

Joint appraisal report

Country	Armenia
Reporting period	<i>Previous appraisal: Internal Appraisal Report, June 2014</i> <i>Current appraisal: June 2015</i>
cMYP period	2011-2015
Fiscal period	January – December
Graduation year	<i>Last year of Gavi funding – 2017</i>

1. EXECUTIVE SUMMARY

1.1. Gavi grant portfolio overview

Gavi began financing immunization activities in Armenia in 2001, providing support for HepB (2001-2008), immunization services (2001-2004), injection safety (2002-2004), HSS (2008-2012), Hib containing pentavalent vaccine (2009-2015), rotavirus vaccine (2012-2015), and PCV (2014-2017). Since 2001, Armenia received a total of \$4,545,972 in disbursements from Gavi, including \$679,086 in 2014. Currently, three vaccine grants remain active (pentavalent, introduced in 2009, rota in November 2012, and PCV in September 2014). An additional grant for IPV was approved in May 2015, with the introduction scheduled for October 2015. There is currently no active HSS grant in Armenia (the only HSS grant Armenia received in 2008 ended in 2012).

The country has entered graduation in 2011, with 2017 being the last year of Gavi's support for vaccines other than IPV (funded through 2018). A graduation grant is expected to be signed in late 2015 and cover the 2016- 2017 period.

As per the June 2015 Gavi Board Decision, Armenia can benefit from access to Gavi's catalytic support for HPV vaccine. There is an interest from the population for introducing HPV in Armenia, but the issue has not yet been discussed by NITAG, and no cost-effectiveness or other studies or analyses have so far been carried out.

For 2016, Armenia is eligible for requesting renewal for only one vaccine grant (PCV), as the country has been informed that it starts fully financing both Pentavalent and Rota vaccines in 2016. The IPV support has already been approved through the end of 2016.

1.2. Summary of grant performance, challenges and key recommendations

Grant performance (programmatic and financial management of NVS grants)

Armenian National Immunization Programme (NIP) continues to be one of the best performing programs in the EURO region, with coverage against most of the antigens being above 95%, as confirmed by WHO/UNICEF coverage estimates, disease surveillance and epidemiology.

In 2014, Armenia continued its strong performance in the area of vaccination for 12 antigens administered within the NIP framework. Coverage rates have been consistently above 90% for both routine and EPI vaccines, and have been gradually increasing since 2008. The drop-out and wastage rates are in accordance with the UNICEF and WHO-suggested targets.

Table 1. Reported Vaccination Coverage, 2010-2014.

Vaccine/coverage	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)
BCG	95	96	96	99	99
HepB (birth dose)	94	95	95	98	98
DTP1 (pentavalent 1)	98	98	98	97	97
DTP3 (pentavalent 3)	94	95	95	95	93
Polio3	96	96	96	96	95
MMR (1 and 2 doses)	97	97	97	97	97

Rota2	-	-	-	90	91
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Source: Official country estimates

During 2014, no outbreaks were detected, which serves as a good indication of the strength of the national immunization program. Polio-free status has been sustained. However, measles-rubella elimination process is challenged by imported cases (8 registered imported cases in 2015 among unvaccinated and under-vaccinated children and adults).

Table 2. Reported Vaccine-preventable Diseases

	2014	2013	2012	2011	2010	2000	1990
Diphtheria	0	0	0	0	0	7	-
Japanese Encephalitis	0	0	-	0	0	-	-
Measles	13	10	0	0	2	15	879
Mumps	2	2	6	15	38	3,431	-
Pertussis	85	30	8	1	4	10	469
Polio	0	0	0	0	0	-	-
Rubella	0	4	1	0	0	673	-
Tetanus (neonatal)	0	0	0	0	0	0	-
Tetanus (total)	1	0	1	0	3	1	-
Yellow Fever	0	0	-	0	0	-	-

Source: WHO

The latest introductions of new vaccines (rotavirus in November 2012 and PCV in September 2014) have been successful, and their coverage, even though currently below target, is expected to reach that of other vaccines soon. 2005 and 2010 DHS surveys, as well as the 2006 coverage survey, show no gender inequity in Armenia with respect to immunization (next DHS is scheduled for the fall of 2015). Outreach immunization services have been institutionalized. Reporting systems used in the country are robust and functional. Timeliness of vaccinations is being closely monitored, with an additional improvement expected to be brought through planned introduction of electronic immunization registries (*E-health*), which are currently in the planning and design stage.

Financial management:

Vaccine resource requirements have been adequately calculated and well communicated to relevant budget holders. The process benefits from multi-year planning in calculating the requirements, with all stakeholders being duly informed.

During 2014, Armenia has not received any cash support from Gavi (PCV introduction grant was disbursed in 2013). No FMA has been conducted in Armenia during the years of Gavi support. There were also no audits of previously disbursed cash grants due to their amounts being below the established threshold.

Country co-financing requirements have been met on time in 2014 and in previous years. The 2015 co-financing requirement has also already been fulfilled (in March 2015).

Key findings

Strengths:

- Strong political commitment to the national immunization programme
- Well-established organizational structure for vaccine management, with defined roles and responsibilities, strong management and committed human resources
- Motivated, functional and influential national immunization technical advisory group (NITAG)
- Strong technical capacity of the national immunization programme
- Successful implementation of the multi-year plan on immunization and national immunization plan (programme financial requirements are met and available resources efficiently used)
- Co-financing requirements fulfilled consistently and on time, including for 2015

- Robust and functional reporting system
- No gender inequity according to DHS and coverage surveys
- Supportive supervision in place, with defined frequency of visits, supervisory tools and feedback mechanism
- Institutionalized outreach immunization services
- Timeliness of vaccinations is being monitored
- Functional rotavirus and invasive bacterial surveillance

Challenges:

- Armenian economy is heavily affected by the global crisis, with 0% projected GDP growth and possible increases in inflation and fluctuations in the currency exchange rates in coming years
- Announced freeze of the MoH budget until 2018
- Serious gaps and shortcomings observed in the functioning of the National Regulatory Agency
- Market authorization for vaccines requires strengthening
- ICC too broad and high-level to be operating effectively
- Newly introduced vaccines require further efforts to catch-up on desired coverage rates
- Reaching the last few % unreached is challenged by hesitancy and refusals by some religious groups
- Non-prequalified cold chain equipment is widely used at service delivery level
- Limited use of cold chain inventory data for further actions (i.e. formal review, needs assessment, equipment planning, maintenance support)
- Lack of institutionalized training programme on immunization and vaccine management
- Human resource availability challenges at sub-national levels
- Moderate progress in implementing Effective Vaccine Management recommendations
- Limited use of computerized data management systems (temperature monitoring, stock management, cold chain inventory, etc.)
- Donated and humanitarian assistance vaccines are not registered (but managed through an Importation Authorization)
- Temperature monitoring in vaccine cold chain requires further strengthening
- Shared budget line for EPI and non-EPI vaccines (threat for EPI vaccines if self-procurement is not efficient, but also an opportunity if used efficiently)

Key recommended actions to achieve sustained coverage and equity

1. Building and strengthening resource mobilization capacities, including diversifying funding sources and reaching out to potential internal and external donors
2. Updating legislation on vaccine management practices and introducing technology to supply chain;
3. Development of specific strategies for reaching those segments of the population who remain unreached by immunization efforts;
4. Addressing medical workers' concerns about safety of new vaccines and immunization in general;
5. Addressing vaccine hesitancy and refusals through use of qualitative research and through developing and implementing communication strategies aiming at behavior change; and
6. Improving data quality and aligning data systems with international requirements by conducting a data quality review and implementing its recommendations.

1.3. Requests to Gavi's High Level Review Panel

Grant Renewals

Request for renewal of PCV in the new presentation (PCV13):

For 2016, Armenia is requesting renewal of support for PCV and change of presentation from PCV10 (two-dose vial) to PCV13 (one-dose vial). The one-dose presentation is critical to Armenia to reduce wastage, which in 2014, in the few months following the introduction in September 2014) was on average 12.7% (and in the rural and remote areas – up to 50%).

Armenia is not eligible for requesting renewed support for other Gavi-funded vaccines, as 2015 was the last year of Gavi funding for Pentavalent and Rota vaccines, and IPV doses have already been approved until the end of 2016.

1.4. Brief description of joint appraisal process

The Joint Appraisal was conducted from 8 to 12 June 2015 together with the GAVI graduation and national regulatory authority assessments. During the mission, participants from Gavi Secretariat, WHO EURO office, UNICEF Supply Division and Sabin Institute met with representatives of the Ministry of Health, National Center of Disease Control and Prevention (NCDC), Standing Committee on Health of the Parliament, National Regulatory Authority (NRA), National Immunization Program, Drug and Medical Technology Expertise Center, Ministry of Finance, NITAG, and the WHO and UNICEF country offices. Based on the discussions during the JA mission and relevant background documents, the Joint Appraisal report was drafted by independent technical expert in close cooperation with GAVI SCM. The report was shared for feedback with mission members and Armenia EPI team, and the final findings and recommendations were discussed with and endorsed by the Minister of Health and ICC members.

2. COUNTRY CONTEXT

2.1. Key contextual factors that directly affect the performance of Gavi grants.

2.1.1. Leadership, Governance and programme management

Armenia's immunization program benefits from strong political commitment and support, experienced and highly qualified programme manager who leads the program since 2006, established communication channels with policy- and decision-makers, strong and influential NITAG, and an ICC with a high-level political representation.

Political support: There is a strong political commitment of the Government to support the immunization program, with immunization clearly expressed as a top government priority, as confirmed by a threefold increase of the immunization budget in 2015 and a 100% execution of the approved budgets. The Minister of Health is chairing the ICC and representatives from other ministries, including the Deputy Minister of Finance, are ICC members. Regular meetings are held between the key MoH officials and the EPI Manager. The Ministry of Finance also maintains awareness of program needs and financial requirements. Fund transfers from the government are timely, and the immunization program hasn't faced any problems related to underfunding of implementation.

Strong leadership and national level program management: The EPI program team is led by experienced manager who has extensive work experience in the field of immunization and proactively addresses implementation challenges. The manager is actively involved in advocacy activities and maintains regular communications with key MoH officials on immunization program's activities. The program maintains good relations with media and successfully provides clear and unequivocal messages in emergency situations (as demonstrated by a recent success with communication on imported measles cases from France and Austria).

ICC: The ICC is chaired by the Minister of Health and is composed of 22 members, including Vice-Ministers from the MoH, deputy ministers of other ministries, including the Ministry of Finance, and in-country partners. Although establishment of the ICC at such a high level is an important evidence of the political commitment to immunization efforts in Armenia, it has been challenging to ensure regular and active participation of its members in regular and ad-hoc meetings and to benefit from effective follow-up and support from this group in proactively addressing immunization challenges.

Legislation Framework: A number of different normative documents cover various immunization-related aspects (e.g. the state's obligation to provide free vaccination, tax exemptions for UNICEF-procured vaccines, etc.). Although Armenia's Sanitarian Norms state the obligation for every citizen to be vaccinated in accordance with immunization calendar, exemptions from vaccination due to medical or other reasons are relatively easy to obtain (through a simple letter of refusal). A new Public Health Law that will specifically address immunization is expected to be adopted by the National Assembly during the 2015 fall session. The National Assembly Health Committee is also discussing a reform bill that aims to harmonize drug registration with European standards and take into

consideration Eurasian Economic Union standards. This bill introduces penalties linked to counterfeiting, a provision for parallel import of drugs (but not vaccines and biologicals), and an electronic drug registration to meet international standards.

Partnership Framework Agreement: The PFA has not yet been signed due to the requirement of Armenia’s law to receive special approval from the Ministry of Foreign Affairs for the signature of all international agreements. Following the approval by the MoFA and the signature of the PFA by Ministers of Health and Finance, the PFA will need to be ratified by the Parliament to become effective. This is expected to be completed before the end of 2015.

National Regulation Authority (NRA): Market authorization function is currently not applied for programme vaccines and mostly registration is waived. Expedited review procedures for registration of WHO pre-qualified vaccines is not in place. Adverse events following immunization surveillance system is functional and managed by the National Immunization Programme, but engagement of the NRA is not at desired level. The NRA requires further strengthening and particularly lacking independence of regulatory system. A new drug law has been submitted to the Parliament, which is expected to contribute strengthening of medicine and vaccine regulatory system in Armenia, if approved.

2.1.2. Costing and financing

Gavi is the only source of external funding for Armenia’s immunization program, but its support will cease in 2018 following the country’s graduation. Armenia has consistently complied with its co-financing obligations and has never defaulted on its co-payments despite a challenging economic situation. MoH budget has been progressively decreasing in relative terms (from 2.2% of GDP in 2008 to 1.73% in 2015, with a further expected decrease to 1.43% in 2018).

cMYP: Armenia’s current cMYP (costed and budgeted) covers 2011-2015. It is being successfully implemented, with programme financial requirements being met and available resources efficiently used. The country is currently working on the 2016-2020 cMYP and expects to finalize it in Q4 of 2015.

Government funding: Armenia’s immunization program benefits from availability of secured funds through the use of a separate budget line for vaccines.

In the recent years, the government has nearly doubled routine vaccine budget (from 400 million dram, or US\$988k, to 772 million dram, or US\$1,9m) and budget commitments have been honored in full and in a timely fashion. The increased vaccination budget is expected to cover growing co-financing commitments in the coming years.

Table 3. Routine Immunization Budget Dynamic, 2005-2015.

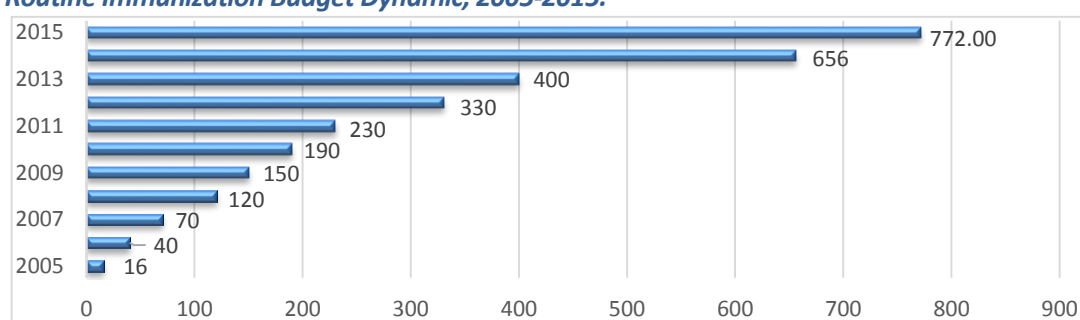


Table 4. Public allocations for immunization program, health care budget, public health budget, 2012-2017, x 1,000 AMD

Expenditure/year	2012	2013	2014	2015	2016	2017
Total Health	67,171	72,020	80,729	84,227	82,097	82,244
Public Health	3,070	3,160	3,983	5,437	5,342	5,813
Routine Immunization	338	400	656	772	1,061	1,061
Government co-financing (routine vaccines)	55%	75%	60%	88%	91%	96%

Sources: National Budget Laws of 2012, 2013, 2014 and 2015; MTEF of 2015-2017; 2014 internal report on EPI performance

Donor funding: GAVI is the only external source supporting Armenia's NIP. From 2016 onwards, the MoH total budget will be capped at around 82 billion drams (\$176m) and no further growth is expected in the immediate future. It is however not expected to affect immunization budget and specifically future co-financing payments, as the government has committed to covering immunization budget needs even if this requires reallocation of funds from other health budget lines. Donor funding from the Global Fund and USAID for areas other than immunization will also cease by 2017, making the coming two years critical for ensuring the sustainability of the Armenian health funding landscape.

Procurement mechanism: Gavi-supported vaccines are procured through UNICEF Supply Division (SD), but the Government's commitment to procure through SD is short-term (on annual basis), and thus vulnerable to potential changes. Among routine vaccines, about 25% in budget terms are self-procured (some, such as Hepatitis A, Meningococcal, and rabies, due to unavailability of relevant presentations through UNICEF). There are some voices in favor of self-procurement for vaccines graduating from Gavi support. The argument provided is that according to the Armenian legislation, the state procurement should be based on the results of an open tender. However, choosing self-procurement for Armenia would not be a sustainable and cost-effective option, and even the most conservative estimates of market prices would be significantly above those available through SD. Continuing procurement through UNICEF SD is especially important and beneficial for Armenia considering the June 2015 Gavi Board decision to approve access to Gavi prices for graduating countries for additional 5 years after graduation.

Table 5. Potential implications of changing procurement modalities in Armenia

Products	Cost/UNICEF	Median Cost /Self-procured	Min Cost /Self-procured
BCG	\$ 10,720	\$ 102,737	\$ 30,977
DTaP	\$ 338,556	\$ 398,936	\$ 114,598
DTwP-Hib-HepB	\$ 337,690	\$ 1,298,808	\$ -
IPV	\$ -	\$ 312,179	\$ 213,932
HepB_Pediatric	\$ 19,049	\$ 225,221	\$ 21,060
MMR	\$ 245,908	\$ 624,743	\$ 170,268
Td	\$ 32,656	\$ 1,011,849	\$ 59,896
Rotavirus	\$ 196,553	\$ 1,266,162	\$ 1,183,946
PCV	\$ 408,197	\$ 6,191,642	\$ 4,081,728
OPV	\$ 37,933	\$ 68,131	\$ 54,118
Total	\$ 1,627,262	\$ 11,500,408	\$ 5,930,523
	Self-procurement/UNICEF	x 7	x 3.6

Source: UNICEF Supply Division data for EURO region

2.1.3. Other system components

HR Management

Armenia's Immunization Program benefits from a strong and well defined structure of program management, with specific roles and responsibilities and committed personnel, under a strong leadership of the EPI manager who has been leading the program since 2006. Commitment to continued education and specialization courses for staff of all relevant structures is strong. On the other hand, understaffing has been noted at NRA for registration and marketing authorization of vaccines. There are also human resources availability challenges at sub-national levels.

Cold Chain and logistics

Armenia has a well-established vaccine management system, including effective cold chain and logistics management systems. Investment in strengthening cold chain capacity is continuous. National guidance documents and visual aids are available to support best vaccine management practices. Immunization supply chain has been optimized by reducing one level (district), bringing the total number of levels to 3 (national, marz, and facility). Armenia has had an uninterrupted and efficient vaccine supply (with no stock-outs, no wasted doses in unopened vials, low open vial wastage).

However, a number of challenges have been identified, including self-procurement for non-EPI vaccines that requires strong procurement capacity, wide use of unqualified cold chain equipment at service provision level, limited use of computerized data management systems (e.g. temperature monitoring, VSSM, CCEM), need for further strengthening of temperature monitoring in vaccine cold chain, and current structure of shared vaccine

management responsibilities by several MoH structures (EPI team, health inspection, national vaccine store manager) that requires clear definition of roles and responsibilities and a strong coordination.

Immunization service delivery

Armenia has extensive experience and well-functioning systems for new vaccine introductions. The country has a strong capacity for implementation of essential activities, including social mobilization of target communities, development and application of AEFI guidelines, conforming to the crisis management plan, and assigning experienced personnel to implementation of program activities on the grass-roots level.

Vaccine management assessments were conducted in 2011 and 2014, and development of improvement plans has been institutionalized, even though implementation of the identified recommendations has been slower than desired due to limited resources and strong need for technical assistance. National guidance documents and visual aids are in place.

2005 and 2010 DHS surveys, as well as the 2006 coverage survey show no gender inequity in Armenia with respect to immunization. Strengthening the immunization program in order to reach the remaining under-vaccinated populations remains a priority. Remaining un- or under-vaccinated in Armenia is multifactorial, with major variables of parents' income and educational status, as well as religious tendencies that lead to refusals.

Surveillance and reporting

Armenia's NIP has strong capacity for evidence-based decision-making through analysis of data obtained from robust reporting and surveillance systems. Supportive supervision program is in place, with defined frequency of visits, supervisory tools and feedback mechanisms. Sentinel surveillance for rotavirus, intussusception and bacterial meningitis is being carried out. However, the surveillance systems have traditionally always been funded by the external resources and there is no confirmation that the government will finance them after graduation. Financial sustainability of these sentinel surveillance systems is thus questionable, despite their high value for measuring vaccination impact.

Safety surveillance of vaccines is duly established in Armenia. Although the Scientific Centre of Drug and Medical Technology Expertise is tasked for that function, it is mainly managed by the National Immunization Programme. AEFI surveillance system is functional and well-equipped to collect and report relevant cases. Vaccine vigilance function is carried out at the immunization service provider level, at regional level, and at the national level. Overall legal framework of the AEFI system is well established and responsibilities of the different stakeholders are well-defined. There are clear pathways of reporting and giving feedback to the relevant parties. Analysis of the data on AEFI is done regularly and results are brought to the attention of decision makers. Approximately 5000 AEFI cases were reported in 2014, out of which 38 were serious cases.

A number of improvements would be beneficial, such as aligning AEFI case definitions with WHO recommendations, filtering cases at facility and/or regional level to avoid reporting of all AEFIs, additional trainings on causality assessments, etc. Currently, the system is very broad, trying to capture every event after immunization, including the minor ones. At the same time, thorough data analysis of AEFI is not performed and does not appear in key reports. AEFI cases are documented and presented in absolute numbers, making it difficult to carry out relevant analyses for action.

Communication

The National Center of Disease Control and Prevention has good relations with the media and is experienced in providing clear and unequivocal messages in emergency situations. Effective media follow-up is in place and importance of the need to periodically inform the population is well recognized. A website to increase public awareness on immunization has been developed with the support of UNICEF, but it has not been operational due to software problems. A crisis communication plan is being developed.

Communications on advocacy issues have however been challenging, especially with respect to communicating to health staff, advocating for resource mobilization, and addressing the small but growing anti-vaccine movement.

3. GRANT PERFORMANCE, CHALLENGES AND RENEWAL REQUESTS

3.1. New and underused vaccine support

3.1.1. Grant performance and challenges

In 2014, Gavi provided support to Armenia for three vaccines – Pentavalent, Rota, and PCV. According to JRF estimates (validated data will be provided to Gavi by WHO in July), for each of these vaccines coverage was above 90%, with the exception of the recently introduced PCV (estimated 76% coverage). Although the achieved coverage rates for newly introduced vaccines is satisfactory, including rotavirus vaccine, PCV vaccination require further efforts to catch-up on implementation to meet the established targets.

The country's own estimations of coverage are slightly different from those presented to JRF due to use of different coverage calculation techniques (cohort and calendar based).

Pneumococcal Vaccine:

PCV10 vaccine was originally scheduled to be introduced in 2013, but the introduction was delayed until September 2014 to obtain sufficient epidemiological data and avoid a sharp increase in co-financing in 2013 (with co-financing having already been affected by the introduction of Rota vaccine in late 2013). Post-Introduction Evaluation is planned for October 2015.

Lessons learned from rotavirus vaccine introduction in 2012 were used for planning and developing strategies that were effectively implemented during the introduction of PCV, including communication with hesitant parents, collecting data on the safety of multiple injections and providing reminders for health facilities on proper temperature monitoring and recording. Important advocacy and communication efforts were undertaken prior to PCV introduction as this vaccine would be less likely to be accepted by parents due to having multiple injections. The vaccine register and child development cards were updated in 2014 to include both Rotavirus and PCV vaccines.

By December 2014 the country received 184,000 doses of PCV10. The vaccine was administered to children born after 1 August 2014. The coverage with the first dose at the end of 2014 was 78%. The second and third dose of PCV were introduced in November and December 2014 respectively and reached 76% coverage rate. Delayed vaccinations (administered after 6, 12 and 18 weeks) were not included in the reported coverage. Considering that there has been less than one year since introduction of PCV in Armenia, it is too early at this stage to draw conclusions on national coverage rates. However, based on the experience and dynamics of Rotavirus vaccine introduction in the country, it is expected that country will manage to reach originally approved coverage rates.

For 2016, Armenia has expressed an interest in switching the preferred presentation to PCV13 (1 dose), notably to reduce wastage.

In 2014, a total of 339 AEFI cases for PCV vaccine have been registered, only 2 of them being serious.

Pentavalent vaccine (DTP-HepB-Hib)

2015 is the last year of Gavi's support for the Hib-containing pentavalent vaccine (DTP-HepB-Hib).

DTP-HepB-Hib was introduced in Armenia in 2009. The national coverage in 2014 reached 93% according to the JRF data. There is a discrepancy between the JRF and country-reported results due to the different way of calculation of target populations used on national level. It has already been agreed to address this issue through a planned data quality review in 2016 and align mentioned reporting systems. In March 2015 Armenia experienced two months of shortage of the pentavalent vaccine caused by the switch from the Lyophilized vaccine presentation to the liquid presentation, but shortage was absorbed by using buffer stock established at the national level and stock out was not experienced.

90% of the country's 51 districts report coverage above 90%, only 10% of districts (5 in total) – between 80 and 90%. In 2014, a total of 3809 AEFI cases for pentavalent vaccine have been registered, only 17 of them being serious.

Rotavirus vaccine

The rotavirus vaccine (Rota) was introduced in September 2012, targeting children born after September 2012. Two doses Rota coverage in 2013 and 2014 was 90.4% and 91.3% respectively. Even though this result is below the 95% coverage target, this still represents the highest coverage rate in the region for this vaccine that is technically difficult to administrate due to challenges with age restrictions and false contraindications. Prior to Rota introduction, EPI organized national conferences on the vaccine for health care professionals and academics and provided comprehensive trainings for the staff of regional health care facilities. Post-introduction evaluation (PIE) was carried out in 2013. The evaluation looked at Rota coverage for children born during October-December 2012 at each visited facility. Almost all facilities visited (except one) had greater than 80% rotavirus vaccination coverage.

Rotavirus sentinel surveillance has been implemented since 2009 in two sentinel hospitals in Yerevan with WHO support using standardized WHO surveillance protocols. All children under five years of age hospitalized due to diarrhoea were tested for rotavirus. The National Rotavirus Laboratory performance was confirmed by the WHO Reference Laboratory to be of a high quality. Data from rotavirus sentinel surveillance showed that from 2009-2012, 34% to 37% of children under the age of five hospitalized with diarrhoea at these sites had rotavirus infection. The NIP plans to utilise sentinel surveillance data to monitor the impact of rotavirus vaccination on the number of hospitalizations and number of rotavirus gastroenteritis in children less than five years of age.

In 2014, a total of 251 AEFI cases for Rota have been registered, only one of them being serious.

3.1.2. NVS renewal request / Future plans and priorities

For 2016, Armenia is eligible for requesting renewed support for only one vaccine – PCV. The country wishes to change the presentation from PCV10 to PCV13 (one-dose vial). Estimated needs for PCV requested from Gavi and covered by the country in 2016 are provided below:

Table 6: Estimated GAVI support and country co-financing (GAVI support)

		2014	2015	2016
Number of vaccine doses	#	152,400	9,300	25,000
Number of AD syringes	#	154,400	8,800	26,200
Number of re-constitution syringes	#	0	0	0
Number of safety boxes	#	1,725	100	275
Total value to be co-financed by GAVI	\$	541,500	32,500	90,500

Table 7: Estimated GAVI support and country co-financing (Country support)

		2014	2015	2016
Number of vaccine doses	#	31,600	43,200	29,100
Number of AD syringes	#	32,000	41,100	30,500
Number of re-constitution syringes	#	0	0	0
Number of safety boxes	#	375	475	325
Total value to be co-financed by the Country ^[1]	\$	112,500	152,500	105,500

As per the June 2015 Gavi Board Decision, Armenia can benefit from access to Gavi’s catalytic support for HPV vaccine. There is an interest from the population for introducing HPV in Armenia, but the issue has not yet been discussed by NITAG, and no cost-effectiveness or other studies or analyses have so far been carried out.

The country has scheduled to introduce IPV in October 2015, with the PIE to be conducted before the end of September 2016. Armenia will receive Gavi support for IPV until the end of 2018.

3.2. Graduation plan implementation

Graduation Assessment in Armenia was carried out in parallel with the Joint Appraisal mission from 8 to 12 June 2015. Graduation Action Plan, covering the period of 2016-2017, is currently being developed based on the findings of the assessment. Following its finalization by partners with inputs from Gavi, it will be shared with the National Center of Disease Control and Prevention for agreement and validation.

The signature of the Graduation Grant that will provide financial support for implementation of activities identified in the Graduation Action Plan, and disbursement of funds will be subject to the signature by Armenia of the Partnership Framework Agreement, expected to take place in late 2015 following the approval of the PFA by the Ministry of Foreign Affairs and its ratification by the Parliament.

Implementation of the Graduation Action Plan will be monitored on semi-annual basis by in-country partners, Gavi Secretariat and WHO EURO and will be aligned with Gavi's monitoring processes.

3.3. Financial management of all cash grants

During 2014, Armenia has not received any cash support from Gavi (PCV introduction grant was disbursed in 2013). No FMA has been conducted in Armenia during the years of Gavi support. There were also no audits of previously disbursed cash grants due to their amounts being below the established threshold.

Funds previously disbursed by Gavi for the NVS and ISS support are held in the same bank account, with US\$ 151,649 available in cash balance as of 31 December 2014. Management of the ISS funds is under the responsibility of Financial-Economic Department of MOH and MOF. The funds are incorporated into the national health sector plans and budgets. The annual budget for the upcoming year is approved by ICC.

In 2014, Armenia used a total of US\$45,516.28 of the remaining NVS/ISS funds as follows:

Table 8: 2014 expenditure of Gavi funds remaining in country

	Budget in AMD	Budget in USD	Actual in AMD	Actual in USD
Trainings				
Administrative expenditures (including training fees)	7,450,000	19,659.07	4,700,000	12,402.36
Per diems	5,760,000	15,199.49	1,703,450	4,495.06
Other expenditure				
Information-related expenditure (including printing)	4,200,000	11,082.96	3,816,000	10,069.66
Monitoring and fuel	5,759,200	15,197.38	5,571,400	14,701.82
Computers for Immunization staff at Central Level	1,458,000	3,847.37	1,458,000	3,847.37
Procurement of cold chain equipment	49,042,000	129,412.08	0	0
Total for 2014	73,669,200	194,398.35	17,248,850	45,516.27

These expenditures have been presented for approval to the Minister of Health, who validated the use of remaining NVS/ISS funds for these purposes. For the funds remaining in the NVS/ISS account as of 1 January 2015, the NIP requested approval of the Minister of Health to use them for procurement of refrigerated trucks and other cold chain equipment. The approval has been granted. At the end of 2015, no cash balance is expected to remain in the NVS/ISS account.

EPI program received an approval from the MoH through a Government Decree for the use of the remaining funds for implementation of the vaccine introduction activities for the IPV vaccine, scheduled for introduction in October 2015.

3.4. Recommended actions

Following the technical meetings and discussions that took place during the combined Joint Appraisal/Graduation Assessment mission, a number of recommendations were raised and discussed by the mission participants with in-country stakeholders, including the Minister of Health and other ICC members. These observations and recommendations focused on the key priority activities and suggested actions for addressing the challenges identified during the Joint Appraisal, notably with respect to enhanced potential for financial and programmatic sustainability of national immunisation programme.

Annex D provides a summary of these recommended actions, together with intended outcome/s, indication of the implementing agency (potential provider), modality, costing and potential sources of funding. A more detailed

activity plan, including full list of proposed technical assistance together with proposed costing, will be available in the coming weeks following the finalization of the Graduation Assessment Action Plan.

In summary, the **key recommended actions for Armenia for the coming years**, as described in the Executive Summary section above, are:

1. Building and strengthening resource mobilization capacities, including diversifying funding sources and reaching out to potential internal and external donors;
2. Updating legislation on vaccine management practices and introducing technology to supply chain;
3. Developing specific strategies for reaching those segments of the population who remain unreached by immunization efforts;
4. Addressing medical workers' concerns about safety of new vaccines and immunization in general;
5. Addressing vaccine hesitancy and refusals through use of qualitative research and through developing and implementing communication strategies aiming at behavior change; and
6. Improving data quality and aligning data systems with international requirements by conducting a data quality review and implementing its recommendations.

4. TECHNICAL ASSISTANCE

4.1 Current areas of activities and agency responsibilities

In 2014, Armenia received technical assistance from the WHO on the following:

- 1) EVM assessment and development of improvement plan
- 2) Workshop on immunization financing and immunization
- 3) Capacity building activities for NITAG members (visit to a well-functioning NITAG)
- 4) Participation in regional technical advisory group and program managers meeting, both from EPI and NITAG side
- 5) Cold chain inventory study
- 6) Monitoring of implementation of prior recommendations
- 7) Preparatory work for PCV introduction
- 8) Technical support and provision of supplies to new vaccine surveillances (IBD and Rota) and to Rota vaccine safety through Intussusceptions Sentinel Surveillance
- 9) Sub-regional workshop on vaccine risk management and risk communication
- 10) Technical support for impact study of rotavirus vaccines

UNICEF was scheduled to contribute to the EVMA through provision of technical assistance, but due to delays in hiring a consultant was unable to do so. No other assistance was provided by UNICEF to Armenia's NIP in 2014, besides vaccine procurement.

4.2 Future needs

As Armenia will graduate from Gavi support in 2017, technical assistance that can be provided to the country is limited to the 2016-2017 period. The majority of technical assistance during this period will be provided through the Graduation Action Plan, which is currently being finalized in close collaboration with partners and in-country stakeholders. Some of the technical assistance, however, notably for the routine on-going immunization activities, is proposed to be channelled through the Joint Appraisal/Partnership Engagement Framework stream. These activities include assistance with IPV post-introduction evaluation, preparation of the new HPV proposal and introduction (if the country applies for HPV support and receives it), standard assessments and evaluations (e. g.

coverage surveys), as well as regional workshops and conferences aimed at increasing capacity of in-country experts in various areas of immunization work. More details are provided below.

The key future priorities for Armenia, as reported by the country in the 2014 APR and redefined during the joint appraisal, are:

Short-term (2015):

1. IPV vaccine introduction (revision of regulatory documents, development of training and communication and social mobilization materials, conducting national and regional workshops, trainings of HCWs and academic staff) – being implemented in 2015
2. Development of cMYP for 2016-2020 – being implemented in 2015
3. Conducting PCV PIE – to be conducted in 2015
4. Procurement of cold chain equipment (refrigerators, cold room, temperature monitoring devices) and distribution to HCFs – to be procured soon.

Medium- to long-term (2016-2017):

5. Stay vigilant to increasing financial resource requirements in coming years.
6. Maintain current procurement modality (procuring through UNICEF Supply Division) in accessing to vaccines at affordable prices.
7. Introduce new technologies to supply chain system to improve its efficiency.
8. Sustain programme performance level by investing in quality of services (through increased training, supervision and monitoring activities).
9. Be proactive in addressing (growing) vaccine hesitancy and refusals.
10. Time to invest in e-health and electronic immunization registries.

Based on above (medium-to-long term) priorities (and key recommendations), the technical assistance areas and activities listed below have been proposed. Detailed list of activities for the next two years – 2016/2017 – (that require technical assistance), together with intended outcome/s, indication of the implementing agency (potential provider), modality and potential sources of funding, is provided in Annex D.

Immunization financing & resource mobilization	<ul style="list-style-type: none"> • Training staff on resource mobilization and development of a resource mobilization action plan • Develop advocacy materials for resource mobilization (to communicate benefits of immunization, impact of vaccination, etc) • Monitor implementation of graduation action plan and report on progress achieved
Vaccine procurement	<ul style="list-style-type: none"> • Explore policy and legal opportunities to grant longer term Government commitment to procurement through UNICEF • Continued advocacy on benefits of procuring through UNICEF • Conduct external review of vaccine procurement practices to identify areas for improvement for efficiency increase • Continued capacity building in (self) procurement (for non NIP and/or vaccines that are not available in UNICEF portfolio)
Evidence-based decision-making	<ul style="list-style-type: none"> • Continued capacity building support to NITAG members (participation to regional meetings, visit to other NITAGs to exchange knowledge and experiences) • Expand disciplines engaged in NITAG (including social & behavioural sciences, health economics) • Conduct cost effectiveness study on introduction of HPV vaccine • Conduct readiness study on HPV vaccination • Document impact of rotavirus and PCV vaccinations • Provide continued technical assistance and supply support to both new vaccine sentinel surveillance networks

Programme performance	<ul style="list-style-type: none"> • Address false contraindications and hesitation to administer vaccines simultaneously through capacity building activities • Conduct IPV PIE and technical assistance in switching to b-OPV • Conduct qualitative study to better understand reasons for vaccine refusals and hesitancy and tailor immunization programme according to needs of un- and under-vaccinated • Conduct MLM training to rayon level and IIP training to facility level staff • Assess and revise medical and nursing curricula according to needs of the NIP • Conduct quarterly supportive supervision • Review legal provisions on immunization (scattered in current legislative documents) and advocate for introduction of consolidated provisions through the new public health law in the pipeline, if any
Data quality	<ul style="list-style-type: none"> • Conduct (external) data quality review to assess areas for improvement • Conduct capacity building in improving target population estimates • External support to review immunization module of the e-health under design • Provide technical support to introduce electronic immunization registries
Communication & social mobilization	<ul style="list-style-type: none"> • Finalize communication strategy and plan • Finalize vaccine safety risk and crisis communication plan • Restore immunization website (upgrade software) • Support to development and printing of key communication materials • Support in conducting communication activities • Provide in-country training on crisis communication • Provide training to media staff
Vaccine management & logistics	<ul style="list-style-type: none"> • Conduct cold chain inventory review and needs assessment • Upgrade cold chain infrastructure by purchasing WHO prequalified equipment for service delivery level • Improve use of computerized data management systems for supply chain • Upgrade temperature monitoring technology used (introduce continuous temperature monitoring system) • Conduct cold room temperature monitoring • Develop a systematic training programme on vaccine management and conduct trainings • Update legislative basis for vaccine management practices
Vaccine regulations & AEFI surveillance system	<ul style="list-style-type: none"> • Introduce market authorization procedures for programme vaccines • Introduce 'expedited review procedures for registration of WHO pre-qualified vaccines' • Familiarize staff to WHO recommendations on AEFI surveillance system (through a sub-regional workshop) • Conduct AEFI surveillance system assessment • Revise AEFI surveillance system in line with assessment recommendations • Train key field staff on revised procedures

5. ENDORSEMENT BY ICC, HSCC OR EQUIVALENT & ADDITIONAL COMMENTS

The findings of the Graduation Assessment and Joint Appraisal have been presented to the Minister of Health, in-country partners (UNICEF and WHO country offices) and other members of ICC on 16 June 2015 during a meeting specifically called for this purpose.

Please find the full presentation in Annex E to this report.

Issues raised during debrief of joint appraisal findings to national coordination mechanism:

During the presentation, the Minister of Health welcomed the June 2015 Gavi Board decision on continued access to Gavi prices for countries graduating from Gavi support for a duration of additional five years and confirmed his strong commitment to continuing the procurement of relevant vaccines through UNICEF Supply Division in the interest of quality and efficient use of resources. The Minister reiterated the key priorities for the Ministry of Health as maintaining the current success of the vaccination program, focusing on preventive activities as a more efficient way of using health resources, investing in tools to reach health targets, developing and establishing the new methodological guidelines on health and adopting the new public health law which will allow the Ministry to undertake additional developments.

6. ANNEXES

Annex A

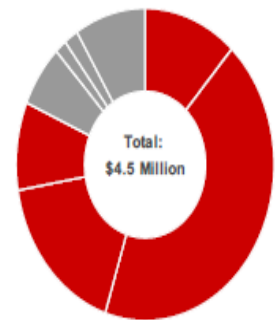
KEY DATA

Armenia

Total population (2015)	2,989,467
Birth cohort (2015)	39,455
Surviving Infants (surviving to 1 year per year, 2015)	38,749
Infant mortality rate (deaths < 1 year per 1000 births, 2013)	14/1000
Child mortality rate (deaths < 5 years per 1000 births, 2013)	16/1000
World Bank Index, IDA (2012)	4.12
Gross Nation Income (per capita US\$, 2013)	3,800
Co-financing status (2015)	Graduating
No. of districts/territories (2013)	51



Non-vaccine support	19%	Vaccine support	81%
	\$836,302		\$3,679,800



Data refers to disbursed values, date as per above chart

Gavi support for Armenia

Type of support	Approvals 2001-2020 (US\$) (31 Mar 2015)	Commitments 2001-2020 (US\$) (31 Mar 2015)	Disbursements 2000-2015 (US\$) (31 Mar 2015)	% Disbursed (31 Mar 2015)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Health system strengthening (HSS 1)	\$291,500	\$291,500	\$291,500	100%															
HepB mono (NVS)	\$530,459	\$530,459	\$530,459	100%															
Immunisation services support (ISS)	\$79,860	\$79,860	\$79,860	100%															
Injection safety support (INS)	\$64,942	\$64,942	\$64,942	100%															
Penta (NVS)	\$1,845,678	\$1,845,678	\$1,953,926	106%															
Pneumo (NVS)	\$841,000	\$841,000	\$783,353	93%															
Product Switch Grant (PSG)	\$11,500	\$11,500																	
Rotavirus (NVS)	\$467,061	\$467,061	\$412,063	88%															
Vaccine Introduction Grant (VIG)	\$400,000	\$400,000	\$400,000	100%															
Total	\$4,532,001	\$4,532,001	\$4,516,103																

Red line on table indicates duration of support based on commitments.
 Commitments: Multi-year programme budgets endorsed in principle by the Gavi Board. These become financial commitments upon approval each year for the following calendar year.
 Approvals: Total Approved for funding

Armenia DTP3 / immunisation coverage

DTP3 - WHO/UNICEF estimates (2013)

Grade of confidence N/A

DTP3 - Official country estimates (2013) 95%

M:F sex ratio at birth (2015) 1.13

Household survey: DTP3 coverage for male (2010) 94.80%

Household survey: DTP3 coverage for female (2010) 95.30%

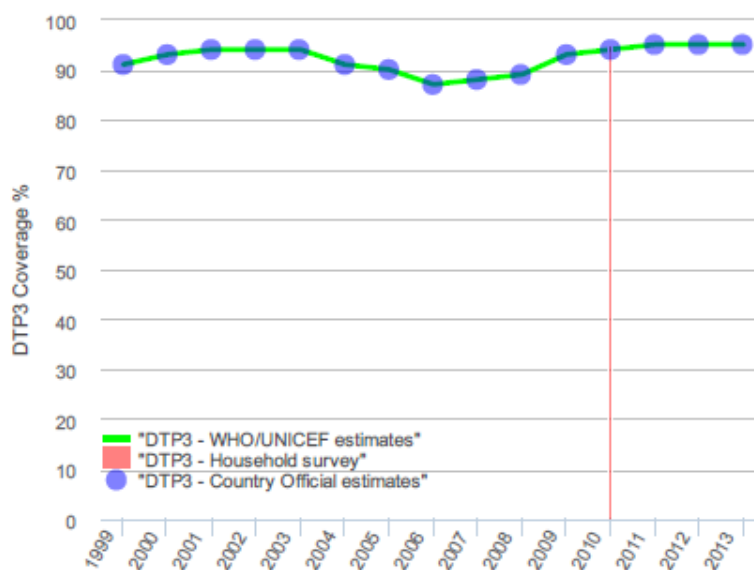
Household survey: Last DTP3 survey (2010) 95%

% districts achieving > 80% DTP3 coverage (2013) 100%

% districts achieving < 50% DTP3 coverage (2013) 0%

MCV WHO/UNICEF estimates (2013) 97%

Polio WHO/UNICEF estimates (2013) 96%



Annex B

Status of implementation of the key actions from the last joint appraisal and any additional High Level Review Panel (HLRP) recommendations

Key actions from the last appraisal or additional HLRP recommendations	Current status of implementation
<p>The country uses standard formula to calculate coverage: number of surviving infants fully vaccinated / number of surviving infants. However, the immunisation program uses different sources for the nominator and denominator. The country needs TA on coverage calculation, and recommendations should be provided on what data to use as denominator to calculate vaccine coverage, including possibility to triangulate available population data.</p>	<p>Specific TA is being proposed through the Graduation Action Plan (to be implemented in 2016-2017)</p>
<p>The recommendations from the EVSM-VMA-EVM, needs to be implemented. During the last three years, only 57% of those recommendations were implemented. The tender on the procurement of the new refrigerators needs to be finalised and the refrigerators needs to be procured. It is planned that a comprehensive cold chain inventory and needs assessment shall be implemented to address cold chain needs at all levels. Country shall focus on procuring WHO prequalified equipment for storing vaccines.</p>	<p>Procurement of refrigerators is under way (through the remaining cash balance and new IPV VIG)</p>
<p>Governmental support towards EPI financing needs to be strengthened.</p> <p>A graduation assessment was conducted in May 2013 and there is an agreed report and plan with key recommendations. As per the GAVI Alliance board decision of November 2013, there will be another assessment by the Alliance (planned for 2015) to further detail the graduation process and develop a costed plan which will be partially supported by GAVI.</p>	<p>Government support toward EPI financing needs has been demonstrated by the fact that the government has nearly doubled routine vaccine budget (from 400 million dram, or US\$988k, to 772 million dram, or US\$1,9m) and budget commitments have been honored in full and in a timely fashion. The increased vaccination budget is expected to cover growing co-financing commitments in the coming years.</p> <p>Development of the final costed Graduation Action Plan is currently under way.</p>
<p>Secretariat to revise targets for dose calculation and decision letter (DL) for 2015 to be amended for PCV, given the delayed introduction of the vaccine and the inability to amend the 2014 DL.</p>	<p>Completed. 2015 Decision Letter was amended as required.</p>
<p>Country is requested to correct information related to GAVI fund's closing balance in income received. As the amount of income of US\$ 44,515 coming from other donor is included in GAVI fund's balance and income, the balance of US\$ 184,251 is overstated by that amount. The real balance of GAVI funds as at 31/12/2013 should be US\$ 139,736.</p>	<p>Final balance as of 31 December 2014 has been discussed with country. Remaining balance has been approved by a Government Decree for reprogramming to procure cold chain equipment in 2015 (refrigerated truck, fridges).</p>

Annex C

Description of joint appraisal process

Three processes (the Joint Appraisal, as well as GAVI graduation and national regulatory assessment) were conducted jointly and simultaneously.

Joint Appraisal and Graduation re-assessment were conducted from June 8, 2015 to June 16, 2015 and were built upon information submitted in 2014 APR, details provided in the 2013 Internal Appraisal, 2013 post-introduction evaluation of rotavirus vaccine, May 2013 graduation assessment, additionally covering programmatic and performance related challenges. In this perspective, the overarching objective was to assess the conditions of continuous performance of the Armenian immunization program, which up to now has been both highly effective and efficient.

Main institutions and persons visited:

- **Ministry of Health of Armenia** (Minister of Health, Deputy Minister of Health, EPI Manager, Legislation and Analysis Division, Finance and procurement Division, National Center of Disease Control and Prevention, Immunization and vaccine preventable disease epidemiology department, Head of International Cooperation Department of the MoH)
- **Drug and medical technology expertise center of Armenia**
- **Ministry of Finance of Armenia** (Deputy Minister)
- **National Assembly of Armenia** (Chair of the Standing Committee on Health Care, Maternity and Childhood)
- **UNICEF Country Office**
- **WHO Country Office**
- **Research community / Academia** - Members of the National Immunization Technical Advisory Groups (NITAG)

Discussions and technical meeting with people and organisations listed above took place during the combined Joint Appraisal and Graduation Assessment mission. The findings of these discussions, as well as the recommendations and proposed activities to be implemented through the Graduation Action Plan and Joint Appraisal technical assistance, have been presented to the MoH, ICC members, and WHO and UNICEF country representatives. The draft Joint Appraisal report has also been circulated to all relevant stakeholders, and feedback received was incorporated in the final version of the report.

- Annex E. Presentation to the ICC and Minister of Health



De-briefing (to the MoH & ICC members): Graduation assessment and action plan development June 2015, Armenia

**WHO Europe
WHO Headquarters
UNICEF Supply Division
GAVI Secretariat
Sabin Institute**

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unicef



**World Health
Organization**

Mission Members

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Aleksandra Krukar (UNICEF Supply Division)
Eka Paatashvilli (Sabin Institute)

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**World Health
Organization**

General Observations - Strengths

- Strong political commitment to the national immunization programme
- Strong technical capacity of the national immunization programme
- Motivated and functional national immunization technical advisory group (NITAG)
- Successful implementation of the multi-year plan on immunization & national immunization plan (programme financial requirements are met and available resources efficiently used)
- Good collaboration among involved structures and with partners
- As a result:
 - High coverage maintained, new vaccines successfully introduced (12 antigens)
 - Vaccine resource requirements very well communicated to budgetary process (vaccine budget tripled as of 2010), progress towards financial self-sufficiency is on track
 - Polio-free status sustained and measles elimination is on track

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General Observations - Challenges

- Armenia economy is heavily affected by the global crisis
 - GDP growth is expected to be 1% in 2015, but expected to recover
 - Government expenditures on health as % of GDP: 1.73 in 2015; 1.53 in 2018
 - Government expenditures on health is not expected to increase, expected to be around 84 B AMD (2015-2018; MTEF projection).
- Measles-rubella elimination process is challenged by imported cases
 - 8 imported cases mostly among un- or under-vaccinated
- Newly introduced vaccines require further efforts to catch-up desired rates, but reached global target (Rota last 91%, rotavirus vaccine coverage is challenged with time limited vaccination; PCV3 76%, introduced in October 2014)
- Vaccine management & logistics require technological upgrade
- Dependence on external financial support for operational activities
- Market authorization for vaccines requires strengthening
- Anti-vaccination movement among certain religious groups

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Immunization financing & resource mobilization - Strengths

- Vaccine resource requirements have been precisely calculated and well communicated to budgetary process (to MoH budget and MTEF process) case
 - Process benefits from multi-year planning in calculating the requirements
 - All stakeholders are well informed about the requirements
- Immunization is a high priority for the Government and Ministry of Health
 - All stakeholders provide support to immunization (benefits of immunization is well communicated to all stakeholders)
- Country co-financing requirements have been met without any disruption and no vaccine stock-out observed due to funding gap
- Vaccine budget has been significantly increased in 2015 and increased amount is expected to cover increasing co-financing in coming years
- Comprehensive Multi-year Plan for the period 2016-2020 will be developed in 2015, which will provide more precise information on resource requirements

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Health and vaccine financing trends

Year	GDP (B AMD)	GHE (B AMD)	GHE/GDP	Vx Bd Total (M AMD)	Vx Bd Rout (M AMD)	Exchange 1 \$ = . AMD	Vx Bd Rout (US\$ 1,000)	Rout. Vx. Req. US\$1,000
2006	2,656.2	39.4	1.5	40	40			
2007	3,149.3	46.9	1.5	70	70			
2008	3,568.2	50.0	1.4	120	120	325	369	
2009	3,141.7	56.2	1.8	150	150	305	492	365
2010	3,460.2	56.1	1.6	190	190	386	492	
2011	3,777.9	63.3	1.7	230	230	358	643	638
2012	4,000.7	64.5	1.6	410	330	379	871	708
2013	4,276.2	64.4	1.5	465	400	405	988	907
2014	4,528.9	76.6	1.7	1,890	656	405	1,620	1,124
2015	4,720.0	84.0	1.73	1,890	772	411	1,878	1,400
2016	4,900.0	83.6	1.70	1,890	1,061			
2017	5,300.0	83.6	1.58	1,890	1,061			
2018	5,700.0	84.4	1.53	1,890	1,061			

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Immunization financing & resource mob. – Challenges & recommendations

- Ministry of Health budget will stay constant till 2018 (MTEF projections)
 - Requires sustaining the current political commitment to the Programme by continuous communication of benefits of immunization – impact of vaccination
- Unexpected increase in inflation and currency exchange rate during upcoming years poses a threat for financial sustainability
 - May require implementation of further efficiency measures in use of available resources – WHO TA in 2016-2017)
- Operational activities that ensure quality of the Programme are heavily under funded (\$2 per infant for activities vs \$50 spent per infant on vaccines)
 - Current external financial support should be taken over by the Government after graduation from GAVI support
- Resource mobilization efforts may/will require further structuring and enhancement
 - Training programme staff and budgeting-financing staff on resource mobilization (WHO tool on resource mobilization - WHO TA)

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Vaccine procurement - Strengths

- Immunization is a high priority for the Government, so the vaccines for the Ministry of Health
- Secured funds through use of a separate budget line for vaccines
 - Process benefits from multi-year planning in calculating the vaccine requirements
 - All stakeholders are well informed about the requirements
- Vaccine budget has been significantly increased in 2015 and increased amount is expected to cover increasing co-financing in coming years and comprehensive multi-year planning exercise for the period 2016-2020 that will be conducted this year will provide more precise information on future requirements
- Benefiting from UNICEF Supply Division procurement services in accessing vaccines at affordable prices (not limited to GAVI-supported vaccines, but all vaccines available in Supply Division's portfolio) and thus maximizing efficient use of available resources

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Comparison of realized vaccine prices through different procurement modalities

Products	Armenia		UNICEF		Governments' self-procurement, 2014		
	2013	2014	2013	2014	Min	Median	Max
BCG	\$ 0.07	\$ 0.07	\$ 0.07	\$ 0.07	\$ 0.19	\$ 0.62	\$ 12.50
DTaP	\$ 8.00	\$ 7.82	\$ 8.00	\$ 8.75	\$ 2.65	\$ 9.21	\$ 22.58
DTwP-Hib-HepB	\$ 2.95	\$ 2.60	\$ 2.95	\$ 2.95		\$ 10.00	\$ 25.00
IPV		\$ 0.00		\$ 1.00	\$ 4.94	\$ 7.21	\$ 12.94
HepB Pediatric	\$ 0.38	\$ 0.44	\$ 0.38	\$ 0.38	\$ 0.49	\$ 5.20	\$ 11.95
MMR	\$ 3.25	\$ 2.84	\$ 3.25	\$ 3.25	\$ 1.97	\$ 7.22	\$ 14.38
Td	\$ 0.11	\$ 0.12	\$ 0.11	\$ 0.12	\$ 0.22	\$ 3.72	\$ 8.90
Rotavirus	\$ 2.50	\$ 2.27	\$ 2.53	\$ 2.59	\$ 13.67	\$ 14.62	\$ 15.57
PCV		\$ 3.00		\$ 3.30	\$ 30.00	\$ 45.50	\$ 66.28
OPV	\$ 0.21	\$ 0.16		\$ 0.18	\$ 0.23	\$ 0.29	\$ 7.67

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Implications of changing procurement modality in Armenia

Products	Cost through UNICEF	Median cost /self-procured	Min cost /self-procured
BCG	\$ 10,720	\$ 102,737	\$ 30,977
DTaP	\$ 338,556	\$ 398,936	\$ 114,598
DTwP-Hib-HepB	\$ 337,690	\$ 1,298,808	\$ -
IPV	\$ -	\$ 312,179	\$ 213,932
HepB Pediatric	\$ 19,049	\$ 225,221	\$ 21,060
MMR	\$ 245,908	\$ 624,743	\$ 170,268
Td	\$ 32,656	\$ 1,011,849	\$ 59,896
Rotavirus	\$ 196,553	\$ 1,266,162	\$ 1,183,946
PCV	\$ 408,197	\$ 6,191,642	\$ 4,081,728
OPV	\$ 37,933	\$ 68,131	\$ 54,118
	\$ 1,627,262	\$ 11,500,408	\$ 5,930,523
	Self-procurement/UNICEF	x 7	x 3.6

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Vaccine procurement– Challenges & recommendations

- Government's current short-term (on annual basis) commitment to procure vaccines through UNICEF Supply Division is vulnerable to potential changes
 - Explore policy and legal opportunities to grant longer term Government commitment to pooled vaccine procurement through UNICEF SD
 - Continued advocacy on benefits of procuring through UNICEF Supply Division
- Self procurement of non-programme vaccines (that are not available in Supply Division's portfolio) require strengthened procurement capacity
 - Continue building capacities in procurement, by improving the knowledge on vaccine market dynamics, how vaccine prices evolve, measures that increase procurement efficiency; such as long-term contracting.
 - Review vaccine procurement practices and identify areas for improvement (WHO TA)
- Shared budget line for programme and non-programme vaccine: threat for programme vaccines, if self-procurement is not efficient. But an opportunity, if used efficiently.
 - Therefore, improve efficiency of self-procurement and use saving to expand the programme vaccines, i.e., HPV vaccine.

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Evidence-based decision-making - Strengths

- Functional and motivated national immunization technical advisory group (NITAG).
 - Established in 2011, restructured in 2012
 - Populated with leading and reputable specialists
 - National Regulatory Authority (NRA), Expert Review Committee (adverse events), National Certification & Verification Committee (NCC & NVC) representation
 - Empowering the Programme (as being spokespersons) and providing strategic guidance (recommendations)
 - Members participated to trainings and WHO meetings
- Rotavirus surveillance is in place since 2009 and functional
 - Sentinel sites are functional and providing surveillance data
 - Case control study on monitoring impact of rotavirus vaccination
 - Intussusception surveillance is in progress
 - Publication of findings is in progress
- Invasive bacterial surveillance is in place since 2012 and functional
 - Expanded in 2013 and providing data on impact of vaccination
 - Plan to shift to PCV-13 in 2016

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Evidence-based decision-making – Challenges & recommendations

- ❑ NITAG members require continuous update on programme policies and strategies
 - Continued WHO support (disseminating guidance and providing training, participation to WHO meetings, visit to other NITAGs, experts attending to NITAG meetings, twinning.)
- ❑ NITAG composition lacks some disciplines
 - Ministry of Health may wish to consider adding members from social & behavioral sciences, health economics.
- ❑ NITAG should consider introduction of HPV vaccine (following collection of local evidence on vaccine cost-effectiveness)
 - WHO support in conducting cost-effectiveness study on introduction of HPV vaccine
- ❑ Sustainability of both new vaccine surveillance systems (after graduation from GAVI support) should be considered
 - Ministry of Health should gradually take over the external financial support provided
 - Armenia's experience and findings should be shared with other countries (publications encouraged – WHO TA)

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Programme performance & data quality - Strengths

- Armenian National Immunization Programme is still one of the most well-performing programmes and presented as a success case
 - Coverage against most of the antigens is above 95%
 - WHO/UNICEF coverage estimates, disease epidemiology and surveillance data verifies the reported high coverage
- Both rotavirus (in Nov 2012) and pneumococcal vaccines (Sept 2014) have been successfully introduced and are expected to catch-up targeted coverage rates
- 90% of districts above 90% coverage with DTP3, rest 80 – 90% (5 out of 51)
- Surveys and study on unvaccinated (in 2012) show no gender inequity
- Outreach immunization services have been institutionalized
- Upcoming public health law should be seen as an opportunity to improve performance further
- Reporting system is robust and functional
 - Timeliness of vaccinations is being monitored
- Ministry of Health is planning to introduce e-health (electronic immunization registries). Planning and designing is in progress.

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Programme performance – Challenges & recommendations

- ❑ Rotavirus vaccine coverage is challenged with time limitation for vaccination
 - Requires further efforts to improve timeliness of vaccinations (by eliminating false contraindications and increasing simultaneous administrations – WHO TA)
- ❑ Reaching the last few percent unreached is challenged by vaccine hesitancy and refusals (by some religious groups)
 - Qualitative studies to better understand reasons for refusals and use WHO tool on Tailoring Immunization Programme – WHO TA
 - Continued training to rayon and facility levels – WHO TA
 - Assessment and revision of medical and nursing curricula – WHO TA
 - Continued quarterly supportive supervision (increased collaboration between the Inspectorate and NCDC)
- ❑ Legislative provisions on immunization of the upcoming public health law should be defined carefully
 - Consult with WHO and other programme partners once legal provisions are drafted and obtain feedback

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Data quality – Challenges & recommendations

- ❑ Vaccination coverage reporting is challenged by use of different coverage calculation techniques (cohort and calendar based)
 - Data quality review in 2016, to assess bottlenecks and areas for improvement – WHO TA
 - Target population estimates require further improvement – WHO TA
 - Annual progress report (APR) and joint reporting form (JRF) require revision
- ❑ Ongoing e-health (and immunization module) development require consultation with technical units (Immunization Programme staff not involved)
 - WHO support in reviewing the pilot design to make sure that it meets programme requirements and benefits from available international knowledge and experience – WHO TA

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Communications & social mobilization - Strengths

- Communication plan exists
- Various communication means have been effectively used to communicate messages on immunization
- Key programme staff received training on communications
- Crisis communication plan is under development

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Communications & social mobilization – Challenges & recommendations

- ❑ Immunization website developed could not be maintained, due to software problems
 - Restoring software problems or replacing with a more user-friendly one (UNICEF TA)
- ❑ Programme requires additional support to enable continuity of key communication materials and communication activities
 - Supporting the Programme in developing and printing key communication materials (UNICEF TA)
 - Support the Programme (financially) in conducting communication activities (UNICEF TA)
- ❑ Additional national level and marz level staff require training on communications (including crisis communication)
 - Provide training to additional national level and sub-national level staff (WHO TA)
- ❑ Media staff requires better understanding on immunization
 - Provide training to media staff (WHO TA)

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Vaccine management & logistics - Strengths

- Vaccine management assessments (2011 and 2014) and development of improvement plans practice have been institutionalized
- National guidance documents and visual aids are in place
- Immunization supply chain is optimized (national – region/marz – health facility)
- Continuous investment in strengthening cold chain capacity
- Uninterrupted and efficient vaccine supply (no vaccine stock-outs, no wasted doses in unopened vials, low open vial wastage)
- Well established organizational structure for vaccine management, defined roles and responsibilities, strong management and committed human resources
- Supportive supervision in place, with defined frequency of visits, supervisory tools and feedback mechanism

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Vaccine management & logistics – Challenges & recommendations (1)

- ❑ Moderate progress in implementing Effective Vaccine Management recommendations
 - Integrate EVM assessment recommendations into annual and multi-year planning and budgeting and; establish a formal procedure to review the progress (i.e. ICC meetings).
- ❑ Further institutionalization of best vaccine management practices
 - Update legislative basis and establish a quality management system, by including definition of roles and responsibilities and developing standard operating procedures for each task. (WHO TA)
- ❑ Fragmented supervision due to new structure (Inspectorate vs NCDC)
 - Improve coordination between the Inspectorate and NCDC (by shared supervisory tools and guidance and by reporting to /findings sharing with NCDC), if this technical task cannot be solely delegated to NCDC.
- ❑ Limited use of computerized data management systems (temperature monitoring, stock management, cold chain inventory, etc)
 - Improve the use of computerized data management systems (i.e temperature monitoring, vaccine stock management, cold chain inventory) at national and marz level. (WHO TA)
 - Establish a process to document and communicate EPI needs to the e-health registry process.
- ❑ Temperature monitoring in vaccine cold chain requires further strengthening
 - Introduce and expand gradually continuous temperature monitoring in vaccine cold chain by procuring equipment and conducting capacity building activities. (WHO – UNICEF TA)
 - Conduct cold room temperature mapping.

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Vaccine management & logistics – Challenges & recommendations (2)

- ❑ Vaccine stock management system requires further improvement
 - Review and update the vaccine stock management system to improve traceability of products (i.e. diluents) and cold chain monitoring.
 - Establish min/max levels, document diluents, monitor cold chain distribution risks.
- ❑ Non pre-qualified cold chain equipment is widely used at service delivery level
 - Develop national requirements for vaccine cold chain equipment, based on WHO's pre-qualification requirements and use them in tender procedures to ensure procurement of adequate equipment
- ❑ Limited use of cold chain inventory data for further actions (i.e. formal review, needs assessment, equipment planning, maintenance support)
 - Conduct a formal cold chain inventory review and needs assessment to guide further actions on equipment planning and maintenance support (WHO – UNICEF TA)
- ❑ Lack of institutionalized training programme on immunization and vaccine management
 - Develop a national systematic training programme on immunization and vaccine management. (WHO TA)
- ❑ Human resource availability challenges at sub-national levels
 - Ensure availability of cold-chain staff at sub-national levels

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Vaccine regulations & AEFI surveillance - Strengths

- National regulatory authority - NRA (Scientific Center of Drug and Medical Technology Expertise) has been assessed and its performance is has been scored
 - **National regulatory system** : 85% (pass)
 - **Market authorization & licensing function** : 72% (pass)
 - **Pharmacovigilance & surveillance function** : 88% (pass)
- Market Authorization and Licensing regulation are aligned with the European and international regulations. All drugs and vaccines used in the country (except donated and humanitarian assistance vaccines) are registered by NRA and published on the Agency website.
- The regulatory system has the capacity to investigate adverse events following immunization (AEFI). AEFI surveillance system is functional. App 5000 AEFI cases were reported in 2014, out of which 38 were serious cases. Case investigation takes place at both marz and national levels.
- New drug law has been approved by the Government and submitted to the Parliament. It is expected to strengthen regulatory functions in Armenia.

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Vaccine regulations & AEFI surveillance – Challenges & recommendations

- Donated and humanitarian assistance vaccines are not registered (but managed through an Importation Authorization). Dossiers are not available to the Agency.
 - Register all vaccines
 - Introduce 'expedited review for registration of WHO pre-qualified vaccines'
- AEFI surveillance system requires update in line with WHO recommendations
 - Familiarize staff to WHO recommendations on AEFI surveillance system by participate to the sub-regional workshop (WHO TA)
 - Conduct AEFI surveillance system assessment to identify areas that require further improvement (WHO TA)
 - Revise the AEFI surveillance system in line with the recommendations of the assessment (WHO TA)
 - Train key field staff on revised procedures (make use of MLM and IIP trainings)
 - Train expert review committee members on causality assessment (WHO TA)
 - Explore possibilities of integrating AEFI reporting to immunization e-module within e-health initiative

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Summary of key recommendations

- ❖ Stay vigilant to increasing financial requirements in coming years
- ❖ Maintain current procurement modality in accessing to vaccines at affordable prices
- ❖ Introduce new technologies to supply chain to improve its efficiency
- ❖ Sustain programme performance level by investing in quality of services
- ❖ Be proactive in addressing (growing) vaccine hesitancy and refusals
- ❖ Time to invest in e-health and electronic immunization registries

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Next Steps

1. The graduation action plan (2016-2017) will be finalized in line with the recommendations provided and shared with the NCDC/MoH soon.
2. Endorsement of the Plan required by the ICC.
3. A communication should be sent to GAVI Secretariat requesting funding for the Plan.
4. Graduation grant will be channeled through WHO and UNICEF country offices to support implementation of activities. (Partnership Framework Agreement is a prerequisite).
5. Technical assistance will be provided by partners in implementing the action plan.
6. Implementation of the plan will be monitored on semi-annual basis (by in-country partners, WHO Regional Office and GAVI Secretariat) and aligned with joint appraisals (on annual basis), where the plan could be updated, if required.