local budget. UNICEF also contributed towards the human resource capacity building at this time, in both of their entities and the BD.

According to the post vaccine introduction evaluation results[47], health care workers knowledge of the advantages of new vaccines and practice of consulting parents on the benefits of immunization was found acceptable. Comprehensive training modules used at HepB introduction are perceived to have been effective, as demonstrated by raising vaccine coverage. Findings of this evaluation were further confirmed by the results of the 2011 KAP survey[48] which revealed that roughly two thirds of doctors considered that they know the vaccination schedule very well, that they had new knowledge of side effects of vaccination, and contraindications to vaccination (78%, 77%, 73%, respectively). Among nurses, most rated their knowledge of vaccine storage temperatures and of the schedule of administration of individual doses highly (88%,83%, respectively). Nonetheless, almost all (90%) of the respondents feel that they need additional training on the advancements in the development of new vaccines, and more than half on risks associated with vaccination (65% doctors, 61% nurses). Very few respondents (2% doctors; 4% nurses) believed that they do not need any further trainings.

Delays in vaccine delivery were reported during the implementation, however, these did not affect achievement of the programmes objectives – In 2006, FBiH faced problems with customs procedures, which caused delay in vaccine delivery. Thanks to the existing buffer stock, there were no interruptions in the programme.

The weak vaccine management capacity observed in the first years of GAVI support was gradually strengthened – In the first couple of years due to the weak local capacity of Ministries of Health in FBiH, RS and the BD. UNICEF handled import license, customs clearance and distribution of vaccines.

A management review of the childhood immunization programme in FBiH was conducted in 2003 by Federation experts of the MoH, cantonal PHIs and representatives of WHO, UNICEF, WB and the Centers for Disease Control/Atlanta (CDC) with the objectives to review immunization strategies and policies; progress towards national targets and objectives as provided in the MYSP 2002-2006 and in the Federation Ministerial Order of March 2003. FBiH followed recommendations provided by the review and strengthened its management capacity accordingly.

[47] Ibid 8
[48] Ibid 5

Later in 2006, the Vaccine Management Assessment (VMA)[49] conducted by the WHO technical support recommended improvement of cold chain system, storage of vaccines and safe disposal. Although no formal action plan was identified through this evaluation, the country gradually addressed these shortcomings. Some evidence of these include[50]: improvement of staffing levels at PHIs and building staff capacity to handle logistical issues; establishment of buffer stocks at entity, canton/district and facility levels; software for monitoring immunization programme in FBiH and staff trained; enhanced federal cold chain infrastructure with the additional cold room and a freezer for oral polio vaccines (OPV); the development of a questionnaire on "data to be used for detailed review and analysis of cold chain", recommended by the WHO, was translated and distributed to providers; Recommendations for cold chain renewal were formulated; Staffing levels, based on the analysis of cold chain, were revised and people responsible for immunization at each level appointed; A minimum set of indicators for monitoring and evaluation of the programme of immunization adopted and delivered to all Immunization coordinators.

The immunisation reporting system was improved, although challenges remained – The immunization reporting forms used by health providers and immunizations centres have been standardized, as planned through the FSP and the 2005 Order on the Implementation of the Programme on Mandatory Immunization. The standardised reporting forms included monthly/annual forms on EPI vaccines coverage, usage and distribution of vaccines and AEFI.

The Post Introduction Evaluation of New Vaccines in BiH[51]conducted by the WHO and CDC in 2009 revealed strengths and weaknesses of the immunization information system. Specifically complete monthly reports were submitted in a timely manner to cantonal and regional levels, individual immunization cards were kept by parents. Nonetheless, the information systems in two entities did not provide adequate data to estimate vaccine coverage and dropout rates, due to problems with both numerator and denominator. For example, health facilities reported the number of children vaccinated with one, two or three doses of DTP, polio, hepatitis B and Hib vaccines, without distinguishing between children under one year of age and children above one year of age. Since the children more than one year were included in the numerator, coverage rates were likely overestimated.

According to the same source, there was no standard information system for the vaccination programme at all facilities. Reporting system used at most health facilities did not permit collection and transmission of the data needed to calculate vaccination coverage appropriately at the health facility level.

The reporting system's challenges were highlighted in the 2011 APR, namely: unreliability of data on target population, incompleteness of reports, delays in reporting, and non-reporting from the private sector providers were noted. Nonetheless, no hard evidence has been obtained by the ET on the actions taken either form the Governments and/or from GAVI to address these challenges.

Respondents reported irregular immunization programme supervision and monitoring – key informants reported irregularity of supervision and monitoring of immunization programmes during the implementation of GAVI support. The ET was not able to obtain written supervision reports and feedback dated back to the GAVI support period at the visited vaccination points, although the APRs reported utilization of GAVI financial support

[49] Ibid 7
[50] BiH APRs
[51] Ibid 8

(US$ 100,000) for supervisory visits (e.g. organization of regular analysis and discussion of quarterly immunization reports, carrying out data quality control, planning activities to target non-vaccinated children for increase of immunization coverage rates, planning strategies for reaching Roma population with the awareness rising and immunization activities etc.). Irregularity and weak supervision is also echoed by the findings of the Post introduction evaluation (see text box).

> "Supervisory visits did not occur regularly at all levels. The frequency of visits prior and/or after introduction of new vaccines was not known".
>
> *Source: Post introduction Evaluation WHO & CDC, 2009*
>
> *"Supervisory* visits are not regular. Supervisor usually looks at cold chain, vaccination provision, etc."
>
> *Quote from Key Informant*

Furthermore, the quality of supervision has been criticized by several informants – supervisory feedback was only practiced when some shortcomings and weaknesses were identified, without providing guidance and plan for mitigation measures and improvements. Respondents did not recall an Immunization Data Quality Audit being carried out at any point during GAVI support. Findings of post vaccine introduction evaluation[52] also confirm these observations.

Advocacy, social mobilization and communication was performed before the introduction of the new vaccines, however effectiveness of these efforts is unclear – Raising public awareness of the benefits of immunization, the quality of the vaccines used, and of potential side effects to prevent interruption of the immunization was one of key FSP strategic objectives. The governments of both entities took responsibility to: i) conduct baseline assessment of public attitudes (e.g. KAP survey); ii) develop the social mobilization (information campaign) strategy; iii) implement the strategy and iv) evaluate changes in public attitudes.

A state level communication plan and protocol were developed. UNICEF BiH supported the governments of two entities and the BD to develop communication plans. The state level communication protocol was developed and launched at the round table hosted by the Federal PHI where representatives of different sectors such as education, media, and social sector were present from both entities and the BD. Based on the communication protocol, educational materials (leaflets and posters) for health professionals and parents were produced and distributed through health centres and maternity wards.

With UNICEF/WHO support, the government of BiH officially announced the introduction of new vaccines through media channels and informed parents on the right of their children to immunization and its importance. Since 2007, the government of BiH continues to organize annual, countrywide European Immunization Week with the support of UNICEF, WHO and other donors. These days are dedicated for awareness rising of policy makers, health workers, and community about immunization related issues.

While substantial efforts were put in place by governments and donors (UNICEF/WHO) for public education and awareness rising, regular communication activities were lacking. The ET was not able to obtain evidence on the timing of communication activities or on implementation of communication plans. Respondents hardly recalled any social mobilization and communication activities prior to introduction of new vaccines, other than communication materials been distributed in insufficient quantities.

[52] Ibid 8

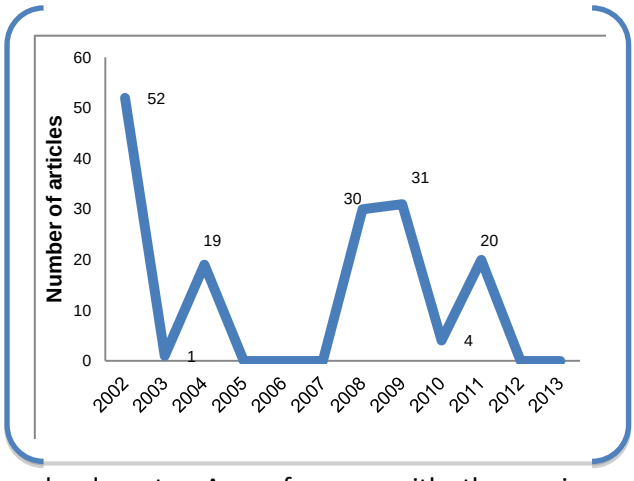
The absence of regular social mobilization potentially could have facilitated the emergence of immunization program vulnerabilities, due to the anti vaccine movement, though in the absence of reliable data on knowledge, attitudes and practices, this cannot be directly evaluated. Nonetheless, the latest KAP survey[53], reports that an overwhelming majority of the health workers (96%), more doctors (96%) than nurses (95%), believe that the vaccines used in the Programme are safe.

The Government's response to the anti- vaccine campaign was carried out mostly in an ad hoc manner– The smooth introduction of new vaccines was periodically hampered by AVCs. The country has experienced issues on adverse effects with various vaccines as discussed in more detail below. The issue came to the attention of the media and was highly publicized. A NGO from the anti-vaccine lobby, which is also working on disabilities with children in BiH, took these cases to the media in 2002. Since 2002, the NGO periodically galvanized AVC activities and the leader of the NGO became a popular figure in public.

In 2009, the death of a 3-year-old girl after administration of DTPa-IPV-Hib in Lukavac, Tuzla, FBiH, resulted in a one-month suspension of immunization programs and initiated a study that revealed inconclusive results for the cause of the death as reported by key informants from MoCA and FBiH PHI. However, the media stir affected the implementation. GAVI followed up together with partners. UNICEF and WHO supported the country in managing communications and advocacy by providing technical assistance and bringing leading professionals to help the country in communicating the messages.

The ET performed media analysis of AVC, but due to time constraints and the bureaucratic procedures required to access TV materials, only press analysis was performed demonstrating intensity of AVC in the period of 2002-2013 (Figure 2). While, only local printed media analysis is not sufficient to judge the negative effects of AVC on immunization coverage, the press analysis revealed periodic intensity of the anti-vaccine campaign. During 2008-2011, the amplification of AVC in the press coincided with the introduction of new vaccines with GAVI support.

Figure 2: Anti Vaccine articles, news in local printed media



Whereas the majority of respondents stated that the AVC was harmfully affecting immunization programmes, the governments demonstrated no systematic, proactive / preventive measures between anti- vaccine campaign phases. For instance, in response to the AVC in 2008, the vaccination was suspended for 2-3 month in FBiH and restored afterwards. The government invited the NGO to life talk on TV. FBiH MoH invited the NGO to discuss complaints and advocate. A conference with the senior professionals was organized to discuss immunization related issues. Albeit the governments' reactive responses mitigated negative effects of the AVC to certain extent, the implementation of preventive communication

[53] Ibid 5

strategy prior to introduction of new vaccines as well as during and between of anti-vaccine campaigns could have minimized adverse outcomes.

Most of the respondents at public institutions and partner organizations strongly believe that the AVC negatively affected and continues to effect immunization coverage, especially creating mistrust to vaccination within general population. Whereas the 2011 KAP survey[54] reports that media negatively influenced only 14% of surveyed parents with least significant influence among urban population.

While most respondents believed that the AVC affected public opinion on immunization and motivated paediatricians to practice defensive medicine, it also generated unintended positive effects. The fear to be prosecuted motivated paediatricians to request more frequent and more modern information about immunization, contraindications and side effects. There is no sound evidence that AVC negatively affected governments' decisions on introduction of new vaccines.

"Decrease of immunization coverage is mostly due to the anti vaccine propaganda, rather than due to the vaccine shortages".

"In response to AVC paediatricians started to practice defensive medicine".

"Anti vaccine propaganda also generated some positive results. Paediatricians started to read and inquire information regarding immunization"

Quotes from Key Informants

Injection safety and waste management practices required improvements – As described in previous section, the injection safety assessment carried In 2005 identified a need to reinforce and ensure behavioural changes among health care workers and staff involved in injection safety and safe disposal, to ensure adequate supply and distribution of injection safety equipment including AD syringes, safety boxes and vaccines, and to ensure the safe collection and disposal of injection equipment.

The ET attempted to learn about the governments' follow up actions for the implementation of recommendation, as well as the National Injection Safety Policy (2005)[55], though no other evidence was obtained. Instead, the APRs always reported 100% achievement, despite noting serious constraints. For example, the APR for 2011 reports absence of country level Injection Safety Policy.

Based on the qualitative data obtained from the key informants, only one out of three recommendations has been fully implemented. Specifically, respondents noted that, with GAVI support, governments ensured adequate supply of safe injection equipment to immunization service providers. However, quantitative data reported in APR 2011, shows that only 60% of immunization service providers were equipped with injection safety equipment.

"AD syringes were provided during GAVI support, but due to lack of instructions to nurses how to use them, most of this supply was not used and destroyed after expiration. Although there is no written instruction to use different needles for filling the syringe and for injection, nurses still practice this, which is one of the arguments against AD syringes"
Quote from Key Informant

"Health professionals who use AD syringes complained that needles were not sharp enough and that needle-tip diameter makes vaccine administration difficult"
Source: APR 2007

BiH has reported progress on the transition of injection safety funded in the APR 2011 (

[54] Ibid 5
[55] Ibid 44

Table 5 below). While GAVI's INS support ended in 2008, the country still had stock of injection safety materials available for use in 2011, due to the limited utilization of safety equipment, largely explained by due to quality complaints of AD syringes by health professionals[56]. Furthermore in one site visited an outdate stock of AD syringes was observed. The same APR mentions that there is no injection safety policy/plan in BiH.

Table 5: Types and sources of funding for injection safety material in 2011

VACCINE	TYPES OF SYRYNGES USE FOR EPI IN 2001	FUNDING SOURCE IN 2011
BCG	AD BCG syringes and needles	Entity Governments
MEASLES	AD syringes and needles/sterile syringes and needles	GAVI & Entity Governments
TT	AD syringes and needles/sterile syringes and needles	GAVI & Entity Governments
DTP Containing vaccine	AD syringes and needles/sterile syringes and needles	GAVI & Entity Governments

The governments were unable to reinforce utilization of injection safety equipment by building health personnel capacity as confirmed by the findings of KAP survey carried out in 2011[57]. Only 50% of doctors reported knowing medical waste disposal methods and 5% considered not having enough knowledge about safe injection practices, whereas 7% of nurses say their knowledge is poor or lacking with regard to safe injection, and 4% with the methods of disposal of medical waste.

During the evaluation respondents often cited lack of instructions on the use of AD syringes, poor quality of AD syringes and weak practical skills for using them.

The entity level policies for immunization waste disposal were not completely implemented. The Law on «Waste Management»[58] has been issued by the Federal Minister of Environment and Tourism, in collaboration with the Federal Minister of Health in 2008. Article 58 of the law provides rules for medical waste management at health facilities. In compliance with the law each immunization service provider facility has a dedicated officer to manage the waste in both entities and the BD. Waste management function in most of the cases is contracted out to public or private company.

According to the post introduction evaluation of new vaccines[59], in some cantons of FBiH and RS regions, syringes and needles were disposed together with the regular city waste. In the APRs BiH also reported about a lack of vehicles for waste transportation and funding in addition to waste disposal challenges. Although problems were adequately reflected in the APRs, no strategic actions have been proposed for problem resolution. Furthermore, there was no evidence of GAVI and/or partner reaction and follow-up on these important issues.

> "RS has a problem with safe disposal of sharps and injection supplies. Currently the safety boxes containing used needles and syringes are being buried with other medical waste."
> *Source: APR 2007*

The only exception, as stated in APR, was a pilot study initiated in Republic of Srpska on final disposal of medical waste, including needles and syringes. Final disposal of safety boxes through incineration or other means of chemical or physical destruction remained as unresolved issue during GAVI support in majority of cantons and districts. With regard to

[56] APR 2011
[57] Ibid 5
[58] Official Gazette FB&H, no. 33/03
[59] Ibid 8

sharp waste management, whilst awareness has increased over time, both entities and the BD lag behind in terms of investing in safe disposal (e.g. incinerators). Thus risks identified by injection safety assessment carried out in 2005 with the technical support of WHO/EURO, have not been adequately addressed during GAVI support.

The decision on vial presentation type for the first dose of HepB vaccine was mostly justified by high wastage[60] – In 2005 FBiH shifted from 10-dose vaccine to mono dose for the 1st dose of HepB. This decision was mainly guided by the concern of high wastage factor arising from the low number of births in most of the health facilities. The MoH of FBiH decided to use thiomersal free HepB vaccine as a neonatal dose.

The government's decision of the BD on local procurement of Pentavalent vaccine was based on cost analysis – The Government of the BD refused to accept GAVI supported ten-doze Pentavalent vaccine. This decision was based on the cost analysis, which revealed self-procurement to be more cost-efficient. Due to time constraints alongside difficulties in obtaining financial analysis performed by the BD authorities in support of this decision, the ET was not able to validate the cost-effectiveness of the self-procurement decision.

> "The cost of registration, customs clearance, transportation and high wastage due to the ten doze presentation of Pentavalent vaccine was high according to our calculations. With minor budget increase we were able to perform local procurement of mono doze presentation and delegate functions for registration, customs duties and logistics to contracted supplier, as well as minimize wastage rate"
>
> *Quote from Key Informant in the BD*

The Governments of both entities and the BD have addressed progress against major financial sustainability – The FSP was approved by the ICC and submitted on time to GAVI secretariat in 2004. An obvious progress against the major FSP financial sustainability strategies, was observed in entities' and the BD. Specifically:

- Policies on the role of financial agents in the mobilization, management and allocation of funds to the different cost categories of the Immunization Programme, as well as endorsement of corresponding legislation/legal acts, have been addressed in 2005.
- A new Public Procurement Law was endorsed to the allow procurement of vaccines from UNICEF Supply Division (SD).
- The Solidarity Fund and the HIF became responsible for procurement of vaccines in FBiH and RS, respectively. According to 2005 APR, governments procured vaccines trough UNICEF SD.
- Progress against key FSP indicators, as well as challenges faced were reported annually.

Programmatic targets were partially met – Although evident progress has been made in immunization coverage for all antigens compared to previous years, all targeted goals were not met as planned (Table 6). In 2011, targets for immunization coverage were only attained for BCG, Hib and HepB, whereas targets for other antigens underperformed. BiH failed to achieve 100% availability of AD syringes and safety boxes at vaccination posts (achieving only 60% in 2011) as well as maintaining drop-out rates for HepB below 8% (actual – 9%). The detailed status of the programmatic targets is provided in Table 6 below.

[60] APR

Among other problems that influenced under-coverage of immunization the following reasons were identified in APRs: unreliable data on target population, untimely and incomplete reporting, problems in financing and provision of vaccines that disrupted continuity in vaccine provision, intensive anti-vaccine movement etc. vaccination carried out in the private clinics has become a concern, due to the absence of mandatory reporting to the government.

Table 6: Status of target indicator achievement

Indicators	Approved Targets	Achievements as per JRF 2011	Status
Total Birth	34,150	32,325	ⓘ
Total Infant Death	250	208	✓
BCG Coverage (%)	96%	94%	ⓘ
OPV 3 coverage (%)	93%	89%	ⓘ
DTP 3 coverage (%)	92%	88%	ⓘ
Hib monovalent coverage (%)	92%	97%	✓
Measles coverage (%)	95%	90%	ⓘ
HepB 1st dose coverage (national)	>95%	97%	✓
HepB 1st dose coverage (subnational level)	>90%	95%	✓
HepB 3rd dose coverage (national)	>93%	88%	ⓘ
HepB 3rd dose coverage (subnational level)	>90%	86%	ⓘ
Annual DTP drop-out rate	2%	7%	ⓘ
DTP wastage factor	1	1	✓
Hib wastage factor	1.05	1	✓
Maximum wastage rate for Hib monovalent, lyophilized	10%	10%	✓
No stock out of vaccines reported throughout the reporting year	None	Periodic Stock outs	ⓘ
Availability of AD syringes and safety boxes in all vaccination posts visited during the reported year	100%	60%	ⓘ
Drop out rate (HepB 3 – HepB 1)	< 8%	9%	ⓘ
Vaccine wastage rate for 10 dose vial	1.33	1.30	✓
Vaccine wastage rate for mono dose	1.05	1.04	✓

Legend: ✓- Met; ⓘ - Not met

Gradual improvement in APR reporting practice and quality has been observed during the GAVI support, though room for further improvement remained – The quality of APRs have been analysed using the following criteria:

Timeliness of reports – during the GAVI support period BiH submitted only 30% of reports on time and the remaining ones with delays varying from 2 weeks to five months. Delays were mainly caused by difficulties associated with the logistics of collecting information from different entities, and signatures from ICC member who were located in different part of the country. Close to the end of GAVI support, BiH submitted APRs to GAVI in a timely fashion.

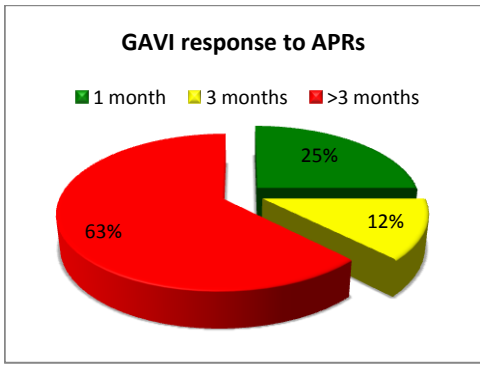
Completeness of the reports **–** the completeness of reports was judged by a review of: i) GAVI IRC reports and decision letters and analysis of issues raised related to compliance with GAVI reporting standards; and ii) APR content on reporting implementation progress, problems/challenges faced during the reporting period, proposed mitigation/corrective measures and/or plans proposed, as well as implementation progress of GAVI comments provided in GAVI IRC reports and Decision letters in response to previous annual reports.

Completeness of the APRs varied from year to year. The main components requested by GAVI related to reporting standards were: reporting of progress against indicators (financial and programmatic) selected by the country in the proposal for GAVI support; signatures from the Minister of Civil Affairs BiH and Minister of Finance and Treasury and endorsed by the members of the ICC; and the attachment of ICC minutes. While progress towards measurable targets was reported in more than 50% of the APRs, reference to the progress in previous reporting period was missing. In the last couple of years of GAVI support, when the ICC minutes have been integrated in the APR format, compliance dramatically improved.

> "Bosnia & Herzegovina will report on the achievements and the required support for the following year in the APR. The APR must contain information on the number of children reported to have been vaccinated with DTP3 and with three doses of Pentavalent vaccine by age 12 months, based on district monthly reports reviewed by the ICC, and as reported to WHO and UNICEF in the annual Joint Reporting Form (JRF). The APRs will also contain information on country's compliance with the co-financing arrangements outlined in this letter".
>
> *Source: IRC Decision Letter*

The analysis of the APRs revealed that BiH gradually improved the content of reported information, though reporting on the progress of GAVI recommendations was not persistently addressed.

GAVI's monitoring function needs improvement – Annual monitoring of country performance during GAVI support was evident. GAVI/IRC performed thorough analysis of the APRs and communicated decisions on funding, recommended further improvements and guided BiH on necessary steps and interventions. However, the timeliness of GAVI's responsiveness, judged by the period between the APR submission and GAVI response was found to vary from 1 to 7 months. Slightly above one third (25% within one month and 12% within 3 month) of GAVI decision/recommendations were provided within three months upon receipt of the APRs. On a couple of occasions, decision letters on funding vaccines was communicated to BiH by end of country fiscal year, with 6-7 months delay, thus leaving no time for budget adjustments by the entities.



Source: APRs and IRC Decision Letters

Progress towards target coverage was mainly monitored based thorough administrative data reported by the country in the APRs and the JMRs. While GAVI was strict to request regular reporting on the progress of indicators, it allowed BiH to postpone recording progress towards immunization targets to the next reporting period. This practice resulted in missing the opportunity to timely advice country on corrective measures when targets were underachieved.

Furthermore, full reliance on administrative data could have been misleading. As discussed in the next section of this report, discrepancies between the administrative data and findings of the MICS, signalling that BiH's coverage indicators lacked accuracy demonstrated by the coverage differences and were regularly reported in the APRs. Data quality concerns

have not been adequately addressed and highlighted in IRC reports and Decision letters. Although, in some instances, GAVI followed up on programmatic and/or implementation weaknesses and challenges reported in the APRs, consistency was not observed.

GAVI was effective to mobilize partner support – GAVI support to BiH was limited to a new vaccine introduction grant and the provision of vaccines and injection safety supplies. Development **partners**, who played important roles both being directly involved in the project management and oversight, and/or in support of localized projects, supported the government of BiH. WHO and UNICEF, in particular, were key participants in the ICC and provided substantial technical and financial support to the government in different functional areas of the immunization programmes.

TYPE OF SUPPORT	WHO	UNICEF
ICC membership and support	✓	✓
Policy Advise	✓	✓
Planning	✓	✓
Cold Chain & infrastructure		✓
HR development /Training	✓	✓
Technical Assistance	✓	✓
Design of social mobilization plan	✓	✓
Surveillance		✓
Situation Analysis, M&E	✓	

Source: ICC minutes

WHO and UNICEF provided significant support to cold chain management, upgrade of cold chain equipment and infrastructure, injection safety assessment, MYSP and FSP development, new vaccine introduction policy development and sustainability plan formulation, vaccine distribution in early years of GAVI support, immunization coverage surveys and other operational research, human resource training, and support in country's communication and awareness rising. .

SUMMARY OF FINDINGS ON EFFECTIVENESS AND EFFICIENCY OF IMPLEMENTATION

EVALUATION QUESTION	FINDINGS	ROBUSTNESS RANKING	
To what extent GAVI support was effectively and efficiently implemented	Programmatic targets were partially met. Targets for immunization coverage were only attained for BCG, Hib and HepB, whereas targets for other antigens underperformed. Some efficiency gains were achieved by procuring vaccines from UNICEF SD.	A	Findings are substantiated through documentary review and widely corroborated the key informants data
To what extent were the activities of the sustainability plan (if one was developed) effectively and efficiently implemented?	The majority of activities planned under the FSP were implemented. The roles of financial agents were defined, revisions in the public procurement law enabling procurement of vaccines through UNICEF SD introduced.	A	Findings are substantiated through documentary review and widely corroborated the key informants data
What where main challenges and how they were addressed?	Although implementation and system related bottlenecks were well documented and reported by BiH, hard evidence on the mitigation	B	Findings are substantiated through documentary review and widely corroborated key

	measures is lacking.		informants data, though for some issues documental evidence was not available
How GAVI supported these efforts?	GAVI followed up on key programmatic and/or implementation weaknesses and challenges reported and managed to mobilize timely support through its partners. However, more consistent follow up on further implementation of planned measures would have been beneficial allowing provision of timely advice on corrective measures to the country.	A	Findings are substantiated through documentary review and widely corroborated the key informants data

3.3 OUTCOMES AND CONTRIBUTION TO SUSTAINABILITY

This section of the report the examines programmatic and financial sustainability of BiH's immunization program, after GAVI support ended. Specifically, it assesses extent to which BiH managed to replace GAVI support and maintained, expended or improved effective immunization systems after GAVI's time-limited support.

KEY EVALUATION QUESTIONS

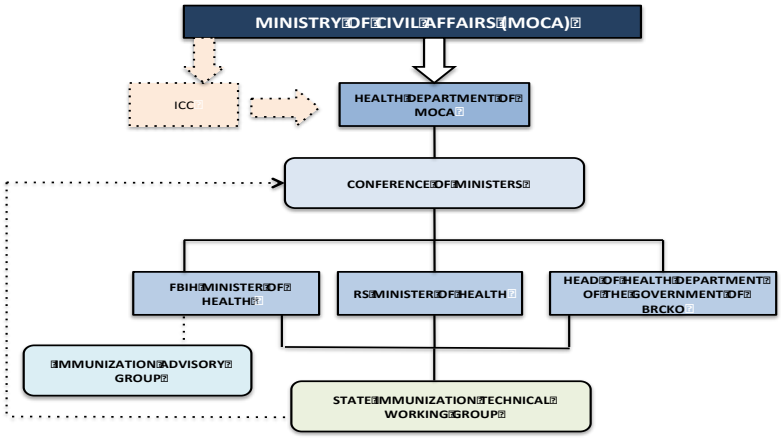
- To what extent have the relevant activities related to 'GAVI support' been continued?
- To what extent have the systems and structures functioning or developed at the time of GAVI support continued to function effectively?
- To what extent have the results (both outcomes and impact) of GAVI supported programmes been sustained, expanded or improved since the conclusion of GAVI's time-limited support?
- What are the main factors explaining the achieved results (positive or negative)?
- What have been the main unintended positive and/or negative effects of the time-limited nature of GAVI support and its conclusion?
- Have new vaccines been introduced in BiH since the conclusion of GAVI support?

PROGRAMATIC SUSTAINABILITY

Coordination mechanism maintained with fewer responsibilities and demonstrated operational weaknesses – Since the end of GAVI support, selected functions of the ICC, specifically the coordination of the partners and the compilation of the reports for international reporting (see Table 7 and Figure 3 below) were handed over to the MoCA HD.

At present, MoCA HD, was among other regular functions, charged with some responsibility for coordination of immunization programmes and the preparation of state-level consolidated reports for international accountability purposes.

Figure 3: ICC transition to new governance structure



Coordination of immunization issues is discussed and achieved at the level of Conference for Health Sector, comprised of minister of civil affairs of BiH and ministers for health from both entities and the BD) with the support of State Immunization Technical Working Group (TWG). As informed by the head of the MoCA HD, although the coordination function is maintained for the immunization programme, the effectiveness of its operations is inadequate mainly

due to the weak functional powers granted by the legislation to the department and limited human resources of the MoCA HD.

Table 7: Transfer of ICC functions to MoCA

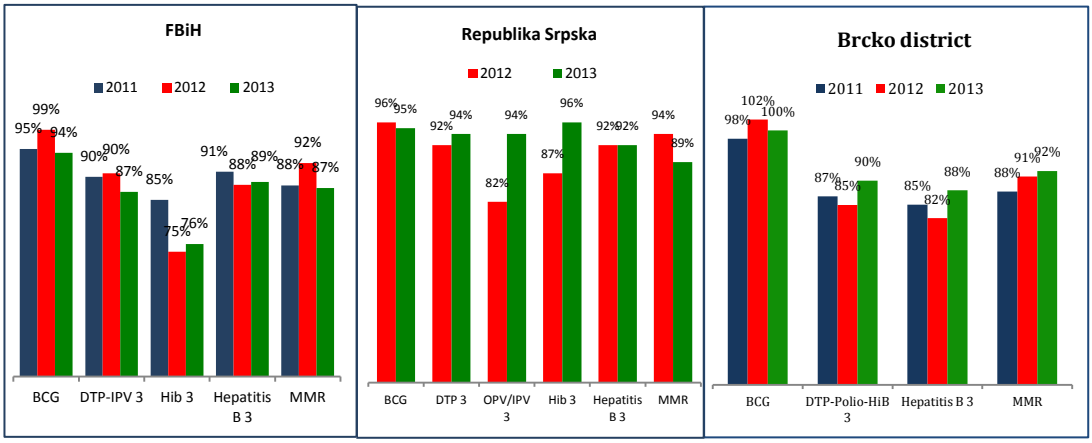
FUNCTIONS	DURING GAVI SUPPORT	AFTER GAVI SUPPORT
Development of plans and policies	✓	ⓘ
Approval of annual Immunization plans	✓	ⓘ
Progress Monitoring	✓	ⓘ
Defining corrective actions	✓	ⓘ
Periodic field assessments	✓	ⓘ
Resource Mobilization	✓	ⓘ
Reporting	✓	✓
Coordination and cooperation with partners	✓	✓
Legend: ✓- Yes; ⓘ - No		

Access to new vaccines ensured – With GAVI support, new vaccines are currently included in mandatory immunization calendar of both entities and the BD and are being provided free of charge to the target groups.

Immunization coverage gradually increased in RS and the BD, while it started to decline in FBiH – Immunization coverage is measured using the administrative method. Data is collected from health centres through the cantonal/regional PHIs for entity level and submitted to MoCA HD for integration at the state level.

According to administrative data, immunization coverage started to decline in 2013 in FBiH, while RS and the BD gradually increase coverage since GAVI support ended (Figure 4).

Figure 4: Administrative Immunization Coverage Rates for FBiH, RS and the BD in 2011-2013



Discussion of progress towards the achievement of child immunization rates in BiH should take into consideration the lack of baseline population data since the 1991 (pre-war) census. Household surveys undertaken since 2000 give slightly more reliable data, but cannot fully compensate for the lack of accurate basic reference point for projections. These challenge have been highlighted on number of occasions in APRs. The 2012 census data, to be released in 2014, will allow BiH to recalculate coverage rates.

The Immunization reporting system underwent some changes since GAVI support ended. For instance, in contrast to the previous reporting forms (as identified by 2009 WHO/CDC post-introduction evaluation) current ones distinguish between children under and more than one year age, that resolved the problem with the numerator. This improvement in the reporting system implemented in 2012, has coincided with the reported decline in the immunization coverage in 2013, thus the ET cannot discount the possibility of the "decline"

to be associated with the improved registration. However the Information system still suffers from shortcomings that undermine the data accuracy. There are no written instructions on how to complete the forms, resulting in ambiguity and variation in registration at the primary care level e.g. during our evaluation, conflicting information was received on determining denominators for various antigens from health facilities in different cantons. The information systems in both entities and the BD do not provide adequate data to estimate full coverage and incomplete immunization rates.

Furthermore, as stated by respondents, the issue of determining the denominator in health remained unresolved in post GAVI period. Entity and cantonal/regional PHI data on the estimated number of surviving infants to calculate coverage rates do not correspond to national statistical data. . Health facilities calculate the implementation rate of planned vaccinations only and cannot distinguish difference between coverage and implementation rates.

Figure 5: Comparative analysis of 2011 MICS 4 & WHO/UNICEF JMR coverage data

	JMR	MICS 4
BCG	94	98 ↑
DTP 1	94	95 ↑
DTP 3	88	86 ↓
HepB 3	88	84 ↓
Hib 3	85	…
MMR	89	80 ↓
Polio 3	89	85 ↓

To substantiate findings of qualitative analysis, the ET performed comparative analysis of administration data with MICS-4 results. Comparison of the WHO/UNICEF joint monitoring report data[61] and MICS-4 coverage rates in 2011 indicate that administrative data are overestimated (Figure 5). E.g. for DTP-3, antigen administrative and MICS-4 coverage rates were 90% and 83% respectively. This difference might be caused by the deficiencies of the immunization information system, as described above.

Governments initiate actions to reach out to the underserved – A special focus of MICS-4 on the Roma population brought to the surface the alarming situation concerning Roma children. Roma are the most excluded population in BiH, suffering from poverty dimensions that translate into bleak figures in terms of the state of health of Roma children. The fact that immunization rates are as low as 4% in Roma children emphasizes the level of urgency required to address immunization service delivery in poor and remote areas and where programme implementation is less than optimal. The existence of such disparities should not be considered as post GAVI phenomena, as planning of immunization strategies and catch-up campaigns targeted at Roma population was planned as recorded in APRs of 2010 and 2011.

Reaching out to underserved populations is discussed in both entities. The RS is currently in the process of developing action plan for improving immunization services in hard to reach populations. As part of this plan the communication, plan for immunization has been prepared. With UNICEF funding, RS already conducted education sessions of nine Roma settlements around Banja Luka.

Serious weaknesses are observed in supervision, monitoring and evaluation functions - Almost all PHIs and health centres responded positively when asked about the implementation of supervision, monitoring and evaluation activities at different levels. However, when questioned more specifically about reported findings, measures taken and

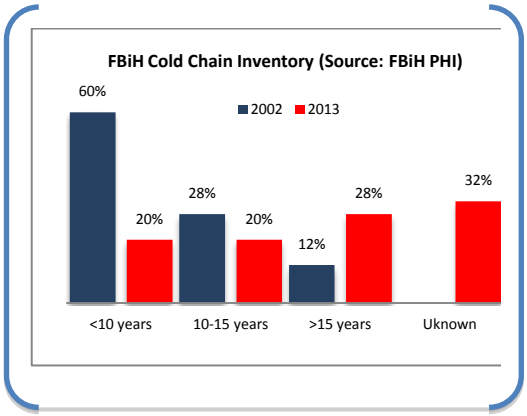
[61] Immunization Summary Report, UNICEF, 2013

future plans, most of them were unable to remember specific, weekly/monthly or even yearly visits to a given site. These answers highlighted the serious lack of effectiveness of supervision activities.

It seems that supervision is not seen as a learning process and a way to improve the programme achievements, but is still perceived as an activity for controlling staff that could lead to disciplinary measures. Supervision thus remains an administrative function of senior public service employees over their subordinates.

Periodic vaccine stock outs for all vaccines including new vaccines are observed in post GAVI period– Since GAVI support ended, as described in the previous section, the governments shifted to local procurement of new vaccines. The long and complicated local procurement process, shortage of financial resources and limited availability of stocks from manufacturers results in periodic vaccine stock outs occur (discussed in details under financial sustainability for the Pentavalent vaccine). This affects the whole supply chain system. While vaccine stock outs may negatively affect immunization coverage rates, respondents informed borrowing from each other to fill the gap.

Cold chain equipment requires renewal – UNICEF alongside with other donors has largely supported BiH's cold chain through provision of cold chain equipment since the post war period. The ET's comparative analysis of FBiH cold chain inventory in 2002 and 2013 demonstrates the aging of cold chain equipment. In 2013, only 40% of cold chain is under age of 15 years compared to 88% in 2002 and the age for 32% of cold chain is unknown. This analyses clearly calls for urgent need of cold chain renewal.



As donor funding becomes scarce, the responsibility for replacement and maintenance of cold chain equipment largely lies with the governments (Table 8).

Table 8: Trend of external funding of BiH health Sector in US$ (OECD DAC Database)

	2008	2009	2010	2011	2012
Health, General	8.696	19.298	30.042	18.284	16.170
Health policy and administrative management	7.600	5.196	2.688	2.811	2.523
Medical research	..	..	0.020	0.075	0.052
Basic health care	1.060	1.482	1.737	1.811	1.753
Including immunization*	0.762	0.094	0.618	0.158	0.008
Infectious disease control	0.224	0.554	0.684	0.811	0.015
Health education	0.464	0.460	0.430	..	..
Health personnel development	..	0.125	..	0.056	..
Population policy and administrative management	0.462	0.337	0.455	0.055	0.413

**Includes GAVI support and UNICEF funds for the routine immunization*

Table 8 shows that the external funding for the immunization has dramatically decreased since GAVI's disengagement. For the year 2012 it only amounted to about 78,000 US$ disbursed by UNICEF for the "routine immunization". The ET tried to obtain donor funding plans for the next two years (2014-2015) specifically for the immunization system and the cold chain, however such plans were not available in OECD-DAC international aid database. Key donors traditionally involved in immunization such as UNICEF and WHO were not in the position to share funding forecast with the ET. For example, cold chain is mostly supported by UNICEF and their funding levels are subject to the approval of the new Country program. As for the WHO it was challenging to separate funds allocated for immunization from their portfolio.

In both entities and the BD, our respondents reported a lack of government funding for replacement of cold chain equipment, with some exceptions. For instance, to ensure adequate cold chain for vaccines, in the absence of cantonal budget in FBiH, the health facility procured refrigerators for domestic use from their own revenues and/or received as a donation from international organizations.

The few vaccine storage facilities in two FBiH cantons visited by our team are in poor conditions and require major refurbishment as observed during the site visits and informed by key stakeholders. Albeit, no hard evidence was available to estimate the magnitude of the given problem. Furthermore, most respondents from the facilities visited complained about the absence of back up energy supply. Although disruptions in electricity supply are rare, the respondents have reported only a few cases of vaccine damage. In such occasions, health facilities transferred available vaccine stock to the PHIs.

Source: Photo from Dom Zdravlja in RS

Injection safety practices discontinued – Utilization of injection safety supplies is not sustained. The majority of the visited facilities in both entities and the BD discontinued procurement of AD syringes and safety boxes. Single use syringes are currently instead. Either carbon boxes from syringes or other plastic boxes replace safety boxes. Only few facilities still continue using safety boxes received during GAVI support. In one facility visited (FBiH) unused stock of expired AD syringes was observed.

BiH failed to fully endorse "Injection Safety Policy". Health personnel, as observed by the ET during the visits to selected health facilities, do not follow injection safety practices thus creating risk to personnel. Supervisory mechanisms for monitoring injection safety are largely absent at PHIs and facility level. According to health personnel and facility managers interviewed, nobody is charged with the function to periodically supervise and monitor injection safety practices in facilities were the vaccinations are performed. Furthermore, our respondents reported the absence of observation or monitoring of injection safety practices from PHI field supervision routines.

"Recently requested the government to provide freezer, though received a refrigerator for domestic use. "

"In the absence of public funding and inability of the government to procure new cold chain equipment, our facility procured equipment using own resources ".

Unsafe waste management practices still not addressed in post GAVI period – the evaluation revealed persistence of poor waste management practices during and post GAVI periods. Both, FBiH and RS, with WHO support, developed and approved policies of waste management. Contracting out waste management services to the public/private companies is widely applied in both entities and the BD. In FBiH cantons, were incinerators are available, immunization waste is initially transferred to these facilities, and only incinerated waste is discharge to waste dumps. However, most health facilities in BiH lack incinerators and needle cutters for safe destruction of syringes and needles and untreated waste is discharged into an uncontrolled, non-engineered open dump, which does not protect the local environment.

> "There is no reason for multi year planning, as budget is approved by parliament on annual basis"...
>
> *Quote from Key Informant*

Sustainability of the immunization programme in BiH is vulnerable to broader health system challenges – Apart from the challenges identified above, the sustainability of immunization programme is compromised by health system challenges, such as: shortage of medical staff, low pay and motivation, absence of effective continuous professional development system etc. These challenges are discussed in details in the introductory chapter of the report. Sustainable routine immunization services are dependent, over the long term, on sustainable health services and systems and if these are not adequately addressed, they will contribute to possible deterioration of immunization services in future.

> "There were no problems moving from GAVI to domestic procurement, because they knew GAVI would end eventually, so they were able to plan 1.5 years ahead to begin the process of domestic procurement. When it was time for transition, the budgets were ready and the transition was smooth"...
>
> *Quote from Key Informant*

Attempts to introduce new vaccines are constraint by scarcity of financial resources. Introduction of Rotavirus and Pneumococcal vaccines have been widely discussed in FBiH, as reported by the HD of MoCA and FBiH PHI. The Immunization Advisory Group prepared sound justification and presented to the Conference of Ministers. While there was an anonymous agreement on the need for introduction of proposed vaccines, the scarcity of financial resources was named as major impediment factor by the Ministry of Finance.

FINANCIAL SUSTAINABILITY

Transition from GAVI support to domestic funding for vaccine procurement was smooth. The Key informants interviewed unanimously noted smooth transition from GAVI support to local funding for the vaccine procurement. The entity governments knew in advance about ending of GAVI funding and ensured allocation of adequate funding for the procurement of vaccines. Transition planning was supported by PHIs in both entities and the BD. PHIs prepared forecasts for required vaccines, while the procurement was handled by the respective institutions/organizations.

Roles of entity agencies in the financing (allocation of public funds) to the immunization programme are clearly defined – By BiH legislation[62] MoCA is responsible for coordination and harmonization of plans and strategies of the Entity authorities. Nevertheless it is not tasked with deciding on the appropriate overall fiscal target for the country, apportioning

[62] Law On Ministries And Other Bodies Of Administration Of Bosnia And Herzegovina, "Official Gazette" Of Bosnia And Herzegovina, 5/03

this target amongst entities and the various government institutions, as well as enforcing and monitoring progress towards targets. The legislation assigns financing roles and responsibilities to entity level.

In FBiH, the budget for procurement of vaccines is allocated to the Federal Solidarity Fund, while salaries of immunization staff and PHIs are covered by the cantonal HIFs and budgets are approved by cantonal parliaments.

In RS, the Ministry of Finance approves annual budgets for immunization. Vaccine requirements and specifications are defined by the PHI, while HIF handles procurement and covers staff salaries.

In the BD, the Ministry of Finance approves budgets for the procurement of vaccines, health service providers as well as for the PHI. Budget forecasts for vaccine procurement is prepared by the HD of the Government of Brcko and submitted for approval to the Ministry of Finance.

Multi-year planning and budgeting practice for immunization programme discontinued – As mentioned in previous sections BiH planned to develop new MYSP in 2011, however, consensus on the preparation of multi-year plan was not reached, as stakeholders suggested that the transition strategy is mainly entity owned and there was no need for preparation of the state level immunization programme financing plan aftermath of GAVI support.

The ET enquired for MYSPs at both entities and the BD, however respondents informed that multi-year planning is mostly practiced for entire health sector, which does not specify separate budget allocation for immunization programme other than allocations for the vaccine procurement. Allocations for non-vaccine expenditures of the immunization programs are included in Health Insurance budgets representing key budget lines such as payroll, communal costs, capital investments, medicines and supplies etc.

> "We face challenges with tenders. Some are difficult, because there are no bids. If no bids, then tender is reissued "...
>
> *Quote from Key Informant*

Financing of vaccine procurement sustained, though can face substantial risks – The governments' of FBiH, RS and Brcko commitment to fully fund all childhood vaccines and sterile syringes, including payments to health workers administering vaccines, effectively resolved sustainability issues related to HepB, HiB and other vaccines. BiH both entities and the BD agreed to individually finance annual procurement of all vaccines included in respective immunization calendars and proceed with local procurement according to the Public Procurement Law. Since GAVI support ended, entities and the BD ensure the availability of vaccines to target groups in their respective administrative territories.

Further sustainability of vaccine supply can be severely undermined by number of factors described in sections below.

Small markets and fragmented procurement – BiH market value for vaccines is clearly very small relative to other middle and high-income countries. Some evidence suggests, that the pharmaceutical industry sees these countries, especially the rapidly growing "emerging markets," as potentially lucrative markets, and is not willing to provide new vaccines to these countries at the same low price it offers to UNICEF/GAVI[63]. Or, for new vaccines such

[63] P. Wilson, Giving Developing Countries the Best Shot: An Overview of Vaccine Access and R&D; Oxfam, 2010

as human papillomavirus, with the initial limited capacity of production, the pharmaceutical industry is not willing to lower the prices until after the years of the profitable sales of the limited output to the higher income countries[64]. Consequently there is a growing concern that with the current economic development the BiH, as many lower-middle income countries[65] may not be able to afford purchase of vaccines, or be forced to divert funds from other health programmes to do so. The situation is further complicated with market fragmentation within BiH, as each entity proceeds with individual procurement of vaccines. The latter further raises risk of financial sustainability, while pooled procurement/centralized state level procurement can serve as a short-term remedy.

Annual procurement vs. long-term commitment – BiH's both entities and the BD procures vaccines annually as required by the local legislation. The annual vaccine procurement practice implies the procurement of a small number of vaccines and increases the probability of procurement process failure due to scarcity of suppliers/lack of competitors and high vaccine costs.

Market equilibrium - Fixed costs, established by BiH regulation, for either registration of vaccines and/or certification of suppliers, is not a barrier for suppliers' entry into BiH market. However, in case of BiH, the interaction of fixed cost with low demand for vaccines, results in market equilibrium that supports only one or few suppliers in BiH vaccine market. Since GAVI support, BiH couple times failed to procure vaccines due to few or no bids. In such cases, the procurement process is reinitiated, leading to delayed vaccine supply to facilities for about another six months.

> "This year we were not able to procure Pentavalent vaccine"...
>
> *Quote from Key Informant*

Lack of competition and high vaccine prices – The lack of competition observed in BiH, gives substantial freedom to suppliers to set prices, hence eventually raising risk of affordability. The price comparison analysis performed by the ET (Figure 6), reveals prices paid by BiH to be 5-20 fold higher than UNICEF/GAVI prices. Higher vaccine prices means fewer resources for other health priorities, especially of non-vaccine immunization services. The unpredictability of future vaccine prices for BiH market imposes further limits on purchasing ability, thus calling for urgency to rethink vaccine procurement strategies and arrangements.

> "During GAVI support vaccines were procured through UNICEF, however after end of GAVI support it was logical to shift to local procurement"
>
> *Quote from Key Informant*

Vaccine shortages and delays at the global market – Shortages of vaccines, in the recommended childhood immunization schedule occurred in the past in many countries[66]. Reasons for these shortages were multi-factorial and included companies leaving the vaccine market**,** manufacturing or production capacity problems, and insufficient stockpiles. Such market dynamics has already affected BiH. According to key informants, Pentavalent vaccine[67] shortage in BiH was caused by inability of companies to supply markets in BiH and a Baltic States with adequate quantities of vaccines. Although BiH can assure administration of Pentavalent vaccine until mid-2015 using their buffer stock, the strategy for the way forward is not yet formulated.

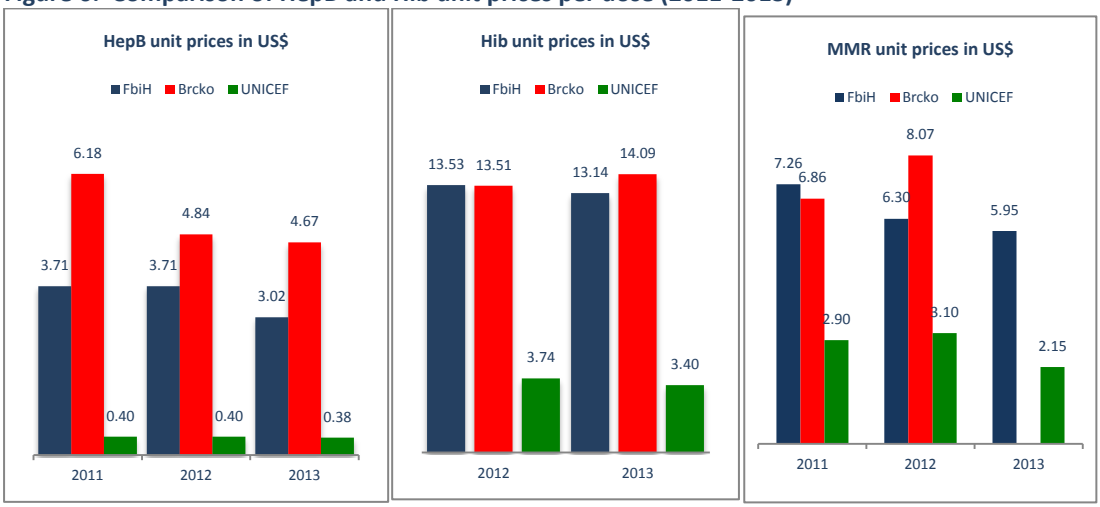
[64] K. Outterson and A. Kesselheim. Market-Based Licensing For HPV Vaccines In Developing Countries. Health Affairs, January 2008 vol. 27 no. 1 130-139

[65] Madsen, L et all. Reduced price on rotavirus vaccines: enough to facilitate access where most needed? Bulletin of the World Health Organization 2012;90:554-556

[66] Vaccine market, WHO, http://www.who.int/immunization/programmes_systems/procurement/market/individual_vaccine/en/

[67] Combine vaccine that protects against diphtheria, tetanus, whooping cough, poliomyelitis and haemophilus influenza type B.

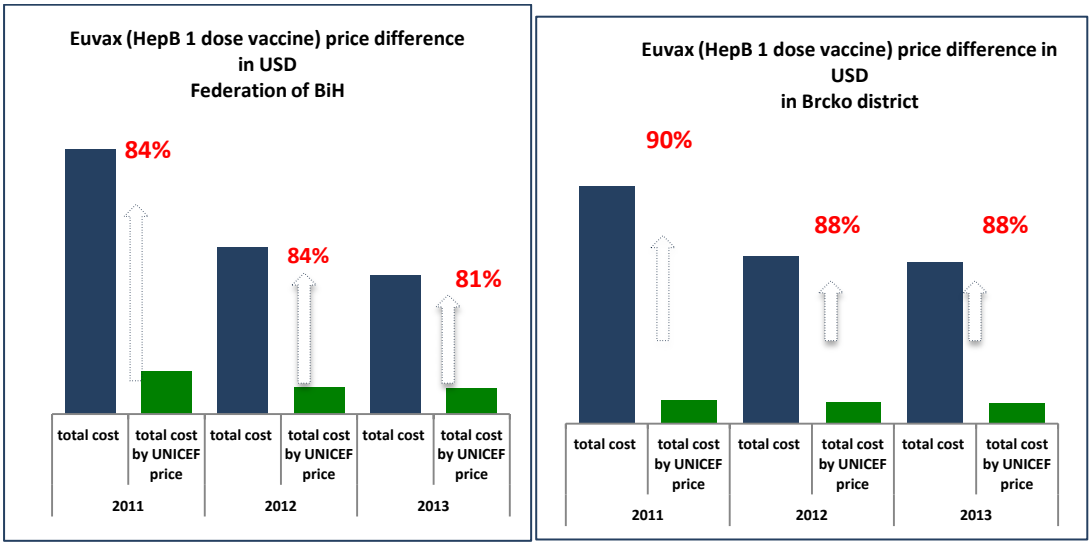
Figure 6: Comparison of HepB and Hib unit prices per dose (2011-2013)

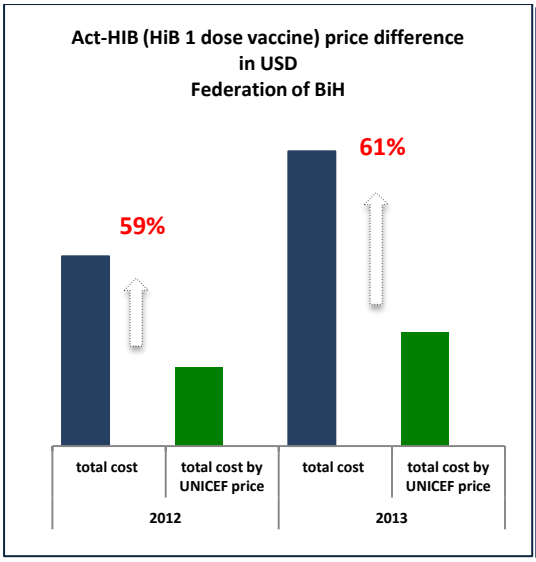


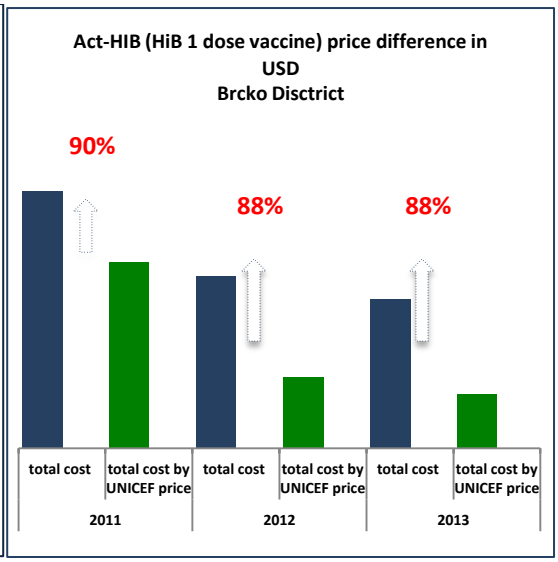
Decision on using local procurement was made without thorough analysis of potential financial implications and operational risks – In preparation for post GAVI period BiH arrived to the decision that both entities and the BD will proceed with self-procurement of vaccines. No hard evidence was collected to examine arguments formulated in favour of local procurement over the UNICEF. Respondents explained that it was logical to move from UNICEF Supply Division (SD) procurement towards local procurement, as vaccine procurement was fully financed from the public purse.

Ultimately, the decision on using local procurement was made without thorough analysis of potential financial implications and operational risks. The ET conducted comparative analysis of local vaccine procurement budget to the budget that could have been spent using UNICEF SD procurement method (Figure 7)

Figure 7: Comparative analysis of vaccine procurement budget difference







Data was obtained from FBiH and the BD on spending and number of doses of particular vaccine purchased for the years 2011 – 2013. UNICEF prices[68] were obtained from UNICEF SD web site and local taxes applied. The Analysis revealed that using UNICEF SD procurement methodology could have saved around 60% to 90% of budgets allocated for the purchase of HepB and Hib enabling governments to use the difference for funding other needs of the immunization programme.

Non-vaccine immunization services are underfunded – To ensure sustainability of the immunization programme in addition to vaccine budgets BiH had to continue adequate funding of non-vaccine immunization costs, such as health workers, transport, demand creation and community mobilization activities, and the supply chain for vaccines. The ET had proposed analysis of governments' total budgets for immunization at entities and the BD level, but learned that budgets other than for procurement of vaccines are co-mingled with other budget lines (salaries, communal costs, supplies etc.) and cannot be easily disaggregated.

According to key informants, the budget reduction to the primary health care observed. This is somewhat inconsistent with the reported increase in the estimated public expenditures on health, from 590 PPP$ in 2010 to 660 PPP$ 2012. Majority of the PHC facility managers interviewed complained about underfunding of the PHC sector, thus limiting health facility to perform outreach activities for improving immunization coverage, purchase consumables and safety boxes, maintenance and or replacement of cold chain, funding training of staff, etc.

> "In general primary health care is severely underfunded. Our facility budget paid from HIF decreased by 10% from 2009 to 2013. We closed last year with substantial deficit."
>
> *Quote from Key Informant*

Inadequate financing undermines the roles of PHIs at all levels – Informants reported poor financing of the PHIs in both entities and the BD. Annual budgets allocated cover only labour costs and communal expenses, while no funding is made available for supervision, enhancement of surveillance and reporting functions, health worker training and public education and awareness raising etc. Current legislation allows PHIs to raise private

[68] Source: https//supply.unicef.org

revenues through provision of commercial services for hygiene and sanitation, etc. Therefore PHI staff is more oriented towards revenue generation activities and less on the enhancement of the immunization services in their respective administrative units.

Although the funding levels of the PHIs have not changed significantly in post GAVI's period, training and supervision expenses were funded by GAVI's Vaccine Introduction Grant in past.

"Monitoring of stock was greatly improved through introduction of regional information system in 2008-2009. PHI from Banja Luka hired company to develop cold change management information system "

"International Expertise provided during GAVI's support helped build immunization management capacity in the country as well as built knowledge base. At present these people provide technical assistance to other countries"

Quotes from Key Informants

3.4 POSITIVE AND NEGATIVE CONSEQUENCIES OF GAVI SUPPORT

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

- The establishment of the ICC promoted mutual dialogue and consensus building between the entities state level and for the first time created a forum in which key health authorities in BiH met on a regular basis.
- GAVI support, for the first time, stimulated introduction of planning and budgeting for vaccine procurement;
- At a time of project design, the FBiH addressed the emerging priority of combating Hib invasive disease by pilot use of Hib vaccine in a four-dose schedule. It is notable that further expansion of the pilot was constraint by limited fiscal space, thus availability of GAVI support catalysed:
  - The move from piloting practice to institutionalization of Hib into the immunization schedule across the country, in both entities and in the BD;
  - Mobilization of governments' commitment and inputs to support access to new vaccines.
  - Procurement of vaccines through UNICEF Supply Division (SD), facilitated by the introduction of revisions to the Public Procurement Law.
- GAVI support ensured uninterrupted vaccine supply and affordable and cost efficient public spending on vaccine procurement;
- GAVI's efforts to mobilize partners' financial and technical resources generated collaborative response towards improving immunization programme management, cold chain and reporting, as well as built knowledge.

"Without GAVI's support the FBiH would not have been able to continue pilot with Hib"

"Preparation of GAVI proposal promoted entities to come together, reach consensus and countersign the proposal"

"For the first time, on request of GAVI the multi-year plan for immunisation was developed with the assistance of international partners"

Quotes from Key Informants

The lack of a transition phase in BiH had an unintended consequence, namely that the county was exposed to the open market where vaccine prices are substantially higher relative to GAVI/UNICEF prices and had to assume high financial burden.

SUMMARY OF FINDINGS ON SUSTAINABILITY AND FACTORS CONTRIBUTING TO SUSTAINABILITY

EVALUATION QUESTION	FINDINGS	ROBUSTNESS RANKING	
To what extent have the relevant activities related to 'GAVI support' been continued?	Majority of GAVI supported activities continued, except of injection safety policy implementation	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 continue to operate, though effectiveness and efficiency concerns have to be addressed	B	Findings substantiated by triangulation of documentary and key informant data
	The roles of entity agencies in the financing and management of immunization programme are clearly defined	A	Findings are substantiated by documentary, quantitative and qualitative data
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?	The deterioration of immunization coverage rates were observed in FBiH, while RS and the BD showed improving rates.	A	Findings are based on analysis of available administrative quantitative data and qualitative data
	BiH ensures adequate funding for vaccine procurement, though the faces potential risks due to small market, fragmented procurement, low competitions and high vaccine prices. BiH can ensure adequate supply of the Pentavalent vaccine for the immunization programmes until mid-2015, using the available stock, however the longer term plans, if the vaccine procurement problems continue, are not in place.	A	Findings are substantiated by documentary, quantitative and qualitative data
	Inadequate funding of non-vaccine related costs are reported	C	Findings are substantiated only by qualitative data in the absence of available quantitative data.
	Cold chain is aging and poorly maintained	A	Findings are substantiated by triangulation of quantitative, qualitative data and findings of facility visits
	Multiyear planning and injection safety practices are discontinued	A	Findings are triangulated between documentary and key informant data
What are the main factors explaining the achieved results (positive or negative)?	Support and guidance provided by GAVI alongside with leveraging partner's support explains achieved results	B	Findings substantiated by triangulation of documentary and key informant data.
What have been the	An unintended 'negative' consequence	B	Findings substantiated by

main unintended positive and/or negative effects of the time-limited nature of GAVI support and its conclusion?	of this programme has been the poor safe disposal/ sharps waste management in BiH – primarily due to a lack of resources in countries.		triangulation of documentary and key informant data
	Challenges of the global vaccine market, especially for Pentavalent vaccines, raises risk of vaccine shortages in coming years in BIH.	B	Findings substantiated by triangulation of documentary and key informant data
	Since GAVI support ended, BiH is exposed to the open market where vaccine prices are substantially higher relative to GAVI/UNICEF prices and has to shoulder a high financial burden.	A	Findings are substantiated by triangulation of quantitative, qualitative data and findings
Have new vaccines been introduced in BiH since the conclusion of GAVI support?	The introduction of new vaccines has been discussed, but the decision is pending until adequate fiscal space is guaranteed.	B	Findings are based on review of immunization schedules of both entities and the BD as well as qualitative data obtained during evaluation

CHAPTER 4: CONCLUSIONS, DISCUSSIONS AND LESSONS LEARNED

This chapter of the report summarizes evaluation findings at pre-, during, and post- GAVI support.

4.1 RELEVANCE AND EFFECTIVENESS OF PLANNING – PRE GAVI SUPPORT

The Coordination mechanism (ICC) established in BiH ensured stakeholder coordination and evidence based decision-making. Sustainability of assistance is stronger when projects are placed in a longer-term holistic policy perspective, with government leadership. GAVI support intended to contribute to strengthening the government's capacity to develop policies and strategies and to enhance management capabilities for immunization services. GAVI's emphasis on ownership through the involvement of local stakeholders in the design and implementation of immunization activities in BiH has helped to improve immunization programmes performance and facilitate understanding, acceptance and implementation of the international recommendations at the policy and programme level. GAVI funds served as a catalyst and helped BiH's national immunization systems' in post-war recovery.

Coordination efforts within and between the BiH entities for the development of the GAVI proposals, MYSP and FSP were unique experiences effective planning in health sector more broadly. The ICC was instrumental in bringing together both entities in preparation of applications for GAVI support; building consensus around introduction of new vaccines and integration into the entities' immunization calendars; assisting entities to jointly identify resources needed to achieve the goals of immunization programme; and periodically monitoring implementation of GAVI support and produced reports. However, key respondents perceived its role in strategic planning, problem solving, oversight function in relation to expenditure tracking or programme review to be weak.

Programmatic and FSP were key issues addressed by GAVI during proposal development and related negotiations and were embodied in the mandatory preconditions for initiating the GAVI support. GAVI has been innovative with regards to developing tools and policies that have supported country financial planning for routine immunization and for the new vaccine introduction. The introduction of FSPs and MYSP was an important innovation for BiH. The process generated more focus on immunization costs and financing, and contributed to a greater understanding of financial implications when introducing new vaccines within government's and politicians.

Planning for the transition away from GAVI support was initiated from the very beginning of GAVI support. The MYSP for the years 2002-2006 being jointly developed by both entities and the BD for immunization was regarded as the means by which BiH aimed to fully restore its Immunization Programmes, to sustain effective control of traditional VPD, as well as to reduce the burden of HepB and Hib infections.

To ensure the sustainability of the immunization programmes, BiH's FSP planned to amend and enforce legislation, which clearly defines responsibilities for the financing of the national immunization programmes in both entities and allows direct procurement of vaccines through UNICEF Supply Division that ensures vaccine procurement at the lowest cost. Furthermore, BiH aimed to revise the vaccination schedule based on the cost-effectiveness analysis.

GAVI support was relevant to country context - GAVI support was relevant to the country needs and essential for funding and strengthening immunization programmes during the early stages of the support. The introduction of new vaccines and injection safety in BiH was in accordance with internationally accepted guidelines and based on thorough situation analysis well documented and communicated to country stakeholders.

The decision to introduce the HepB vaccine was based on WHO/EURO recommendations and the experience of other European countries with intermediate and low endemicity of HepB (Italy, Germany, Spain, Greece etc.). The HepB Universal Immunization Action Plan 2002-2006 was developed in 2001, aiming to create five immune birth cohorts and paving the way to HepB low endemicity in BiH through sustained immunization. The plan provided detailed, time bound actions planned for implementation.

A Hib Rapid Assessment and Injection Safety Assessment carried out in 2004 largely informed introduction of Hib vaccination and injection safety practices in BiH and guided GAVI's support to the country. The MYSP identified control of HepB and Hib vaccination alongside with injection safety as key objectives among other eleven strategic objectives of the EPI and provided financial plan for sustainment of HepB vaccination.

In all instances GAVI's financial support was critical and relevant for the introduction of new vaccines and support to injections safety strategies. According to the key informants, sufficient funds were not available in BiH health sector budgets to finance the introduction of new vaccines. Thus GAVI support was highly relevant, timely and key for improving the country's immunization programmes.

4.2 EFFECTIVENESS AND EFFICIENCY OF IMPLEMENTATION – DURING GAVI SUPPORT

The majority of activities planned under the MYSP for Immunization and FSP were implemented, though some of the programmatic targets were not fully met and effectiveness of implementation varied across FSP objectives. More specifically:

The immunization schedule for GAVI supported HepB vaccine was harmonized in all three entities, though general immunization schedules differed among the entities and the BD. The Hib schedule was standardised in FBiH and RS (2, 4, 18 months) while the BD introduced the third dose of Hib at 6 months.

Extensive trainings of healthcare workers to address key immunization programmes' bottlenecks on the new vaccines and injection safety were commenced prior to the vaccines introduction, mostly financed through GAVI's Vaccine Introduction Grant. However, the uneven coverage of health personnel training offerings were reported by health personnel interviewed. According to the post vaccine introduction evaluation, health care workers' knowledge regarding use and advantages of new vaccines was found acceptable and the practice of consulting parents on the benefits of immunization was observed. However, according to the latest KAP survey, health personnel's knowledge in relation to injection safety and waste management was insufficient, and, can result in underperformance of injection safety practices during GAVI support implementation.

Injection safety and waste management practices required improvements. No hard evidence is available in support of the governments' follow up actions for implementation of injection safety assessment recommendations carried out in 2005 and national policy on injection safety (2005). The APR for 2011 reports absence of country level Injection Safety

Policy as well as only 60% of immunization service providers being equipped with injection safety equipment. While GAVI's INS support ended in 2008, the country still had a stock of injection safety materials available for use in 2011, due to limited utilization of safety equipment. Underutilization of INS equipment was also evident during the site visits.

The BiH did not sufficiently build health personnel capacity and was therefore unsuccessful in reinforcing the utilization of injection safety equipment. Lack of instructions on the use of AD syringes, poor quality of AD syringes (sharpness and needle-tip diameter) and weak practical skills for using them were sites as main reasons for underutilization of INS by immunization service providers.

The entity level policies for immunization waste disposal were not completely implemented during the GAVI support. The post-introduction evaluation of new vaccines[69] reported that the disposal of syringes and needles with the regular city waste in some cantons of FBiH and RS regions. Although problems were adequately reflected in the APRs, BiH has proposed no strategic actions for their resolution. GAVI and partners could have addressed weak implementation of Injection Safety policies, however there was no evidence of GAVI and/or partner reaction and follow-up on these important issues. Based on the problems reported in APRs, GAVI could have been instrumental in requesting the Governments to formulate time bound mitigation strategic plans. Furthermore, GAVI could have mobilized partner support for enhancement of injection safety policy implementation in BiH as well as for regular monitoring of government's follow-up actions.

Substantial efforts were put in place by governments and partners (UNICEF/WHO) for **public education and awareness raising, but measures for the mitigation of negative AVC influence on immunization coverage lacked were ad hoc**. Advocacy, social mobilization and communication plans were developed and campaigns implemented prior to new vaccine introduction and aftermath but lacked regularity. With UNICEF/WHO support, the government of BiH officially announced introduction of new vaccines through media channels and informed parents on the right of their children to immunization and its importance. The smooth introduction of new vaccines was periodically hampered by AVCs. Government's response to AVC carried mostly an ad hoc character. Most of the respondents at public institutions and partner organizations strongly believe that AVC negatively affected and continues to effect immunization coverage, especially creating mistrust to vaccination within general population. However, a recent KAP survey[70] reports that AVC negatively influenced only 14% of surveyed parents with least significant influence among urban population and an overwhelming majority (96%) of the health workers believe that the vaccines used in the programme were safe.

Weak vaccine management capacity observed in the first years of GAVI support was gradually strengthened and significantly improved in response to VMA recommendations[71]**.** To name few, BiH managed to improve staffing levels at the PHIs and built staff capacity to handle logistical issues; introduced buffer stocks at entity, canton/district and facility levels; Institutionalized software for monitoring immunization programme in FBiH; Enhanced cold chain infrastructure, built additional cold room and a freezer for OPV vaccines in FBiH; Developed recommendations for cold chain renewal and revised staffing levels based on the analysis of cold chain; Appointed people responsible for immunization programme at each

[69] Ibid 8
[70] Ibid 5
[71] Vaccine Management Assessment in BiH, WHO, 2006

level appointed; adopted a minimum set of indicators for monitoring and evaluation of the programme of immunization adopted and delivered to all Immunization coordinators.

Respondents from both entities and the BD cited irregularity of immunization programme supervision and monitoring. Irregularity and weak supervision is also echoed by the findings of the Post introduction evaluation carried out in 2009.

Delays in vaccine and INS delivery were reported during the implementation, mostly due to customs related issue, though they did not affect achievement of the programmatic objectives.

Immunisation reporting system was improved but challenges remained. Immunisation reporting system was enhanced and reporting forms standardised. Reporting forms included monthly/annual forms on EPI vaccines coverage, usage and distribution of vaccines and AEFI. The Post Introduction Evaluation of New Vaccines in BiH[72] carried out in 2009 revealed weaknesses of the immunization information system, particularly there was no standard information system for the vaccination programme at all facilities and reporting system used at most health facilities did not permit collection and transmission of the data needed to calculate vaccination coverage appropriately at the health facility level. The challenges of reporting system were highlighted in 2011 APR, but no hard evidence was obtained on the actions taken either form the Governments and/or from GAVI.

Programmatic targets for immunization were partially met (see Table 6). In 2011, targets for immunization coverage were only attained for BCG, Hib and HepB, whereas targets for other antigens underperformed. BiH failed to achieve 100% availability of AD syringes and safety boxes at vaccination posts as well as maintaining drop out rates for HepB below 8%.

BiH gradually improved annual country progress reporting practice and quality, though room for further improvement remained even during implementation. Close to the end of GAVI support BiH managed to improve timely submission of the APRs to GAVI, though completeness of reports remained a challenge. Main problems frequently cited in GAVI letters were absence of i) reporting on progress against financial and programmatic indicators; ii) reports to be signed by the Minister of Health and endorsed by the members of the ICC; and iii) ICC minutes to be attached.

Annual monitoring of the country performance from GAVI during implementation was evident, though timeliness of GAVI secretariat's response desired improvement. Observed delays in GAVI's responses to BiH could have left insufficient time for required budget adjustments by the entities. Progress towards target coverage, mainly monitored based on the administrative data reported by the country in the APRs and the JMRs, could have been misleading due to the identified and reported weaknesses of reporting system. While GAVI was strict to request regular reporting on the progress of indicators, it allowed BiH to postpone recording of progress in attainment of immunization targets to the next reporting period. This practice resulted in missing the opportunity for GAVI to provide BiH with timely advice on corrective measures when targets were underachieved. Data quality concerns have not been adequately addressed and highlighted in GAVI IRC reports and Decision letters.

Although GAVI support to implementation and system related bottlenecks were well documented and reported by BiH, hard evidence on related mitigation measures is lacking.

[72] Ibid 8

GAVI followed up on key programmatic and/or implementation weaknesses and challenges reported and managed to mobilize timely support through its partners. However more consistent follow up on further implementation of planned measures would have been beneficial, allowing the provision of timely advice on corrective measures to the country. Close to the end of GAVI support BiH managed to improve the timely submission of APRs to GAVI, though the completeness of reports remained a challenge. Annual monitoring of the country performance from GAVI during implementation was evident, however timeliness of GAVI secretariat's response desired improvement.

Certain evidence of efficiency gains during the GAVI support exists. Namely:

The Governments of both entities **have achieved progress against major financial sustainability strategies.** Namely, the policy options with the role of financial agents in the mobilization, management and allocation of funds to the different cost categories of the Immunization Programme as well as endorsement of corresponding legislation/legal acts has been addressed and new Public Procurement Law was endorsed to allow procurement of vaccines from UNICEF Supply Division (SD).

GAVI's efforts to ensure effective coordination with partners and other international donors, helped to ease the mobilization of financial and technical resources and increased collaboration towards the mitigation of programmatic and implementation challenges faced by the country.

4.3 OUTCOMES AND RESULTS OF GAVI SUPPORT – AFTER GAVI SUPPORT

Programmatic sustainability faces challenges:

- **Coordination mechanism maintained with fewer responsibilities, demonstrating operational weaknesses** – Since the end of the GAVI support, selected functions of the ICC, specifically the coordination of partners and the compilation of reports required for international reporting were handed over to the MoCA HD. Although a coordination function is maintained for immunization programme, the effectiveness of its operations is inadequate, mainly due to the weak functional powers granted by the legislation to the department and the limited human resources at MoCA HD.
- **Access to new vaccines is ensured, but intermittent vaccine stock-outs and shortages of medical supplies are observed**. With GAVI support, new vaccines were included in the mandatory immunization calendar of both entities and the BD and are being provided free of charge to the target groups. Periodic vaccine stock-outs and shortages of medical supplies are observed in the post-GAVI period due to lengthy and complicated procurement process. To date, immunization targets have not been affected. Availability of the buffer stocks allowed the governments to ensure the immunization program's continuity.
- **Cold chain equipment and its maintenance and management are deteriorating** due to the inadequate public funding for maintenance and replacement of ageing cold chain equipment. The current situation substantiates an urgent need for the equipment renewal in order to ensure the proper functioning of all immunization programmes.
- **Immunization programme management structures continue to operate, but serious weaknesses are observed in supervision, monitoring and evaluation function performance.** Observed irregularity and poor quality of immunization program supervision in BiH indicates that supervision is not seen as a learning process and a way to improve the programme achievements. It is still perceived as an activity for

controlling staff that could lead to disciplinary measures. Supervision thus remains an administrative function of senior public service employees over their subordinates.

- **Despite certain improvements after GAVI support the information system demonstrates deficiencies**. The current information systems in two entities and the BD do not provide adequate data to estimate vaccine coverage and drop-out rates, due to problems with both numerator and denominator assessments.
- **Injection safety practices are discontinued and irregularities in unsafe waste management practices observed.** BiH failed to fully endorse the Injection Safety Policy.[73,74] The majority of the visited facilities in both entities and the BD discontinued procurement of AD syringes and safety boxes, rather single use syringes are used ensuring injection safety for beneficiaries. Health personnel, as observed by the ET during site visits, do not follow injection safety practices. Supervisory mechanisms for monitoring injection safety were largely absent at PHI and facility level. Most health facilities in BiH lack incinerators and needle cutters for the safe destruction of syringes and needles and untreated waste is discharged into an uncontrolled, non-engineered open dump, which does not protect the local environment.
- **The immunization systems struggle due to the broader health systems challenges** in the country, including shortage of medical personnel, low pay, and lack of motivation, high turnover of health workers, and the absence of effective continuous professional development system. Sustainable routine immunization services are dependent, over the long term, on sustainable health services and systems and if not adequately addressed will possibly contribute to deterioration of immunization services in future.
- **Attempts to introduce new vaccines are constrained by scarcity of financial resources.**

Financial Sustainability for vaccine procurement is at risk. Specifically:

- **The transition from GAVI support to domestic funding for vaccine procurement was smooth.** The key informants interviewed unanimously noted smooth transition from GAVI support to local funding for the vaccine procurement. The entity governments knew in advance about ending of GAVI funding and ensured allocation of adequate funding for the procurement of vaccines. Transition planning was supported by PHIs in both entities and the BD. PHIs prepared forecasts for required vaccines, while the procurement was handled by the respective institutions/organizations.
- **Countrywide planning and budgeting mechanisms for immunization programmes**, **created during the GAVI support, were crippled upon completion of the GAVI support**. The latter occurred mainly due to administrative-territorial arrangement and due to political specificity of the country and should not be viewed as unintended negative outcome of the GAVI support.
- **Financing of vaccine procurement is sustained, though can face substantial risks** due to small market, fragmented procurement, low competition and high vaccine prices. The failure in the procurement tenders for Pentavalent vaccine in BiH during the last year was caused by inability of companies to supply markets in BiH with adequate quantities of vaccines. Although BiH can assure the administration of the Pentavalent vaccine until mid-2015, using their buffer stock, the strategy for the way forward is not yet formulated. Since GAVI support ended, BiH is exposed to the open market, where vaccine prices are substantially higher relative to GAVI/UNICEF prices and has to shoulder high financial burden. The price comparison analysis performed by the ET

[73] Ibid 11

[74] Ibid 12

(Figure 6), reveals that prices paid by BiH relative to UNICEF/GAVI prices being 5-20 fold higher. Higher vaccine prices mean fewer resources for other health priorities, especially of non-vaccine immunization services. The unpredictability of future vaccine prices for BiH market imposes further limits on purchasing ability, thus calling for urgency to rethink vaccine procurement strategies and arrangements. Challenges of the global vaccine market, especially for Pentavalent vaccines, raises risk of vaccine shortages in coming years in BIH. The Government lacks well formulated strategy to cope with shortage of Pentavalent vaccines.

Non-vaccine immunization services are largely underfunded. The majority of public sector PHC facility managers interviewed complained about underfunding of the PHC sector, thus limiting health facility to perform outreach activities for improving immunization coverage, purchase consumables and safety boxes, maintenance and or replacement of cold chain, funding training of staff, etc.

Inadequate financing undermines the roles of PHIs at all levels and raises risks for effectiveness and sustainability of immunization programs. Poor financing of the PHIs in both entities and the BD was cited by all PHIs visited. Annual budgets are limited to cover only labour costs and communal expenses, while no funding is made available for supervision, enhancement of surveillance and reporting functions, health worker training and public education and awareness raising etc.

CHAPTER 5: LESSONS LEARNED

- The strong focus on country ownership to achieve results has proven effective. Country ownership should continue to be the starting point GAVI's support effectiveness. The ICC coordination mechanism, required by GAVI in all eligible countries, proved its benefits even in countries like BiH, with fragile and weak political and governance structures. The challenge is to put the country genuinely in charge, to listen, adjust priorities, and measure results.

- Mobilizing long-term donor funds has enabled the GAVI Alliance to make multi-year funding commitments to BiH up to 2011, aligned to countries' own plans. This has given BiH a confidence to introduce new vaccines and sufficient time to plan for financial transition to domestic resources.

- In the absence of well-formulated transition policy, BiH experienced the conclusion of GAVI funding without benefitting from a thorough assessment of the country readiness for sustaining results and self-sufficiency. The phase out of GAVI's support should be systematic and its efforts should facilitate graduation with pre-determined financial and technical benchmarks. Furthermore, GAVI should maintain political support to assure financing of products and programmes continue after graduation.

- Through its innovative approach to develop tools and policies, GAVI supported BIH's financial planning for routine immunization and for new vaccine introduction. This process generated more focus on immunization costs and financing and contributed to a greater understanding of the financial implications when introducing new vaccines within government's and politicians.

- After the end of GAVI's support, the BiH entity governments made policy decisions based on lowest vaccine price, without having full understanding of what market prices were and how they may affect overall long-term programme costs and sustainability. The price increases after the end of GAVI funding further strains limited public funding for immunization and significantly increases sustainability risks. Moreover, such developments will impede and delay the introduction of additional new vaccines in the national schedules.

- In order to sustain its achievements and maximize the potential impact of vaccine introductions in the Phase II countries, the GAVI Alliance will need to focus on strengthening national immunization systems and improving coverage to reach the most disadvantaged and underserved children. This will entail increasing GAVI's investments in health systems strengthening, better tailoring these investments to country-specific needs, and ensuring that plans for implementing the investments are designed in such a way that they focus on achieving immunization-specific outcomes. BiH's experience clearly demonstrates GAVI's value added in organizing partner's support especially for those countries that do not accessed Health System Strengthening grant and or Immunization Service Support from GAVI.

- Weaknesses identified in GAVI's monitoring of country performance, resulted in missed opportunities to timely address challenges faced and calls for enhanced grant

management tools for monitoring, tracking issues and identifying risks and requires face to face monitoring visits during and after GAVI support.

- GAVI and partners could have addressed weak implementation of Injection Safety policies, however there was no evidence of GAVI and/or partner reaction and follow-up on these important issues. GAVI could have been instrumental in requesting the Governments to formulate time bound mitigation strategic plans should it been more attentive to the problems reported in APRs. Furthermore, GAVI could have mobilized partner support for enhancement of injection safety policy implementation in BiH as well as for regular monitoring of government's follow-up actions.

CHAPTER 6: RECOMMENDATIONS

6.1 COUNTRY SPECIFIC RECOMMENDATIONS

RECOMMENDATION 1: ENHANCE COUNTRY COORDINATION MECHANISM

In line with the observed health system challenges and on-going health system reforms in BiH, a pluralistic, 'immunization coordination system' should be maintained at MoCA, with representatives from the wider health sector, regulatory authorities, civil society, private sector, and developing partners active in health care sector. Coordination meetings should serve as a platform for discussion of the immunization programme and system challenges, as well as for building consensus between constituencies on integration of remedial actions in the broader health sector reform agenda.

RECOMMENDATION 2: PRACTICE MULTI-YEAR PLANNING OF IMMUNIZATION PROGRAMMES

The state-level MYSP set an excellent precedent of developing state level MYSP and budgeting of immunization services practiced during GAVI support. In order to ensure further sustainability and effectiveness of immunization programme, the MYSP has to be given a priority again. The ICC, as well as international partners on the ground (UNICEF and WHO), are encouraged to advocate and facilitate discussions around this issue and to obtain consensus among constituencies, as well as to mobilize partners' technical assistance in support of longer term planning. The MYSP should ensure accurate calculation of all related costs associated with the effective delivery of immunization services. Furthermore, the country is advised to reflect MYSP funding requirements for vaccine procurement, for cold chain upgrade, as well as for non-vaccine related immunization services in BiH's and/or entity's mid-term expenditure frameworks/plans.

RECOMMENDATION 3: REVISIT VACCINE PROCUREMENT CHOICES

The analysis of expenditures on new vaccines clearly demonstrates spending inefficiencies when moving to entity/canton level procurement. Whereas local procurement is the preferred choice for purchasing vaccines of both entities and the BD, existing analyses revealed that the small market alongside with market segmentation, low competition and high vaccine prices, are detrimental for the scarce public resources and access to vaccines. Therefore, BiH is encouraged to explore alternative procurement options and ensure sustainment of vaccine availability for the population.

Specifically, in the short term, BiH is advised to reach consensus on state level procurement mechanism, which will enable the consolidation of BiH vaccine market, the negotiation of better vaccine prices with suppliers, and the signing of a simple procurement framework contract by both entities and the BD. The proposed mechanism is a framework contract or an agreement between one or more contracting authorities and one or more economic operators, whose purpose would be to establish the terms governing contracts to be awarded during a given period, in particular with regard to price and, where appropriate, the quantity envisaged. Such an arrangement could allow BiH to achieve some efficiency in spending on vaccine procurement. The implementation of the proposed mechanism may require harmonization of immunization schedules for all antigens by all constituencies.

Alternatively, BiH can also explore the possibility of vaccine procurement through UNICEF SD, though this option may be shorthanded for some forms of new vaccines introduced by the country.

Furthermore, BiH is not the only country in the region facing challenges with vaccine procurement. Small Balkan countries (e.g. Montenegro, Moldova, and others) face similar problems. BiH can capitalize on the experience of a recent regional procurement event facilitated by WHO. While developing a regional procurement mechanism is a labour and time-consuming exercise, BiH has to regularly raise this issue and actively discuss it with the neighbouring countries. UNICEF/WHO could be active players in facilitating such discussions.

RECOMMENDATION 4: ENHANCE SUPERVISION AND MONITORING OF IMMUNIZATION SERVICES AND IMMUNIZATION INFORMATION SYSTEM

The evaluation of BiH's immunization programs revealed weaknesses in the immunization supervision system, substantiated by lack of financial resources and a need for straightforward supervision and monitoring guidelines, procedures and reporting forms. Besides, during the evaluation key informants have extensively discussed a need in strengthening of immunization information system. Albeit efforts are put in place for piloting modern information system in FBiH, application of this system in both entities and the BD has to be accelerated.

A well-functioning information system will be instrumental for recalculation and further monitoring of immunization coverage rates as well as identification of those in need to be reached out. PHIs in both entities and the BD are advised to elaborate entity level strategies for follow up and reaching out underserved target groups.

RECOMMENDATION 5: PRIORITISE FUNDING FOR COLD CHAIN AND LOGISTICS

An effective logistics system and a well-maintained cold chain are essential for safe and effective immunization service delivery. An improperly functioning cold chain can lead to wasted vaccines, missed opportunities to immunize due to lack of vaccines, and children receiving vaccines that do not protect them as intended or that actually make them sick. Outdated and broken cold chain equipment was often cited as major problems negatively affecting routine immunization efforts. Additional problems include a lack of technically trained staff, inadequate financing for procuring new equipment, and transporting technicians and/or broken equipment.

BiH is advised to continue periodic assessment of cold chain equipment needs and replace broken equipment not worth repairing. PHIs should be charged with regularly inspecting the cold chain equipment, planning and monitoring and provision of preventive, and scheduling corrective maintenance and/or repair services. Technicians will need considerable training to be able to correctly repair defective cold chain equipment. As BiH experiences a scarcity of trained technicians, an alternative option could be to contract out maintenance services. Financing for cold chain and logistics must also be given priority.

RECOMMENDATION 6: DEVELOP AND IMPLEMENT STATE LEVEL COMPREHENSIVE AND EFFECTIVE PUBLIC COMMUNICATION STRATEGY

Over the past decade, BiH has been troubled by the rise of a strong anti-vaccine sentiment. Wide-ranging in origin, motive, source, and specific objectives, the AVC has succeeded in negatively influencing the vaccination decisions of parents and health workers.

Focused strategies need to be developed to tactically address and counter, diffuse or mitigate AVC impact. Therefore governments, international agencies and other partners – in particular the medical community – need to combine forces to identify the source and arguments of these influences, map the extent to which they control negative decisions, develop more effective communication strategies, and ultimately reverse this counterproductive trend.

As social media continuously evolves, it can be expected that the ways the anti-vaccination advocates interact in social media will constantly change in terms of channels and tactics and continue influencing population. On-going monitoring of social media should also be conducted.

RECOMMENDATION 7: DEVELOP AND IMPLEMENT STRATEGY FOR HARD TO REACH POPULATION

Further efforts should be made to provide services in hard-to-reach communities, restore trust between minorities and health providers and adapt communications to achieve this. Immunization of migrant children has to be a priority for both entities and the BD through a collaborative and innovative approach.

6.2 RECOMMENDATIONS TO GAVI

RECOMMENDATION 1: ENHANCE COUNTRY COORDINATION MECHANISMS

The ICC, the principal coordination mechanism for GAVI immunization investments, are functioning well in relation to information sharing and proposal application processes, but less well in areas of evaluation, strategic gap analysis. The coordination mechanism in country is indicative of effective partnering amongst all immunization donors and stakeholders. However, we understand this approach is less effective for health system strengthening activities.

In an era of more pluralistic and complex health systems, such as in BiH, it will be increasingly important for immunization planners to link to a wider coordination system that is inclusive of the health sector, regulatory authorities, civil society, and private sector interests. Managing through systems, rather than being over-reliant on committees, may broaden participation in implementation and, in doing so, expand the reach of immunization and maternal and child health care services in GAVI eligible countries.

RECOMMENDATION 2: IMPROVE MONITORING AND EVALUATION DURING AND AFTER GAVI SUPPORT

GAVI's programme processes have improved over time and have been considered favourably in comparison to the Global Fund's. The main thing that set GAVI apart from other donors, is the level of 'country ownership' it provides. However, areas of weakness were identified with regard to: (i) the effectiveness of GAVI communications/feedback with countries; and (ii) its approach to capturing and proactively monitoring quality of country level immunization data.

RECOMMENDATION 2.1: Shift away from reliance on coverage and population data and consider alternative forms of application and performance requirements.

A country's application for GAVI support for new and under-used vaccines is based on immunization coverage data, expressed as a percentage of the population reached. These percentages are used to determine the kind of support they receive. The BiH evaluation revealed serious problems in the reliability of basic immunization coverage data, either because of inaccurate population estimates, overzealous immunization reporting, or simply possible misclassification arising from immunizations schedules. Furthermore, reliance on immunization coverage data in high coverage countries, like BiH, without focus on improving equity or consistency in coverage could be misleading and further marginalize underserved groups.

GAVI is advised to amend its application process in one of two ways, either by supporting improvements in the quality of immunization performance reporting, census or demographic health surveys, or by altering the nature of its baseline and progress assessments. GAVI should shift away from its reliance on coverage and population data and consider alternative forms of application and performance requirements as well as consider additional and/or different measures of immunization performance in higher coverage countries – such as improving equity or coverage consistency.

RECOMMENDATION 2.2: Enforce the utilization of regular Data Quality Audit practice

Whilst countries, such as BiH, may not apply to GAVI ISS support and are not accountable to carry out independent data quality audits, GAVI may consider the introduction of mandatory Data Quality Audit requirement to timely identify weaknesses in the reporting system and advise and assist countries to plan remedial measures for improving monitoring and evaluation (M&E) systems particularly during GAVI support.

RECOMMENDATION 2.3: Establish country level monitoring system and procedures to respond to country-level problems quickly

The evaluation revealed cases when the IRC recommended the country to react on weaknesses identified as well as include reporting of missing financial and performance indicators in the next year APRs. GAVI should consider establishing a process for actively following up on information reported in the APRs as part of routine monitoring procedures. Timely follow-up on incorrect or inconsistent expenditure and coverage data is strongly encouraged to promote vigilance in data quality. The APRs sometimes report specific problems, but there is no mechanism for GAVI follow-up. GAVI should establish a country level monitoring system, documenting all problems identified (including those highlighted by

the IRC), tracking country responses and resolution, which could be shared and updated regularly with the country partners.

GAVI should establish procedures to respond to country-level problems quickly, drawing on support from all GAVI partners in country and at regional level. While GAVI has a procedure for rewarding high performers, it does not currently have any mechanism to support underperforming countries. Options to consider include providing direct technical assistance to underperforming countries (as strong technical inputs seem closely linked with the improved performance), or facilitating reviews of underperforming countries among key partners to map out new strategies and additional inputs from all them. These reviews could result in partners committing to specific response plans in target countries. Moreover, face-to-face monitoring visits have to be institutionalized during and after GAVI support.

RECOMMENDATION 2.4: Harmonize country progress reporting and GAVI's response due dates with country budget cycle.

The BiH evaluation revealed room for improvement in GAVI's response to monitoring of country performance. The country progress reporting and GAVI's response deadlines should be harmonized with the country budgetary cycle to promote timeliness and to allow countries to modify their budgets according to GAVI's decision on next year funding.

RECOMMENDATION 3: INCREASE THE PREDICTABILITY AND SUSTAINABILITY OF LONG-TERM FINANCING FOR THE NATIONAL IMMUNISATION PROGRAMME

One of GAVI's key value added as a global financing mechanism lies in its ability to provide increasing amounts of funding to support national immunization programme, in a manner that is both, **predictable**- so as to allow countries to plan for their immunization programmes and support the efficient procurement of vaccines, and **sustainable** – so that countries can continue to meet the expenditure needs for the provision of immunization services to their population. BiH evaluation demonstrated that GAVI has overall been successful in increasing the predictability of funding for national immunization programmes, but supporting sustainability of its financing has been an area of weaker performance, particularly due to the political, economic and health system and health market challenges faced by BiH.

At present the situation in BiH is increasingly contentious, as the country faces a double challenge in affording vaccines. BiH has no access to international assistance to buy vaccines, but at the same time entities have to pay significantly higher prices than GAVI countries for vaccines, as a result of industry's practice. Pharmaceutical companies see BiH as a non-lucrative market and do not offer lower prices, similar to what they provide to GAVI eligible countries. There is a growing concern that BiH, which is slightly above GAVI eligibility threshold, may not be able to afford new vaccines in future, or continue to divert funds from other health programs, thus ensuring availability of the vaccines at the expense of other immunization expenditure.

The case of BiH can possibly serve as a model example for GAVI graduating countries. Achievement of "graduated country" status may not ensure financial sustainability of immunization programmes in the middle-income countries. In order to increase predictability and sustainability of the immunization programmes in these countries GAVI is

advised to institutionalize long-term graduation-planning exercise which addresses vaccine procurement policies and practices, market intelligence (forecasted prices, expected entry of new suppliers and vaccine products, etc.), national regulatory capacity, and immunization technical advisory bodies and their effective functioning. Furthermore, GAVI should consider the elaboration of pooled procurement mechanism for the graduated countries. In doing so, GAVI can learn from PAHO's tiered pricing Revolving Fund experience, which allows graduated countries to procure vaccines at the middle market price after graduation. Pooled procurement mechanism will increase country bargaining power vis-a-vis pharmaceutical firms and suppliers.

RECOMMENDATION 4: ASSIST COUNTRIES TO MAKE EFFICIENT PROCUREMENT CHOICES

Weak capacity of public procurement system constrains the sustainability of the immunization programmes. The predictability of funding for vaccine procurement only is not sufficient to ensure sustainability, rather focus on efficient procurement should also be given due attention. While strengthening public procurement system is beyond GAVI's responsibilities, procurement issues should be considered as a key priority and addressed in partnership with other donors/partners working on public administration reform. Countries can be advised to apply for WHO assistance that offers independent assessments of current procurement procedures or of a country's preparedness to conduct self-procurement; assistance to achieve identified improvements following an assessment; and occasional regional training sessions and workshops to assist in developing vaccine procurement action plans specific to each country's needs.

The assessment of public procurement system and actions directed towards enhancement of procurement system capacity should be adequately reflected in FSPs and implementation closely monitored during GAVI support.

One measure that would help is advising these countries to procure from UNICEF SD or proceed with regional pooled procurement options when applicable.

RECOMMENDATION 5: JOIN FORCES WITH PARTNERS AND OTHER DONORS FOR HEALTH SYSTEM STRENGTHENING

Recognizing that achieving immunization coverage is dependent upon strong service systems, GAVI took the first steps to widen GAVI support to health system strengthening (HSS) in early 2005. In view of financial and technical resource constrains revealed by the GAVI HSS evaluation in 2009[75], GAVI is advised to join forces with the partners and other donors and increase and deepen focus on health system strengthening aspects, whether this be for health sector coordination, procurement supply management, immunization information system strengthening and/or for human resources development.

[75] GAVI Health System Strengthening Support Evaluation, HLSP, 2009

ANNEXES

ANNEX 1: LIST OF DOCUMENTS REVIEWED

#	Document Name	Year
1	Evaluation of GAVI's Injection Safety Support	2009
2	GAVI Alliance evaluation of IRC (HLSP)	2010
3	Second GAVI Evaluation Report	2010
4	GAVI Alliance second evaluation S43-Evaluation methodology	2010
5	GAVI Alliance Board Meeting Co-financing Policy Revision	2010
6	GAVI Alliance Revised Co-financing Policy	2010
7	GAVI Alliance M&E framework and strategy	2010
8	GAVI Alliance Strategy 2011-2015 and Business Plan	2010
9	GAVI Alliance Evaluation Policy	2012
10	GAVI Alliance Board meeting Country Program Update	2013
11	Evaluation of GAVI China Hepatitis B Vaccination Program	2012
12	Health in Transition, BiH, WHO Observatory	2002
13	MICS3 Final Report, BiH, UNICEF	2006
14	MICS4 Final Report, BiH, UNICEF	2011
15	MICS Roma Final Report, BiH, UNICEF	2012
16	BiH Injection Safety Assessment report 2005	2005
17	BiH Multi-year Strategic Plan for Immunization 2002-2006	2002
18	BiH Plan of action for HepB introduction 2002-2006	2002
19	BIH Strategic Plan Hib introduction	2005
20	BiH National Policy Injection Safety	2005
21	BiH, Financial Sustainability Plan	2005
22	FSP Costing, Financing and Gap Analysis Tool	2005
23	BiH National Plan of Action Immunization Safety 2006-2010	2006
24	Clarification note on HibRAT	2005
25	Proposal HepB and Injection Safety, BiH	2000
26	BiH Proposal Hib and INS 2005	2005
27	BIH Proposal Hib 2006	2006
28	Letter of Resubmission 2002 (on HepB and INS proposal)	2002
29	GAVI decision letter	2001
30	GAVI Decision Letter	2001
31	GAVI Decision Letter	2004
32	GAVI Decision Letter (on approval INS proposal 2005)	2005
33	GAVI Decision Letter 2006 (on Hib approval)	2006
34	GAVI Decision Letter 2007 (on 2006 report)	2007
35	GAVI Decision Letter 2008 (on 2007 report)	2008
36	GAVI Decision Letter 2009 (on 2008 report)	2009
37	GAVI Decision Letter 2010 (on 2009 report)	2010
38	GAVI Decision Letter	2011
39	BiH Annual Progress Report	2002
40	BiH Annual Progress Report	2003

#	Document Name	Year
41	BiH Annual Progress Report	2004
42	BiH Annual Progress Report	2005
43	BiH, Annual Progress Report	2006
44	BiH, Annual Progress Report	2007
45	BiH, Annual Progress Report	2008
46	BiH, Annual Progress Report	2009
47	BiH, Annual Progress Report	2010
48	BiH, Annual Progress Report	2011
49	GAVI IRC Report 2004 (on 2003)	2004
50	GAVI IRC Report 2005 (on 2004)	2005
51	GAVI IRC Report 2006 (on 2005)	2006
52	GAVI IRC comment 2006 (on 2006 proposal)	2006
53	GAVI IRC Report 2007 (on 2006)	2007
54	GAVI IRC Report 2009 (on 2008)	2009
55	GAVI IRC Report 2010 (on 2009)	2010
56	GAVI IRC Report	2011
57	ICC Minutes Sept 2004	2004
58	ICC Minutes Nov 2004	2004
59	ICC Minutes Jan 2005	2005
60	ICC Minutes Aug-Sept 2005	2005
61	ICC Minutes Apr-Jun 2006	2006
62	ICC Minutes Sept 2006	2006
63	ICC work plan 2005	2005
64	WHO advice Hib introduction, 2005	2005
65	BiH Response to GAVI for Hib Sept 2006	2006
66	FBiH cold store Sept 2006	2006
67	BiH IRC Report 2008 (on 2007)	2008
68	BiH commitment and disbursement, inception Report	2013
69	BiH Public Expenditure Review, World Bank	2012
70	BiH EVM report	2012
71	BiH Post Introduction Evaluation of New Vaccines	2009
72	BiH Social & Health Needs Families & Children UNICEF	2012
73	BiH Public Procurement Law	2004
74	WHO BiH country cooperation strategy at glance	2013
75	Constitution BiH	
76	Constitution FBiH	
77	Constitution RS	
78	FBiH Immunization Decree provisions	2013
79	FBiH PHI Health Report	2012
80	FBiH Medical Waste Management Decree	2008
81	RS Medical Waste Management Decree	2010
82	RS Draft Action plan for Improvement Immunization Communication	2012
83	RS Analysis of Population health	2011

ANNEX 2: LIST OF PEOPLE MET

#	NAME	INSTITUTION	POSITION	ENTITY
1	Draženka Malićbegovic	MoCA, Department of Health	Assistant Minister, Department of Health	BiH
2	Snježana Brčkalo	MoCA, Department of Health	Senior Expert Associate for projects	BiH
3	Selena Bajraktarević	UNICEF	Health Officer, Former Member of ICC	BiH
4	Haris Hajrulahović	WHO	Head of Country Office, Former Member of ICC	BiH
5	Doina Bologna	UNFPA	Representative forBiH, Country Director for Kosovo, FYROM and Serbia	BiH
6	Fatima Čengić	UNFPA	Reproductive Health Program Analyst	BiH
7	Aida Kurtović	Partnerships in Health	Executive Director, Partnerships in Health, GFATM Board Member, Eastern Europe and Central Asia Constituency	BiH
8	Biljana Tubić	Agency for Medicines and Medical Devices, Banja Luka	Assistant Director for Sector of Drugs	BiH
9	Tanja Savanović	Agency for Medicines and Medical Devices, Banja Luka	Secretary, procurement specialist	BiH
10	Ranko Tošić	Solidarity Fund, FBiH		FBiH
11	Aida Pilav	FMoH	Assistant Minister, Head of sector for Public Health, monitoring and evaluation	FBiH
12	Zineta Mulaosmanović	Dom Zdravlja, Canton Sarajevo	Head Nurse of the working unit of Ilidza Dom Szravlja	FBiH
13	Zulfo Godinjak	Gynecology & Obstetrics clinic, Sarajevo	Head of the clinic, Professor of Medical University	FBiH
14	Goran Pavić	Posavski Cantonal Public Health Institute	Epidemiologist, PHI former director	FBiH
15	Berislav Živković	Posavski Cantonal Ministy of Health, Labor and Social Affairs	Assistant Minister	FBiH
16	Ruzica Vukić	Posavski Cantonal Hospital	Manager	FBiH
17	Milka Tunjić	Posavski Cantonal Hospital	Paediatrician	FBiH
18	Mirjana Kotorić	Dom Zdravlja, Domaljevac	Immunization nurse	FBiH
19	Ljiljana Leovac	Dom Zdravlja, Orašje	Manager	FBiH
20	Taiba Nurkić	Dom Zdravlja, Orašje	Immunization nurse	FBiH
21	Lejla Isić	Dom Zdravlja, Orašje	Immunization nurse	FBiH
22	Diana Mamić	PHI - Canton 10 (Livno)	Manager	FBiH
23	Tomislav Perković	PHI - Canton 10 (Livno)	Sanitary engineer in charge of immunization	FBiH
24	Stipe Pavić	HIF Canton 10 (Livno)	Assistant manager	FBiH
25	Dominika Šiško	Dom Zdravlja Livno	Paediatrician	FBiH

#	NAME	INSTITUTION	POSITION	ENTITY
26	Blanka Sučić	Dom Zdravlja Livno	Immunization nurse	FBiH
27	Vesna Konta	Dom Zdravlja Livno	Immunization nurse	FBiH
28	Vesna Brnas	Dom Zdravlja Tomislavgrad	Paediatrician	FBiH
29	Vahida Baković	Dom Zdravlja Tomislavgrad	Immunization nurse	FBiH
30	Andja Krišto	Dom Zdravlja Tomislavgrad	Immunization nurse	FBiH
31	Jelena Ravlija	PHI FBiH	Chief epidemiologist	FBiH
32	Dr Zlatko Vučina	PHI FBiH	Chief of resource centre	FBiH
33	Dr Zlatko Čardaklija	MoH FBiH	Minister counsellor	FBiH
34	Jadranka Mihić Ruvić	EU delegation in BiH	Programme Manager for Education and Health at EU Delegation to BiH	FBiH
35	Zaim Jatić	Dom zdravlja Sarajevo	Head of family medicine department	FBiH
36	Dženana Tanović	Dom zdravlja Sarajevo	General Manager	FBiH
37	Jesenko Osmanagić	NGO Foundation for creative developement	Director	FBiH
38	Alen Šeranić	MOH, Banja Luka	Head of immunization program	RS
39	Brankica Babić	HIF, Banja Luka		RS
40	Sanja Stanić	Victoria NGO, Banja Luka	Director of NGO	RS
41	Slobodan Stanić	PHI, Banja Luka	Director	RS
42	Janja Bojanić	PHI, Banja Luka	Assistant director for medical works	RS
43	Ljubica Jandrić	PHI, Banja Luka	Epidemiologist	RS
44	Jela Aćimović	PHI, Banja Luka	Head of Epidemiology Department	RS
45	Mitar Tešanović	PHI, Banja Luka	Epidemiologist	RS
46	Dobroslav Ćuk	Regional PHI, Trebinje	Director	RS
47	Julija Kralj	Regional PHI, Trebinje	Epidemiologist	RS
48	Čalija Radivoje	Regional PHI, Trebinje	Assistant director	RS
49	Snežana Škrivan	Regional PHI Trebinje	Nurse	RS
50	Brenjo Nada	Hygienic Epidemiologic Services, Trebinje	Head nurse	RS
51	Snežana Butulija	Hygienic Epidemiologic Services, Trebinje	Higher sanitary technician	RS
52	Dejan Barač	Hygienic Epidemiologic Services, Trebinje	Sanitary technician	RS
53	Sladjana Artenović	Regional PHI, Foča	Director	RS
54	Dragomirka Komlenović	Regional PHI, Foča	Medical Technician working on immunization	RS
55	Jelena Firesku	University Hospital, Foča, Department for Tropical and infectious diseases	Health of department, Infectious diseases specialists	RS
56	Dr. Vladimir Čančar	University Hospital, Foča, Department of Obstetrics and Gynaecology	Ob/Gyn doctor	RS

#	NAME	INSTITUTION	POSITION	ENTITY
57	Gordana Kovač	University Hospital, Foča, Department of Obstetrics and Gynaecology	Midwife	RS
58	Radmila Kapetanov	Dom Zdravlja, Foča	Paediatric consultant	RS
59	Ranka Perović	Dom Zdravlja, Foča	Medical Technician/Nurse	RS
60	Vesna Golijanin	Dom Zdravlja, Foča	Assistant Director, Epidemiologist, Head of HES	RS
61	Gordana Kovač	Dom Zdravlja, Foča	Medical Technician/Nurse	RS
62	Hajrudin Jusufović	Department of finance District of Brčko	Counsellor	BD
63	Mirjana Kuzmanović	Department of Health of District of Brčko	Manager	BD
64	Zorka Mijatović	Department of Health of District of Brčko	Head Nurse	BD
65	Borislav Đulabić	Health center Brčko	Manager of Primary health care	BD

ANNEX 3: IMMUNIZATION SCHEDULES

Routine EPI vaccination schedule as of 2014

AGE	TYPE OF VACCINE		
	FBiH	RS (Since 01.05.2013)	BD
First 24 hours	HepB-1, BCG	HepB-1, BCG	BCG+ HepB 1
1st month	HepB-2	HepB-2	HepB 2
2nd month	DTPa-IPV-1, Hib-1	DTPa-IPV-Hib-1	DTPw, OPV1-6, Hib 1
4th month	DTPa-IPV-2, Hib-2	DTPa,-IPV-Hib-2	DTPw, OPV1-6, Hib2
6th month	DTPa-IPV-3, HepB-3	DTPa-IPV-3, HepB-3	Hep B, DTPw, OPV1-6, Hib 3
12th month	MMR-1	MMR-1	MMR
18th month	OPV-1, Hib-3	DTPa,-IPV-rev, Hib-3	Hib, OPV rev.
5th year	DTPa-IPV rev	OPV, MMR-2, dT	DTPw, OPV1-6,
6th year	MMR-2	OPV, dT	MMR
14th year	dT, OPV-3	TT	dT, DTaP, OPV rev.
18th year	TT	HepB-1, BCG	BCG+ Hep 1

ANNEX 4: EVALUATION FRAMEWORK

ID	CRITERION/ QUESTIONS	SPECIFIC QUESTIONS/ INSTRUCTIONS	PERFORMANCE	PLAN	IMPL	RESULTS	METHODS OF DATA COLLECTION			
							DESK REVIEW	II	FGD	SITE VISIT
R	**RELEVANCE**									
R0	What were the main challenges of the health care system and main priorities that guided the planning for GAVI's support?	What was the main population health status, immunization coverage concerns? What were main immunization system challenges? Weaknesses of organizational structure? Lack of vaccines and/or cold chain equipment? Poor stock management and logistics? Problems in procurement? Lack and/or weak human resource capacity? Limited financial resources? Low level of population awareness and/or trust in immunization? Etc.		*			BiH Government and health strategy documents, GAVI proposals,	Key informants from Top-Level interview group; Key informants from Facts Finding/data interview group		
R1	To what extent were the design and objectives of GAVI's support to BiH relevant to BiH's needs and priorities as well as to GAVI's strategic priorities?	**R1.1** Assess availability of evidence for targeted support	GAVI support responded to the epidemiological needs of the country	*			BiH Government and health strategy documents	Key informants from Top-Level interview group; Key informants from Facts Finding/data interview group		

		R1.2 Review the BiH health strategy documents whether the GAVI support is aligned to the objective and needs of the country	The design and objectives of GAVI's support to BiH is in line with GAVI's strategic priorities	*			GAVI proposals, GAVI graduation policy, GAVI support strategy	Key informants from Top-Level interview group;		
R2	To what extent did BiH prepare and plan for the transition away from GAVI support?	**R2.1** Assess the proposal and plans whether they contain transition activities	The BiH prepared and the planned activities for easy transition from GAVI support	*			Country proposals, GAVI management letters	Key informants from Top-Level interview group;		
		R2.2 Assess institutional arrangement (governance structure) set by the country for planning and implementation of GAVI support	Institutional arrangements put in place facilitates participatory decision making, ensures representation of all respective competent entities and has decision making power	*			ICC charter, ICC membership, ICC Minutes of the meetings	Key informants from Top-Level interview group;		
		R2.3 Was the planning participatory and evidence based? Assess the decision making and planning process	The planning/decision making process ensures wide participation of all stakeholders and coordination. Available quantitative and qualitative data was used.	*			ICC Minutes of the meetings, GAVI proposals	Key informants from Top-Level interview group;		
		R2.4 To what extent were the processes or support put in place by GAVI to address both financial and programmatic sustainability?	Process and initial guidance is provided by GAVI to BiH	*			ICC Minutes of the meetings, GAVI proposals	Key informants from Top-Level interview group;		

R3	To what extend the government prepared plan/proposal was evidence based and comprehensive?	Assess the final plans/proposals	The plans/proposals contain sound justification of needs and systematic weaknesses and explains how the plan will contribute towards meeting the priorities, fill existing gaps. The Plan includes activities directed towards programmatic and financial sustainability	*			Country proposals, GAVI management letters	Key informants from Top-Level interview group; Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers, Beneficiaries	*
R4	To what extend potential risks were identified and mitigation measures planned? The role of GAVI and other institutions in this process	Assess risks identified and response planned Allows construction of the network map to understand who was engaged in the transition process and when – and also how responsibilities shifted	Risks are identified and relevant mitigation measures planned	*	*		Country proposals, GAVI management letters	Key informants from Top-Level interview group; Key Informants from Subject - specific Interview group		
EF	**EFFECTIVENESS**									
EF1	Was the implementation plan detailed enough to ensure effective implementation of programme?	**EF1.1** Assess availability of annual implementation plans, degree of details and implementation	Implementation plans were developed with adequate level of details (activity, timeline, responsible, clear output) and implemented as planned	*	*		Country proposals, Programme Implementation Plans, Progress Reports, GAVI monitoring Reports	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview		

								group		
		EF1.2 Assess whether the implementation plans were communicated to respective stakeholders	Implementation plans were communicated to respective stakeholders		*		Country proposals, Programme Implementation Plans, Progress Reports,	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers	
EF 2	What were the main programmatic arrangements put in place to ensure effective implementation?	**EF 2.1** Assess programmatic arrangements at the planning and implementation phases:	Programmatic arrangements put in place ensures integration of GAVI support into the general health system	*	*		Progress Reports	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers, Beneficiaries	
		EF 2.2 Programme Governance	Effective governance structure in place with adequate staffing levels, competent and motivated staff; regularly monitors implementation and takes corrective steps when needed		*	*	Annual Immunization Programs, MOH organization structures, functional responsibilities of respective institutions/departments, units etc.	Key Informants from Subject - specific Interview group	Service Providers	*

		EF 2.3 Enabling legal environment	Adequate legislative documents issued and endorsed	*		*	Legal documents	Key Informants from Subject - specific Interview group		
		EF 2.4 Service Organization	Organization of service delivery clearly outlined, ensures equal access to services and is fully operational	*	*	*	Documents describing service organization and distribution	Key Informants from Subject - specific Interview group	Service Providers, Beneficiaries	*
		EF 2.5 Competent health workforce	Health workforce capacity development needs and arrangements clearly outlined in the plan and implemented accordingly	*	*	*	Implementation Plans; Progress Reports	Key Informants from Subject - specific Interview group	Service providers	
		EF 2.6 Vaccines, equipment, consumables	Sound procurement, supply and distribution arrangements established. Costing exercise conducted.	*	*	*	Procurement Plans; Progress Reports	Key Informants from Subject - specific Interview group; Key informants from Facts Finding/data interview group;	Service providers	*
		EF 2.7 Information System	Information system to track implementation as well as surveillance data fully operational and ensures data quality		*	*				*

EF 3	What were the main Financial arrangements put in place to ensure effective funding?	Assess availability and adequacy of funding (internal/external) and disbursements as well as BiH efforts for mobilization of additional funding? Did GAVI helped to negotiate better prices for BiH?	Short, medium and long term budgets (with sources and financial gaps) developed and endorsed	*	*		Medium Term Expenditure Framework; cMYP Annual Health Budgets and Immunization programme budgets and budget execution reports	Key informants from Top-Level interview group;		
			Mobilization strategy for additional funding developed and applied in practice				Progress Reports;	Key Informants from Subject - specific Interview group; Key informants from Facts Finding/data interview group;		
			Disbursements were in line with plan	*	*		Budget execution and Disbursement reports			
EF 4	Where the implementation plans coordinated?	Assess the level of coordination during planning and implementation of the GAVI support	Implementation plans were developed and executed in a coordinated manner	*	*		Minutes of ICC and HSSC minutes; Donor coordination meeting minutes; etc.	Key informants from Top-Level interview group ;Key Informants from Subject - specific Interview group; Key informants from Facts Finding/data interview group;	Service Providers	

EF 5	What were main challenges identified during the implementation and how were they addressed by the BiH and GAVI?	Assess effectiveness of monitoring implementation phase from country and GAVI, outline challenges identified by both parties and ways addressed	Regular monitoring of the implementation evident from BiH and GAVI, challenges/bottleneck identified and mitigation measures proposed and implemented		*		Minutes of ICC and HSSC minutes; Progress Reports; GAVI monitoring reports	Key informants from Top-Level interview group; Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers	
		Assess to what extend GAVI supported these measures	GAVI demonstrates commitment and support to mitigation measures through advocacy, technical support, additional funding etc.		*					
EF6	Was the sustainability plan developed, approved and endorsed?	Assess availability of the sustainability plan(s), whether it is developed in participatory manner and approved before GAVI's support	Sustainability Plan developed and endorsed	*	*		Minutes of ICC and HSSC minutes; Progress Reports; GAVI monitoring reports	Key informants from Top-Level interview group;		
		Has the sustainability plan been revised according to the newly emerging challenges?	Sustainability plan is periodically reviewed and addresses newly emerged challenges.	*	*					
EF 7	To what extend were stakeholders informed and cognizant of the implications of GAVI's time limited support?	Assess level of stakeholder awareness	Stakeholders were informed and cognizant of the implications of GAVI's time-limited support	*	*			Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group		

EF 8	What activities took place sustainability plan, if one was not developed?	Assess activities implemented in the absence of sustainability plan	Activities implemented in the absence of the sustainability plan were effective to ensure sustainability of GAVI's support		*		Annual Immunization Plans; Progress Reports;	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group		
		How were these activities coordinated?					Annual Immunization Plans; Progress Reports;	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group		
EF 9	What have been consequences of the absence of sustainability plan?	Assess negative and/or positive consequences of the absence of sustainability plan on the implementation effectiveness and efficiency as well as continuation of activities after GAVI's support			*	*		Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers, Beneficiaries	*
EFF	**EFFICIENCY**									

EFF 1	Was the project's actual expenditure in line with expectations and plans?	Assess the level of budget expenditure /disbursements against budget	Project's actual expenditure is in line with expectations and plans		*		Annual budget plans as per proposal; Annual Immunization Programme and budget; Budget execution reports; Progress Reports; cMYP	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group		
EFF 2	How the programmatic and financial arrangements put in place ensured efficient use of resources?	Assess efficiency of resource utilization	Resources were efficiently used		*		Annual budget plans as per proposal; Annual Immunization Programme and budget; Budget execution reports; Progress Reports; Development Partner reports on expenditures for same type of input	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers, Beneficiaries	
EFF 3	The degree to which the alternative procurement arrangements put in place ensures adequate prices for vaccines, equipment and consumables compared to UNICEF supply division?	Assess procurement arrangements put in place, compare prices of procured vaccines, supplies and goods to UNICEF supply division's prices	Procurement arrangement put in place ensures adequate cost of vaccines and supplies		*		National Procurement Plans and budgets; Progress Reports; Procurement Prices of vaccines and supplies from UNICEF supply division	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group		
IM	**IMPACT**									

IM 1	To what extent has the GAVI supported programmes achieved their objectives?	Assess objectives set in each GAVI support proposal; Collect latest information on the status of targeted indicators and assess the status of the indicator. If the indicator is not met as stated in the Programme please provide explanation of reasons for not meeting targets Identify hindering/enabling factors.	Intended objective and targets are met.			*	Program Proposal; Progress Reports, HMIS and Surveillance data; Other research (MICS, etc.)	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers, Beneficiaries	
IM 2	Could the better results have been achieved with the same or fewer inputs by doing things differently?	Assess whether better results could have been achieved by applying different strategies using same or fewer inputs	The best implementation strategies have been deployed resulting in the balance of inputs and output/outcomes			*	Program Proposal; Progress Reports, HMIS and Surveillance data; Other research (MICS, etc.)	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers,	
IM 3	What are the main factors explaining the achieved results (positive or negative)?	Identify all factors explaining the achieved results (negative or positive)				*	Official and unofficial researches and studies	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group		
		What have been the main intended and unintended positive or negative effects of the time-limited nature of GAVI support and its conclusion?				*				
S	**SUSTAINABILITY**									

S1	To what extend have the relevant activities related to GAVI support, such as delivery of vaccines, injection safety procedures, addressing inequalities, surveillance and monitoring been continued?	Assess and collect sound evidence that new vaccines and injection safety procedures continue to be practiced as well as whether the surveillance system produces quality data.	New vaccines (supported by GAVI) are introduced and continued to be delivered with equal access to all groups of target beneficiaries			*	Legal documents; Program documents, progress reports; NHA data, Household Surveys, Annual Immunization Program	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers	
			Injection safety procedures introduced, practiced, compliance measured regularly and response (when needed) generated			*				
			Surveillance system operates and ensures quality data production			*	Annual Statistical Reports; Immunization coverage data, secondary quantitative data and operational research			
			Immunization and injection safety monitoring system established and operates effectively			*				
S 2	To what extend 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?	Assess: Immunization Coverage, Injection safety compliance rates and degree of the data quality collected by the surveillance system	Immunization coverage gradually increases and more health providers adhere to injection safety procedures. Surveillance system operates and demonstrates data quality (timeliness, accuracy and completeness)			*	Annual Statistical Reports; Immunization coverage data, secondary quantitative data and operational research	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group		
		Assess whether the improvement of Hep B and Hib during the GAVI period are a result of GAVI support?	Improvement of Hep B and Hib during the GAVI period are a result of GAVI support			*	Annual Statistical Reports; Immunization coverage data, secondary	Key informants from Facts Finding/data interview		

		Assess whether the adaptations/improvements /expansions were introduced	Adaptations/improvements/expansions introduced			*	quantitative data and operational research	group; Key Informants from Subject - specific Interview group		
		Explain what adaptations were made to the immunization programme following the conclusion of GAVI's support? What was a possible impact on intended or unintended outcomes (particularly coverage, safety, financial sustainability etc.) of this adaptation? What was the decision making process around these adaptations?	Adaptations having positive impact introduced through participatory and evidence based decision making process		*	*				
S3	To what extend have the systems and structures functioning or developed at the time of GAVI support continues to function effectively?	Solicit sound evidence on the operations of governance	Governance system and structures put in place is fully integrated in the general health system and continuous effective operation demonstrated by evidence based policy and planning, oversight and supervision of compliance with legal and regulatory framework, responsiveness to challenges and needs, etc.			*		Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers	

S4	To what extend the service delivery system continues to provide equal access to target beneficiaries?		Services are continued to be directly and permanently accessible with no undue barriers of cost, language, culture, or geography. Service delivery is designed so that all people in a defined target population are covered; Health services are of high quality, i.e. they are effective, safe, centered on the patient's needs and given in a timely fashion; and Local area health service networks are actively coordinated			*	Service organization structures in each entity; coverage and quality standards; Insurance and state programmes;	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers, Beneficiaries	
S5	To what extend the system continuous to deploy competent and motivated health workforce?		The system is staffed with confident (educated) workforce motivated to deliver high quality services			*		Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers	
S6	To what extend the system ensures uninterrupted supply, storage and distribution of vaccines, equipment and consumables?	Assess:				*				
		To what extend the procurement arrangements put in place continue to operate effectively and efficiently?	Procurement arrangements continue to operate effectively and efficiently by maintaining adequate staffing, compliance with international/local procurement procedures and ensures procurement of immunization materials of high quality at a lower cost and adequate supply levels			*	Procurement documents	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group		

		To what extend the logistical arrangements put in place operates effectively and efficiently?	Systems for storage and distribution operates effectively and efficiently demonstrated by adequate storage and timely distribution of vaccines and supplies in required quantities			*		Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers	*
		To what extend the waste management system operates effectively and efficiently?	The waste management system put in place continues to operate effectively			*	Legal documents; operational procedures; standards; norms; supervision reports	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group		*
		To what extend there is a procurement and logistics oversight that continues to function effectively and efficiently?	The procurement and logistics oversight continues to regularly monitor compliance and provides support when needed			*	Supervision Reports	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers	

S7	To what extend the system put in place ensures adequate information of policy makers, partners, implementers and population?	To what extend the information system put in place operates effectively?	The information system is fully operational and ensures quality data collection measured by data timeliness, completeness and accuracy			*	Information communication strategy; Knowledge Surveys; Assessment reports of the HIS; Policy documents; Partner cooperation agreements and progress reports	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group	Service Providers, Beneficiaries	*
		To what extend information collected by the system is analyzed and utilized?	Information collected through HIS and surveillance system is analyzed and utilized for evidence based decision making and planning			*				
		How has community acceptability of routine vaccination changed – media events of the transition process?	The public information campaigns are regularly conducted and adequate media coverage is achieved to ensure improved community acceptance of the vaccination.							
		What is a degree of partner technical support to ensure sustainability?				*				
		To what extend the general public is aware of the services and its benefits?	There is a demonstration of general public awareness and knowledge of the services and benefits.			*				
S8	To what extent BiH continues to ensure financial sustainability of GAVI support after the years?	Collect information on the source or sources of funding used to procure vaccines, syringes and safety boxes in each year after GAVI support ended as well as to finance operation of the immunization programs	BiH demonstrates viable financial sustainability of GAVI support			*	National immunization programme Manager reports; MTEF, Annual Immunization Reports, cMYP	Key informants from Facts Finding/data interview group; Key Informants from Subject - specific Interview group		
S9	What are the ongoing challenges BiH faces for sustainability of its immunization programme? What				*			Key informants from Facts Finding/data interview		

	are the facilitating factors?							group; Key Informants from Subject - specific Interview group		

ANNEX 6: INTERVIEW GUIDE

Even though in-depth interviews are flexible, they require rigorous preparation. Based on the Evaluation criteria, the Evaluation Team will decide which questions (provided in the Evaluation Framework) are most appropriate for the subject respondent and list them as a checklist. The given checklist/guide will be used during the interview. Sample guides for each key informant group is provided in the Figure 8 and Figure 9 below:

INDEPTH INTERVIEW CHECKLIST FOR TOP-LEVEL INTERVIEW GROUP

Figure 8: indepth interview Checklist for Top-level interview Group

Relevance	R0; R1; R2; R4
Effectiveness	EF3; EF4; EF5; EF6
Efficiency	EFF1.1;
Impact/Result	IM1;
Sustainability	S9

Introduction prompt: Thank you for agreeing to speak with us today. As we have mentioned to you when we set up this interview, we have been contracted to carry out the final evaluation of GAVI's support to BiH. GAVI support to BiH started in 2002, when GAVI provided a Vaccine Introduction Grant in advance of GAVI's support for the Hepatitis B monovalent vaccine starting in 2003. GAVI then began supporting the monovalent Hib lyophilized vaccine provision with the first introduction grant given to Republika Srpska in 2008. And final GAVI supported vaccines were shipped to BiH in 2011. We will use this opportunity to ask you about your role related to GAVI's support to BiH, as well as to BiH's [FBiH/RS/BD], transition from GAVI support.

1. Could you please share what your role and position was during the years of GAVI support to BiH [FBiH/RS/BD],?

GAVI support pre-transition

2. How did GAVI support respond to the needs of the [FBiH/RS/BD]??
    a. How was the decision for GAVI support to BiH [FBiH/RS/BD] made?
    b. What evidence was used?
    c. How did GAVI adapt their support to the unique health system structures that exist in these three areas?

3. How had GAVI supported programmes achieved their objectives before BiH crossed the GNI threshold and became ineligible for GAVI support?
    a. Did all three entities [FBiH/RS/BD] cross the threshold/become ineligible for GAVI support at the same time? If not, what discussions took place at the entity and national levels?
    b. What could have been improved in the implementation of GAVI support to ensure that impact objectives were met?

The transition from GAVI support

Initial announcement

4. What was your role and position during BiH transition in the [FBiH/RS/BD] from GAVI support?

5. Were you aware of GAVI eligibility criteria and when the BiH became ineligible?

    a. When did you first hear about the fact that BiH was no longer eligible for?
        i. Who did you hear this from?
        ii. What was your initial reaction?
        iii. How do you think your counterparts in [FBiH/RS/BD] reacted to this news?

    b. At that time, how did you and others think that becoming ineligible for GAVI support would affect service delivery for immunizations and the health system of [FBiH/RS/BD] more broadly? How was ineligibility for GAVI support perceived by other donors in the context of phasing out of other donors (the Global Fund) from the country?

BiH planning for transition process

6. Thinking about the transition process, what did [FBiH/RS/BD] do to prepare and plan for the end of GAVI support?
    a. At which levels did preparations occur: Preparations of respondent and their team; variations in preparations between the three regions; preparations at lower levels?
        i. What mechanisms and institutional arrangements were put in place to manage the transition process?
    b. What were the main concerns or risks that were identified during this planning process? What aspects of the transition process was there least concern about?
        i. What type of evidence was used to determine these risks and opportunities?
        ii. Which individuals or groups were in charge of identifying this evidence?
        iii. Which individuals or groups were in charge of making the final decisions about the plans?
    c. Which other actors were important in the transition process? (External/internal actors)
        i. What was GAVI's role in the planning and preparation of the transition plans?
        ii. What other actors (e.g. UNICEF, other partners) were involved and what was their role in the planning process?
        iii. (ef1)If none of these actors were involved in the planning process, were these plans communicated with them? If yes, how?
    d. What is your perspective on the effectiveness of the transition process?
        i. How do you think that the preparations matched the risks identified? How were these preparations able to take advantage of existing strengths in the system?
    e. Probe about comparing proposals and plans to respondent perspectives: (opportunity to cross-check what was in the proposals and plans from the document review)

7. How did the government and other actors ensure that sufficient financial resources would be available after the end of GAVI support?
    a. What arrangements were made to ensure raising of sufficient funds?

   i. Probe about: short-term, medium, and long-term budgets?
   ii. What gaps in the budget were the most difficult ones to fill?
   iii. What kind of trade-offs was considered?
   iv. What do you think about the adequacy of these arrangements
   b. Did country carry out financial projections of vaccine costs by funding source? If yes to what extant was it useful?

8. What discussions took place about institutional sustainability?
   a. What do you think about ICC and GAVI-relevant coordination mechanisms?
   b. What should have been their role after transition from GAVI funding?
   c. Should these coordination mechanisms have been sustained?

9. How was the transition process coordinated?
   a. Who was in charge of coordinating GAVI support before the transition process began
   b. How did this coordination change during the transition?

10. What is your perspective about what worked well and what did not work well in this transition planning process? Why?
   a. Probe about challenges identified during implementation of the transition plan and how these were addressed?

Post-GAVI - sustainability and Impact

11. What could have been improved in the process of transitioning away from GAVI support?
   a. How have program objectives been sustained after the completion of GAVI support?
   b. If the indicators have not been met, probe about why.
   c. How do you think that cessation of GAVI support changed the population's perspective/acceptability of routine immunization?

12. What is your perspective on how the systems and structures in [FBiH/RS/BD] function after GAVI support ended?
   a. Probe about service delivery; vaccine availability and logistical management; finances; ownership and accountability; role of external actors (e.g. UNICEF, others); differences among the three regions

13. In the future, how do you think BiH [FBiH/RS/BD] will handle the introduction of new vaccines? Or scale-up of existing programs?
   a. Probe about ownership and accountability
   b. Probe about local capacity to advocate for new vaccine introduction (prepare solid justification based on disease burden analyses, cost-effectiveness analyses)
   c. Probe about how the program has evolved since graduation from GAVI
   d. Across all – probe about differences in the three regions

INDEPTH INTERVIEW CHECKLIST FOR SUBJECT SPECIFIC INTERVIEW GROUP AND FACTS FINDING/DATA INTERVIEW GROUP

Figure 9: indepth interview Checklist for Subject Specific interview Group and Facts finding/data interview Group

Relevance	R3; R4
Effectiveness	EF1; EF2.1; EF 2.2; EF 2.3; EF 2.4; EF 2.5; EF 2.6; EF 2.7; EF 3; EF 4; EF5; EF7; EF8; EF9.
Efficiency	EFF 1; EFF 2; EFF 3.
Impact/Result	IM1; IM2; IM3; IM4; IM5
Sustainability	S1; S2; S3; S4; S5; S6; S7; S8; S9

Introduction prompt: Thank you for agreeing to speak with us today. As we have mentioned to you when we set up this interview, we have been contracted to carry out the final evaluation of GAVI's support to BiH. GAVI support to BiH started in 2002, when GAVI provided a Vaccine Introduction Grant in advance of GAVI's support for the Hepatitis B monovalent vaccine starting in 2003. GAVI then began supporting the monovalent Hib lyophilized vaccine provision with the first introduction grant given to Republika Srpska in 2008. And final GAVI supported vaccines were shipped to BiH in 2011. We will use this opportunity to ask you about your role related to GAVI's support to BiH [FBiH/RS/BD], as well as to BiH's transition from GAVI support, once the country was no longer eligible for this support.

1. To begin with, could you please share what your role and position was during the years of GAVI support to [FBiH/RS/BD]?
2. When did you first hear about the fact that BiH crossed the GNI threshold and became ineligible for GAVI support?
    a. Who did you hear this from and what was your initial reaction?

The transition from GAVI support

Initial announcement

3. What was your role and position during [FBiH/RS/BD] transition from GAVI support?

4. Were you aware of GAVI eligibility criteria and when the BiH became ineligible?
    a. When did you first hear about the fact that BiH was no longer eligible for GAVI support?
        i. Who did you hear this from?
        ii. What was your initial reaction?
        iii. How do you think your counterparts in [FBiH/RS/BD] reacted to this news?

5. At that time, how did you and others think that GAVI graduation would affect service delivery for immunizations and the health system more broadly in [FBiH/RS/BD]

BiH planning for graduation

6. Thinking about the transition process, what did [FBiH/RS/BD] do to prepare and plan for the end of GAVI support?

a. At which levels did preparations occur: Preparations of respondent and their team; variations in preparations between the three regions; preparations at lower levels?
    i. What mechanisms and institutional arrangements were put in place to manage the transition process?
b. What were the main concerns or risks that were identified during this planning process?
    i. What type of evidence was used to determine these risks and opportunities?
c. Which actors were important in the transition process? (External/internal actors)
    i. What was GAVI's role in the planning and preparation of the transition plans and final decisions about the plans?
    ii. What other actors (e.g. UNICEF? Other partners?) Were involved and what was their role in the planning process?
    iii. If none of these actors were involved in the planning process, were these plans communicated with them? If yes, how?
d. What is your perspective on the effectiveness of the transition process?
e. Probe about comparing proposals and plans to respondent perspectives: (opportunity to cross-check what was in the proposals and plans from the document review)

7. How did the government and other actors ensure that sufficient financial resources would be available after the end of GAVI support?
    a. What arrangements were made to ensure rising of sufficient funds?
        i. Probe about: short-term, medium, and long-term budgets/gaps most difficult to fill/adequacy of arrangements?

8. Was a sustainability plan developed? (under sustainability plan we also mean Financial Sustainability Plan, comprehensive Multi Year Plan)
    a. If yes,
        i. Has the FSP been updated since 2005?
        ii. Which stakeholders were involved in this process?
        iii. What is your perspective on how realistic it was and how much buy-in there was for the plan?
    b. If not or plan was not updated for the last 5 years,
        i. What happened in the absence of a (new) sustainability plan? Who was in charge of coordinating?
        ii. Why the plan was not developed/updated? probe for need, local capacity
    c. What were the main advantages/disadvantages of having a plan [or not having a plan]
        i. How did these vary for [FBiH/RS/BD]

9. What were the main programmatic components of the transition plans?
    a. What type of governance structures were put in place?
        a. What happened to the ICC and other GAVI-coordinating structures?
    b. What preparations were made to ensure appropriate organization of service delivery/ adequate workforce/ procurement/ supply/ distribution/ legal framework?

   a. What justifications were used for different schedules in FBiH/RS/BD?
   b. Have roles of financial agencies to fund immunization defined in the legislation?
   c. Have PHC medical personnel responsibilities in immunization been included in the payment contracts?
   d. Do reimbursement schemes of PHC providers consider appropriate incentives for immunization services?
   e. Is cold chain equipment at PHC level included in the PHC standards?
   f. Do appropriate changes been made in the Immunization HIS to allow coverage rate calculation?
c. What kind of changes should have been made that weren't?

10. What financial arrangements were made to ensure efficient use of resources?
    a. As plan was implemented, was the actual expenditure in line with expectations and plans? If not, why not?

11. What alternative procurement arrangements were put in place to ensure most efficient prices for vaccines, equipment, and other consumables?
    a. How does this compare to the period pre-graduation, with the support of UNICEF?

12. From your perspective, what could have been improved in the implementation of this process?

Post-GAVI - sustainability and Impact

13. How have GAVI supported programmes achieved their objectives before funding ended?
    a. How have these objectives been sustained after the completion of GAVI support?

14. What could have been improved in the process of transitioning away from GAVI support?

15. What is your perspective on how the systems and structures in [FBiH/RS/BD] function after GAVI support ended?
    a. Probe about service delivery; vaccine availability and logistical management; safe injection practices and waste management; strategies to reach hard-to-reach population?; finances; ownership and accountability; technical capacity, advocacy activities, role of external actors (e.g. UNICEF, others); differences among [FBiH/RS/BD]
       i. Does existing legislation specify national government allocations to the immunization (e.g. specific budget lines)?
       ii. Have role of sub-national governments in immunization been defined?
    b. Probe about population's perspective/acceptability of routine immunization
    c. Probe role of media in acceptability of immunization

16. In the future, how do you think [FBiH/RS/BD] will handle the introduction of new vaccines? Or scale-up of existing programs?
    a. Probe about ownership and accountability

b. Probe about local capacity to advocate for new vaccine introduction (prepare solid justification based on disease burden analyses, cost-effectiveness analyses)
c. Probe about how the program has evolved since graduation from GAVI
d. Across all – probe about differences in the three regions

INDEPTH INTERVIEW GUIDE WITH IMMUNIZATION FINANCING TEAM MEMBERS

Introduction prompt: Thank you for agreeing to speak with us today. As we have mentioned to you when we set up this interview, we have been contracted to carry out the final evaluation of GAVI's support to BiH. GAVI support to BiH started in 2002, when GAVI provided a Vaccine Introduction Grant in advance of GAVI's support for the Hepatitis B monovalent vaccine starting in 2003. GAVI then began supporting the monovalent Hib lyophilized vaccine provision with the first introduction grant given to Republika Srpska in 2008. And final GAVI supported vaccines were shipped to BiH in 2011. We will use this opportunity to ask you about your role related to GAVI's support to BiH [FBiH/RS/BD], as well as to BiH's transition from GAVI support, once the country was no longer eligible for this support. Specifically, we would like to know about your experience as part of the Immunization Financing and Sustainability Task force

1. Could you please share what your role and position was during the years of GAVI support to [FBiH/RS/BD]?

    a. Any members that were involved in GAVI-related activities?

Current activities

2. How does it engage/work with stakeholders from [FBiH/RS/BD] to ensure adequate financing for vaccination?
3. How does it work with other donors for these purposes?
4. Is there a sustainability plan currently active?

The transition from GAVI support

BiH planning for graduation

5. Thinking about the transition process, what did [FBiH/RS/BD] do to prepare and plan for the end of GAVI support?
    a. At which levels did preparations occur: Preparations of respondent and their team; variations in preparations between [FBiH/RS/BD]; preparations at lower levels?
        i. What mechanisms and institutional arrangements were put in place to manage the transition process?
    b. What were the main concerns or risks that were identified during this planning process?
        i. What type of evidence was used to determine these risks and opportunities?
    c. Which actors were important in the transition process? (external/internal actors)
        i. What was GAVI's role in the planning and preparation of the transition plans and final decisions about the plans?
        ii. What other actors (e.g. UNICEF? Other partners?) Were involved and what was their role in the planning process?

iii. (ef1)If none of these actors were involved in the planning process, were these plans communicated with them? If yes, how?

d. What is your perspective on the effectiveness of the transition process?
e. Probe about comparing proposals and plans to respondent perspectives: (opportunity to cross-check what was in the proposals and plans from the document review)

6. How did the government and other actors ensure that sufficient financial resources would be available after the end of GAVI support?
    a. What arrangements were made to ensure raising of sufficient funds?
        i. Probe about: short-term, medium, and long-term budgets/gaps most difficult to fill/adequacy of arrangements
        ii. Does existing legislation specify national government allocations to the immunization (e.g. specific budget lines)?
        iii. Have role of sub-national governments in immunization been defined?

7. Was a sustainability plan developed? (under sustainability plan we also mean Financial Sustainability Plan, comprehensive Multi Year Plan)
    a. If yes,
        i. Has the FSP been updated since 2005?
        ii. Which stakeholders were involved in this process?
        iii. What is your perspective on how realistic it was and how much buy-in there was for the plan?
    b. If not or plan was not updated for the last 5 years,
        iv. What happened in the absence of a (new) sustainability plan? Who was in charge of coordinating?
        v. Why the plan was not developed/updated?
    c. What were the main advantages/disadvantages of having a plan [or not having a plan]
        vi. How did these vary for [FBiH/RS/BD]
8. What were the main programmatic components of the transition plans?
    d. What type of governance structures were put in place?
        a. What happened to the ICC and other GAVI-coordinating structures?
    e. What preparations were made to ensure appropriate organization of service delivery/adequate workforce/procurement/supply/distribution/legal framework
    f. What kind of changes should have been made that weren't?

9. What financial arrangements were made to ensure efficient use of resources?
    a. As plan was implemented, was the actual expenditure in line with expectations and plans? If not, why not?

10. What alternative procurement arrangements were put in place to ensure most efficient prices for vaccines, equipment, and other consumables?
    a. How does this compare to the period pre-graduation, with the support of UNICEF?

11. From your perspective, what could have been improved in the implementation of this process?

Post-GAVI - sustainability and Impact

12. How have GAVI supported programmes achieved their objectives before funding ended?
    a. How have these objectives been sustained after the completion of GAVI support?

13. What could have been improved in the process of transitioning away from GAVI support?

14. What is your perspective on how the systems and structures in [FBiH/RS/BD] function after GAVI support ended?
    a. Probe about service delivery; vaccine availability and logistical management; finances; ownership and accountability; technical capacity, advocacy activities, role of external actors (e.g. UNICEF, others); differences among [FBiH/RS/BD]
    b. Probe about population's perspective/acceptability of routine immunization

15. In the future, how do you think BiH [FBiH/RS/BD] will handle the introduction of new vaccines? Or scale-up of existing programs?
    a. Probe about ownership and accountability
    b. Probe about possibility of increased budget allocations for vaccine procurement
    c. Probe about how the program has evolved since graduation from GAVI
    d. Across all – probe about differences in the three regions

ANNEX 7: RFP/TOR

Final Evaluation of GAVI Alliance's Support to Bosnia and Herzegovina

1.0 PURPOSE OF THE EVALUATION

This evaluation is being commissioned by the GAVI Alliance Secretariat in accordance with the GAVI Alliance Evaluation Policy, which calls for the conduct of a final evaluation where GAVI Alliance[76] support has ended. An end of support evaluation has already been conducted in China. Bosnia & Herzegovina will therefore represent the second graduated country in which an evaluation is conducted following the conclusion of GAVI's time-limited support to the country.

The evaluation's main objectives are to: (i) assess the sustainability of programmes previously supported by GAVI in Bosnia &Herzegovina and their results and (ii) identify factors contributing to the sustainability of these programmes and their results.

The evaluation will contribute to greater accountability to GAVI donors, partners, the public health community (including governments, civil society and the private sector) and intended beneficiary populations. The results of this evaluation will:

Generate and document experiences related to Bosnia &Herzegovina's transition away from GAVI support, that could be used by the GAVI Alliance and other stakeholders, and;
Provide lessons learned and recommendations that could inform GAVI's Graduation Policy going forward.

The main audience for this evaluation will be the GAVI Alliance Board, although the results will be of interest to the country, the GAVI donors and partners, the broader public health community and all organizations concerned with sustainability issues.

2.0 RFP INSTRUCTIONS

i. GAVI invites you as a Service Provider to submit a competitive bid through responding to this "Request for Proposal" (RFP) for the Final evaluation of GAVI Alliance's support to Bosnia & Herzegovina. Please follow these instructions in completing your bid.

ii. This entire RFP and all related discussions, meetings, exchanges of information, and subsequent negotiations that may occur are confidential and are subject to the confidentiality terms and conditions of the Intent to Participate letter attached as Annex 1. All bidders are required to complete and return the Intent to Participate letter.

iii. The issuance of this RFP in no way commits GAVI to make an award. GAVI is under no obligation to justify the reasons for its supplier(s) choices as a result of this RFP.

iv. GAVI reserves the right to:
- Reject any proposal without obligation or liability to the potential Service Provider;
- Withdraw this RFP at any time before or after submission of bids, without prior notice, explanation or reason;
- Modify the evaluation procedure described in this RFP;
- Accept other than the lowest price offer;

[76] The terms "GAVI" and "GAVI Alliance" are used interchangeably in this RFP. When referring to "GAVI", this means the Alliance as a whole, rather than the Secretariat specifically, unless stipulated.

- Award a contract on the basis of initial offers received, without discussions or requests for best and final offers;
- Decide not to award any contract to any Service Provider responding to this RFP,
- Award its total requirements to one Service Provider or apportion those requirements among two or more Service Providers, as GAVI may deem necessary.

v. All bids must indicate that they are valid for no less than sixty (60) days from the quotation due date.

vi. Faxed copies will not be accepted. Late quotations are subject to rejection.

vii. GAVI reserves the right to request additional data, information, discussions or presentations to support part of, or your entire bid proposal. Service Providers or their representatives must be available to discuss the details of their proposal during the evaluation process.

viii. All responses should be submitted in writing and electronic version.

ix. The proposed time plan set out below indicates the process GAVI prepares to follow. If there are any changes to this time plan, GAVI will notify you in writing.

2.1 Tender Process Timelines

The contracting will be conducted in two phases with two different contracts:

- **First contract**: to cover the delivery of the inception report
- **Second Contract**: to cover the conduct of the evaluation if the inception report is found satisfactory. Else GAVI will not grant this second phase of project to the same provider.

Event	**Responsible Party**	**Time lines**
Launch RFP November 2013	GAVI	15
Send Intent to Participate letter November 2013	Service Provider	25
Q&A sent to GAVI November 2013	Service Provider	25
Conflict of Interest sent to GAVI November 2013	Service Provider	25
GAVI open response to Q&A November 2013	GAVI	29
Proposals received by GAVI December 2013	Service Providers	6
Service Provider Selection December 2013	GAVI	16

2.2. Instructions to Service Providers

Any Service Provider may request further clarification on matters pertaining to this RFP by submitting its question(s) in writing to the individual identified below. Due date for Q&A submission is stated in Section 2, para 2.1. In order to keep the RFP competition fair, questions on the substance of the RFP will be answered in a public document released as

stated in Section 2, para 2.1. Please do not contact other GAVI staff to discuss the RFP. When submitting your questions, please use the form attached as Annex 2.

2.3 Confirmation of Intent / Confidentiality

Please transmit your intent to participate using and signing the document in Annex 1. Each Service Provider is required to transmit a written confirmation of intent or decline to participate as stated in Section 2, para 2.1. Confirmations of intent should be submitted by email to Calin Schiau (contact details below).

Acceptable means of transmission include mail or computer file with digital signature.

2.4 Conflict of Interest

No members of the ET may have been involved in the design, implementation, supervision or coordination of any intervention or policy to be assessed. Please complete, sign and send this conflict of interest form with your intent to participate as indicated in Section 2, para 2.1.

GAVI Alliance RFP Contact Information			
Question Type	**Contact Person**	**Contact Role/Title**	**Contact Information**
Contractual RFP & Contract Terms & Conditions, Proposal Format, etc.	Calin Schiau	Head of Procurement	Calin Schiau GAVI Alliance 2, Chemin des Mines 1211, Geneva 2 Switzerland Phone: +41 22 909 29 19 email: cschiau@gavialliance.org
Technical RFP Deliverable Specifications & Requirements	Abdallah Bchir	Head of Evaluation	Abdallah Bchir GAVI Alliance 2, Chemin des Mines 1211, Geneva 2 Switzerland Phone: +41 22 909 65 42 Email: abchir@gavialliance.org

2.5 Required Proposal Format

Responses to this RFP must consist of the following (see also chapters 9, 10 for technical and financials):

1. Cover letter, which includes:
   - ✓ Name and address of the Service Provider
   - ✓ Name, title, telephone number, and e-mail address of the person authorized to commit the Service Provider to a contract

- ✓ Name, title, telephone number, and e-mail address of the person to be contacted regarding the content of the proposal, if different from above
- ✓ A signature of this letter done by a duly authorized representative of your company

2. Electronic copy

- ✓ Documents and spread sheets in **Office 2007/2010 format.**
- ✓ Diagrams and drawings in **Visio 2007 or PowerPoint Office 2007/2010 format**
- ✓ The electronic copy must be submitted by CD-R or by e-mail. If sent by e-mail, the proposal must not exceed 2MB. In the case that the proposal exceeds 2MB, Service Providers may send multiple emails.
  - ✓ Documents have to be compressed using a WinZip 8.0 compliant format.

Please do not submit generic marketing materials, broadly descriptive attachments, or other general literature.

3.0 GAVI OVERVIEW

3.1 Mission

The mission of the GAVI Alliance is to save children's lives and protect people's health by increasing access to immunisation in poor countries. It aims to do this by supporting the update and rollout of new vaccines in the world, strengthening systems to deliver immunisation, ensuring sustainability and shaping vaccine markets.

3.2 Organisation

The GAVI Alliance is a unique organisation that aligns public and private resources in a global effort to create greater access to the benefits of immunisation. It brings together key actors in immunisation including developing country and donor governments, the World Health Organization, UNICEF, the World Bank, the vaccine industry in both industrial and developing countries, research and technical agencies, civil society organisations, the Bill & Melinda Gates Foundation and other private philanthropists.

The GAVI Alliance Secretariat, which previously was hosted by UNICEF, became an independent international organisation – a Swiss Foundation, with privileges and immunities in Switzerland - effective from 1 January 2009. The GAVI Alliance is the first organisation to receive such recognition under the Swiss Host State Act.

The GAVI Alliance Secretariat is responsible for the day-to-day operations of GAVI, including: mobilising resources to fund programmes; coordinating programme approvals and disbursements; legal and financial management; collaboration and coordination with other global health agencies; monitoring and evaluation; and administration for the GAVI Alliance Board and committees.

For more information about GAVI, please visit our website: www.gavialliance.org

4.0 BACKGROUND FOR THIS CONSULTANCY

The concept of graduation and sustainability in GAVI

In 2009, the GAVI Alliance board approved a graduation policy for countries, which first came into effect in January 2011.

Prior to adoption of this policy, GAVI support to countries ended once they reached a certain GNI per capita threshold. At this time, they became ineligible to apply for new support, though GAVI continued to meet any existing multi-year commitments for support. As such, until adoption of this policy, there were no formal or explicit procedures to guide countries as transitioned from eligibility to ineligibility. Country co-financing did come into effect in 2007. However, there was no explicit link in the policy to graduation from GAVI support.

The paper presented to the GAVI Alliance Board in November 2009 on graduation from GAVI support noted that this lack of a clearly defined policy, *"has created uncertainty for, and potentially inhibited decision-making by, GAVI-eligible countries"* (http://www.gavialliance.org/about/governance/gavi-board/minutes/2009/).

Since then, more has been learned about the graduation process and the institutional adjustments the graduating countries must make to successfully transition away from GAVI financing.

The Board paper also noted the following three main difficulties for countries due to the absence of graduation procedures:

1) Uncertainty over when eligibility may be updated and what graduation would entail, making planning for graduation difficult if not possible;
2) The abrupt end of GAVI support;
3) The considerably higher and more unpredictable prices graduating countries face for some vaccines, particularly newer vaccines.

The Graduation Policy sought to address these difficulties and cushion the transition from GAVI support to self-financing.

Eligibility and graduation in GAVI phase I and phase II

In GAVI Phase I (2000 to 2006), the GNI per capita eligibility threshold was US$ 1,000 (based on 1998 World Bank data). Seventy-four countries were initially eligible for GAVI support. In 2002, Timor-Leste was added to the list of eligible countries as it became an independent state.

In GAVI Phase II (2007 to 2010), country eligibility was based on the 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 four countries (Albania, China, Bosnia & Herzegovina, and Turkmenistan) surpassed the threshold while another (Kiribati) dropped below it. This reduced the number of countries eligible to apply for new support from GAVI in phase II to 72. During this period, there was no support or policy to assist countries when their initially approved time-limited support came to an end, although any prior approved multi-year commitments were respected. A revised eligibility and graduation policy were approved in 2009, with an effective start date of January 2011.

Eligibility and graduation in GAVI Phase III

The GAVI Alliance Graduation Policy is applicable to all Phase III (from 2011 to 2015) eligible countries, as is the eligibility policy, which sets a threshold that is adjusted annually for inflation.

For 2013, countries are eligible for GAVI support if their GNI is less than or equal to U$1,550. As such, 17 countries (see below) have surpassed the threshold and are classified as graduating. These 17 countries cannot apply for new GAVI support and experience a linear ramp-up of their co-financing contributions, as per the GAVI Co-Financing Policy.

Fully graduated countries (phase I rules apply)			
1.	Albania	3.	China
2.	Bosnia & Herzegovina	4.	Turkmenistan

Graduating or graduated countries (phase II or phase III rules apply)			
1.	Angola	10.	Honduras
2.	Armenia	11.	Indonesia
3.	Azerbaijan	12.	Kiribati
4.	Bhutan	13.	Moldova
5.	Bolivia	14.	Mongolia
6.	Congo (Republic of)	15.	Sri Lanka
7.	Cuba	16.	Timor Leste
8.	Georgia	17.	Ukraine
9.	Guyana		

Key policies to be reviewed for this work

- GAVI Graduation Policy http://www.gavialliance.org/about/governance/programme-policies/graduation/
- GAVI Eligibility Policy http://www.gavialliance.org/about/governance/programme-policies/country-eligibility/
- GAVI revised Co-financing Policy http://www.gavialliance.org/about/governance/programme-policies/co-financing/

Bosnia & Herzegovina

The final evaluation of GAVI's support for China's Hepatitis B programme was the first of a series of final evaluations to be commissioned by the GAVI Alliance[77]. The final evaluation of GAVI support to Bosnia & Herzegovina (BiH) will be the second in this series of final evaluations, with other countries to follow.

At the launch of GAVI support, BiH was continuing to rebuild a health infrastructure weakened by civil war. Routine immunisation coverage had fallen during the war (WHO/UNICEF estimated DTP3 coverage to be 55% and routine measles coverage to be 53% in 1995), and in 2002, WHO/UNICEF estimated DTP3 coverage to be 80%[78].

[77] http://www.gavialliance.org/results/evaluations/evaluation-of-the-gavi-government-of-china-hepatitis-b-vaccination-programme/

[78] These coverage estimates represent national coverage estimates (BiH actually consists of two entities: FBiH and RS as well as of the BD as a unique administrative unit of local government under the sovereignty of BiH).

GAVI support to BiH began in 2002 with the Vaccine Introduction Grant in advance of GAVI's support for the Hepatitis B monovalent vaccine starting in 2003. GAVI then began supporting the monovalent Hib lyophilized vaccine, with the first introduction using GAVI supported vaccines in Republika Srpska in 2008. The final GAVI supported vaccines (for Hib monovalent vaccine) were shipped to BiH in 2011. A summary of GAVI's support to BiH is provided below.

GAVI support to BiH			
	Years[79]	**Approved (USD)**	**Disbursed (USD)**[80]
Hep B mono	2003	70,000	70,000
	2004	25,962	25,962
	2005	31,218	31,218
	2006	44,011	44,011
	2007	53,129	53,129
	2008	33,449	36,796
	2009	1,563	1,563
	Total	259,332	262,679
Hib mono	2007	415,532	415,532
	2008	345,000	346,675
	2009	367,000	367,233
	2010	375,500	361,976
	2011	369,500	368,357
	Total	1,872,532	1,859,773
Injection Safety Support (INS)	2006	24,221	24,221
	2007	15,207	15,207
	2008	13,702	13,702
	Total	53,130	53,130
Vaccine Introduction Grant	2002	100,000	100,000
	Total	100,000	100,000
Total		**2,275,583**	**2,275,583**

BiH did not experience a graduation phase similar to current graduating countries from phase III. Their support was concluded when the time-limited multi-year period for which support had been approved came to an end.

Although BiH was acknowledged by GAVI's Independent Review Committee (responsible for recommending to the Board approval of new grants and renewal of ongoing grants) in 2009 for its progress in improving immunisation coverage, BiH had reported notable challenges

[79] Year refers to the year of shipment or disbursement of funds from GAVI to country

[80] Although reflected in dollar amounts, when disbursements relate to a vaccine, such as Hepatitis B monovalent vaccine, these equate to the total number of doses provided.

for its immunisation services prior to the conclusion of GAVI support. At that time, financial sustainability of the National Immunisation Programme was flagged as a significant concern and according to the final IRC report in 2011, BiH reported that if costs were to escalate, it may need to reduce the planned quantities by 20%.

Another challenge identified by BiH through its annual reporting to GAVI was the anti-vaccine movement in the country. Several stories about possible adverse events following vaccination received large media attention. This subsequently caused significant disruption to routine programme implementation and negatively impacted demand for immunisation.

For further information on BiH, please refer to its approved GAVI proposals and APRs from 2002 to 2011. The documents are available on the GAVI website: http://www.gavialliance.org/country/bosnia-herzegovina/

5.0 EVALUATION SCOPE AND QUESTIONS

The evaluation should assess both financial and programmatic sustainability through an in-depth analysis of BiH's experiences and immunization programme performance, both before, during and after the conclusion of GAVI's time-limited multi-year period of support to the country. The recommendations should help further define M&E and potentially programmatic activities to be conducted in graduating countries in the future.

The evaluation should consider the types and quantity of support received and the way in which GAVI's support to BiH was concluded. The evaluation should seek to assess the support received from GAVI across both entities in BiH (FBiH and RS) and the BD.

Bidders are encouraged to propose additions and amendments to the evaluation questions, as well as any alternative tools and approaches they feel could be beneficial, with appropriate justification.

he evaluation will address the following specific questions:

Planning

- To what extent were there processes or support put in place by GAVI to address both financial and programmatic sustainability? To what extent were these relevant, realistic, well-documented and well communicated?
- To what extent did BiH prepare and plan for the transition away from GAVI support?
- To what extent was the planning put in place by the country relevant, feasible (considering socio-economic and political context) and coordinated?
- To what extent was the planning put in place comprehensive (covering both financial and programmatic aspects) and institutionalized (integrated into the health system planning)?
- What were the main financial arrangements put in place to ensure sustainability? What were the main programmatic arrangements put in place to ensure sustainability?
- To what extent did GAVI support these efforts?
- To what extent were stakeholders informed and cognisant of the implications of the conclusion of GAVI's time-limited support?

Implementation

- To what extent were the activities of the sustainability plan (if one was developed) effectively and efficiently implemented?
    - What were the main challenges and how were they addressed?
    - To what extent did GAVI support these efforts?
    - What activities took place in the absence of a sustainability plan, if one was not developed?
    - How were these activities coordinated? How were they initiated?
    - What have been the consequences of the lack of a plan?

Results

- To what extent have the relevant activities related to 'GAVI support', such as delivery of vaccines, injection safety procedures, addressing inequities, surveillance and monitoring, 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 (both outcomes and impact) of GAVI supported programmes been sustained, expanded or improved since the conclusion of GAVI's time-limited support?
    - To what extent has the anti-vaccine movement posed a challenge (and continues to pose a challenge) to the implementation and impact of the immunisation programme in BiH (both during and after GAVI support)?
    - What are the ongoing challenges BiH faces for sustainability of its immunisation programme? What are the facilitating factors?
    - What adaptations were made to the immunisation programme 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?
- What are the main factors explaining the achieved results (positive or negative)?
- What have been the main unintended positive and/or negative effects of the time-limited nature of GAVI support and its conclusion?
- Have new vaccines been introduced in BiH since the conclusion of GAVI support? If so, what are the financing and procurement arrangements and the prices being paid for these vaccines? If not, what are the main barriers to new vaccine introduction?

Lessons learned

- What are the key lessons learned from GAVI's support and the conclusion of this support in BiH?
- To what extent could GAVI utilise these lessons and experiences to inform its graduation policy going forward? What are some key recommendations you would make to the GAVI Alliance and to other countries graduating from GAVI support now and in the future?

6.0 METHODOLOGY

In order to respond to the above questions and provide a high quality assessment of experiences with graduation and sustainability in BiH, evaluators are strongly advised to consider a mixed methods approach to this evaluation.

The following methods should be considered (with appropriate triangulation across data to follow):

- Desk / literature review
  - Review of all key GAVI documentation regarding Graduation, Sustainability, and Bosnia & Herzegovina (including, but not limited to: all policy documents, data on GAVI and country websites, proposals submitted by countries, annual progress reports, Board and Committee meeting minutes and papers etc)
  - Review of previous evaluations conducted by GAVI, particularly the Injection Safety Support evaluation and the first and second GAVI evaluations
  - Review of previous evaluations and documentation by partners, particularly EPI reviews, vaccine procurement and financing assessments, communication strategies
  - Literature review of exit/sustainability strategies in other Global Health Partnerships and funding organisations
  - Analysis of available quantitative data
- Country visit[81]
  - Qualitative field methods such as Key Informant Interviews, focus group discussions and other observational techniques (including visits to a limited number of health / vaccination centres across both entities in BiH and the BD– sampling to be finalised during inception phase)
  - Analysis of available quantitative data (including relevant documents in local languages)
- Other relevant approaches

The selected evaluators will be expected to consult an evaluation Steering Committee that will be created for this evaluation (which will consist of public health representatives from both entities in BiH and the BD, in-country partners and GAVI Secretariat representatives) before their methodology is finalised.

The evaluation should be conducted in accordance with the principles described in GAVI's Evaluation Policy.[82]

7.0 EVALUATION CRITERIA

The decision to award any contract as a result of this RFP process will be based on Service Provider's responses to this RFP and any subsequent negotiations or discussions.

The decision making process will consider the ability of each Service Provider(s) to fulfil GAVI requirements as outlined within this RFP, and cost of the review. Proposals will be evaluated as appropriate against the following criteria:

- **Technical criteria (80%):**

[81] It is not foreseen that primary data collection should require more than 2-3 weeks.
[82] http://www.gavialliance.org/about/governance/corporate-policies/evaluation/

- ✓ Evaluation framework and design
- ✓ Demonstrated understanding and operationalization of the evaluation questions
- ✓ Appropriate methods proposed for undertaking the work
- ✓ Ability of the bidder to carry out scope of work (based on qualifications of the team, including CVs of key experts). Preference will be given to local / regional institutions or those partnering with local / regional institutions.

➢ **Financial criteria (20%)**
- ✓ Overall cost
- ✓ Realistic costing of the proposal

If a Service Provider would like GAVI to consider any other criteria during the decision making process, it should notify GAVI in writing when confirming intent to participate (see Intent to participate letter attached as Annex 1).

8.0 PROPOSAL REQUIREMENTS

8.1 Requirements for Technical Proposal

Following the issuance of the RFP, all interested contractors are invited to submit a proposal which describes:

- evaluation framework and design
- detailed description of the evaluation methods
- detailed work plan, budget and timeline
- team composition with full CVs and breakdown of the tasks assigned to each member
- statement of potential conflict of interest

The ET should demonstrate qualification, experience and competencies in the following areas:

a) professional background and competency in complex analyses and public health;
b) experience conducting evaluations, including extensive experience with appropriate evaluation design and methods;
c) advanced knowledge of, and experience with health economics/health financing ;
d) excellent communication skills including writing and presentation skills (in both English and local languages);
e) experience of working in the region and preferably in BiH (as noted above, preference will be given to local / regional institutions or those partnering with local / regional institutions);
f) sound knowledge of GAVI or previous experience with similar ogranisations / evaluation of similar projects;
g) ability to meet tight deadlines with quality products.

The composition of the team should be presented in detail, including a break-down of the tasks assigned to each member, proposed length of time for in-country primary data collection and estimated time taken for all work tasks. The team is expected to include a small number of locally-based consultants (who can provide contextual background, help conduct interviews in local languages, review literature in local languages and help with

logistics). An organization chart illustrating the reporting lines, together with a description of the organization of the team structure should support the proposal (if local consultants cannot be identified at time of submitting proposal, they must be identified prior to contracting the selected firm).

Bidders are encouraged to include links to any similar previous work products available on-line that demonstrate their relevant experience and expertise.

8.2 Requirements for Financial Proposal

The financial proposal should be a standalone document (using excel). This should:

i. Provide full details of your financial offer. This should include fixed costs and any variable costs.
ii. Indicate the components of your financial offer.
iii. We recommend to use the template inserted as Annex 3.

Please note that in accordance with GAVI's Headquarters Agreement with the Swiss Government, GAVI is exempt from VAT, as well as customs taxes and duties in Switzerland. Consequently, your prices will have to be submitted to us net of any tax and in US$. The necessary documents will be sent to the selected provider(s) upon the ordering procedure.

9.0 DELIVERABLES&TIMELINES

9.1 Expected deliverables

- Inception report
  - ✓ Satisfactory inception report required to issue a second contract to complete the evaluation
- Monthly reports
  - ✓ During implementation, the evaluation team will provide monthly progress reports
- Draft report
  - ✓ A draft report in English
- Final report
  - ✓ A final report in English and translated into local languages
- Executive summary
  - ✓ A standalone document (in English and translated into local languages) that describes the methods, questions and main findings of the evaluation; length to be less than 10% of the length of the final report.
- Recommendations
  - ✓ A standalone document (in English and translated into local languages) that contains the evaluators' recommendations for GAVI's graduation policy and future graduating countries
- Presentation to GAVI Secretariat
  - ✓ Including slides summarising the methods and findings
- Presentation to in-country stakeholders
  - ✓ Including slides summarising the methods and findings as well as any recommendations to improve the BiH immunisation programme

9.2. Timelines

Deliverable	Date
Submission of inception report	**28 February 2014**
Submission of draft report	**31 May 2014**
Submission of final report	**30 June 2014**
Submission of recommendations document	**30 June 2014**
Presentations	**TBD (in consultation with GAVI Secretariat and the evaluation Steering Committee)**

10.0 MANAGEMENT and OVERSIGHT

This evaluation will be outsourced in its entirety to consultants. In accordance with the GAVI Board instituted process for conducting evaluations, the GAVI Secretariat will conduct a procurement exercise to recruit the consultants and assume responsibility for day-to-day management of the evaluation. The GAVI Alliance Board's Evaluation Advisory Committee will report to the Board on the quality and usefulness of the report.