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 [Georgia]

Date of submission: [9 September 2016]

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	*December 2017*
Target population	12 409 (Year 1) 14 816 (Year 2)
Number of districts	*4 (Tbilisi, Kutaisi, Ajara, Abkhazia)*
Vaccine preference	*Gardasil quadrivalent (Merck)*
Total Budget (Year 1 + Year 2) requested from Gavi	*$191,000*
Total costs to be covered by country and/ or other partner resources	*$50,500*
Estimated date of national introduction	*December 2017*
Programme manager/ coordinator	*Lia Jabidze* *Manager, Expanded Program on Immunizations* *Head, Immunoprophylaxis Divsion* *National Center for Disease Control and Public Health, Georgia*

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)	*December 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.
[Type text] Cervical cancer in the third-leading cause of cancer among women in Georgia. According to Globocan 2012 data, the 5-year prevalence of cervical cancer in Georgia was 57.7 cases per 100,000 population. The age-standardized mortality rate associated with cervical cancer was 5.7 per 100,000 population, and the incidence of cervical cancer was 14.2 per 100,000 population. Figures from the Georgia National Office of Statistics are similar to Globocan estimate. In 2014, for example, the incidence of cervical cancer was 9.0 per 100,000 women, the prevalence of cervical

cancer was 76.6 per 100,000 women and cervical cancer-related mortality was 3.8 per 100,000 women. In 2013, the incidence of cervical cancer was 7.3 per 100,000 women, the prevalence of cervical cancer was 65.6 per 100,000 women and cervical cancer-related mortality was 4.3 per 100,000 women.

In light of these significant morbidity and mortality rates related to cervical cancer, the government of Georgia is applying to introduce HPV vaccine in 9-year old girls in the context of a demonstration project.

Georgia's National immunization Technical Advisory Group recommended the Ministry of Health to include HPV vaccination in the national immunization programme. This recommendation was based on consideration of the public health importance of cervical cancer in Georgia, data on efficacy and safety of HPV vaccines, and preliminary data on the impact of HPV vaccine from countries that introduced this vaccine earlier. The Committee noted that many questions remain about the optimal communication strategies and delivery strategies for HPV vaccine in Georgia as a whole and in different regions of the country. For this reason, the NITAG recommended that the MoH first implement the HPV demonstration programme and take advantage of this opportunity to obtain GAVI support to answer critical questions that could inform decisions about nationwide HPV vaccine introduction. The Georgian 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.

Georgia has decided to target 9 year-old girls for HPV vaccination based on WHO recommendations and programmatic considerations, and because the country wants to ensure that girls are vaccinated at an age before they are sexually active. Georgia plans to implement the HPV Demonstration Programme in 4 diverse provinces of the country which represents urban and rural populations, include people from relatively diverse socioeconomic and religious backgrounds, and represent settings with higher and lower immunization coverage. The projected population of 9-year-old girls in these provinces in 2017 (11,697) is less than the maximum population allowed for the HPV demonstration programme.

The objectives of the demonstration project are as following:

- develop optimal communication and social mobilization strategies to overcome existing vaccine hesitancy and ensure good acceptance and high vaccine uptake of HPV vaccine in diverse sub-populations
- evaluate if existing vaccine delivery system for children beyond infancy is capable to successfully deliver two doses of HPV vaccine to 9 years old girls in the regions with high and lower immunization coverage

The MoH is confident that the National Immunization Programme has programmatic capacity to implement HPV demonstration programme in these four regions because Georgia has been successful in vaccinating 5-years old children with second dose of MMR vaccine, with coverage rates over 85% in Tbilisi, Adjara, and Kutaisi and 50% in Abkhazia. However, HPV vaccine requires administration of two doses which is a new challenge for existing system to deliver vaccines to children beyond infancy. Taking into account controversy regarding safety and benefits of HPV vaccine in Georgia and in many countries of WHO European Region, the MoH anticipates challenges in acceptance of this vaccine among medical workers, 9-year girls, and their parents. Therefore, prior to nation-wide introduction of HPV vaccine, the MoH would like to implement demonstration project to develop and optimize different communication strategies tailored to the needs of communities with different cultures and socioeconomic backgrounds and to evaluate and optimize existing vaccine delivery system to accommodate HPV vaccine.

Vaccine delivery strategy

Vaccination of 9 years old girls will be organized in primary health care facilities in all four regions. The medical workers will develop micro-plans and will vaccinate 9-year old girls who are registered in their health facilities. They will invite girls and their parents for vaccination, record vaccinations in the medical documentation and immunization cards, and recall those who did not come for vaccination in time. The children immunization is covered by the universal medical insurance in Georgia and therefore all 9-year girls in the country are registered in primary health care facilities and have universal access to health care.

In the rural parts of Kutaisi, Ajara, and Abkhazia healthcare delivery works through rural doctors. These rural doctors will be responsible for micro planning and vaccination of 9 year-old girls in their catchment area. The rural doctors will work with communities to inform 9 years old girls and their parents about HPV vaccination and vaccination days. Health facility staff will also be responsible for recalling girls that did not come for vaccination.

In the region of Abkhazia where coverage with routine vaccines in infants and in children is lower than in the rest of the country, the immunization programme will undertake additional efforts to address weaknesses indicated in the recent EPI programme review and improve routine and the new vaccines uptake. The introduction of HPV vaccine will be used as an opportunity to strengthen immunization system. We believe that high level political commitment obtained for HPV vaccine demonstration project as well as implementation of preparatory activities related to education of medical workers, supportive supervision, communication and social mobilisation, will help not only to achieve high coverage with HPV vaccine but also to improve coverage with the second dose of MMR vaccine in 5 years old children.

At the end of Year 1 of demonstration project the selected delivery strategies will be evaluated and optimized.

Possible barriers in achieving high coverage with HPV vaccine in Georgia

We anticipate encountering a number of potential significant challenges in our attempt to achieve high coverage for HPV during the demonstration programme and subsequent national introduction.

First, 9 years old girls, their parents, medical worker and the public in general may express concerns about vaccine safety. There also may be clusters of anxiety-related Adverse Events Following Immunization (AEFIs). We anticipate these concerns because other middle-income countries of WHO European Region have encountered these challenges. 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 were widespread on the Internet and social media. As a result, the MoH of Romania had to stop HPV vaccination and destroy its stock of HPV vaccine. In MKD the HPV vaccine coverage was much lower than coverage for other vaccines for teenagers, likely because of negative public perception of the vaccine. In Kazakhstan HPV vaccine was associated with 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 in the European region, had similar clusters of anxiety-related AEFIs that negatively affected previously successful HPV vaccination programmes. In Denmark the HPV coverage dropped from 86% to 15% within one year. A cluster of anxiety-related AEFIs reported in Japan led to suspension of HPV vaccination in that 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. There is a real concern that the introduction of HPV vaccine in Georgia may lead to similar events, which will require quick and thoughtful responses

on the part of the public health community.

Second, taking into account the lower coverage rates for routine and newly introduced vaccines in Abkhazia, the immunization programme will have to undertake additional efforts to implement recommendations of recent EPI programme review, including reduction of false contraindications, improvement of timeliness of vaccination, introduction of supportive supervision, and developing the strategies to reach children in remote villages.

Development of tailored communication plans for sensitising and mobilising communities

In light of likely concerns about the vaccine safety among the public and medical personnel, the demonstration programme will be used to identify the most appropriate communication strategies to address concerns about HPV vaccine safety in different socioeconomic, cultural, and religious sub-populations of Georgia. 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 and negative perceptions of HPV vaccine in Georgia. Georgia's National Centre for Disease Control, in collaboration with UNICEF, will conduct context-specific formative research to better understand barriers and enablers to HPV vaccination, including an evaluation of knowledge, attitude, practice and beliefs towards HPV vaccine in different sub-populations. This research will help create communication strategies that will address their specific needs.

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

- Identifying the main target audience
- Developing tailored messages and communications material and activities specific to cervical cancer, HPV infection, and HPV vaccine,
- Identifying the most relevant and sufficient distribution and communications channels

The communication strategies will be defined based on the results of formative research.

In summary, we expect that the demonstration project will help to develop, pilot, and evaluate different HPV vaccine communication strategies in provinces with different sub-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 Georgia.

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*	*N/a*	*N/a*
DTP 3	*90.6%*	*93.7%*		
MMR 2 (5 years ols children)	*86.6%*	*91.0%*		

*National Center for Disease Control and Public Health (reporting from regional public health centers)

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	Tblisi		Ajara		Kutaisi		Abkazia	
	Statistic	Data Source	Statistic	Data Source	Statistic	Data Source	Statistic	Data Source
Topography (% urban, % semi-urban, % rural, % remote, etc.)	*Urban – 97.4% Rural- 2.6%*	*National Statistics Office of Georgia , 2016*	*[Urban – 50.1% Rural- 49.9%*	*National Statistics Office of Georgia, 2016*	*Urban – 100%*	*NCDC*	*Urban – 50.3% Rural- 49.7%*	*http://abhaz.com*
Number and type of administrative subunits, e.g., counties, towns, wards, villages	*6 administrative units*	*NCDC*	*5 districts, 1 city*	*NCDC*	0	*NCDC*	1 city, 7 districts	*http://ugsra.org/rld.com*
Total population	*1,175,200*	*National Statistics Office of Georgia , 2016*	*396,600*	*National Statistics Office of Georgia, 2016*	147,900	*National Statistics Office of Georgia , 2016*	178,000	Statistical Yearbook of Georgia 2005: Population, Table 2.1, p. 33, Department for Statistics, Tbilisi (2005)
Total female population* (%)	*514,296 (44%)*	*National Statistics Office of Georgia , 2016*	*207,025 (52.2%)*	*National Statistics Office of Georgia, 2016, 2015*	*77,203 (52.2%)*	*National Statistics Office of Georgia , 2016, 2015*	92916 (52.2%)	*National Statistics Office of Georgia, 2016, 2015*

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 – 44,121 (8.6% of total female population)* *7741* *9647* *9057* *8886* *8790*	*Immunization Program Data, NCDC, 2016*	*Total female population aged 9-13 years – 10,521 (5.1% of total female population)* *2170* *2097* *2093* *1955* *2206*	*Immunization Program Data, NCDC, 2016*	*Total female population aged 9-13 years – 5267 (6.8% of total female population)* *1194* *990* *923* *810* *1350*	*Immunization Program Data, NCDC, 2016*	*Total female population aged 9-13 years – 5,856 (6.4% of total female population)* *1304* *1194* *1128* *1103* *1208*	*Electronic immunization registry in Abkhazia*
Number and type of public health facilities	*All health facilities are private in Georgia*	*National Statistics Office of Georgia, 2016*	*All health facilities are private in Georgia*	*National Statistics Office of Georgia, 2016*	*All health facilities are private in Georgia*	*National Statistics Office of Georgia, 2016*	*154*	http://ugsra.org/ (2015)
Number and type of health workers in all district public health facilities	*All health facilities are private in Georgia*	*National Statistics Office of Georgia, 2016*	*All health facilities are private in Georgia*	*National Statistics Office of Georgia, 2016*	*All health facilities are private in Georgia*	*National Statistics Office of Georgia, 2016*	709 physicians 1,539 nurses	http://ugsra.org/ (2015)
Number and type of private health facilities	*334*	*National Statistics Office of Georgia, 2016*	*227*	*National Statistics Office of Georgia, 2016*	*13 (these are only for immunization programs)*	*National Statistics Office of Georgia, 2016*	**0** *All health facilities are public*	http://ugsra.org/ (2015)
Number and type of health workers in	*14100 doctors* *7900 nurses*	*National Statistics Office of Georgia*	*1800 doctors* *1000 nurses*	*National Statistics Office of Georgia, 2016*	*1179 doctors* *491 nurses*	NCDC	0 *All health facilities are*	http://ugsra.org/ (2015)

private health facilities in the district		*, 2016*					*public*	
Number and type of public and private primary and secondary schools	*300*	*National Statistics Office of Georgia, 2016*	*255*	*National Statistics Office of Georgia, 2016*	54	*National Statistics Office of Georgia, 2016*	138	*df Ministry of Education and Science of Abkhazia*
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**	 100% 99% 97% 95% 96%	*Ministry of Education and Science, Education in Georgia Statistical Directory*	 100% 99% 97% 95% 96%	*Ministry of Education and Science, Education in Georgia Statistical Directory*	 100% 99% 97% 95% 96%	*Ministry of Education and Science, Education in Georgia Statistical Directory*	 100% 99% 99% 99% 99%	*df Ministry of Education and Science of Abkia*
Estimate the numbe		*Ministry of*		*Ministry of*		*Ministry of*		*Ministry of Education*

r 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**	*0%* *1%* *3%* *5%* *4%*	*Education and Science, Education in Georgia Statistical Directory*	*0%* *1%* *3%* *5%* *4*	*Education and Science, Education in Georgia Statistical Directory*	*0%* *1%* *3%* *5%* *4*	*Education and Science, Education in Georgia Statistical Directory*	*0%* *1%* *3%* *5%* *4*	*and Science, Education in Georgia Statistical Directory*
Is any routine vaccine currently given to children using schools as delivery points?	*NO but the country has routine immunization of children at the age beyond infancy in health facilities*	*NCDC*	*NO but the country has routine immunization of children at the age beyond infancy in health facilities*	*NCDC*	*NO but the country has routine immunization of children at the age beyond infancy in health facilities*	*NCDC*	*NO but the country has routine immunization of children at the age beyond infancy in health facilities*	*NCDC*

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.

Georgia plans to implement the HPV Demonstration Programme in four areas of the country that are diverse and representative of the population as a whole. The selected districts represent urban and rural populations, different cultural and religious groups, and a politically contested region. The selected regions also represent setting with strong immunization systems and relatively high coverage rates for routine and newly introduced vaccines and less performing settings with lower immunization coverage rates.

The first region is Tbilisi, the capital, which is home to nearly one-third of the country's population, represents almost entirely urban population. Although the coverage rates in Tbilisi are relatively high, the city has the largest proportion of vaccine hesitant population. Success of the HPV introduction in Tbilisi is critical to the success of the national program. The second region is Ajara with a large population of Muslims and other religious minorities. Introducing the vaccine in this part of the country will require special cultural sensitivity and creative communication strategies to ensure high vaccine coverage in all cultural sub-populations. This region has also relatively high immunization rates. The third region is Kutaisi, the second-largest city in Georgia and another key setting to optimize communications messages and delivery of this new vaccine to an urban population with a significant proportion of vaccine-hesitant parents. The last region is Abkhazia, a politically contested region on the east coast of the Black Sea that still remains under the jurisdiction of the National Ministry of Health. This region will also require development of specific communication strategy that will address the needs of population residing in politically contested region. This region has less performing immunization system and will require implementation of additional activities to achieve high coverage with HPV vaccine. The demonstration project will be used as an opportunity to strengthen immunization system and improve uptake with the second dose of MMR vaccine in 5 years old children.

In summary, the implementation of demonstration programme will provide the country with the opportunity to develop the most optimal communications strategies in a wide variety of settings that represent almost all sub-populations in Georgia: different cultural and religious groups, urban and rural communities, as well as populations residing in politically contested regions. It will also help to optimize existing immunization system for children beyond infancy in order to successfully deliver and achieve high coverage with to-dose HPV vaccine. We also hope that implementation of demonstration project will help to strengthen immunization system and improve coverage with other childhood vaccines in less performing regions. The strategies and approaches piloted during demonstration project will be relevant for entire population of the country and will be utilised for nationwide introduction of HPV vaccine.

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

Component	Tbilisi	Ajara	*Kutaisi*	*Abkhazia*
Number and type of administrative subunits (e.g. health facilities) used for routine vaccine delivery	*6*	*6*	*1*	*8*
Number and type of outreach sessions in a typical month used for routine vaccine delivery	*None for routine vaccinations*	*None for routine vaccinations*	*None for routine vaccinations*	*None for routine vaccinations; to be considered for HPV vaccine in remote villages*
DTP3	*96% (2015)*	*98% (2015)*	*94% (2015)*	52% (2015)
Polio3 coverage	*99.6% (2015)*	*98% (2015)*	*99.8% (2015*	60% (2015)
Measles first dose coverage	*99% (2015)*	*96% (2015)*	*97.4% (2015)*	49% (2015)
Pentavalent 3 coverage	*96% (2015)*	*98% (2015)*	*94% (2015)*	52% (2015)
MMR second dose in 5 years old	*92% (2015)*	*93% (2015)*	*85% (2015)*	50% (2015)
TT2+ (pregnant women)	*N/A*	*N/A*	*N/A*	*N/A*

*information from NCDC National Immunization Program

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 National-International Review of Immunization and VPD Surveillance Report for Georgia, which included on-the-ground evaluations in Tblisi, Ajara, Kutsisi, and Abkhazia. While the report describes increased awareness about vaccines among parents, it also highlights shortcomings in health promotion. For the demonstration programme will offer an opportunity to focus work on health promotion for HPV vaccine specifically and vaccines in general.

Major achievements nationally

- National immunization schedule followed by service providers, and in line with WHO recommendations
- Immunization practices and vaccines handling observed during the review: in general good
- Rotavirus vaccine and PCV implementation proceeding fairly well
- Around 95% of all vaccinations are provided by the state program, share of commercial vaccines minimal
- Improved knowledge and awareness of parents on immunization in recent years
- Health Promotion team at national level with increased capacity (human and financial resources)

Major issues identified

- False contraindications still widespread, including temporary ones, inducing low coverage and drop-out
- Active follow up of children: a challenge for health staff (cost, time, motivation) for urban areas
- Larger health facilities with inpatient department less interested in implementing immunization
- Increasing vaccine hesitancy among parents in large cities
- Lack of trained/skilled professionals for health promotion (at all levels)

Main recommendations

- Explore various strategies to reduce false contraindications (scientific workshops, behaviour change models)
- Explore intervention/recommendation by MLHSA for school/kindergarten entry requirements (immunization/health certificate)
- Develop comprehensive communication strategies; allocate sufficient resource, training and information material
- Increase capacity in health communication in NCDC and DPHCs, with technical assistance

Specific issues identified in politically contested region of Abkhazia:

- Weak primary health care systems; lack of paediatricians, nurses, and other relevant health staff
- High drop-out rates among children of pre-school age
- Existence of false contraindications and delayed immunization
- Major communication challenges, lack of consistent advocacy for immunization
- Insufficient engagement and commitment of higher political authorities to immunization
- Access challenges due to remoteness of certain villages and absence of functioning health points in some villages

Recommendations for Abkhazia:

- Invest in strengthening immunization efforts, especially in rural areas (in short-term – though regular mobile outreach, in long-term – through re-establishment of health points in vies and strengthening primary health care)
- Strengthen advocacy and communication efforts among parents, medical staff and teachers
- Invest in/establish VPD surveillance
- Advocate for stronger political commitment and engagement at the region's government level, and for regular and sustainable financing of the immunization efforts
- Improve vaccine management system
- Introduce and strengthen supportive supervision

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 four regions conduct routine vaccination of 5 year-old children with MMR 2. The second doses of MMR vaccine are administered in primary healthcare facilities by GPs and vaccinators in urban settings. In villages and in rural areas, vaccinations are delivered through village doctors and rural nurses. These rural doctors and nurses have more direct interaction with patients and the community, and therefore ensuring that rural doctors are well informed about HPV vaccine is critical for the demonstration programme. Both healthcare facility staff in urban setting and rural doctors and nurses in rural settings are responsible for inviting children for vaccination and following up with those who did not come for vaccination in time. They will be responsible for doing the same for both doses of HPV vaccine.

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 Georgia, we anticipate challenges related to HPV vaccine safety concerns among public and health care professionals. Negative public perception can be fuelled through messages disseminated by mass media and social networks. In order to be prepared to address these anticipated challenges, we plan to conduct a study to evaluate knowledge, attitudes and perceptions towards HPV vaccine in different socioeconomic, cultural, and religious sub-populations. We will then develop tailored communication strategies and try to define the most effective communication channels for each target sub-population, using innovative approaches to engage urban and rural populations and different religious and cultural groups. The NCDC will also develop a communication working group to prepare for actual or perceived AEFIs, including potential anxiety-related clusters. This group will involve all relevant stakeholders and help to build country capacity to timely and effectively respond to any HPV vaccine safety events that may happen after the introduction.

Another challenge is to ensure effective communication with vaccine-hesitant parents in order to persuade them to vaccinate their daughters; this can be accomplished through improving medical workers' communication skills and providing medical workers with extensive information about the risks and benefits of HPV vaccination.

We anticipate challenges in achieving high coverage with HPV vaccine in Abkhazia, the region with lower coverage rates for routine and newly introduced vaccines. The EPI programme review conducted in July 2015 revealed the main weaknesses of immunization programme in Abkhazia and developed recommendations which are being implemented. During preparing for and implementation of the demonstration project we plan to undertake additional efforts to address challenges related to false contraindications and delayed vaccinations by educating and training medical workers, improve immunization programme performance by conducting regular supportive supervision, and increase immunization coverage by developing appropriate strategies to reach children in remote villages.

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.

The data from national immunization registry show that differences in vaccination coverage between boys and girls were minimal. For example, in Tbilisi in 2015 48.2% girls were vaccinated with hexavalent vaccine, compared to 51.8% of boys. In Ajara, 47.2% of girls were vaccinated compared to 52.8% of boys, and in Kutaisi 48.8% of girls were vaccinated compared to 51.2% of boys. Ongoing studies in Georgia are currently being conducted by the NCDC together with the US CDC to better understand the differences in vaccine coverage by socio-economic status. The findings should be available later this year and will be used for development of vaccine delivery and communication strategies for the HPV vaccine demonstration programme.

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 Georgia we plan to vaccinate 9 year- old girls in 4 regions of the country. High quality data on the size of the target population are available in the NCDC from the National Statistics Office of Georgia. 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 2008 (N=12409); in the second year the target group will be girls born for the period from January until December 2009 (N=14816). The second-year

target population is estimated to be larger than the first-year target population. This difference is related to dramatic changes in vital statistic during the South Ossettia war that occurred in Georgia in 2008.

The first dose of HPV vaccine will be delivered in September and the second dose in March. We recognize that some girls may turn 10 by the time of administration of the second dose. However, as long as a 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, we do not anticipate problems with coverage estimate. We will estimate coverage for 2008 birth cohort during year 1 implementation and for 2009 birth cohort during year 2 implementation.

Target population	Tbilisi	Ajara	Kutaisi	Abkhazia	Total
Who are the girls eligible for HPV vaccine based on the criteria set by the programme?	**Total eligible**	**Total eligible**	**Total Eligible**	**Total eligible**	**Eligible**
1. Girls born in 2008 (Year One)	7741*	2170*	**1194***	**1 304****	**12 409**
2.Girls born in 2009 (Year 2)	**8947***	**2885***	**1579***	**1 405****	**14 816**
TOTAL	**16688**	**5055**	**2773**	**2,709****	**27225**

*NCDC, Immunization Program, 2016
** Immunization Registry in Abkhazia, 2016

12b. HPV vaccine delivery strategy

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

[Type text]

We have selected 9 year-old girls because we intend to vaccinate girls before they become sexually active and due to programmatic considerations. Finally, this age group was recommended as a target group for HPV vaccination by WHO (girls between 9 and 13 years old); we wanted to target them at the youngest age recommended.

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.

Vaccination of 9 years old girls will be organized in primary health care facilities in the four regions. The approach to vaccination in urban and rural areas will be different. In Tbilisi and Kutaisi and urban populations of Adjara and Abkhasia, the vaccination will be conducted in primary health care facilities. The healthcare workers will develop lists of names of 9-year old girls registered in their health facilities and to be vaccinated in the current calendar year, using immunization registries. The health facilities staff will inform parents about the specific vaccination day by phone or home visits. The healthcare facilities will vaccinate 9 years old girls, record immunizations in immunization cards and in the national electronic immunization registry. Based on these records, they will identify girls that did not come for

vaccination in time and will recall them for vaccination by home visits. The doctors will communicate the risks of the disease and benefits of vaccination with families that are hesitant to vaccinate their girls.

In the rural sub-regions of Ajara and Abkhazia healthcare delivery works through rural doctors. These rural doctors will be responsible for developing name-based lists of 9 year-old girls in their catchment areas, who are eligible for HPV vaccination in the current calendar year. The rural doctors and the vaccinators will work with communities to inform 9 years old girls and their parents about HPV vaccination and vaccination days (community meetings, phone calls, home visits). The rural doctors and vaccinators will vaccinate girls, record immunization in immunization cards and immunization registries, and will be responsible for recalling girls that did not come for vaccination in time (home visits). The rural doctors will communicate the benefits and risks of HPV vaccination with parents who may refuse to vaccinate their girls due to vaccine safety concerns. The immunization programme in Abkhazia will develop and implement effective strategies to reach girls in remote villages, including introduction of our-reach immunization sessions.

At the end of Year 1 the selected delivery strategies will be evaluated and optimized. After the second year the optimized delivery approaches will be recommended for a national wide implementation in rural and urban settings.

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. Girls born in 2008	12409	Primary health care facilities and rural doctors		
2. Girls born in 2009			14816	Primary health care facilities and rural doctors
TOTAL	12409		14816	

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.

In Tbilisi, Kutaisi and urban areas of Adjara and Abkhasia, where HPV vaccination will be conducted by health care facilities, the medical staff from health facilities will be responsible for recalling girls who did not come for vaccination due to health or any other reasons. They will identify not-vaccinated girls by reviewing the immunization registries and will recall them for vaccination by phone or home visit. If parents refuse to vaccinate their girls due to vaccine safety concerns, the medical staff will communicate with them the risk of cervical cancer and other HPV diseases and benefits of vaccination.

In rural areas of Ajara and Abkhazia, where HPV vaccination will be conducted by rural doctors, the rural doctors and vaccinators will recall girls who missed vaccination day. They will phone the girls families and/or visit households.

The vaccinations are provided free of charge to all residents throughout the country. In the majprity of the selected regions we do not have hard-to-reach populations or marginalized group of people in Georgia that do not have access to primary health care. In the remote villages of Abkhazia, additional out-reach sessions will be organized to vaccinate girls that missed vaccinations due to health or other reasons.

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 Georgia implements an opt-out procedure of parental consent for childhood vaccinations. Parents are informed about vaccination and can refuse from vaccinating their children.

The NIP plans to add HPV vaccine into existing immunization programme; therefore the same opt-out parental consent procedure is going to 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 the vaccine acceptance among 9 years old girls, 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.

Families of girls will be informed about vaccination dates by health facilities staff and rural doctors by

phone or in rural areas at community meetings. They will be invited to health facility together with their daughters and will have an opportunity to receive additional information about the HPV diseases and vaccines and make informed decisions on vaccination of their girls. If there will be parents that decide not to vaccinate their girls, the medical workers will make sure that they understand the risks of diseases and risk and benefits of HPV vaccination. If the parents do not change their decision their children will not be vaccinated.

The NIP will implement comprehensive communication and social mobilization activities prior to the introduction of HPV vaccine to inform the 9 year-old girls, their parents, and the public about cervical cancer burden and benefits of vaccination and to create demand for vaccination.

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).

Georgia had very positive experiences with the introduction of three new vaccines - pentavalent, rotavirus, and, most recently, PCV. The immunization programme review conducted in 2015 found that PCV introduction had gone smoothly and confirmed good coverage rates following the new vaccine introduction. The NCDC has effectively managed the technical elements of new vaccines delivery. The findings from the 2015 Joint National-International Review of Immunization and VPD Surveillance in Tbilisi, Ajara, and Kutaisi are presented below:

Immunization delivery:

- There is a universal access to immunization services in all visited regions. In big cities health facilities vaccinate children every day; in rural areas with low number of children, immunization is provided on designated days in order to reduce vaccine wastage rates.
- Well-trained, highly dedicated staff at regional and health facilities levels
- Strong involvement of health staff in follow-up with parents on immunization timelines (phone-sms reminders of the need to bring children for vaccination, efforts to explain to parents the value and safety of immunization)
- Good immunization practices and vaccines handling in health facilities

Immunization quality and safety, including AEFI surveillance

- Central level: Existing good equipment for cold chain, temperature monitoring, transportation; cold storage capacity adequate; EVM (2014) recommendations and SOPs implemented for a good part; national vaccine store with high quality standard
- Regional level: Vaccine storage and distribution system well structured and fairly well functioning; Cold chain inventory assessment conducted (2013)
- New equipment provided (central, district) from GoG budget covering 1/3 of country need
- AEFI surveillance system in place, guidelines currently renewed
- NRA: Institutional Development Plan exists

Immunization coverage and monitoring, including program performance

- Overall good immunization coverage system; data generally processed timely and complete
- New immunization e-module introduction improving child registry, with ID number. Planned introduction of e-birth registration
- Regular supervisory activities from national to regional levels allowing checking the best practices and corrective action
- Sufficient funds to implement supervisory activities

The evaluation identified the following issues:

- still wide spread false contraindications
- lack of trained/skilled professionals for health promotion
- domestic refrigerators used to store vaccines in health facilities
- lack of supervision at health facilities level

Specific issues identified in politically contested region of Abkhazia:

- Weak primary health care systems; lack of paediatricians, nurses, and other relevant health staff
- High drop-out rates among children of pre-school age
- Existence of false contraindications and delayed immunization
- Major communication challenges, lack of consistent advocacy for immunization
- Insufficient engagement and commitment of higher political authorities to immunization
- Access challenges due to remoteness of certain villages and absence of functioning health points in some villages

The implementation of provided recommendations is ongoing and will help to further improve immunization programme implementation in selected regions. Additional efforts will be undertaken in Abkhazia to implement EPI review recommendations. Implementation of demonstration project will be used as an opportunity to educate medical workers, conduct supportive supervision, improve immunization communication and social mobilization.

Component	Tbilisi	Ajara	Kutaisi	Abkhazia
Number and type of cold storage facilities	Refrigerators and freezers: 254, including 33 for storage at Regional Public Health Centers. One cold room at Public Health Center (2015, NCDC)	Refrigerators and freezers: 155, including 33 for storage at Public Health Centers; in addition, one cold room at the Regional Public Health Center (2015, NCDC)	Refrigerators and freezers: 45, including 33 for storage at Regional Public Health Centers. One cold room at Public Health Center. (2015, NCDC)	Combined number of refrigerators and freezers: 38, including 17 for storage at District Hospitals. One cold room at Sukhumi Central Store. (2015, df MoH of Abkhazia)
Functioning and working order of the facilities	All are functioning and working	All are functioning and working	All are functioning and working	All are functioning and working
Storage capacity (any excess)	.-20°C: 1 230 Litres; .+2°C to +8°C: 20 388 Litres	.-20°C: 1 029 Litres; .+2°C to +8°C: 13 175 Litres	.-20°C: 652 Litres; .+2°C to +8°C: 10 750 Litres;	.-20°C: 484 Litres; .+2°C to +8°C: 8 480 Litres
Distribution Mechanism	From central to regional level by refrigerated trucks; from regional to individual facility in cold boxes according to pre-arranged delivery times	From central to regional level by refrigerated trucks; from regional to individual facility in cold boxes according to pre-arranged delivery times	From central to regional level by refrigerated trucks; from regional to individual facility in cold boxes according to pre-arranged delivery times	From central to regional level and from regional to individual facility in cold boxes according to pre-arranged delivery times
Number and status of vaccine carriers	123 unit with net volume 403.4 litres. There are no shortages in vaccine carriers	181 unit with net volume 767.8 Litres. There are no shortages in vaccine carriers	9 unit with net volume 411 Litres. There are no shortages in vaccine carriers	12 units with net volume 628 litres. There are no shortages in vaccine carriers
Number and status of (any shortages or excess)	There are no shortages in vaccine carriers	There are no shortages in vaccine carriers	There are no shortages in vaccine carriers	There are no shortages in vaccine carriers

17b HPV vaccine delivery strategy

There are currently no shortages in the cold chain capacity. The cold chain volume in the four regions is sufficient to accommodate HPV vaccine. Some refrigerators in health facilities are old and will likely need to be replaced over the next two years.

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.

The four districts will use the same approach in conducting trainings for medical workers on HPV vaccine introduction that were used for the introductions of new childhood vaccines. This approach was proven to be effective in achieving smooth introductions and high new vaccines uptake. First, we will conduct national meeting for healthcare professionals, with a particular focus on oncologists, gynecologists, and paediatricians, professional associations, non-governmental organizations and representatives of medical universities and colleges. These health care professionals will not administer HPV vaccine but as opinion leaders will influence parents' decisions to vaccinate their children. The NCDC will provide them with comprehensive information about HPV disease and HPV vaccine to ensure their support to HPV vaccine introduction.

We also plan to conduct meetings for educational universities and colleges such as medical schools. These meetings will help to engage all stakeholders in implementation of HPV demonstrating project and ensure their support to HPV vaccination. The national level health care professional associations will also work with NCDC in advocating for inclusion of HPV vaccine into routine immunization programme after the demonstration project is finished.

NCDC will arrange trainings for regional public health centers staff. General practitioners and vaccinators from health facilities will be trained on site by NCDC staff and regional public health centers staff. 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.

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

We also plan to conduct national and regional trainings of health care professionals on vaccine safety and contraindications to reduce missed opportunities to vaccinate children due to false contraindications and improve timelines of vaccination.

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.*

In 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 (e.g., sensitisation, mobilisation, immunisation, supervision, monitoring, etc.)	Training content (e.g., basics on cervical cancer, HPV, HPV vaccine, IEC messages, safe injections, AEFI monitoring, etc.)	Who will provide the training?
Healthcare workers (doctors, nurses)	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 Disease Control*
Immunization staff from regional public health centers	*Supervision, monitoring*	basics on cervical cancer, HPV, HPV vaccine, IEC messages, safe injections, AEFI monitoring and communication	*National Center Disease Control*
Professional Associations (i.e. National Pediatric Associations, National Cancer Association, etc) **Medical schools, nursery schools**	*Advocates, social mobilization, sensitizers*	cervical cancer disease burden; efficacy and safety of HPV vaccines, IEC messages , AEFI communication	*National Center for Disease Control*
NCDC programme staff	sensitisation, mobilisation, immunisation, supervision, monitoring	cervical cancer disease burden; efficacy and safety of HPV vaccines, IEC messages, safe injections, AEFI monitoring and communication, immunization reporting, supportive supervision	*National Center for Disease Control*

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 and social mobilization plans will be developed for each sub-population, including urban and rural populations, different religious groups, and populations residing in political contested regions. In order to develop optimal communications messages for the different target populations, a behavioral analysis will be conducted among key informants (health care officials, vaccinators, immunization staff, general practitioners and pediatricians, and parents) through focus groups. Research will assess level of knowledge among members of various groups about cervical cancer. The research will evaluate perceived causes/risks factors of cervical cancer, benefits and risks of HPV vaccination, and ascertain key decision-makers about vaccination within families. Based on the results of the focus groups, disaggregated by education level, age, income, religious, and residence, various

IEC messages and materials on cervical cancer, HPV infections, and HPV vaccine will be developed. These materials will be tailored to different sub-populations. Different types of IEC materials will be developed, including leaflets, posters, media spots for communities, and a handbook for doctors in Tbilisi and Kutaisi, rural and urban populations of Ajara, and residents of Abkhazia. Experts will review and pre-test the materials before finalization.

As the NCDC does not have sufficient capacity to conduct KAPB research and develop tailored communication strategies, UNICEF technical support will be requested in order to conduct these activities.

In addition to IEC materials, NCDC will design and conduct a series of trainings to ensure that, healthcare providers have adequate knowledge about HPV vaccine, cervical cancer, and communication skills. The focus in urban areas will be health facility staff, while in rural areas there will be a particular effort to train village doctors and rural nurses. The trainings will include modules aimed to improve medical works communication skills.

Key communication messages will be delivered before and during HPV vaccination sessions through a wide range of communication channels, including mass media, posters, and leaflets.

The following communication channels will be used:

- Indirect communication through TV, poster and leaflets.
- Direct communication, including public health television shows.
- Communication campaign prior to vaccination sessions.

Communication content will 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 features, vaccination schedule, vaccination target groups, and potential side effects.

Communication messages will be tailored to specific target groups. For example, information for girls will cover details about cervical cancer, the vaccination program, including topics such as the vaccination schedule, eligible groups, and side effects of the vaccine. Parents will receive different information than girls, and this information will be varied by geographic area. Parents in the rural regions will receive consistent information mainly related to eligible age, preparation before/after vaccination, the quality of the vaccine and the price of the vaccine in the market. Parents in the urban regions will receive similar information. However, if our research shows concerns about vaccine safety in urban areas, we will provide urban parents with more detailed information about side effects and safety of vaccine, and dealing with rumors. Separate communication messages will be developed for religious groups and residence of Abkhasia.

We will also implement activities to prepare immunization programme and all relevant stakeholders to timely identify and properly address vaccine safety events, including AEFIs, HPV vaccine safety allegations, and rumours. We plan to conduct a training for medical workers on vaccine safety, contraindications and adverse events following immunizations. This training will address medical workers concerns about safety of HPV and other vaccines. It will also help to improve medical workers' communication skills.

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

The table below includes activities we consider to be included into the plan however, the detailed final plan will be developed based on the findings of KAPB study.

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.)
Information about burden of cervical cancer and benefits of HPV vaccine	Health care officials, medical scientists, immunization staff, general practitioners, community leaders, parents and girls	Internet, social media (mainly for urban populations) Mass media (TV, radio, news papers)	Immunization Programme Health care workers	At least three months before and throughout the project implementation
Information about cervical cancer, HPV, HPV vaccine, HPV vaccine communications, crisis communication Pocket book Training and education materials	Health care officials, medical scientists, immunization staff, general practitioners (including rural doctors and vacciantors)	Scientific conference National regional, and health facility level trainings Articles in medical journals	Immunization programme in collaboration with leading clinicians Trainers	At least three months before the project implementation
Information about burden of cervical cancer and benefits of HPV vaccine Leaflets, factsheets, FAQs, handouts	Parents, 9 year-old girls in urban provinces	Meetings with parents	GPs	Within one month before vaccination days
Information about burden of cervical cancer and benefits of HPV vaccine Leaflets, factsheets, FAQs, handouts	Parents, 9 year-old girls, community leaders	Community discussions, face to face communication with health workers	Primary health facility staff	Within one month before vaccination days
Information about burden of	Religious leaders	Direct meeting	Primary health facility staff	Within one month before

cervical cancer and benefits of HPV vaccine				vaccination days
Media Kit FAQs List of trusted sources of information	Journalists	Round tables Internet	Immunization Programme	At least three months before the project implementation
Information about burden of cervical cancer and benefits of HPV vaccine Leaflets, factsheets, FAQs, handouts	NGOs	Round tables Internet	Immunization Programme Primary health facility staff	At least three months before the project implementation

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 anti-vaccination sentiment in Georgia, particularly in Tbilisi and other urban locations, we anticipate challenges related to HPV vaccine safety concerns among public and health care professionals. Anti-HPV information could be posted on the Internet and disseminated through 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 project. We will conduct a knowledge, attitudes and practices study targeting specific groups of interest (parents and girls, general practitioners and nurses, gynecologists and oncologist, community leaders, religious leaders, and relevant NGOs). We will develop our communications messages and strategies based on the research findings. The communication strategies piloted and evaluated during the demonstration project will be than revised in accordance to the evaluation results and used for nation-wide implementation of HPV vaccine.

We will develop a crisis communication plan in Georgia to ensure that the NIP, MoH and all relevant stakeholders are prepared to effectively address and communicate vaccine-safety events. We will establish a communication working group in the MoH which will coordinate crisis preparedness activities. The plan will include strategies to monitor the internet, mass media, and social networks to timely identify rumours or vaccine safety concerns so that relevant communication activities can be promptly implemented. The plan will define the relevant stakeholders and describes their role in communication of crisis situation.

Cervical cancer incidence and mortality are high in Georgia and are perceived as a serious public health problem. Health care professionals in particular are aware of the existence of cervical cancer in the country. 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 Public Health will conduct HPV vaccine post-introduction evaluation at the end of the first year of programme implementation to assess the feasibility of HPV vaccine delivery, to identify possible errors and correct them in a timely way, and to develop lessons learned for nation-wide introduction of HPV vaccine. The NCDC has a group of trained experts who have already conducted PIEs for new childhood vaccines using standardized WHO methodology. We will request WHO and UNICEF technical support in conducting the PIE to ensure that possible errors in introduction of HPV vaccine are correctly identified and timely addressed.

The NCDC will conduct a community-based coverage survey to validate administratively reported coverage with two doses of HPV vaccine in the 4 selected regions. The NIP will use WHO HPV Cluster Survey tool adapted to HPV demo programme framework. The NIP does not have experience in conducting coverage survey therefore will request WHO and UNICEF technical support.

After one year of project implementation the NCDC will perform a micro-costing analysis to estimate HPV vaccination costs. The estimate will be conducted using WHO Cervical Cancer Prevention and Control Costing Tool. As the NCDC does not have capacity to conduct such analysis the 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 and UNICEF technical support will be requested to conduct HPV vaccine post-introduction evaluation, community-based coverage survey, and the assessment of the cost of HPV introduction. WHO Regional Office for Europe and WHO Country Office will identify technical specialists and international experts to provide technical support to Georgia.

The Government of Georgia will also request WHO and UNICEF support in conducting KAPB study, development of tailored communication strategies, messages, and a communication plan, preparedness for HPV vaccine crisis communication, and conducting education of health care professionals. The NCDC does not have sufficient capacity to implement these activities without external consultancy support.

The funds that the Government of Georgia 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 finances partners through other funding mechanisms to ensure that Georgia will receive technical and consultancy support for preparedness, implementation, and evaluation of 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).

The MoH, through NCDC's leadership 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 NCDC staff involved in prevention of non-communicable chronic diseases, staff from the Ministry of Sport and Youth Affairs, GPs and paediatricians with an expertise in adolescent health, and the Ministry of Education. The group will work in close collaboration with relevant stakeholders, including HPV Technical Advisory Group, WHO, and 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).*

Currently NCDC's Division of Chronic diseases is involved in interventional activities targeting adolescents in Georgia. Data has been collected on physical activity and nutrition through a knowledge, attitudes and practices study in adolescents. Awareness activities are currently being conducted among children in the 3rd-6th grades across the country. There is also a general strategy for prevention of non-communicable diseases, which includes measure related to increasing physical activity and improving nutrition in adolescents.

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).

Efforts related to the demonstration project will attempt to capitalize on nationwide cancer control efforts already being undertaken by NCDC, UNPA and the Georgian National Cancer Screening Center. The national strategy for cancer prevention and control was developed in 2011. It includes free state-sponsored PAP testing in 25-60 year-olds for every 3 years, but the coverage rate has been low - only 10-11%. Stakeholder meetings, which will include the TAG, will be conducted to modify the existing strategy in order to include nation-wide HPV vaccination and to address the issue of low coverage with cervical cancer screening.

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.*

There is currently a revised strategy for cancer prevention and control that was developed by NCDC, UNFPA, and the Georgian National Cancer Screening Center in 2011. The program includes strategies targeting cervical, breast, colorectal and prostate cancer. As part of the cervical cancer prevention component of the program, there is free state-sponsored PAP testing in 25-60 year-olds for every 3 years. However, coverage rate is only 10-11 %. There is currently only funding for procedures but there is a lack of funds to increase awareness of population. UNFPA is working with the national cancer center and with NCDC to implement organized cancer screening across the country, so that the targeted population is reached. There are currently over 30 facilities in country that perform PAP smears. A population-based cancer registry has been in existence since 2015.

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 NCDC, the Head of the National Oncology Center, a representative from the Oncologists Association, the Chair of the National Immunization Technical Advisory Group, the ICC, Ministry of Education, GPs, and a representative from the National Association of Paediatricians. The TAG will report to the ICC.

*Note: this information is preliminary and the composition of the TAG will be finalized after it is established.

Agency/Organisation	Name/Title	Area of Representation[1]
NCDC	*TAMAR DOLAKIDZE*	*NCDC, Immunprophylaxis Division*
Ministry of Labor, Health and Social Affairs	*EKA ADAMIA*	*State Program Division, Head*
National oncology center	*To be done*	
Association of Georgian Oncologists	*To be done*	
National Association of Paediatricians	*IRAKLI PAVLENISHVILI*	*Paediatrician, Professor*
Representatives from the leading paediatrics clinics in Georgia	*TEMUR MIKELADZE*	*Paediatrician*
Tbilisi Mayor's Office	*TSITSO DILEBASHVILI*	*Director of Public Health Centre*
National Immunization Technical Advisory Group	*IVANE CHKHAIDZE*	*Chair of NITAG*
ICC	*MAIA KHERKHEULIDZE*	*Paediatrician, Professor*
Ministry of Education	*To be defined*	
Ministry of Sport and Youth Affairs	*To be defined*	
UNFPA	*To be defined*	
National Cancer Screening Center	*Rema Gvamichava,*	*Director*

Goergian Society of Clinical Oncology	*To be defined*	
Georgian Oncogynecological Society	*To be defined*	

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	*PAATA IMNADZE*	*National centre of Disease Control & Public Health*	*Professor, Deputy Director*

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	*Lia Jabidze*	**Title**	*Head, Immunoprophylaxis Planning and Monitoring Division, National Center for Disease Control and Public Health (NCDC)*
Tel no	*995-599-583790*		
Fax no		**Agency**	*NCDC*
Email	*l.jabidze@ncdc.ge*	**Address**	*Asatiani St. 9 Tbilisi, Georgia*

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="4">Activities</td><td rowspan="2">Planning
Training
Supply
Distribution
Sensitisation
Mobilisation

Orientation workshop</td><td rowspan="2">First year of vaccination

PIE at the time of final dose</td><td rowspan="2">Evaluation of Year 1

Coverage survey within 6 weeks of final dose</td><td rowspan="2">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>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="3">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 to receive funds to implement project in Tbilisi, Kutaisi, and Ajara. The funds to implement project in Abkhazia will be delivered via UNICEF Country Office.

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 NCDC requests GAVI to transfer the grant to support the activities of the HPV vaccine demonstration project to the government using financial management modalities indicated in the FMA and agreed with Gavi. The funds to support project in Abkhazia should be delivered via UNICEF Country Office. The letter form UNICEF Office for Georgia confirming UNICEF agreement to receive funds for Abkhazia is attached.

9. SIGNATURES

9.1 Government

31. Signatures

The Government of *Georgia* 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 *Georgia* 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 *Georgia* 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 *Georgia* 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 *Georgia* 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 *Georgia*'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	*Mr. Valery Kvaratskhelia, Deputy Minister, MoHLSA*	**Name**	*N/A*
Date		**Date**	
Signature		**Signature**	

33. Signatures

This application has been compiled by:

[Enter the family name in capital letters]

Full Name	**Position**	**Telephone**	**Email**
Lia Jabidze	*Manager, Expanded Program on Immunizations Head, Immunoprophylaxis Divsion National Center for Disease Control and Public Health, Georgia*	*995-599583790*	*l.jabidze@ncdc.ge*

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 *[Type date]* **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
[Type text]	*[Type text]*	*[Type text]*
[Type text]	*[Type text]*	*[Type text]*
[Type text]	*[Type text]*	*[Type text]*
[Type text]	*[Type text]*	*[Type text]*
[Type text]	*[Type text]*	*[Type text]*
[Type text]	*[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	*Lia Jabidze*		
Tel no	*9950322398946*	**Title**	*Manager, Expanded Program on Immunizations, Head, Immunoprophylaxis Divsion NCDC&PH*
Fax no	*[9950322398946*	**Address**	*9 M. Asatiani Street, 0177 Tbilisi, Georgia*
Email	*[l.jabidze@ncdc.ge*		
Mobile no	*995599583790*		

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.

Tbilisi
- capital city, largest population of children so it is challenging. Hard to ensure coverage because doctors have opinions, parents are more educated – have opinions about vaccination; some rural areas, but this is more of suburbs
Ajara
-geographically more diverse and has religious minorities, and it is a well-functioning autonomous republic. Well functioning immunization staff.
-village doctors are located here, high mountainous area. They get coldboxes from regional public health centers, people come to their office and get vaccinated. By word of mouth they spread word that people will show up on day of vaccination.
Kutaisi
-second-largest city. Only an urban population; center of imereti region. If this goes well, doctors are opinion leaders for the rest of the region.
Abkhazia
-occupied territories, IDPs, it is in country's interest to include this population. Other routine vaccines. Mix of rural and urban.

Mention UNICEF