Application Form for Human Papillomavirus Vaccine (HPV) Demonstration Programme

Deadlines for submission of application:
15 January 2016
1 May 2016
9 September 2016

Submitted by:

The Government of [Armenia]

Date of submission: [insert date]

Form revised in 2015
(To be used with Guidelines of October 2015)

The application form and attachments must be submitted in English, French, Portuguese, Spanish, or Russian.

Please ensure that the application has been received by the Gavi Secretariat on or before the day of the deadline.

SUMMARY TABLE

Component	Country information
Date of introduction	*September 2017*
Target population	*15,000*
Number of districts	*11*
Vaccine preference	*Gardasil quadrivalent (Merck)*
Total Budget (Year 1 + Year 2) requested from Gavi	*$294,000*
Total costs to be covered by country and/ or other partner resources	*$91,000*
Estimated date of national introduction	*September 2017*
Programme manager/ coordinator	*Gayane Sahakyan* *Manager, National Immunization Program* *Advisor to the General Director, National Center for Disease Control and Prevention, Armenia*

1. APPLICATION SPECIFICATION

1a. Application specification		
Please specify vaccine preference.		
Preferred vaccine **Bivalent (GSK) or Quadrivalent (Merck)** **See below for more information**	**Month and year of first vaccination**	**Preferred second presentation[1]**
Quadrivalent (Merck)	*September 2017*	

[1] This "**Preferred second presentation**" will be used in case there is no supply available for the preferred presentation of the selected vaccine ("**Vaccine**" column). If left blank, it will be assumed that the country will prefer waiting until the selected vaccine becomes available.

1b. Application specification
Please summarise the rationale for choice of preferred vaccine. Also, please clarify whether the vaccine is licensed for use in the country **We have chosen quadrivalent vaccine because it includes two additional HPV types (6 and 11) that prevent genital wards, the price of quadrivalent vaccine offered by GAVI is slightly lower than bivalent vaccine, and it is supplied in single-dose vials which will help to reduce wastage rate. The quadrivalent vaccine is licensed in the country for use in single-dose vials.**

	For more information on WHO prequalified vaccines: www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/index.html

2. EXECUTIVE SUMMARY

2. Executive Summary
Please summarise the rationale and the expected outcome of the HPV vaccination demonstration programme Plan. **According to figures from Globocan 2012, cervical cancer is the fourth-most common cancer in women in Armenia in terms of incidence and mortality. In 2012 the estimated incidence of cervical cancer was 13.8 per 100,000 women (Globocan), the morality rate from cervical cancer was 5.2 per 100,000 women, and the 5-year prevalence of cervical cancer was estimated at 53.0 per 100,000 women (Globaocan, 2012). Because approximately 70% of cervical cancers are caused by HPV, and because HPV infection is most common in people in their late teens and early 20s, Armenia is very interested in introducing HPV vaccine in young girls in the country.**

Because many populations in Armenia have limited access to screening for cervical cancer later in life, early vaccination with HPV in Armenia is particularly important.

The National immunization Technical Advisory Group recommended the Ministry of Health to include HPV vaccination into national immunization programme. The recommendations were based on consideration of the public health importance of cervical cancer in Armenia, data on efficacy and effectiveness of HPV vaccines, and preliminary data on the impact of HPV vaccine from countries that have already introduced this vaccine. The Committee noted that many questions remain about the optimal communications strategies and delivery strategies for HPV vaccine in Armenia as a whole and in different regions of the country. For this reason, the NITAG recommended that the MoH implement the HPV demonstration programme and take advantage of this opportunity for GAVI support. The Ministry of Health has decided to submit this application to support a vaccination demonstration programme, with the goal of considering national implementation of HPV vaccine once important questions have been answered through the vaccine demonstration programme.

Armenia decided to target 13-years old girls for HPV vaccination based on WHO recommendations, the results of a national survey on the age of sexual debut, and programmatic considerations.

Armenia plans to implement the HPV Demonstration Programme in 11 provinces of the country. The population of 13-year-old girls in these provinces (16,400 for Year 1 and 17,100 for Year 2) is roughly the same size as the maximum population allowed for the HPV demonstration programme. The Ministry of Health plans to use HPV vaccine provided by GAVI to vaccinate 15,000 of 13-year old girls and procure additional doses of vaccine to vaccinate the remaining 1,400 and 2,100 girls in the Year 1 and Year 2, respectively.

The MoH is confident that the National Immunization Programme will be able to implement HPV demonstration programme in 11 provinces because Armenia has multi-year successful experience in vaccinating 15 year-old teenagers with dT booster doses. High coverage rates (96%) have been reported for the period more than 10 years. However, HPV vaccination requires administration of two doses of vaccine, whereas other teenage vaccinations include administration of only one dose of vaccine. Therefore the NIP will need to modify the existing delivery system to ensure that it will achieve high coverage with two doses of vaccine.

Vaccine delivery strategy

We will organize vaccination of teenage girls in primary health care facilities in all 11 provinces. However, in Yerevan city and Lori, Kotayk, and Syunik provinces, which have predominantly urban populations and big schools, the vaccination will be conducted in collaboration with school-based medical workers. The school nurses will develop and provide health facilities with lists of names of pupils to be vaccinated in the current calendar year. The school medical staff will inform parents about the specific vaccination day, release teenage girls from school and refer them to their appropriate health facility on a given date. The school nurse will identify girls who did not come for vaccination due to absence from school or health reasons and refer them for vaccination as soon as they return to school. The school medical workers will be the main source of information about HPV vaccination for teenage girls, teachers, and their parents. Together with health care facilities staff, school medical workers will communicate with families that decided not to vaccinate their girls. The health care facilities will provide vaccination to teenage girls that attend schools. Healthcare facilities will record immunizations, and inform the school nurse about pupils who did not come for vaccinations. According to the Ministry of Education only 4% of teenage girls do not attend secondary schools. The health care facility staff will be responsible for inviting out-of-school girls for vaccination, and will recall girls who did not come for vaccination in time. The health facility staff will also be responsible for

communicating the risks of disease and benefits of vaccination with the families of out-of-school girls.

In Aragatson, Ararat, Armavir, Gegjarkunik, Shirak, Vayots Dzor, and Tavush provincies where the majority of the population lives in rural settings, and schools may not have medical staff, we will use a slightly different delivery strategy. The primary health facility staff will be responsible for development of name-based lists of teenage girls to be vaccinated in the current calendar year, based on information obtained from municipalities and schools. They will work with communities to inform teenage girls and their parents about HPV vaccination and vaccination days. The health facility staff will vaccinate girls who attend schools and those who do not attend schools. Health facility staff will also be responsible for recalling girls that did not come for vaccination.

At the end of the demonstration project we will evaluate both urban and rural delivery strategies. We will select the most effective approaches for national wide implementation in rural and urban settings. If collaboration with medical staff at schools will lead to significantly higher uptake of HPV vaccine, we will recommend that the Ministry of Education recruit medical staff in schools located in rural areas to participate in HPV vaccination.

Possible barriers in achieving high coverage with HPV vaccine in Armenia

We anticipate that the main impediment in achieving high coverage with HPV vaccine in Armenia will be vaccine safety concerns among the teenage girls, their parents, medical worker and the public in general. We also anticipate the possibility of clusters of anxiety-related Adverse Events Following Immunization (AEFIs). These concerns are based on the experience of introduction of HPV vaccine from other middle-income countries of WHO European Region. Since 2009 only three middle-income countries have introduced HPV vaccine: Romania, The former Yugoslav Republic of Macedonia (MKD), and Kazakhstan. Although all these countries implemented communication and social mobilisation activities prior to the administration of vaccine, there was low acceptance of HPV vaccine among the public and members of medical societies. Rumours about negative effects of vaccination on teenage girls' health and scepticism about benefits of HPV vaccination flooded the Internet and social media. As a result, the MoH of Romania had to cancel HPV vaccination and destroy the vaccine that it had procured. In MKD the HPV vaccine coverage was much lower than coverage for other teenage vaccines.. In Kazakhstan HPV vaccine caused clusters of anxiety-related adverse events following immunization which later transformed into widespread psychogenic / hysteria reactions that created very negative publicity. As a result The MoH of Kazakhstan had to cancel its HPV vaccination program and destroy its vaccine. Recently Denmark and Ireland, high income countries of our region, had similar clusters of anxiety-related AEFIs that negatively affected previously successful HPV vaccination programmes. In Denmarkthe HPV coverage dropped from 86% to 15% within one year. The cluster of anxiety related AEFIs were reported in Japan and lead to suspension of HPV vaccination in this country. The information about vaccine safety events in Kazakhstan, Denmark, and Japan has been broadly disseminated through the Internet, mass media, and social media in all countries of the Region. The governments and immunization partners at regional and national levels have undertaken continuing efforts to restore the trust of the public and parts of the medical community in HPV vaccination; however, many medical workers and parents still have concerns about safety of HPV vaccine.

Development of tailored communication plans for sensitising and mobilising communities:

In light of likely concerns about the vaccine among the public and medical personnel , MoH would like to learn from the demonstration project to identify the most appropriate communication strategy to address concerns about HPV vaccine safety. The experience from countries that introduced HPV vaccine earlier, suggests that traditional communication strategies used by immunization programmes may not be sufficient. We hope to use the demonstration project to help identify innovative approaches to address HPV vaccine hesitancy in Armenia. The NIP, in collaboration with WHO, will conduct

context-specific behavioral analysis to understand barriers and enablers to HPV vaccination incl. knowledge, attitude, practice and belief towards HPV vaccine.

Based on the results of the behavioral analysis, tailored approaches will be developed, including:

Identifying the main target audience

Developing tailored messages and communications material and activities on cervical cancer, HPV infections, and HPV vaccine,

Identifying the most relevant and sufficient distribution and communications channels

The NIP will use different approaches in regions with predominantly urban population and provinces with mainly rural settings. The communication strategies will be defined based on the results of behavioural analysis. We anticipate that in urban areas the influence of the Internet and social media will be more significant, whereas in rural areas the main sources of information about HPV vaccine may be mass media and local medical workers. We expect that the religious leaders will play an important role in ensuring good acceptance of HPV vaccine in rural settings. Therefore effective communication packages for rural provinces could involve religious leaders.

In summary, we expect that the demonstration project will help to develop, pilot, and evaluate different HPV vaccine delivery and communication plans in urban and rural provinces populations. Results of the demonstration project will guide decision-making about strategies for nation-wide implementation.

We believe that successful implementation of HPV demonstration project as well as involvement and support from all relevant stakeholders will help the MoH to make a final decision on inclusion of HPV vaccine into the routine immunization program in Armenia.

3. IMMUNISATION PROGRAMME DATA

3. Immunisation programme data

Please provide national coverage estimates for DTP3 for the two most recent years from the WHO/UNICEF Joint Reporting Form in the table below. If other national surveys of DPT3 coverage have been conducted, these can also be provided in the table below.

Trends of national DTP3 coverage (percentage)				
Vaccine	**Reported**		**Survey**	
Year	*2014*	*2015*	*[Type text]*	*[Type text]*
DTP 3	*93%*	*94%*	*[Type %]*	*[Type %]*

*National immunization data, monthly reporting from healthcare facilities

4. Immunisation programme data

If survey data is included in the table above, please indicate the years the surveys were conducted, the full title, and if available the age groups the data refer to.

***Note:** The IRC may review previous applications to Gavi for a general history of a country's capacities and challenges.*

Not applicable.

4. HPV VACCINATION DEMONSTRATION PROGRAMME PLAN

4.1 District(s) profile

5. District(s) profile

Please describe which district or districts have been selected for the HPV vaccination demonstration programme, completing all components listed in the table below. Also, kindly provide a district level map of the country.

For further information on factors to consider when selecting the districts, please refer to Annex 2 of the HPV Demonstration Programme Guidelines.

Component	Urban provinces (Yerevan, Lori, Kotayk, and Syunik)		Rural provinces (Aragatson, Ararat, Armavir, Gegjarkunik, Shirak, Vayots Dzor, and Tavush)	
	Statistic	Data Source	Statistic	Data Source
Topography (% urban, % semi-urban, % rural, % remote, etc.)	*Urban – 84.5%* *Rural-15.5%*	*National Statistical Service, 2016*	*Urban-36.2%* *Rural-63.8%*	*National Statistical Service, 2016*
Number and type of administrative subunits, e.g., counties, towns, wards, villages	*4 provinces*	*National Statistical Service, 2016*	*7 provinces*	*National Statistical Service, 2016*
Total population	*1,686,403*	*National Statistical Service, 2016*	*1,324,197*	*National Statistical Service, 2016*
Total female population (%)	*53.1%*	*National Statistical Service, 2016*	*50.9%*	*National Statistical Service, 2016*
Total female population aged 9-13 years by age (% of total female population) **9 years** **10 years** **11 years** **12 years** **13 years**	*Total female population aged 9-13 years – 44572 (4.9% of total female population)* *9 years-8999* *10 years – 8950* *11 years – 8763* *12 years – 8893* *13 years – 8967*	*National Statistical Service, 2016*	*Total female population aged 9-13 years –35728 (5.4% of total female population)* *9 years-7061* *10 years – 7110* *11 years – 7297* *12 years – 7167* *13 years – 7093*	*National Statistical Service, 2016*
Number and type of public health facilities	*Hospitals-52;* *Primary Health Facilities-559*	*National Statistical Service, 2016*	*Hospitals - 41* *Primary Health Facilities - 439*	*National Statistical Service, 2016*

Number and type of health workers in all district public health facilities	*Physicians-5538* *Nurses-7647*	*National Statistical Service, 2016*	*Physicians-4352 Nurses-6008*	*National Statistical Service, 2016*
Number and type of private health facilities	*22 private hospitals; 69 private primary health care clinics*	*National Statistical Service, 2016*	*17 private hospitals;* *54 private primary health care clinics*	*National Statistical Service, 2016*
Number and type of health workers in private health facilities in the district	*4,034, including 1,807 physicians and 2,227 nurses*	*National Statistical Service, 2016*	*3,170 including 1420 physicians and 1750 nurses*	*National Statistical Service, 2016*
Number and type of public and private primary and secondary schools	*768 public schools; 40 private*	*National Statistical Service, 2016*	*603 public schools;* *26 private*	*National Statistical Service, 2016*
Estimate the number and percent of girls in school for each of the following ages: **9 year old girls** **10 year old girls** **11 year old girls** **12 year old girls** **13 year old girls**	9 year-old girls: 8999 (100%) 10 year-old girls: 8945 (99%) 11 year-old girls: 8523 (97%) 12 year-old girls: 8448 (95%) 13 year-old girls: 8609 (96%)	*Ministry of Education and Science, Education in Armenia Statistical Directory*	9 year-old girls: 7071 (100%) 10 year-old girls: 7033 (99%) 11 year-old girls: 7089 (97%) 12 year-old girls:6797 (95%) 13 year-old girls:6764 (96%)	*National Statistical Service, 2016*
Estimate the number and percent of girls out of school for each of the following ages: **9 year old girls** **10 year old girls** **11 year old girls** **12 year old girls** **13 year old girls**	*9 year-old girls: 0%* *10 year-old girs: 1%* *11 year-old girls: 3%* *12 year-old girls: 5%* *13 year-old girls: 4%*	*Ministry of Education and Science, Education in Armenia Statistical Directory*	*9 year-old girls: 0%* *10 year-old girs: 1%* *11 year-old girls: 3%* *12 year-old girls: 5%* *13 year-old girls: 4%*	*National Statistical Service, 2016*
Is any routine vaccine currently given to children using schools as delivery points?	*NO* *but the country has routine immunization of 15 years old teenagers with dT booster*	*National Immunization Program, National Centers for Disease Control*	*NO* *but the country has routine immunization of 15 years old teenagers with dT booster*	*National Immunization Program, National Centers for Disease Control*

	dose in health facilities		*dose in health facilities*	

6. District(s) profile

Please give a brief description of why this district (or districts) was (were) selected to participate in the HPV vaccination demonstration programme. s

The population of 13-year-old girls in these provinces (16,400 for Year 1 and 17,100 for Year 2) is roughly the same size as the maximum population allowed for the HPV demonstration programme. The Ministry of Health plans to use HPV vaccine provided by GAVI to vaccinate 15,000 of 13-year old girls and procure additional doses of vaccine to vaccinate remaining 1,400 and 2,100 girls in the Year 1 and Year 2, respectively.

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The 11 provinces were selected to develop and evaluate different HPV vaccine delivery and communication strategies. In four provinces (Yerevan, Lori, Kotayk, and Syunik) that have predominantly urban populations and large schools, HPV vaccination will be conducted in health care facilities in collaboration with school medical workers. In these provinces, school medical staff will conduct microplanning for HPV vaccination, explain the justification for and details related to HPV vaccination to teenage girls and their mother, and call and recall school girls for vaccination. We will use communication strategies targeted towards urban populations which will be developed in accordance with the results of the behavioural study. In these urban provinces we will likely use the Internet and social media to deliver communication messages. In eight other provinces (Aragatson, Ararat, Armavir, Gegjarkunik, Shirak, Vayots Dzor, and Tavush), where the majority of population lives in rural settings, only health facilities staff will be involved into HPV vaccination. The health facility staff will conduct microplanning, implement communication activities, invite school and out-of-school girls for vaccination and follow up with girls who do not come for vaccination. In these provinces the NIP will use communication strategies that target the rural population. These strategies will be also developed based on the results of the behaviour study. We expect that in rural areas, communication messages will be delivered mainly through mass media and medical workers, and wie will likely involve community and religious leaders in the communications campaign.

After evaluating the demonstration programme in detail, we will select the most appropriate HPV vaccine delivery and communication plans for nation-wide HPV implementation.

The MoH is confident that the National Immunization Programme will be able to implement HPV demonstration programme in 11 provinces because Armenia has positive multi-year experience in vaccinating 15-year old teenagers with dT booster dose.

7. District(s) profile

Please describe the operations of the EPI programme in the district(s) selected for the HPV vaccination demonstration programme.

Component	**Urban provinces (**Yerevan, Lori, Kotayk, and Syunik)	**Rural provinces (**Aragatson, Ararat, Armavir, Gegjarkunik, Shirak, Vayots Dzor, and Tavush)
Number and type of administrative subunits (e.g. health facilities) used for routine vaccine delivery	*132*	*239*
Number and type of outreach sessions in a typical month used for routine vaccine delivery	*Vaccinations are offered daily only in health facilitates;*	*Vaccinations are offered daily only in health facilitates;*
Polio3 coverage	*95.6% (2015)*	*96.7 % (2015)*
Measles first dose coverage	*96.6% (2015)*	*97.5 %; (2015)*
Pentavalent 3 coverage	*93.3% (2015)*	*95.4%; (2015)*
dT booster coverage among 15 year old teenagers	*95.3% (2015)*	*96.7% (2015)*
TT2+ (pregnant women)	*N/A*	*N/A*

*information from MoH vaccination facility registry
**vaccine coverage information from National Statistical Service

8. District(s) profile

Please summarise the performance of the district EPI programme as reported in any recent evaluation, for example identifying resources available, management, successes, and challenges. If information from a recent effective vaccine management (EVM) assessment is available, please include.

[Type text]

The following summary and list of strengths and challenges were taken from the 2015 Joint Appraisal Report for Armenia:

The 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.

All 11 provinces have reported high coverage rates for 2015 for all antigens included into immunization programme. The coverage with pentavalent vaccine and MMR vaccine is slightly higher in rural provinces.

The most recent post-introduction evaluation of pneumococcal vaccine (PCV-10), from November 2015, highlighted the following findings about the resources, management, successes and challenges of immunization program in selected provinces:

In all provinces the health care workers (HCWs) were satisfied with the training they received prior to the rollout of the new vaccine. Vaccine coverage was high although it is slightly higher in rural provinces if compared with urban.

The health facilities in all provinces had qualified personnel, well-established immunization planning, recording and monitoring systems, and well-functioning reminder and recall systems to bring children in for vaccination. HCWs in rural areas reported going to extra lengths to reach parents who might not otherwise come in at the scheduled time (such as more frequent reminders). 97% of HCWs and regional staff in all selected provinces reported that introduction of PCV has been a smooth or very smooth process and all felt that it has improved the immunization programme.

In the provincial vaccine stores, vaccines were observed to be adequately stored in refrigerators and there was adequate cold chain capacity in all health facility sites. In Tavush region one health facility reported an interruption in power; and in Kotayk province one health facility and a regional centre reported needing to make changes to the cold chain prior to the introduction of PCV10 (i.e. acquiring a new refrigerator). All provinces reported no problems with the cold chain since PCV10 was introduced. All refrigerators or freezers had temperature/freeze monitors in place, and all had observed temperatures within the acceptable range.

All provinces have a well-established system of forecasting, ordering, and distributing vaccines. Monthly reports on number of vaccinated infants are submitted on time by health facilities. All the immunization recording and reporting forms, vaccine registers and child development cards were updated to accommodate PCV10. All health facilities visited had immunization policy guidelines for vaccine management available on site.

Each provincial immunization centre received a supervisory visit from the National Center for Disease Control and Prevention after the introduction of PCV10, and centres reported that they had received written feedback.

The provincial immunization staff conducted supervisory visits to health facilities quarterly.

Auto-disable (AD) syringes were being used in all health facilities visited and all sites were disposing of their syringes in safety boxes. In urban provinces most health facilities contract with a private company for waste disposal (or are linked with a facility that has a contract). In rural provinces many health facilities, particularly smaller policlinics and rural health posts that have a very small volume of waste, burn their waste in pits. In all cases observed, this was done in accordance with WHO recommendations.

The immunization program has guidelines for AEFI monitoring which clarify reporting of severe and mild AEFIs and include PCV10. The health facilities in all provinces, the Ministry of Health order describing the process for monitoring and reporting of AEFIs was present. Health facilities in Kotayk and Ararat provinces reported having had AEFIs since introduction of PCV (these AEFIs were not specific to the PCV vaccine).

PCV10 was well accepted by HCWs and most parents. Of the health facilities visited, 17%, mainly in the city of Yerevan, had experienced resistance from the community regarding vaccines in general, but not PCV10 specifically.

There were some challenges associated with PCV-10 introduction, and the PIE report suggested that certain actions be undertaken in the future. In the realm of community advocacy and social mobilization, PCV10 was well accepted by medical workers and most parents. However, in urban provinces there were vaccine-hesitant and anti-vaccine populations that refused all vaccinations. The PIE report recommended continually monitoring attitudes among parents and carrying out advocacy and social mobilization activities to address parents' concerns and counter any false claims. This effort should include maintaining a dedicated website on immunization and social media monitoring.

In order to address the request of HCWs from primary health care facilities for more education, the report recommended conducting continuing education of HCWs and medical specialists to provide updated information about vaccinations including the benefits of vaccination, contraindications and vaccine safety data.

Finally, in order to Improve waste management, it was recommended that sites ensure proper immunization waste disposal in rural provinices by establishing contracts with a waste disposal company where possible, or by organizing central storage of waste at a facility that has such a contract.

9. District(s) profile

Please describe any current or past linkages the district EPI programme has had with the primary and/or secondary schools or other outreach locations in the district, e.g., going to schools for health education, delivery of vaccinations, fixed routine outreaches (used by the routine immunisation programme), etc.

All 11 provinces conduct routine vaccination of 15 years old teenagers against diphtheria and tetanus. The dT booster doses are administered to teenagers in primary health care facilities by GPs and vaccinators. In urban areas the health facilitiy staff work in close collaboration with school nurses. School nurses develop a list of of names of 15-year old teenagers to be vaccinated and send the list to the primary health care facility. School nurses inform teenagers and their parents about vaccination days and make sure that teenagers are released from schools. GPs and nurses from the primary health care facilities administer vaccine to teenagers and inform the school nurse about the teenagers who have not come to get vaccinated. The school nurses refer these teenagers for vaccination as soon as they are back to school. High coverage rates (96%) with dT booster dose have been reported for the last 10 years.

10. District(s) profile

Please describe the potential challenges to access and deliver HPV vaccinations to girls and the ways in which these challenges will be addressed. For example, special sensitisation activities that will be done to reduce the potential for rumours.

Taking into account challenges in introduction of HPV vaccine in other countries of the Region and acknowledging strong anti-vaccination groups in Armenia, we anticipate challenges related to HPV vaccine safety concerns among the public and among health care professionals. These concerns can be triggered by anti-HPV information available on the internet and spread by mass media and social networks. In order to address these anticipated challenges we plan to conduct a behavioural analysis to identify attitude and perceptions towards HPV vaccine. Based on the results, we will develop tailored communication strategies. We will define key target audiences and identify the most effective communication channels for each target group. The NIP will also develop a communications working group to prepare for actual or perceived AEFIs, including anxiety-related clusters. This working group will involve all relevant stakeholders and aim to build in-country capacity to timely and effectively respond to any HPV vaccine safety event that may happen after the introduction.

We plan to develop different communication packages for urban and rural provinces. After the evaluation of the HPV demonstration project, we will select the most effective strategies for nation-wide implementation.

11. District(s) profile

Please describe any recent studies, evaluations, or summaries of lessons learned related to socio-economic and/or gender barriers to the immunisation programme. If disaggregated vaccine coverage data by sex or wealth quintile is available from the routine immunisation programme, please note them in this section.

Findings from the 2010 National Demographic and Health Survey (DHS) in Armenia show that differences in vaccination rates by gender, residence (urban vs. rural), mother's education status, and wealth quintile were minimal. The table taken from the 2010 DHS (Attachment 5) shows the percentage of children aged 18-29 months who received specific vaccines at any

time before the survey (according a health facility card or the mother's report), and the percentage of children with a health facility vaccination card.

4.2 HPV vaccine delivery strategy

12a. HPV vaccine delivery strategy

Please identify a single year of age (or single grade in school) at the target vaccination cohort within the target population of 9-13 year old girls and provide information below (see HPV Demonstration Programme Guidelines section 3.2). Countries are encouraged to use the comprehensive list of resources on HPV available at www.gavi.org/library/documents/gavi-documents/guidelines-and-forms/hpv-resources/ to understand data sources and methods for estimating the target population in their country.

Note: The total target population for the Gavi HPV vaccination demonstration programme cannot exceed 15,000 girls per year (all districts combined). Please see section 3.2 of the HPV Demonstration Programme Guidelines for exceptions.

Countries should explicitly define the target population and where and how various subpopulations will be reached.

A preliminary estimate of the number of eligible girls in the target population for each district included in the HPV vaccination demonstration programme should be made by consulting district-level data that may be available from the national statistics office, census bureau, Ministry of Education, district health office, and education department at the district level. Countries should seek support from partners if they need assistance in making this estimate.

WHO has produced national level estimates of the 9-13 year old population by single year of age and sex for each member state. WHO, in collaboration with UNESCO, has also produced country profiles of the female 9-13 year old population in-/out-of- school by urban/rural status, and for income quintile groups. Countries are encouraged to use these estimates, as well, in informing the selection of the target population for the HPV demonstration programme.

In Armenia we will plan to vaccinate 13 year-old girls in 11 provinces of the country. HIgh quality data on the size of the target population are available from the Armenia National Statistical Service. According to 2016 estimates, 16,060 13-year old girls reside in 11 provinces; the projected numbers of 13 year-old girls are 16,400 in 2017 and 17,100 in 2018. The Ministry of Health plans to use HPV vaccine provided by GAVI to vaccinate 15,000 of 13-year old girls and will procure additional doses of vaccine to immunize remaining 1,400 and 2,100 girls in the Year 1 and Year 2, respectively.. The target population will be defined as a one-year birth cohort. In the first year the target group will be girls born for the period from January until December 2004; in the second year the target group will be girls born for the period from January until December 2005. The first dose of HPV vaccine will be delivered in September and the second dose in March. We recognize that some girls may turn 14 by the time of administration of the second dose. However, the single birth cohort will be used as a denominator for the first and the second doses and the second dose will be given to only girls that received the first dose. Therefore we do not anticipate problems with coverage estimate.

Target population	Urban provinces (Yerevan, Lori, Kotayk, and Syunik)		Rural provinces (Aragatson, Ararat, Armavir, Gegjarkunik, Shirak, Vayots Dzor, and Tavush)	
Who are the girls eligible for HPV vaccine based on the criteria set by the programme?	**Total eligible Year 1**	**Total eligible Year 2**	**Who are the girls eligible for HPV vaccine based on the criteria set by the programme?**	**Total eligible Year 1**
1. Girls born in 2004	N = 8820		N = 7580	
2.Girls born in 2005		N = 9576		N = 7524
TOTAL				

12b. HPV vaccine delivery strategy

Please describe the rationale for the choice of the target population.

[Type text]

Primarily, we have selected 13 year-olds because we believe that Armenian girls do not generally become sexually active until they are older than 13 years-old. The Health Behaviour of School-Aged Children survey, conducted in Armenia in 2016, found that only 1% of girls aged 15 reported already having had sexual intercourse. Second, this age group has very high school attendance. Although HPV vaccination will be conducted in primary health care facilities, in urban provinces we will involve school nurses to help in conducting microplanning, calling and recalling girls for vaccinations, and following up with those who were not vaccinated. Finally, this age group was recommended as a target group for HPV vaccination by WHO (teenage girls between 9 and 13 years old).

13. HPV vaccine delivery strategy

Please describe the delivery strategies that will be used to reach the target population in each district of the HPV vaccination demonstration program. Countries should explicitly define the target population and the delivery strategy that will be used for vaccination.

In all 11 provinces the HPV vaccination will be conducted primary health care facilities.

In Yerevan city and Lori, Kotayk, and Syunik provinces, which include predominantly urban populations and large schools, the vaccination will be conducted in collaboration with school medical workers. The school nurses will develop and provide health facilities with lists of names of pupils to be vaccinated in the current calendar year. The school nurse, together with health facilities, will define the vaccination day and will inform teenage girls and their parents about the vaccination day at school meetings. The school medical staff will ensure that teenage girls are released from school on the day of vaccination. The health facility medical workers will vaccinate girls and will record vaccinations in log books, individual immunization cards, and name-based registries. Health facility medical workers will inform the school nurses about teenage girls who did not come for vaccination. The school nurse will refer these girls for vaccination as soon as they are back in school.

The school medical workers will be the main source of information about HPV vaccination for teenage girls, teachers, and their parents. School medical workers, together with health care facilities staff, will communicate with families that decide not to vaccinate their girls. The country has compulsory education policy for primary and secondary schools. Therefore school coverage in Armenia is relatively high. According to the Ministry of Education only 4% of teenage girls do not attend secondary schools. The health care facilities will be responsible for vaccination of out-of-school girls. They will develop a list of out-of-school girls based on the information obtained from municipalities and invite them for vaccination by phone. To recall those who do not come for vaccination on time, the health facility staff will visit households and discuss the benefits of vaccination with girls and their parents.

The NIP plans to obtain support to HPV vaccination from school administration. School principals will issue orders that require teachers to release teenagers on the day of vaccination so that they can go to the health facility and receive their vaccines.

In Aragatson, Ararat, Armavir, Gegjarkunik, Shirak, Vayots Dzor, and Tavush provincies, where the majority of the population lives in rural settings, and schools may not have medical staff, we will use slightly different delivery strategy. The primary health facility staff will be fully responsible for the vaccination of girls who attend schools and out-of-school girls. Health facility medical staff will develop name-based lists of 13-year old girls to be vaccinated in the current calendar year based on information obtained from municipalities and schools. Health facility medical staff will work with the communities to inform teenage girls and their parents about HPV vaccination. The health facility staff will inform girls who attend schools and their parents about HPV vaccination day at school meetings and will phone families of girls who do not attend schools. The health facility staff will conduct home visits to recall those who did not come for vaccination.

Medical staff from primary health care facilities in all provinces will define the size of the target population, record HPV vaccinations, estimate coverage, and send reports to regional immunization centers. The centers will report the aggregated data to the national level.

The vaccinations will be conducted in September and March. The denominator will be a single birth cohort – girls born in 2004 for the first year and girls born in 2005 for the second year. Only girls from defined target groups will be eligible for HPV vaccination, and only girls who receive the first dose in September will be vaccinated in March. As long as a single birth cohort will be used as a denominator to estimate coverage with the first and the second doses, we do not anticipate problems if some girls turn 14 by the time they receive the second dose of vaccine.

Please complete the table below for each district in the HPV vaccination demonstration programme. An example for illustrative purposes only is provided below.

Target age or grade	**Year 1**		**Year 2**	
Who are the eligible girls?	**N. of girls**	**Delivery strategy**	**N. of girls**	**Delivery strategy**
1. **Urban provinces (Yerevan, Lori, Kotayk, and Syunik)**	***8820***	***Primary health care facilities in collaboration with school nurses***	***9576***	***Primary health care facilities in collaboration with school nurses***
2. **Rural provinces (Aragatson, Ararat, Armavir, Gegjarkunik,**	***7580***	***Primary health care facilities***	***7524***	***Primary health care facilities***

Shirak, Vayots Dzor, and Tavush)				
TOTAL	***16400***		***17100***	

EXAMPLE: *This may assist in defining which strategy will be used to deliver HPV vaccine with which proportion of the target population.*

Countries are encouraged to use resource materials available in Annex A to learn what has been done elsewhere, and discuss and carefully select the delivery strategies that would work best in their local context.

Target age or grade	***Year 1***		***Year 2***	
Who are the eligible girls?	***N. of girls***	***Delivery strategy***	***Who are the eligible girls?***	***N. of girls***
All girls attending primary school grade 5	*3,000*	*At schools*	*3,300*	*At schools*
All 10 year old girls who are not attending school at all.	*250*	*Through mobile outreach by health workers*	*275*	*Through mobile outreach by health workers*
All 10 year old girls who live in hard-to-reach villages in the mountains	*500*	*At villages' health centre*	*550*	*At villages' health centre*
TOTAL	*3,750*		*4,125*	

14. HPV vaccine delivery strategy

Please describe the mechanism or strategy for reaching all the target girls with two doses[1] who were missed on the main vaccination days, specifying plans for reaching hard-to-reach or marginalized girls.

[Type text]

In Yerevan city and Lori, Kotayk, and Syunik, provinces where HPV vaccination will be conducted by health care facilities in collaboration with school nurses, the school medical workers will be responsible for recalling girls who did not come for vaccination due to absence from school, health reasons or any other reasons. School nurses will receive information about girls who did not receive their vaccine, and these girls will be referred for vaccination as soon as they are back in school.

In Aragatson, Ararat, Armavir, Gegjarkunik, Shirak, Vayots Dzor, and Tavush, provinces where HPV vaccination will be conducted by health facilities only, the medical workers from health facilities will recall girls who attend schools but missed vaccination day. They will phone the girls' families or visit the household.

In both urban and rural communities, we plan to conduct school meetings with parents of eligible children. This approach will be undertaken as part of a broad communications and social mobilisation plan. It aims to maximize compliance by ensuring that all parents are aware of where and when the vaccine will be given to their children.

In all provinces, the health care facilities staff (GPs and vaccinators) will be responsible for calling and recalling out-of-school girls in order to inform them about the vaccine and invite them to get vaccinated at healthcare facilities. The 4% of girls who do not attend schools in Armenia are still registered in health facilities. If a girl does not come for vaccination, a nurse from the health care facility will visit the household to discuss HPV vaccination with the girl and her parents and invite the girl for vaccination again.

Based on the findings from the 2010 DHS, there are not large differences in vaccination rates by gender, residence (urban vs. rural), or socioeconomic status (see Appendix 5). The vaccination will be provided free-of-charge to all residents of the country. There are no hard-to-reach populations or marginalized groups of people in Armenia that do not have access to primary healthcare. All teenagers are registered in health facilities based on the data provided by municipalities and schools. Because immunization is a priority for primary health care facilities in Armenia, we are confident that it will be possible to achieve high coverage with two doses of HPV vaccine. Vaccine coverage is one of the indicators that are used to evaluate the performance of healthcare facilities; therefore, to maximize vaccination rates, GPs and vaccinators at all healthcare facilities undertake extensive efforts to contact parents of children and teenagers who have not been vaccinated in order to encourage them to bring their children for vaccination.

[1] *NB: Three doses are required only for those known to be immunocompromised.*

15a. HPV vaccine delivery strategy

Please provide a description of the process currently used to obtain (parental or guardian) consent for other vaccines given to adolescents, e.g., meningitis, hepatitis, measles, or other vaccines. Please specify whether there are any specific legal requirements for parental/guardian consent for vaccinations given to the same age group targeted for HPV vaccine delivery.

Currently Armenia implements an opt-out procedure of parental consent for teenager vaccinations. Parents are informed about vaccination at school meetings and can refuse to have their children vaccinated.

The NIP plans to add HPV vaccine into the existing immunization programme for teenagers, and the same opt-out parental consent procedure will be used for HPV vaccination. The experience from other countries in the Region suggests that changes in informed consent requirements introduced together with HPV vaccine may cause rumours that wrongly associate HPV vaccine with an experiment and negatively affect vaccine acceptance among teenagers, parents, and medical workers.

15b. HPV vaccine delivery strategy

Please describe the consenting procedure that will be used for HPV vaccine delivery. Specify how the parents or guardians will be informed about HPV vaccination and how they can express their willingness to allow their daughters/girls to be vaccinated or not.

Parents of girls who attend schools will be informed about introduction of HPV vaccine and planned dates of administration of the first and the second doses of HPV vaccine at school meetings. Parents will receive comprehensive information about HPV disease and HPV vaccine; based on this knowledge they will be able to make informed decisions regarding the vaccination of their daughters. Parents who decide not to vaccinate their girls will have an opportunity to inform the school nurse about this decision. The school nurse and GPs from health care facilities will follow up with these parents to ensure that they understand the risks and benefits

of HPV vaccination. If the parents do not change their decision, their child will not be vaccinated.

The day before vaccination, the school nurse will remind the teenage girls about the vaccination and ask them to inform their parents. The parents will have a second opportunity to revise their decision about vaccination of their child. This is a routine practice that is currently being used in the childhood and teenage immunization programmes in Armenia.

The families of out-of-school girls will be informed about HPV vaccination by healthcare facility staff by phone. Parents will be invited to come to together with their teenage girls to receive additional information about HPV vaccine and confirm their interest in getting vaccinated.

The NIP will implement extensive communication and social mobilization activities prior to the introduction of HPV vaccine in order to ensure that teenage girls, their parents, and the public are well informed about cervical cancer burden and the benefits of vaccination, with the goal of creating demand for the vaccine.

16. HPV vaccine delivery strategy

Please summarise ability to manage all the technical elements which are common to any new vaccine introduction, e.g. cold chain equipment and logistics, waste management, vehicles and transportation, adverse events following immunization (AEFIs), surveillance, and monitoring, noting past experience with new vaccine introductions (such as rotavirus, pneumococcal vaccine, or others).

Armenia had very positive experiences with introduction of three new vaccines - pentavalent, rotavirus, and PCV. The post-introduction evaluations demonstrated smooth introductions and confirmed high coverage rates achieved shortly after the introductions. The NIP has effectively managed the technical elements of new vaccines delivery. The findings from rotavirus vaccine PIE and pneumococcal vaccine PIE are presented below:

- **All of the health care workers (HCWs) interviewed were satisfied with the new vaccine training. Some requested continuous education and training on vaccinations to keep them updated on new information.**
- **The health facilities visited had qualified personnel, well-established immunization planning, recording and monitoring systems, and well-functioning reminder and recall systems to bring children in for vaccination. Some HCWs reported going to extra lengths to reach parents who might not otherwise come in at the scheduled time (such as more frequent reminders). 97% of HCWs and immunization staff interviewed reported that introduction of PCV has been a smooth or very smooth process and all felt that it has improved the immunization programme.**
- **The national vaccine storage site has adequate storage capacity and cold chain monitoring systems in place. Vaccines were observed to be adequately stored in refrigerators, and there was adequate cold chain capacity in all health facility sites. Only one health facility reported an interruption in power (on 2 November 2015). 100% of health facilities reported no problems with the cold chain since PCV10 was introduced. All health facilities visited have refrigerators on site – two small rural health facilities did not have refrigerators but brought vaccines from the district vaccine store on the day of vaccination and kept them in cold boxes. At the district level vaccine stores had functioning refrigerators and/or freezers:**

- all refrigerators or freezers had temperature/freeze monitors were in place;
- all refrigerators and freezers had observed temperatures within the acceptable range;

- **Armenia has a well-established system of forecasting, ordering, and distributing vaccines. Monthly reports are submitted on time by health facilities. All the immunization recording and reporting forms, vaccine registers and child development cards were updated to accommodate PCV10. All health facilities visited had immunization policy guidelines for vaccine management available on site. There were no vaccines stock-outs reported, and there were no expired vaccines or vaccines with vaccine vial monitors at stage III or IV observed during the evaluation.**
- **Annual supervisory visits are made to each region by central level staff and to each district by regional level staff. The regions and districts are responsible for conducting quarterly visits to each health facility in their jurisdiction. All regions reported that they had received at least one supervisory visit since the introduction of PCV10 and that they had received written feedback. Of the 29 health facilities visited, 24 (83%) had received at least one supervisory visit from district or regional staff in the preceding 6 months. Of these 24 health facilities, all but 7 had written documentation of these supervisory visits.**
- **During vaccination sessions observed in 24 sites, vaccines were stored and handled properly and appropriate vaccine administration techniques were used. Most of the mothers interviewed had good knowledge about PCV10 and the vaccines their children had received.**
- **Auto-disable (AD) syringes were being used in all health facilities visited and all sites were disposing of their syringes in safety boxes. Most health facilities contract with a private company for waste disposal (or are linked with a facility that has a contract). 12 (41%) of 29 health facilities, particularly smaller polyclinics and rural health posts that have a very small volume of waste, burn their waste in pits. In all cases observed, this was done in accordance with WHO recommendations.**
- **The immunization program has guidelines for AEFI monitoring which clarify reporting of severe and mild AEFIs and include PCV10 (These guidelines will be extended to include HPV). All of the health facilities visited had the Ministry of Health order describing the process for monitoring and reporting of AEFIs. Only one site at regional level and four health facilities reported having had AEFIs since introduction of PCV (but not specific to the PCV vaccine).**
- **In collaboration with WHO, the NIP has developed a comprehensive crisis communication plan for AEFIs. The NIP currently implements the majority of the plan's procedures, but the plan itself has not yet been officially adopted.**
- **PCV10 was well accepted by HCWs and most parents. Of the health facilities visited, 17%, mainly in the city of Yerevan, had experienced resistance from the community regarding vaccines in general, but not specifically PCV10.**
- **Regarding coverage and reporting, all health facilities that were visited reported data on the number of vaccine doses administered on a monthly basis to the district offices, where these data are compiled and submitted to the regional level. The regional offices compile the district level data and submit monthly reports to the NIP. In addition, data on vaccine doses administered were reported on a monthly basis by all health facilities that were visited. The main reasons given for children not being vaccinated were**

parental refusal of all vaccines (not specifically PCV) due to anti-vaccine or religious beliefs.

Monitoring of AEFIs related to HPV vaccine will be incorporated into the existing AEFI monitoring and response system. The NIP will review the national AEFI monitoring guidelines accordingly. The monitoring of HPV vaccine coverage will be incorporated into existing immunization recording and reporting system for teenage vaccinations. The NIP will revise the immunization recording and reporting forms accordingly. The modules on revised AEFI monitoring guidelines and revised immunization recording and reporting will be included into the pre-introduction trainings of medical workers. The revised guidelines and reporting forms will be printed and disseminated to primary health care facilities.

17a HPV vaccine delivery strategy

Please describe the cold chain status for the selected district and the data source(s) for this information. Information such as the number of cold storage facilities, function and working order of the facilities, storage capacity (and any excess capacity), distribution mechanism for routine delivery of vaccines, status of vaccine carriers and icepacks (e.g., supply shortages or excesses), and plan for HPV vaccine storage and distribution during the HPV vaccination demonstration programme.

HPV vaccine will be stored and distributed according to the current system for vaccine storage and distribution, which is outlined below, according to reports from the 2014 EVM assessment for Armenia.

In Armenia, in-country vaccine deliveries follow a fixed interval, variable quantity distribution schedule. The central storage unit delivers routine vaccines to district storage units quarterly, and to health facilities in Yerevan City monthly. District storage units also distribute vaccines to their health facilities in a monthly delivery program. In addition to these routine deliveries, the NIP organizes additional transfers to accommodate campaign and seasonal vaccine needs (From the EVM assessment, Armenia, 2014). District delivery of vaccines occurs through the use of two refrigerated trucks.

The logistics structure has been designed as a push and delivery system; decisions on delivery quantities are made centrally based on the data provided from the districts and vaccines are distributed to their destinations by vehicles provided from higher levels (central and regional stores).

The recently renovated central store has enough space inside the building for maintenance and stock movements. The EVM assessment from 2014 reported that the central store had four cold rooms with 70 m^3 total gross volume. Shelved vaccine storage volume is 11.1 m^3, and that the dry store is large enough to cover all syringes, diluents and safety boxes. (From the EVM assessment, Armenia, 2014) .

In addition to the information reported in the EVM from 2014, there have been new procurements. At the national warehouse, there is an additional 50 m^3 cold room store (one room of 40 m^3 and one room of 10 m^3). The national warehouse also has an additional 75 kilowatt stand-by generator specifically for the warehouse. In addition, the alarm system has been updated to a wireless, web-based alarm system (from discussions with National Immunization Program, June 2016).

An inventory of cold chain equipment in all healthcare facilities was performed in 2015. Following this assessment, 140 refrigerators (200L capacity each) were procured for all healthcare facilities that had inadequate cold chain capacity.

The current cold chain volume vr maximum volume required to accommodate HPV vaccine in urban and rural provinces is provided in the table below. *The current capacity estimate includes 9 cold rooms that were procured in 2016 and will be installed in provincial vaccine stores by the end of 2016. The MoH will use funds from Transition Plan to cover the cost of the installation.*

Table 1. Cold chain volume by provinces vs volume required to store all VPI vaccines, including HPV vaccine (**832 cm3 per child per year)**

Name of province		Existing cold chain volume at provincial level (Lt)	Maximum required cold chain volume (Lt)	Balance (Lt)
Urban provinces	**Yerevan**	**10000**	**8,431**	**19%**
	Lori	**10540**	**1,331**	**692%**
	Kotayk	**11080**	**1,553**	**613%**
	Syunik	**600**	**314**	**91%**
Rural provinces	**Aragatson**	**10432**	**9,545**	**1075%**
	Ararat	**10648**	**1,553**	**586%**
	Armavir	**10432**	**1,479**	**605%**
	Gegjarkunik	**10560**	**1,405**	**652%**
	Shirak	**10648**	**1,331**	**700%**
	Vayots Dzor	**675**	**296**	**128%**
	Tavush	**3432**	**666**	**416%**

There are no shortages in cold chain capacity in the entire country. However, there will be a need to update refrigerators in a number of sites in the next two years (discussions with managers at National Immunization Program, June 2016).

Tags for temperature monitoring have been purchased for refrigerators at all healthcare facilities. All facilities have been trained on the use of these devices. These devices allow verification of temperatures during the past 30 days. All temperatures are recorded electronically automatically. In

addition, because data can be downloaded and printed out, weekly temperature data are printed out and maintained.

Component	Urban provinces (Yerevan, Lori, Kotayk, and Syunik)	Rural provinces (Aragatson, Ararat, Armavir, Gegjarkunik, Shirak, Vayots Dzor, and Tavush)
Number and type of cold storage facilities	*2 cold rooms and 26 refrigerators at provincial level vaccine stores in Lori, Kotayk, and Syunik. Health facilities in Yereven receive vaccines directly from the National Vaccine Store, which has 6 cold rooms and 3 refrigerators*	*6 cold rooms and 35 refrigerators at provincial level vaccine stores*
Functioning and working order of the facilities	*All are well functioning; however some refrigerators at healthcare facilities are old and need to be replaced over the next two years*	*All are well functioning; however some refrigerators at healthcare facilities are old and need to be replaced over the next two years*
Storage capacity (any excess)	*Existing volume is 42,200 Lt; the maximum required volume for all NIP vaccines including HPV vaccine is 9, 134 Lt. The balance is + 13,086 Lt*	*Existing volume is 56,827 Lt; the maximum required volume for all NIP vaccines including HPV vaccine is 7, 617 Lt. The balance is + 49,210 Lt*
Distribution mechanism	*From central to provincial level by refrigerated trucks; from provincial vaccinia stores to health facilities by cars in cold boxes according to pre-arranged delivery time. In Yerevan City health facilities receive vaccines directly from the national vaccine store*	*From central to provincial level by refrigerated trucks; from provincial vaccinia stores to health facilities by cars in cold boxes according to pre-arranged delivery time.*
Number and status of vaccine carriers	*No current shortages; none anticipated for HPV vaccine*	*No current shortages; none anticipated for HPV vaccine*
Number and status of icepacks (any shortages or excess)	*No current shortages; none anticipated for HPV vaccines*	*No current shortages; none anticipated for HPV vaccine*

17b HPV vaccine delivery strategy

The existing volume of cold chain in all selected provinces significantly exceeds the maximum volume required to store all NIP vaccines, including HPV vaccine.

Some refrigerators in health facilities are old and are planned to be replaced over the next two years. The MoH will procure 215 refrigerators in 2016-2017. The government funds will be used to procure 200 refrigerators and the HPV Demonstration Project funds will be used to procure 15 refrigerators. The government will request partners' financial support for the procurement of 30 daily temperature record systems to monitor temperature in cold rooms at provincial level.

4.3 HPV vaccine delivery training and community sensitisation & mobilisation plans

18a HPV vaccine delivery training and community sensitisation & mobilisation plans

Please describe plans for training of health workers and others who will be involved in the HPV vaccination demonstration programme.

In all 11 provinces we will use the same approach for conducting trainings for medical workers on HPV vaccine introduction that was used for the introductions of new childhood vaccines. This approach was proven to be effective in achieving smooth introductions and high uptake of new vaccines. First, we will conduct national meeting for medical academia and healthcare professionals, with a particular focus on oncologists, gynecologists, and paediatricians. These health care professionals will not administer HPV vaccine, but as opinion leaders, they will influence parents' decisions to vaccinate their children. The NIP will provide these individuals with comprehensive knowledge about HPV disease and HPV vaccine to ensure their support for HPV vaccine introduction.

We also plan to conduct meetings for educational institutions such as medical and nursing schools. These meetings will help to inform training institutions about the implementation of the HPV demonstration programme and ensure their support to HPV vaccination. Health care professionals and institutions at the national level will also play an important role in advocating for inclusion of HPV vaccine into routine immunization programme after the demonstration project is finished.

The trainings for general practitioners and vaccinators will be arranged according to a "cascade" mechanism; first national trainers will be trained, who will then train GPs, vaccinators, and other health care professionals at the district and health facility levels. In urban provinces (Yerevan, Lori, Kotayk, and Syunik), the school nurses will be included in the trainings. The training materials will be developed with technical support from WHO and will consist of presentations, case studies, and pre and post-training surveys. The training modules will be printed and disseminated among trainees. In addition the HPV introduction guidelines will be developed and disseminated during the trainings.

The HPV training will be incorporated into the continuous professional education for medical doctors, and specific credits will be assigned.

The NIP will implement activities to prepare medical staff to effectively respond to actual or perceived AEFIs, including anxiety-related AEFI clusters. The trainings will involve all relevant stakeholders and include information about crisis communication.

18b HPV vaccine delivery training and community sensitisation & mobilisation plans

(Optional) *If available, countries may provide additional detail in the table below on training content, role, and framework.*

I*n addition to training, community sensitization and mobilization strategies and plans will be developed, based on a study on knowledge, attitudes and practices that will be conducted in order to identify optimal messages for each target population.*

Who will be trained	Role in vaccine delivery	Training content	Who will provide the training?

	(e.g., sensitisation, mobilisation, immunisation, supervision, monitoring, etc.)	(e.g., basics on cervical cancer, HPV, HPV vaccine, IEC messages, safe injections, AEFI monitoring, etc.)	
Health workers	sensitisation, mobilisation, immunisation, supervision, monitoring	cervical cancer disease burden; efficacy and safety of HPV vaccines, IEC messages, safe injections, AEFI monitoring, immunization reporting, AEFI communication	*National Center for Disease Control and Prevention*
Supervisors	*Supervision, monitoring*	basics on cervical cancer, HPV, HPV vaccine, IEC messages, safe injections, AEFI monitoring and communication	*National Center for Disease Control and Prevention*
Teachers/ School officials	*advocates*	basics on cervical cancer, HPV, HPV vaccine, IEC messages	*National Center for Disease Control and Prevention*
Regional government officials	*advocates*	basics on cervical cancer, HPV, HPV vaccine, IEC messages	*National Center for Disease Control and Prevention*
Academic Institutions (medical and nursing schools)	*Advocates, sensitization*	cervical cancer disease burden; efficacy and safety of HPV vaccines, IEC messages , AEFI communication	*National Center for Disease Control and Prevention*
Civil Societies	*Advocates, social mobilization*	basics on cervical cancer, HPV, HPV vaccine, IEC messages	*National Center for Disease Control and Prevention*
Professional Associations (i.e. National Pediatric Associations, National Cancer Association, etc)	*Advocates, social mobilization, sensitizers*	cervical cancer disease burden; efficacy and safety of HPV vaccines, IEC messages , AEFI communication	*National Center for Disease Control and Prevention*
Religious leaders	*advocates*	basics on cervical cancer, HPV, HPV vaccine, IEC messages	*National Center for Disease Control and Prevention*
Immunization programme staff		cervical cancer disease burden; efficacy and safety of HPV vaccines, IEC messages, safe	*National Center for Disease Control and Prevention*

		injections, AEFI monitoring and communication, immunization reporting, supportive supervision	

19a. HPV vaccine delivery training and community sensitisation & mobilisation plans

Please describe the communication plans for sensitising and mobilising communities (e.g. girls, parents, teachers, health workers, district officials, community groups, etc.) for the HPV vaccination demonstration programme.

Communication is integral to every public health response/matters, and understanding the local context is essential when creating useful communications plans. Each community's understanding of diseases and their severity (e.g. cervical cancer and HPV) is complex, context-dependent, and culturally-mediated. Often there is a significant difference between urban and rural areas, including the surrounding environment, the influencers, publics perceptions as such, most popular communications channels etc. Therefore, a one-size-fits-all approach is not sufficient and we are aiming at developing tailored communications and social mobilization plans for both urban and rural provinces with the following goals:

- Ensure that people understand the benefits and risk of HPV vaccination
- Support trust in vaccine and those who deliver them
- Build population resilience against vaccine safety scares
- Encourage Individuals to seek vaccination
- Build robust programmes that are able to respond to trust-related event

We plan to conduct behavioral analysis research among different key informants to understand barriers and enablers to HPV vaccination. These analyses will help us identify key messages that will be used in our communications plan to sensitize and mobilize communities and other relevant audiences about HPV vaccination. Informants could include health care officials, medical scientists, immunization staff, general practitioners and pediatricians, MoE officials, school teachers and directors, community leaders, parents and girls, religious leaders, NGOs etc..

This research will be done through focus groups, individual interviews, and community survey and will assess the level of knowledge among members of various groups about cervical cancer, how they perceive causes of and risks factors of cervical cancer, benefits and risks of HPV vaccination, and their understanding of who makes decisions regarding vaccination. In other words, to identify enablers, influencers and barriers that affect the girl's decision of being vaccinated. Based on the results of the behavioral analysis tailored approaches will be developed including:

- Identifying the main target audience
- Develop tailored messages and communications material and activities son cervical cancer, HPV infections, and HPV vaccine,
- Identify the most relevant and sufficient distribution and communications channels

Experts and community members will review and pre-test the materials before finalization. As the NIP does not have sufficient capacity to conduct a behavioral study and to develop tailored communication strategies, we will request technical support from WHO to perform these activities.

We have listed below some examples of potential target audiences, communications messages and materials and channels. The behavioral analysis will form the basis of specific tailored approaches; the

main target audience, the messages and the communication channels will vary in the strategies for urban and rural areas.

Example of target audience:

- school teachers
- health care workers
- parents
- teenage girls
- community leaders
- etc.

Examples of communication channels could be:

- Indirect communication through mass media; TV, radiospots, poster, leaflets, social media etc
- Direct communication in schools, meetings with targeted girls and their parents.
- Interpersonal communication in the community, including home visits.
- Communication campaign prior to vaccination sessions.
- Counseling in schools and commune health centers.

Examples of communications messages could include:

- basic knowledge of cervical cancer
- causes of cervical cancer and the relationship between HPV and cervical cancer
- specific and non-specific preventive measures
- HPV vaccines including vaccination schedule, vaccination targets, and potential side effects.

In addition, the MOH will design and conduct a series of trainings to ensure that school nurses, health providers, and school teachers have adequate knowledge about HPV vaccine and cervical cancer. Training of Trainers (TOT) courses focused on communication will be organized at the national level. During these trainings, supportive supervision will be conducted to ensure the quality for trainers and participants.

We will also implement activities to prepare the NIP and all other relevant stakeholders to timely identify and properly address vaccine safety events, including Adverse Events Following Immunizations (AEFIs), HPV vaccine safety allegations, and rumours.

19b HPV vaccine delivery training and community sensitisation & mobilisation plans

Below table cannot be filled out prior the behavioural analysis as the types of information and materials, audience and method of delivery are very context specific and will be define as a result of the analysis.

Types of information or materials (e.g., leaflet, poster, banner, handbook, radio announcement, etc.)	Audience receiving material (e.g., girls, parents, teachers, health workers, district officials, community groups, etc.)	Method of delivery (e.g., parent meetings, radio, info session at school, house visit, etc.)	Who delivers (e.g., teachers, health workers, district official, etc.)	Frequency & Timing (e.g., daily, weekly, twice before programme starts; day of vaccination, two weeks before programme begins, etc.)

20. HPV vaccine delivery training and community sensitisation & mobilisation plans

Briefly describe any potential barriers or risks to community acceptance and the process or communication plan that might be used to address this. Considerations for rumour management and crisis communication should also be described. Consider briefly describing any positive leverage points that might be beneficial for programme implementation to promote acceptability.

Taking into account challenges in introduction of HPV vaccine in other countries of the region and acknowledging strong anti-vaccination groups in Armenia, we anticipate challenges related to HPV vaccine safety concerns among the public and among health care professionals. These concerns may be caused by anti-HPV information available on the Internet, and may be spread by mass media and social networks. In order to address these anticipated challenges we plan to develop and implement effective communications strategies prior to the implementation of HPV Demonstration programme. We will conduct a behavioural analysis in both rural and urban areas of Armenia including key informants such as health care officials, medical scientists, immunization staff, general practitioners and pediatricians, MoE officials, school teachers and directors, community leaders, parents and girls, religious leaders NGOs etc.. Based on the results of the behavioral analysis tailored approaches will be developed.The tailored communication plans for sensitising and mobilising communities *will be* piloted and evaluated during the demonstration project and will be revised in accordance to the evaluation results and used for nation-wide implementation of HPV vaccine.

A crisis communication plan is already in place in Armenia. We will continue its implementation to ensure that the NIP, MoH and all relevant stakeholders are prepared to effectively address vaccine-safety events. We will develop a communication working group in the MoH which will coordinate crisis preparedness activities. The plan includes a mechanism to monitor the internet, mass media, and social networks in order to timely identify rumours and vaccine safety concerns. The plan also addresses the implementation of relevant communication activities. The plan defines the roles of relevant stakeholders in the communication-related response during a crisis.

Cervical cancer incidence and mortality are high in Armenia and are perceived as a serious public health problem. Health care professionals and the public are well aware of this problem. We will use this as a leverage point, emphasizing the seriousness of the disease and its complications, and highlighting the benefits of vaccination. We plan to use oncologists as opinion leaders to advocate for HPV vaccination.

4.4 HPV vaccine delivery evaluation

21a. HPV vaccine delivery evaluation

The National Center for Disease Control and Prevention will conduct the HPV vaccine post-introduction evaluation at the end of the first year of the project implementation with the following goals:

- **to assess the feasibility of HPV vaccine delivery**
- **to identify possible errors and correct them in a timely manner**
- **to develop lessons learned for nation-wide introduction of HPV vaccine.**

The NIP has a group of trained experts who have conducted PIEs for three new childhood vaccines (pentavalent, rotavirus vaccines and PCV) using standardized WHO methodology. We will request WHO technical support in conducting the PIE to ensure that possible errors in the introduction of HPV vaccine are correctly identified and addressed in a timely manner.

The NIP will conduct a community-based coverage survey to validate administratively reported coverage with two doses of HPV vaccine in 11 selected districts. The NIP will use the WHO HPV Cluster Survey tool adapted to the HPV demo programme framework. The NIP does not have experience in conducting coverage survey and therefore will request WHO technical support.

After one year of project implementation the NIP will perform a micro-costing analysis to estimate HPV vaccination costs. The estimate will be conducted using the WHO Cervical Cancer Prevention and Control Costing Tool. As the NIP does not have capacity to conduct such analysis, WHO technical support will be requested.

21b. HPV vaccine delivery evaluation

(Optional) *Technical partners (e.g. local WHO, UNICEF, other organisation staff) are sponsored by Gavi to offer assistance to the evaluations of HPV vaccine delivery. Please specify if these expert(s) have been identified (name, title, organization). Technical assistance can be requested through technical partners. Please refer to the Gavi PEF roster (available on the Gavi website) to identify partner TA available to you.*

WHO technical support will be requested to conduct the HPV vaccine post-introduction evaluation, the community-based coverage survey, the assessment of the cost of HPV introduction, the desk review of adolescent interventions and the selection of the adolescent interventions that will be delivered jointly with HPV vaccine. The WHO Regional Office for Europe and the WHO Country Office will identify technical specialists and international experts to provide technical support to Armenia.

The MoH of Armenia will also request WHO and UNICEF support in conducting behavioural study, developing tailored communication plans for sensitising and mobilising communities, , preparing for HPV vaccine crisis communication, and conducting education of health care professionals. The NIP does not have sufficient capacity to implement these activities without external consultancy support.

The funds that the MoH will receive from GAVI for implementation of operational and project evaluation activities will not be sufficient to cover WHO and UNICEF technical support. Therefore we request that GAVI finance partners through other funding mechanisms to ensure that Armenia receives partners' support for preparedness, implementation, and evaluation of the HPV demonstration project.

4.5 Assessing potential integration of adolescent health interventions

22a. Assessing potential integration of adolescent health interventions

Please summarise the anticipated activities for the assessment of integration of adolescent health interventions, such as planning milestones, stakeholder meetings, process for identifying a lead for this activity, and the process to involve the TAG in this work (see HPV Demonstration Programme Guidelines section 4.1 and Annex 6).

[Type text]

The integration of adolescent health care interventions, including immunization activities, is an important part of the National Child and Adolescent Health Protection Strategy, which is in the process of being approved by the Government. The platform encompasses health protection, prevention, curative services, monitoring and evaluation activities, and immunization, including HPV.

The MoH will establish a coordination committee to assess the feasibility and define adolescent health interventions to be integrated with HPV vaccination. The Committee will consist of diverse leadership, including paediatricians with an expertise in adolescent health, the Mother and Child Health Department from the Ministry of Health, experts from the Child Adolescent Health Institute in Yerevan, the Ministry of Education, and the regional municipality. The Committee will be led by the Deputy Minister of Health and will work in close collaboration with relevant stakeholders, including HPV Technical Advisory Group, WHO, UNICEF. The Committee will assess the feasibility of integration of the following adolescent health interventions: vision screening, nutritional counselling, and reproductive health education.

The joint-delivery of selected adolescent health interventions will be implemented in year two and will be included in the evaluation report to GAVI at the end of year one.

22b. Assessing potential integration of adolescent health interventions

(Optional) *Countries can provide a brief summary below of the current adolescent health services or interventions and health education activities given in the district(s).*

The Institute of Child and Adolescent Health (ICAH) at the Arabkir Medical Centre is the focal point for adolescent health services in Armenia. The ICAH develops national health policies and regulations related to child and adolescent health; implements strategic and investment programs; builds the capacity of health care specialists; introduces innovative approaches for adolescent health care; and facilitates the exchange of experience between specialists, and local and foreign experts. The ICAH activities contribute to sustainable development of health care in the sphere of child and adolescent health.

In addition, adolescent health education has recently become a focus of the Ministry of Education - the subject of “healthy lifestyles” for adolescents has been recently introduced in the school curriculum.

4.6 Development or revision of cancer control or cervical cancer prevention and control strategy

23a. Development or revision of cancer control or cervical cancer prevention and control strategy

Please summarise the planned activities for the development or revisions of a national cervical cancer prevention and control strategy, such as planning milestones, stakeholder meetings, methodology for developing the strategy, process for identifying a lead for this activity, and the process to involve the TAG in this work (see HPV Demonstration Programme Guidelines section 4.1 and Annex 6).

Armenia had implemented a national plan for cervical cancer control for the period of 2006-2015. Currently the country is developing a new 5-year national strategy and action plan for comprehensive cervical cancer prevention and control for the period 2016-2021. The plan will include HPV vaccination, cervical cancer screening and follow-up treatment, as well as education of the medical community and the public. The MoH plans to establish a working group that includes cytologists, gynecologists, midwifes, oncologists and other relevant personnel to coordinate the development of comprehensive cervical cancer prevention and control plan. The development of the plan is included into GAVI Graduation Plan and will be financed by GAVI accordingly. The final draft of the plan will be developed and submitted for the Government approval by the end of 2016.

23b. Development or revision of cancer control or cervical cancer prevention and control strategy

(Optional) *Provide a brief summary of the current cervical cancer prevention and treatment services and implementing agencies in the district selected to implement the HPV vaccination demonstration programme. If available, countries can include information on target populations, delivery structure, and funding sources.*

Opportunistic PAP smear screening has been in place In Armenia for many years; in January 2015, with support from the World Bank, the organized cervical cancer screening programme was introduced throughout the country. In cities, the screening is performed by gynecologists in primary health care facilities. In rural areas the screening is conducted by gynecologists during outreach sessions. In 2015, 58,600 women aged 30-40, 41-50, and 51-60 were screened. Of these women, in 7.1%, pathological changes in the utierine or cervix were detected, and invasive carcinoma was detected in 0.6% of the patients who had cervical changes (data from the Ministry of Health Program Implementation Unit, 2016). Patients are referred to the national center of oncology for specific treatment. In addition to World Bank support, there are co-payments from the government to support the screening program.

In 2014, there were 229 new cases of cervical cancer (incidence: 14.6 per 100,000 people); of these 157 (68.5%) were advanced stage disease. 108 cervical cancer-related deaths (incidence: 6.9 per 100,00 people) were recorded. In 2015, there were 257 new cases of cervical cancer (incidence: 16.3 per 100,000 people); of these 153 (59.5%) were advanced stage disease. 127 cervical cancer-related deaths (incidence: 8.1 per 100,00 people) were recorded (Source: Ministry of Health).

4.7 Technical advisory group

24. Technical advisory group

Please identify the membership and terms of reference for the multi-disciplinary technical advisory group established that will develop and guide implementation of the HPV vaccination demonstration programme and list the representatives (at least positions, and ideally names of individuals) and their agencies (see HPV Demonstration Programme Guidelines section 4.1 and Annex 6).

Countries are encouraged to use their ICC (Intersecral Coordination Committee on immunization) or a subset of the ICC as the multi-disciplinary TAG.

The TAG must at least have representatives from the national EPI programme, cervical cancer prevention and control, education, the ICC (if separate from the ICC), representative(s) from adolescent and/or school health (if they are represented within the Ministry of Health), and representative(s) from civil society organisation(s) that reach the target population of 9-13 year old girls.

The Ministry of Health will establish a Technical Advisory Group to develop and guide implementation of HPV Vaccine Demonstration Project. The TAG will include representatives from National CDC, Maternal Health Department of the Ministry of Health, the Chair of the National Immunization Technical Advisory Group, the ICC (which includes Deputy Minister for Education), oncologists, GPs from the primary health care facilities, and representatives from the Arabkir Child and Adolescent Health Institute. In addition, because many government staff from the Ministry of Health, will be involved, the TAG will report to the ICC.

[Enter the family name in capital letters]

Agency/Organisation	Name/Title	Area of Representation[1]
National CDC	*[Type text]*	*Immunization*
Maternal and Child Health Department, Ministry of Health	*[Type text]*	*immunization*
Chair, National Immunization Technical Advisory Group	*[Type text]*	*Immunization*
Arabkir Child and Adolescent Health Institute		*Adolescent health*
Ministry of Education		*Education*
Association of Armenian Oncologists		*Cervical cancer screening and treatment*
Primary Care Physicians from Polyclinics		*Immunization; cervical cancer screening*
Non-Communicable Diseases Department, National Center for Disease Control and Prevention		*Prevention and control of cervical cancer*

[1]Area of representation includes cancer control, non-communicable disease, immunisation, adolescent health, school health, reproductive health, maternal or women's health, cervical cancer prevention, nursing association, physicians, health communications, midwives, civil society group, education, etc.

25. Technical advisory group

If known, please indicate who will act as the chair of the technical advisory group.

[Enter the family name in capital letters]

	Name/Title	Agency/Organisation	Area of Representation

Chair of Technical Advisory Group	*Sergey Khachatryan*	*Ministry of Health, Deputy Minister*	*Health care and public health*

4.8 Programme manager/coordinator

26. Programme manager/ coordinator			
List the contact details, position, and agency of the person who has been designated to provide overall coordination for the day-to-day activities of the two-year HPV vaccination demonstration programme, taking note that a technical officer/lead/manager from EPI might be most suitable as a part of their current role and responsibilities. *[Enter the family name in capital letters]*			
Name	*Gayane Sahakyan*	**Title**	*Advisor to the director-general, NCDC, National Immunization Program Manager*
Tel no	*374-93-55-29-73*		
Fax no	*[Type text]*	**Agency**	*NCDC, Ministry of health*
Email	*gsahakyan63@yahoo.com*	**Address**	*Heratsy 12 Yerevan Armenia*

5. TIMELINE

The HPV vaccination demonstration programme will include immunisation of the cohort of girls in two consecutive years (Figure I). Countries are required to begin vaccinating in the demonstration district(s) within two years of the application.

Figure I. HPV vaccination demonstration programme timeline

<table>
<tr><td></td><td>Planning</td><td colspan="3">Implementation Year 1
(begins first day of dose 1)</td><td colspan="3">Implementation Year 2
(begins at first day of dose 1)</td></tr>
<tr><td>Timing</td><td>Up to 8 months</td><td>Months 1-6</td><td>Months 7-9</td><td>Months 10-12</td><td>Months 1-6</td><td>Months 7-9</td><td>Months 10-12</td></tr>
<tr><td rowspan="3">Activities</td><td rowspan="2">Planning
Training
Supply
Distribution
Sensitisation
Mobilisation

Orientation workshop</td><td>First year of vaccination

PIE at the time of final dose</td><td>Evaluation of Year 1

Coverage survey within 6 weeks of final dose</td><td>Meeting to review Year 1 evaluation and lessons learned

Adjust programme for Year 2

Report of Year 1 to Gavi

If country is ready, prepare application for National support</td><td rowspan="2">Second year of vaccination</td><td rowspan="2"></td><td rowspan="2">Report of Year 2 to Gavi</td></tr>
<tr><td colspan="2">Costing analysis starts after the first dose</td></tr>
<tr><td colspan="3">Assessment of adolescent health interventions</td><td>Incorporate joint delivery in programme for Year 2 (optional)</td><td>If feasible, implement joint delivery of services</td><td>If applicable, evaluate joint delivery - coverage survey & costing study</td><td></td></tr>
<tr><td></td><td colspan="4">Start drafting cervical cancer prevention & control strategy</td><td colspan="2">Completion of draft cervical cancer prevention & control strategy</td><td>Approved Cervical Cancer strategy to Gavi</td></tr>
</table>

27. Timeline

Please draft a chronogram using the Gavi chronogram template for the main activities for HPV vaccination preparations and implementation, assessment of adolescent health interventions, evaluation of the demonstration programme, and development/revision of a national cervical cancer prevention and control strategy.

Please download the Excel chronogram template from the Gavi online country portal, accessible via www.gavi.org, and attach to the application form as Attachment 2.

Countries should ensure enough time is scheduled for planning activities prior to delivery of HPV1. For programme tracking purposes, Year 1 starts with delivery of the first dose of vaccine.

6. BUDGET ATTACH THE BUDGET

28. Budget

Please provide a draft budget for year 1 and year 2, identifying activities to be funded with Gavi's programmatic grant as well as costs to be covered by the country and/or other partner's resources. The budget should include costs for planning and preparations, vaccine implementation, assessment

of adolescent health interventions, evaluation of the demonstration programme, and development/revision of a national cervical cancer prevention and control strategy.

Please download the Excel budget template from the Gavi website at: www.gavi.org/support/apply, and attach to the application form as Attachment 3.

Note: If there are multiple funding sources for a specific cost category, each source must be identified and their contribution distinguished in the budget.

7. PROCUREMENT OF HPV VACCINES AND CASH TRANSFER

In the HPV Demonstration programme, HPV vaccines will be provided at no cost to the country and will be procured through UNICEF. Auto-disable syringes and disposal boxes will be provided.

Please note that, using the estimated total for the target population in the district and adding a 10% buffer stock contingency, the Gavi Secretariat will estimate supplies needed for HPV vaccine delivery in each year and communicate it to countries as part of the approval process.

29. Procurement of HPV vaccines and cash transfer

Please indicate how funds for operational costs requested in your budget in section 6 should be transferred by Gavi (if applicable).

We will use the same account we have used for previous GAVI cash grants.

8. FIDUCIARY MANAGEMENT ARRANGEMENTS DATA

30. Fiduciary Management Arrangements Data

Please indicate below whether the grant to partially support the activities of the HPV vaccination demonstration programme is to be transferred to the government, or to WHO or UNICEF. Please note that WHO and/or UNICEF will require administrative fees of approximately 7% and 8% respectively which would need to be covered by the operational funds

If the grant for the HPV vaccination demonstration programme should be transferred to the government, countries which have completed a financial management assessment (FMA) should confirm whether the financial management modalities – including bank details – agreed with Gavi are still applicable, or alternatively provide details of any modification they intend to submit relating to the existing financial management arrangements.

Countries without an FMA, but who would like the grant for the HPV vaccination demonstration programme to the Government, should provide as Attachment 4 a description of their proposed funding mechanism to manage the grant for the HPV demonstration programme, covering the following processes:

1. *Planning, budget and coordination*
2. *Budget execution arrangements including internal controls*
3. *Procurement arrangements*
4. *Accounting and financial reporting*
5. *External audit arrangements*
6. *Internal audit oversight*

The MoH requests GAVI to transfer the grant to partially support the activities of the HPV vaccination demonstration programme to the government using financial management modalities indicated in FMA and agreed with Gavi.

9. SIGNATURES

9.1 Government

31. Signatures

The Government of *Armenia* acknowledges that this Programme is intended to assist the government to determine if and how it could implement HPV vaccine nationwide. If the Demonstration Programme shows that HPV vaccination is feasible (i.e. greater than 50% of a one-year cohort selected from the population of 9-13 year old girls in at least one district and one delivery strategy of the Expanded Programme on Immunisation (EPI)) and sustainable, Gavi will encourage and consider a national application. To ensure continuity, the application should be submitted during the first or second year of the Demonstration Programme. Application forms and guidelines for national applications are available at www.gavi.org/support/apply/. The data from the Demonstration Programme and timing of a national application are intended to allow uninterrupted provision of vaccine.

The Government of *Armenia* would like to expand the existing partnership with Gavi for the improvement the health of adolescent girls in the country, and hereby requests for Gavi support for an HPV vaccination demonstration programme.

The Government of *Armenia* commits itself to improving immunisation services on a sustainable basis. The Government requests that Gavi and its partners contribute financial and technical assistance to support immunisation of targeted young adolescent girls with HPV vaccine as outlined in this application.

The Government of *Armenia* acknowledges that some activities anticipated in the demonstration programme could be considered research requiring approval by local ethics committees (e.g., collecting data from a random sample of parents of eligible girls for the HPV vaccine coverage survey). The Government of *Armenia* acknowledges responsibility for consulting and obtaining approval from appropriate local ethics committees (e.g., human subject protection committee or Institutional Review Boards) in country, as required. By signing this application, the Government of [Type text] and the TAG members acknowledge that such approval may be necessary and that it will obtain such approval as appropriate.

The table in Attachment 3 of this application shows the amount of support requested from Gavi as well as the Government of *Armenia*'s financial commitment for the HPV vaccination demonstration programme.

Please note that this application will not be reviewed by Gavi's Independent Review Committee (IRC) without the signatures of both the Minister of Health and Minister of Education or their delegated authority.

32. Signatures

Please provide appropriate signatures below.

[Enter the family name in capital letters]

Minister of Health (or delegated authority)		Minister of Education (if social mobilization, vaccination or other activities will occur through schools) (or delegated authority)	
Name	*[Type text]*	**Name**	*[Type text]*
Date		**Date**	
Signature		**Signature**	

33. Signatures

This application has been compiled by:

[Enter the family name in capital letters]

Full Name	Position	Telephone	Email
Gayane Sahakyan	*Manager, National Immunization Program*	*374-93-55-29-73*	*gsahakyan63@yahoo.com*
[Type text]	*Advisor to the Director General, National Center for Disease Control and Prevention, Armenia*	*[Type text]*	*[Type text]*
[Type text]	*[Type text]*	*[Type text]*	*[Type text]*
[Type text]	*[Type text]*	*[Type text]*	*[Type text]*

9.2 National Coordinating Body – Inter-Agency Coordinating Committee (ICC) for Immunisation

34. Signatures

We the members of the ICC, HSCC, or equivalent committee met on July 29th, 2016 to review this proposal. At that meeting we endorsed this proposal on the basis of the supporting documentation which is attached.

The endorsed minutes of this meeting are attached as Attachment 1.

[Enter the family name in capital letters]

Name/Title	Agency/Organisation	Signature
A.MURADYAN/Minister of Health/ Chair of ICC	*Ministry of Health*	
V. POGHOSYAN/Deputy Minister of Health	*Ministry of Health*	
S. KHACHATRYAN /Deputy Minister of Health	*Ministry of Health*	
K.ISAKHANYAN/Deputy Minister of Territorial Administration and Development	*Ministry of Territorial Administration and Development*	
J.BAGHDASARYAN/ Deputy Minister of Labour and Social Affairs	*Ministry of Labour and Social Affairs*	
D.KARAPETYAN/ Deputy Minister of Emergency Situations	*Ministry of Emergency Situations*	
M.MKRTCHYAN/ Deputy Minister of Education and Sciences	*Ministry of Education and Sciences*	
V.PETROSYAN/Head of Medical Department of the National Security Service of the Government of RA	*National Security Service of Government of RA*	
J.ASATRYAN/ Advisor to the Head of Division of the Financial Program on Budgetary Expenditures of Ministry of Finance	*Ministry of Finance*	
G.GEVORGYAN/Member of State Council on Statistics	*National Statistic Service*	
K.KHACHATRYAN/Head of Medical Department of the Armed Forces of Ministry of Defence	*Ministry of Defence*	
K.SARIBEKYAN/Head of Mother and Child Health Department of Ministry of Health	*Ministry of Health*	

A.VANYAN/Director General of the National Center of Disease Control and Prevention of Ministry of Health	*Ministry of Health*	
G.SAHAKYAN/National Immunization Program Manager, Advisor to the Director General of the National Center of Disease Control and Prevention of Ministry of Health/Secretary of ICC	*Ministry of Health*	
G.Ghukasyan / WHO country Office	*WHO country Office*	
L.Hovakimyan/UNICEF country Office	*UNICEF country Office*	
Z.Mkrtchyan/USAID country Office	*USAID country Office*	
Representative /<Armenian Parents Corner> Public Group	*<Armenian Parents Corner> Public Group*	*Not attended*
Representative / <My Kid> Public Group	*<My Kid> Public Group*	
Representative / <Women Resource Center> NGO	*<Women Resource Center> NGO*	*Not attended*

Gayane Sahakyan	*Manager, National Immunization Program*	*374-93-55-29-73*	*gsahakyan63@yahoo.com*
[Type text]	*Advisor to the Director General, National Center for Disease Control and Prevention, Armenia*	*[Type text]*	*[Type text]*

35. Programme manager/ coordinator

In case the Gavi Secretariat has queries on this submission, please contact:

[Enter the family name in capital letters]

Name	*Gayane Sahakyan*	**Title :** *Manager, National Immunization Program Advisor to the Director General, National Center for Disease Control and Prevention, Armenia*	
Tel no			
Fax no	*[Type text]*	**Address 0025, Heratsi 12, Yerevan, Armenia**	*[Type text]*
Email	*gsahakyan63@yahoo.com*		
Mobile no	*+374-93-55-29-73*		

10. ATTACHMENTS

Attachment 1. Minutes of the Inter-Agency Coordinating Committee meeting endorsing the HPV vaccination demonstration programme application.

Attachment 2. Chronogram for the HPV vaccination demonstration programme.

Attachment 3. Budget and finances for the HPV vaccination demonstration programme.

Attachment 4. Proposed funding mechanism for HPV vaccination demonstration programme. This is required ONLY for countries without an existing FMA and countries currently receiving Gavi direct financial support through a UN agency.

Attachment 5. Percentage of children aged 18-29 months who received specific vaccines at any time before the survey (according a health facility card or the mother's report), and the percentage of children with a health facility vaccination card (From 2010 Demographic and Health Survey, Armenia).

Table 11.1 Vaccinations by background characteristics

Percentage of children age 18-29 months who received specific vaccines at any time before the survey (according to a health facility card or the mother's report), and percentage with a facility vaccination card, by background characteristics, Armenia 2010

Background characteristic	BCG	DPT 1	DPT 2	DPT 3	Polio 1	Polio 2	Polio 3	Measles (MMR)	All basic vaccinations[1]	No vaccinations	Hepatitis 1	Hepatitis 2	Hepatitis 3	All[2] + hepatitis	Percentage with a health facility card seen[3]	Number of children
Sex																
Male	99.2	98.1	96.5	94.8	99.0	97.5	96.0	94.8	91.3	0.8	98.2	96.5	88.4	85.2	90.6	174
Female	100.0	100.0	95.7	95.3	99.8	97.0	94.5	96.2	91.7	0.0	98.4	96.9	90.9	89.0	94.4	132
Birth order																
1	99.1	98.0	95.2	94.8	98.9	96.1	96.1	95.1	92.3	0.9	96.4	95.8	90.8	89.0	90.8	149
2-3	100.0	99.2	97.0	95.0	99.2	98.3	94.4	95.5	90.3	0.0	100.0	97.5	87.8	84.2	93.4	150
4-5	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	5
6+	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	1
Residence																
Urban	100.0	99.5	96.9	95.9	99.2	97.1	95.9	94.9	90.9	0.0	97.8	97.1	90.9	87.9	89.8	181
Rural	98.9	98.1	95.1	93.7	98.9	97.5	94.5	96.1	92.3	1.1	98.9	96.1	87.5	85.3	95.9	124
Mother's education																
Basic	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	16
Secondary	98.7	98.2	92.3	92.3	98.2	94.6	92.8	94.6	90.7	1.3	98.7	96.0	88.6	87.0	96.0	107
Secondary special	100.0	100.0	100.0	98.2	99.8	99.8	97.7	94.1	91.2	0.0	98.1	96.6	87.5	83.9	87.9	105
Higher	100.0	98.3	98.3	98.3	99.5	99.5	99.5	97.4	96.1	0.0	100.0	99.5	96.3	92.9	96.3	79
Wealth quintile																
Lowest	97.6	97.6	91.3	88.3	97.6	94.6	88.3	94.6	88.3	2.4	97.6	94.4	84.4	84.4	91.3	58
Second	100.0	100.0	100.0	99.1	100.0	100.0	100.0	99.1	98.2	0.0	100.0	97.6	95.3	92.4	99.1	64
Middle	100.0	97.4	94.2	94.2	99.6	96.4	94.2	96.8	89.4	0.0	96.4	95.5	87.4	85.4	84.1	61
Fourth	100.0	99.5	96.1	96.1	99.5	96.1	96.1	94.1	90.8	0.0	100.0	98.9	90.6	88.2	96.5	70
Highest	(100.0)	(100.0)	(99.4)	(96.9)	(100.0)	(99.4)	(97.8)	(91.8)	(90.2)	(0.0)	(96.6)	(96.6)	(91.5)	(87.3)	(88.9)	52
Total	99.5	98.9	96.2	95.0	99.4	97.3	95.3	95.4	91.5	0.5	98.3	96.7	89.5	86.8	92.3	306

Note: Figures in parentheses are based on 25-49 unweighted cases. An asterisk indicates that a figure is based on fewer than 25 unweighted cases and has been suppressed.
[1] BCG, measles, and three doses each of DPT and polio vaccine (excluding polio vaccine given at birth)
[2] Includes immunization passports kept by the parent/guardian