Application Form for Country Proposals

Providing two years of support for an HPV Vaccination Demonstration Programme

Deadlines for submission of application:
25 January, 8 September 2015

Submitted by:

The Government of Kenya

Date of submission: 7th September 2015

Please submit the Proposal using the form provided.

Enquiries to: proposals@gavi.org or representatives of a Gavi partner agency. Unless otherwise specified, the documents will be shared with Gavi partners, collaborators and the general public. The Proposal and attachments must be submitted in English, French, Spanish, or Russian.

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

The Gavi Secretariat is unable to return submitted documents and attachments to countries. Gavi

1. Application specification

Q1a. Please specify vaccine preference.

Preferred vaccine Bilavent (GSK) or Quadrivalent (Merck) See *below* for more information	Month and year of first vaccination	Preferred second presentation[1]
Quadrivalent (Merck)	April 2016	Bilavent (GSK)

Q1b. Please summarize the rationale for choice of preferred vaccine. Also, please clarify whether the vaccine is licensed for use in the country.

During the recently concluded HPV demonstration project conducted in Kenya from Year 2013 to 2015, girls were vaccinated using the quadrivalent (Merck) vaccine. This was favourable to the country as it also offers protection against genital and anal warts in addition to cervical cancer.

The country will continue to offer the quadrivalent vaccine due to the above reason and so as to maintain the same dosing schedule in the county where it was introduced.

Both the quadrivalent and bivalent vaccines are licensed for use in Kenya.

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

[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.

2. Executive summary

Q2. Please summarize the rationale and the expected outcome of the HPV vaccination demonstration programme Plan.

Cervical cancer is the second most common cancer and the leading cause of cancer deaths in Kenya. It is estimated that every year 2454 women in the country are diagnosed with the disease, approximately 68% (1676) of whom die annually. At present, approximately 10.3 million women aged above 15 years are at risk of developing the disease. Unless concerted efforts are made to prevent and control the disease, it is projected that the incidence of cervical cancer will rise to 4261 cases per year with 2955 (69%) annual deaths by the year 2025. About 38.8% women in the general population are estimated to harbour cervical human papillomavirus (HPV) infection, approximately 61% of them harbouring types 16 and 18 [WHO, 2010].

Kenya conducted the first two year HPV vaccination demonstration project from 14th May, 2013 to 22nd May 2015 in 16 districts in Kitui County through the school health program. Target group was girls in Standard 4 in school and girls aged 10 years old out of school. The vaccine was administered to girls in schools by health care providers from the nearest health facility. The vaccination period was scheduled for 5 working days, and mop up conducted the following week. This delivery strategy demonstrated success with high acceptability and coverage of over 85 % in both demonstration years. The cost of delivering the vaccine through the school health program was however high with the financial and economic costs amounting to US$ 20.67 and US$ 44.77 respectively (inclusive of vaccine costs). This was deemed as not sustainable if rolled out as a national program.

In view of this, the Government of Kenya, through the Ministries of Education and Health intend to review the delivery strategy to facility based in the same county. This is expected to reduce both the financial and economic costs for vaccine delivery in the county.

The proposed demonstration programme is aimed at vaccinating at least 75% of the eligible 21,840, girls in Standard 4 in school, and 170 girls aged 10 years old out of school in each of the demonstration years. At the end of the two years, findings from the evaluations focusing on the proportion of girls that will have been vaccinated, acceptability of the vaccine, feasibility, and cost of delivering the vaccine will be reviewed. This data will inform the plan for the national introduction of the HPV vaccine in Year 2018.

3. Immunisation programme data

Q3. 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.

NOTE: Applications for the HPV vaccination demonstration programme will be open to any Gavi-eligible country with at least 70% DTP3 coverage at the national level, based on the latest available WHO/UNICEF estimates.

Trends of national DTP3 coverage (percentage)				
Vaccine	**Reported**		**Survey**	
	2013(WHO/UNICEF Joint reporting Form)	2014 (WHO/UNICEF Joint Reporting Form)	2008-2009 (Kenya Demographic and Health Survey)	2014 (Kenya Demographic and Health Survey)
DTP 3	73.0%	79.0%	86.4%	90%

Q4. 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.

Data on the DHS DTP3 vaccination coverage was collected based on a cohort of children aged 12-23 months born within the five years preceding the survey.
Note: The IRC may review previous applications to Gavi for a general history of a country's capacities and challenges.

4. HPV vaccination demonstration programme plan

4.1 District(s) profile

Q5. 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 D of the HPV Demo Supplementary Guidelines.

Component	Kitui County
Topography (% urban, % semi-urban, % rural, % remote, etc.)	Urban: 28% Rural: 72% *Data source: Administrative data*
Number and type of administrative subunits, e.g., counties, towns, wards,	16 Districts *Data source: District Health Information Software 2 (DHIS2)*

villages		
Total population	1,012,709 *Data source: Kenya Population and Housing Census report, 2009*	
Total female population (%)	526,608 (52%) *Data source: Kenya Population and Housing Census report, 2009*	
Total female population aged 9-13 years by age (% of total female population) 9 years 10 years 11 years 12 years 13 years	131,652 (13%) *Data source: Kenya Population and Housing Census report, 2009*	
Number and type of public health facilities	Dispensary	183
	Health Centre	34
	Sub districts Hospital	9
	District Hospital	2
	Data source: MOH Master Facility List (www.ehealth.or.ke)	
Number and type of health workers in all district public health facilities	Medical Specialists	9
	General Medical Officers	37
	Clinical Officers	53
	Kenya Registered Community Health Nurses	221
	Kenya Enrolled Community Health Nurses	109
	Nursing Officers	52
	Public Health Officers	34
	Public Health Technicians	22
	Community Health Extension Workers	94
	Health Record & Information Officers	8
Number and type of private health facilities	Health Record & Information Technicians	12
	Pharmacists	4
	Pharmaceutical Technologists	16

	Medical Engineering Technologists	10
	Data source: District Health Information Software 2 (DHIS 2) [https://hiskenya.org/]	
	Private Enterprise Health Facilities	19
	Private Practice – Clinical Officer	2
	Private Practice - Nurse/Midwife	9
	Private Practice – Unspecified	2
	Data source: MOH Master Facility List- (http://www.ehealth.or.ke)	
Number and type of health workers in private health facilities in the district	General Medical Officers	4
	General Clinical Officers	21
	Nurses	90
	Laboratory Technicians	21
Number and type of public and private primary and secondary schools	Primary schools	771
	Secondary Schools	179
	Data source: Ministry of Education- Kitui County	
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	8104 (98.0%)
	10 year old girls	8289 (98.0%)
	11 year old girls	6584 (98.0%)
	12 year old girls	7359 (98.0%)
	13 year old girls	7620 (98.0%)
	Data source: Kenya National Bureau of Statistics	
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	162
	10 year old girls	166
	11 year old girls	132
	12 year old girls	147
	13 year old girls	152
	Data source: Kenya National Bureau of Statistics	

Q6. Please give a brief description of why this district (or districts) was (were) selected to participate in the HPV vaccination demonstration programme.

Under the promulgated Constitution (2010), the administrative unit in Kenya is the county. This is a devolved governance entity that is made of several small districts and constituencies. The county essentially represents the original 47 districts that were present in the country at independence. As such, counties are equivalent to the original districts except that they are semi-autonomous in terms of governance. The selected region will therefore cover the entire county.

During the recently conducted HPV demonstration project, Kitui County was selected due to its resemblance to many of the other 46 Counties in the country. The county, located in Eastern Kenya is large and comprises of 16 districts. Consisting of a 72% rural population, the majority of inhabitants are subsistence farmers. Due to its large size, the county resembles a large proportion of the rest of the country. While the north-eastern part of is wet, the rest of the county is semi-arid and consists of a large proportion of hard-to-reach population, both geographically and economically. The county's urban areas resemble most urbanized parts of the country. Though it is largely populated by people from one ethnic community, it's urban and border populations have mixed ethnic and sociocultural dynamics. This makes the county almost a replica of the country.
The county's profile will make it possible for data that will be generated from the HPV Demonstration Programme to be generalised to the rest of the country. Such data will include the logistics of vaccinating adolescents; effective modalities for advocacy, communication and social mobilization, and coordination of multiple players within and outside the health sector.

The second demonstration project in the same county (Kitui) will also offer continuity of vaccine administration to girls in Standard 4 and allow the program to compare the costs incurred, coverage, and acceptability of the vaccine using a different vaccine delivery strategy. (I.e., the facility based strategy compared to the school health strategy in the same community). The project will also build on the lessons learnt from the first demonstration project in a community facing the same issues/challenges.

The county also has an elaborate Cervical Cancer Program where in addition to cervical cancer screening and treatment of early lesions, HPV DNA screening in health facilities and community outreach is ongoing after being recently launched by the Kenya's first lady in this county. This is expected to offer a platform to a more vibrant Prevention of Cervical Cancer Programme in the county that will include active community engagement. This will allow the demonstration programme the opportunity to document successes and challenges for HPV vaccination and use the lessons learned to successfully plan and implement a national roll out in 2018.

Q7. Please describe the operations of the EPI programme in the district(s) selected for the HPV vaccination demonstration programme.

The EPI programme in Kitui County performs well in routine vaccination and outreach campaigns. Data from DHIS2 demonstrates that in 2014, the county reported DTP3 coverage of 73.6% (DHIS 2014)

Coverage for PCV3 was by DHIS2 reported as 86.5% for the county against 83.0% for the country. This supports the finding that despite parts of the county being hard-to-reach, the cold chain compares remarkably well to the rest of the country. Though routine measles vaccination coverage is low in the county at 75.1%, compared to the national average of 84.1%, coverage during vaccination campaigns has been adequate.

Kitui County has the following health care infrastructure and activities to support to routine vaccination and outreach campaigns.

Component	**District 1** Kitui County	
Number and type of administrative subunits (e.g. health facilities) used for	Type of Health Facility	No.
	Dispensary	186
	District hospital	2

routine vaccine delivery	Health centre	34
	Other Hospital	2
	Sub District	9
Number and type of outreach sessions in a typical month used for routine vaccine delivery	Outreach vaccination visit by community health extension workers (CHEWs):	10 sessions
DTP3 coverage	2011- 88.3% *Data source: District Health Information Software 2(DHIS2)*	
Polio3 coverage	2011- 86.3 % *Data source: DHIS2*	
Measles first dose coverage	2011- 78.9% *Data source: DHIS2*	
Pentavalent 3 coverage		
TT2+ (pregnant women)	2011- 56.5% *Data source: DHIS2*	

Q8. 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.

The Post Introduction Evaluation for the recently concluded HPV demonstration project was conducted in July 2014. This involved interviews with the Ministries of Health and Education at both national and county levels, World Health Organization, and other partners, community leaders, and girls in Class 4 within the county.

The National Government was very committed and contributed to the procurement of the shortfall of the HPV vaccine doses for 13,000 girls from the Ministry of Health budget.

The major successes reported included strong programme leadership, political will, and well-coordinated communication (including introduction plan) and training. Strong partnership was also realized due to the National advocacy and strong political commitment by the government.

On average, health care workers had good knowledge and practice of the cold chain.
Health workers, Head Teachers, Community leaders and eventually parents and girls had been briefed on cervical cancer and HPV vaccines and the benefits of the vaccination. The use of Cervical Cancer Prevention platform to advocate for HPV vaccination created a very strong community demand for the vaccination.

The challenges included inadequate participation by some key stakeholders, erratic vaccine supply linked to the change in the number of the targeted population after submission of the application, and long distances with harsh terrains.

Q9. 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.

The Ministry of Health through the Division of Family Health conducted the first 2 year HPV vaccination demonstration project in Kitui County. This was conducted through the school health program where girls in Standard 4 were vaccinated. The health facilities were linked to the nearest schools (both public and private) where the health care providers vaccinated girls in the specified schools. The activity was conducted for 5- 6 days and involved volunteers, vaccinators, and supervisors from both the national and county levels. At the end of the 2 years, more than 40,000 girls were vaccinated with coverage of over 85% in both years.

The Ministry of Health through the Division of Vaccines and Immunisation, also vaccinated Primary school adolescent girls with tetanus toxoid through a school based programme covering several Counties, which included Kitui. Lessons that were learnt from the programme included the need for community engagement and male involvement in such interventions.

The Ministry of Health has had other successful health programmes targeting primary and secondary schools with health education messages, de-worming and hand washing in Kitui County through the Division of Child and Adolescent Health and the Division of Reproductive Health.

Q10. 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.

Negative publicity has been received on the recently conducted immunizations such as the tetanus toxoid immunization, mass polio vaccination, and the HPV vaccination. This will be addressed by developing a communication plan. There will also be engagement with the community gate keepers and the community which will include dissemination of relevant IEC materials. The religious leaders' representatives at the national, county, and sub county levels will also be involved in the planning meetings.

Vast distances might hinder children from accessing the vaccine at the health facility. This will be mitigated by the county will conducting integrated outreaches using the Beyond Zero mobile vans to reach areas where health facilities are not easily accessible to homesteads. The mobile vans are currently used to provide reproductive health services (including cervical cancer screening and treatment of early lesions with cryotherapy, and HPV DNA testing).
A mop up of those not vaccinated during the designated days will be conducted

Inaccurate target numbers of girls to be vaccinated was experienced during the first demonstration project which caused a miscalculation of the required number of vaccines. This led to a number of challenges including shortage of vaccines and logistics of administration caused by 2 different dosing schedules. The Government of Kenya however procured the additional vaccines to fill the gap, This has been rectified by ensuring full participation of the county in the proposal application, inclusion of all the sub counties, and confirming number of schools registered in each sub county. The Ministry of Health will also identify girls of school using the community health strategy.

Disruption of vaccine schedule due to unexpected/ irregular closure of schools was experienced in the previous demonstration project. Administering the vaccine during school holidays will ensure that the vaccination schedule is adhered to.

Q11. 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.

There is currently no gender barriers in accessing and utilising immunisation services by Kenyan children from all surveys carried out in the country. Research demonstrates no significant gender differences in access and utilisation of immunisation services in Kenya between boys and girls. A report by the Swiss Tropical Institute titled *Gender and Immunisation (*funded by GAVI and WHO) demonstrates that in Kenya, boys and girls have equal access to immunization services.

However, reports demonstrate the existence of socioeconomic barriers to immunisation. These factors have been identified through several qualitative surveys and include, competing tasks by the caregiver for time to go to health facility, long distance to the health facility, long waiting time at the health facility, illness of the mother or caregiver, reluctance of the mother or caregiver to take the child for immunisation, lack of clean clothes to cloth the child in while coming to the health facility and lack of knowledge about vaccine schedule.

These barriers are currently being addressed with the ongoing improvement of immunisation services through increased number of immunising health facilities to increase access, and through increased reduces distance, and reduces populations hence waiting periods at these facilities

One of the lessons learnt from the HPV demonstration project is that despite boys (or their parents) requesting to be vaccinated, with adequate and continuous sensitization of the community; there are reduced chances of developing gender barriers in vaccination of girls only.

4.2 Objective 1: HPV vaccine delivery strategy

Q12a. 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 Demo Supplementary Guidelines section 3.2). Countries are encouraged to use the resources in Annex A of the HPV Demo Supplementary Guidelines 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 Demo Supplementary Guidelines for exceptions for large countries.

The HPV Vaccine Demonstration Programme will be delivered through a facility based strategy aiming at vaccinating girls in Standard 4 of Primary Education and girls aged 10 years who are out of school.

The Ministry of Health acknowledges that the target number of girls to be vaccinated exceeds the maximum number for the demonstration project. However, the national and county governments prefer to have the same target population (all the 16 sub counties) as in Demo 1. A change in target population may negatively affect acceptance of the vaccine. In addition, it will be difficult to compare the results from the first and second demonstration projects if a different target number is used.

The Ministry of Health also intends to conduct vaccination of girls who are currently in Standard 5 who will have missed the vaccination in the current year. This cohort was not vaccinated while they were in class 4 as the 2 year demonstration was covering those in class 4 and 5 at that time.
For the credibility of the demonstration project, it is prudent to vaccinate these girls for continuity and acceptability of the vaccine by the community. In addition, the county has been requesting for the vaccine for these girls and have indicated the community's fears of those girls not being vaccinated.

Target population	**District 1** Kitui County	
Who are the girls eligible for HPV vaccine based on the criteria set by the programme?	**Total eligible Year 1**	**Total eligible Year 2**
1. In school (Class 4)	21,840	21,860
2. Out of school (10 years)	170	170
3. Out of school (Class 5)	21,200	0
TOTAL	43,210	22,030

Q12b. Please describe the rationale for the choice of the target population.

Of all the school-going girls who are in standard 4 in Kitui County, 94% of them are aged 9-13 years. Of the 6% who are outside the age bracket of 9-13 years, 2% are 8 years or younger below while 4% are aged 14 years or older.
Data source: Ministry of Education, Kitui County.

Q13. 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.** A variety of delivery strategies are available, e.g., schools, health facilities, fixed outreaches, mobile teams, and other innovative approaches.

The target group will be girls in Standard 4 of Primary Education, and girls aged 10 years who are out of school.

The vaccine will be delivered through the health facilities and mobile integrated outreaches for the hard to reach areas using the Beyond Zero mobile vans.

The girls in schools will be issued with the vaccination cards at school. This will be presented to the health facility for vaccination. The card will be returned to school at the beginning of the term and those not vaccinated will be vaccinated following arrangement with the nearest health facility. Those who are out of girls will be issued with the vaccination cards by the community health volunteers and the same will be presented to the health facility, or during the integrated outreaches.

The schedule for administering the vaccine will be synchronised with the school calendar. It is expected that the first dose will be administered in April 2016 during the first term school holidays. The second dose will be administered during the third term holidays in November and December 2016. Vaccines will be available at the health facilities during this months and 1 month following opening of schools. The same vaccination card will be presented to the health facility and returned at the opening of the following year.

Parents of the girls in the target class will have been sensitized on the immunization and issuance of vaccination cards. The parents/ guardians will therefore be expected to ensure safe keeping of the cards during school holidays.
Girls who transfer from schools will still be followed up in the school they have transferred to in within Kitui County.

Considering that the country has previously completed the HPV vaccination demonstration project using a different strategy, if the facility based strategy is deemed more costly or coverage is compromised greatly, then after the completion and evaluations of the first year vaccination, the country may review to a different strategy.

Please complete the table below for each district in the HPV vaccination demonstration programme. **TWO examples for illustrative purposes only are provided**.

Target age or grade	**Year 1**		**Year 2**	
Who are the eligible girls?	**N. of girls**	**Delivery strategy**	**N. of girls**	**Delivery strategy**
1. School going (class 4)	21,840	At health facilities and Integrated outreach	21,860	Facility based
2. Out of school	170	At health facilities and scheduled outreaches	170	Facility and outreach
3. School going	21,200	At health facilities and Integrated outreach		
TOTAL	43,210		22,010	

EXAMPLE 1 below may assist in defining which strategy will be used to deliver HPV vaccine with which proportion of the target population.

Target age or grade	Year 1		Year 2	
Who are the eligible girls?	N. of girls	Delivery strategy	N. of girls	Delivery strategy
All girls aged 10 years	3,000	At schools	3,300	At schools
2. [Type text]	250	At health centres	275	At health centres
3. [Type text]	500	At fixed routine outreaches	550	At fixed routine outreaches
4. [Type text]	[Type text]		[Type text]	
TOTAL	3,750		4,125	

EXAMPLE 2 below may assist in defining which strategy will be used to deliver HPV vaccine with which proportion of the target population.

Target age or grade	Year 1		Year 2	
Who are the eligible girls?	N. of girls	Delivery strategy	N. of girls	Delivery strategy
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
4. [Type text]	[Type text]		[Type text]	
	3,750		4,125	

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.

Q14. Please describe the planned schedule for vaccinations for each dose by the delivery strategies listed in Q13. For example, one session for each dose at two fixed times a year, or continuous availability at vaccination locations, or week-long or month-long availability twice yearly, etc.

Vaccinations will be conducted for a month-long, twice yearly in April and November/ December.

Q15. 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.

All girls in the target group will be issued with vaccination cards at school. These will be returned to school once the schools open. Girls not vaccinated will be referred to the nearest health facility for vaccination. This mop up is expected to take place within 2 weeks of school opening.

The girls who are out of school and are eligible for the vaccination (i.e. 10 year old girls), will be issued with the vaccination cards through activities conducted in the community such as door to door visits, barazas, and others. Those who cannot access the facility will receive the vaccine through the outreaches and integrated outreach programs. Mop up after the planned vaccination period will be coordinated by the community health volunteers.

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

Q16. Please provide a description of the process currently used to obtain (parental or guardian) consent for other vaccines given to the same age group targeted for HPV vaccine delivery, 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.

No written consent was required during the first HPV demonstration project.
However, as previously done, parents will be notified by the school head teachers, teachers and community health volunteers about the vaccination.

Q16b. 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.

Note: Consenting procedures should in all cases be consistent with Ministry of Health policy on consent for vaccination (see HPV Demo Supplementary Guidelines section 3.2, item 5).

Parents will be notified during parents-teachers meetings, and by community health volunteers about the HPV vaccination dates. IEC materials will also be printed and distributed to inform the community of cervical cancer in general and the importance of HPV vaccination including the scheduled dates for vaccination.
Those willing to have their girls vaccinated will take them to the nearest health facility or outreaches for vaccination.
In addition, the community health volunteers will undergo sensitization workshops so as to have the right information to give parents if any additional information is needed.

Q17. 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).

Countries are encouraged to use data and information from recent post-introduction evaluations (PIE) of routine vaccine delivery to inform and provide evidence of the ability to manage the technical elements of vaccine delivery for the HPV vaccination demonstration programme.

The country has a vast experience with vaccines, including introduction of new ones such as HPV vaccine, rotavirus vaccine and measles second dose. The logistics for introduction of HPV vaccine, including cold chain, waste management transport surveillance and monitoring will fit in snugly within an established and functional immunization programme. The vaccine has also been introduced in the same county before and will therefore build on previous experiences.

The sub counties will conduct micro planning which will include defining the sub county target population, and calculation of their vaccines and supplies needs.

Using the previous experience with the HPV demonstration project, vehicles and other means of transport (for regions not accessible by road) will be identified and budgets for transport and other logistics will be planned for in good time.

The Adverse Event Following Immunization form will be that was developed during the previous HPV demonstration project will be printed, distributed and disseminated during the sub county trainings/ updates.

The routine integrated supportive supervision tool in use at the county will be revised and updated to include the key immunization indicators.

Q18a. 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.

Component	Kitui County
Number and type of cold storage facilities	77
Functioning and working order of the facilities	Refrigerators: Functioning well- 65 Non-functional- 6
Storage capacity (any excess)	7844 litres (+2-+8 □C), 21% of the facilities have surplus storage
Distribution mechanism	Pull system at the district level. The districts collect vaccines and commodities from a regional store then distribute to health care facilities using a pull system
Number and status of vaccine carriers	315 vaccine carriers and cool boxes in functional order 4 non-functional
Number and status of icepacks (any shortages or excess)	300 (small) 134 (medium) 124 (large

The HPV vaccination project will ride on the existing cold chain in the county.

Q18b. Additional district cold chain information if necessary:

4.3 Objective 1: HPV vaccine delivery training and community sensitisation & mobilisation plans

Q19a. Please describe plans for training of health workers and others who will be involved in the HPV vaccination demonstration programme.

At the national level and county level, a team of trainers exists and has been tasked with reviewing of the training materials and tools. This team consists of experts in vaccines, reproductive health, community strategy, trainers in health training institutions, researchers already involved in HPV demonstration at institutional level among others.

Considering that most of the health care workers have already been trained, this team will conduct top up trainings to the sub county health teams. The trained sub county health trainers will train / update health care workers as well as conduct supportive supervision in their respective regions.

Q19b. (***Optional***) If available, countries may provide additional detail in the table below on training content, role, and framework.

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?**
Health workers	Immunisations, Supervision	Basics on cervical cancer, HPV, HPV vaccine, IEC materials, AEFI,	Sub County Health management

		monitoring, injection safety	team
Supervisors	Sensitisation, Supervision, Mobilisation	Basics on cervical cancer, HPV, HPV vaccine, IEC materials, AEFI, monitoring	National, and county teams
Teachers	Mobilisation, sensitisation	Basics on cervical cancer, HPV, HPV vaccine, IEC materials, AEFI	County and sub county teams
School officials	Mobilisation, sensitisation	Basics on cervical cancer, HPV, HPV vaccine, IEC materials, AEFI	County and sub county teams
District leaders	Mobilisation	Basics on cervical cancer, HPV, HPV vaccine, IEC materials	County and sub county teams
Ministries of Education and Health, County officials	Mobilisation, sensitisation	Basics on cervical cancer, HPV, HPV vaccine, IEC materials	National teams
Community health volunteers	Mobilisation, sensitisation	Basics on cervical cancer, HPV, HPV vaccine, IEC materials	County teams
Other:	[Type text]	[Type text]	[Type text]

Q20a. 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.

During the training, the health workers will be sensitised on the IEC material and asked to make use of them. As part of the training, health workers will also be oriented on interpersonal communication that can be used to create and sustain demand for the vaccine, with a specific focus on reducing community misconceptions of the vaccine.

The school teachers, head teachers and district education officers will be educated on general knowledge about cervical cancers, HPV vaccine and how to communicate and engage the community. They primary school officials will be used as advocates for the programme both within and outside the school system.

The community health units will be trained and sensitised to provide information on vaccination importance and scheduled vaccination days.

General sensitisation and mobilisation will include both electronic and print materials such as radio and television where applicable and newspapers, posters and flyers for girls, their teacher and their parents.

Q20b. (***Optional***) If available, countries may provide additional detail in the table below on the types of information and/or materials that may be used/disseminated, to which audience, by which mechanism, and the frequency of each.

The project will use training material available on HPV vaccination that is already available

Types of information or	**Audience receiving**	**Method of delivery**	**Who delivers** *(e.g., teachers,*	**Frequency & Timing**

materials *(e.g., leaflet, poster, banner, handbook, radio announcement, etc.)*	**material** *(e.g., girls, parents, teachers, health workers, district officials, community groups, etc.)*	*(e.g., parent meetings, radio, info session at school, house visit, etc.)*	*health workers, district official, etc.)*	*(e.g., daily, weekly, twice before programme starts; day of vaccination, two weeks before programme begins, etc.)*
ACSM Power point presentation	Health workers Teachers District officials	Sessions	County and sub county health officials	One week before vaccination dates
Posters and leaflets	Community	At designated places in the community e.g churches	Community health volunteers	One month before vaccination dates
Power point on data collection tools	Teachers, health workers, Health records officers	Sessions	National, county, and sub county teams	One week before vaccination dates
Supervision check list	Supervisors	Sessions	National, county, and sub county teams	One week before vaccination dates
[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]	[Type text]	[Type text]
[Type text]	[Type text]	[Type text]	[Type text]	[Type text]

Q21. 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.

Data from studies on HPV and tetanus toxoid vaccination in Kenya have been useful in informing the planned HPV Demonstration Project on potential barriers and how to overcome them.

The fact that the vaccination programme targets girls only may become a barrier to acceptability if messaging is not packaged well. We plan to engage the community in Kitui with education, advocacy and social mobilization to prevent the risks of myths and misconceptions derailing the programme. Prior to initiation of vaccination, community buy-in will be sought through meetings with key opinion leaders and shapers.

The project will also be linked to the first demonstration project, cervical cancer screening and treatment. These have been widely accepted by the community

4.4 Objective 1: HPV vaccine delivery evaluation plan

Q22a. Indicate the agency/person who will lead the evaluation of coverage and acceptability, feasibility, and costs required for the "Learn by Doing" objective.

The Ministry of Health will lead the technical evaluation with support from partners. The funding for the demonstration assessment will include funds from Government of Kenya, GAVI funding and other partners.

The assessment will evaluate the following key objectives

1. Vaccine coverage
2. Acceptability, feasibility, affordability and sustainability of the delivery strategy
3. Appropriateness and acceptability of information, educational and communication material
4. Effectiveness of strategies to reach girls who are out of school

Monitoring and evaluation will be guided by the technical advisory group with the day to day running being managed by a local team of experts in each district in the county.

Q22b. (***Optional***) Technical partners (e.g. local WHO staff) are required to participate in planning and conducting the evaluation of HPV vaccine delivery. Please specify if such (an) expert(s) already exist on the country team (name, title, organization). Alternatively, or in addition, an international participant can be requested through technical partners if additional expertise is thought necessary.

4.5 Objective 2: Integration of adolescent health interventions

Q23a. Please summarise the anticipated activities for the 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 Demo Supplementary Guidelines section 3.2, item 7).

The assessment for possible adolescent health interventions was conducted during the first demonstration project and finalized in May 2015.

Using the assessment report, a consultative meeting will be held with the county and sub county teams to identify the most suitable lead activity to integrate with the second HPV vaccination demonstration project. Members of the TAG will form part of the consultative meeting. The agreed on intervention will be integrated during the first and second years of the project.

The Ministry of Health in collaboration with UNFPA- Kenya country office will take lead in implementing the agreed on intervention.

Q23b. (***Optional***) Countries can provide a brief summary below of the current adolescent health services or interventions and health education activities and implementing agencies in the district(s) selected to implement the HPV vaccination demonstration programme.

The current adolescent health interventions that are conducted in the county include de-worming, hand washing and hygiene. These are mainly implemented through the school health program. The Ministries of Health and Education are also engaging stakeholders on integration of comprehensive sexuality education in the curriculum. This will entail passing age-appropriate information on adolescent health in schools and can also be included as a co-deliverable intervention with HPV vaccination.

4.6 Objective 3: Development or revision of cancer control or cervical cancer prevention and control strategy

Q24a. 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 Demo Supplementary Guidelines section 3.2, item 8).

The National cervical cancer prevention program strategic plan 2012- 2015 will be reviewed during the third and fourth quarters of year 2015. This will also include review of The National Guidelines for Prevention and Management of Cervical, Breast and Prostate cancers.

The first review meeting will include participation from the Ministry of Health, and stakeholders some of whom are members of the TAG.

Following compilation by the identified consultant, a validation meeting will be held before finalization of the strategic plan.

Dissemination of both documents to the counties will be conducted during the first quarter of Year 2016

Q24b. (***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.

4.7 Technical advisory group

Q25. 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 Demo Supplementary Guidelines section 2.7).

- Countries are encouraged to use their ICC 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.

Enter the family name in capital letters.

Agency/Organisation	Name/Title	Area of Representation[1]
Ministry of Health	Dr. Bartilol KIGEN	Reproductive Health
Ministry of Health	Dr. Nakato JUMBA	Reproductive Health
Ministry of Health	Dr. Ephantus MAREE	Vaccines and immunizations
Ministry of Health	Dr. Collins TABU	Vaccines and immunizations
Ministry of Health	Dr. Alfred KARAGU	Non communicable diseases
Ministry of Health	Dr. Anne NGANGA	Reproductive Health
Ministry of Health	Teclar KOGO	Monitoring and Evaluation
Ministry of Health	Dr. Stewart KABAKA	Adolescent health
Ministry of Health	Erastus KARANI	School health
Ministry of Health	Dr. Salim HUSSEIN	Community health strategy
Ministry of Education	Victoria MULILI	Education/Guidance and Counselling
Ministry of Education	Martina MUOKI	Education
WHO	Dr. Sergon KIBET	Vaccines and immunizations
WHO	Dr. Joyce LAVUSSA	Reproductive Health
Unicef	Dr. Peter OKOTH	Vaccines and immunizations

Unicef	Dr. Chris OUMA	Reproductive Health
Unfpa	Dr. Dan OKORO	Reproductive Health
Jhpiego	Dr. Gathari NDIRANGU	Reproductive Health
Jhpiego	Dr. Ruth JAHONGA	Reproductive Health
Clinton Health Access Initiative	Dr. Anthony NGATIA	Vaccines and immunizations
PSI- Kenya	Lucy MAIKWEKI	Reproductive Health- IEC
Kenyatta National Hospital	Dr. Nelly MUGO	Reproductive Health Research
Kenya Network of Cancer Organization	Dr. David MAKUMI	Reproductive Health/ Oncology

[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.

Q26. 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	Dr. Bartilol KIGEN	Ministry of Health	Reproductive Health

4.8 Project manager/coordinator

Q27. 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 family name in capital letters.

Name	Dr. Nakato JUMBA	**Title**	Program Manager
Tel no	+254 724730347		
Fax no		**Agency**	Ministry of Health, Reproductive and Maternal Health Services Unit
Email	ajnakato@gmail.com	**Address**	P.O. Box 43319- 00100 Nairobi

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

Gavi Funding Approval	**Planning**	**Implementation Year 1** (begins first day of dose 1)			**Implementation Year 2** (begins at first day of dose 1)		
	Up to 8 months	6 months	3 months	3 months	6 months	3 months	3 months
	Planning Training Supply Distribution Sensitisation Mobilisation	First year of vaccination PIE at the time of final dose	Evaluation of first year Coverage survey within 6 weeks of final dose	Review lessons learned Adjust program for Year 2 Report of Year 1 to Gavi (Results from all evaluations, surveys and assessments) NITAG/ICC/vaccine policy body discussion on introduction and if relevant draft Gavi application for national introduction	Second year of vaccination		Report of Year 2 to Gavi
		Desk Review of adolescent health interventions		Decide if joint delivery will be in Year 2 If decided, incorporate joint delivery in program for Year 2	If feasible, implement joint delivery of services	Evaluate joint delivery (Coverage Survey & the costing study)	
		Start drafting cervical cancer prevention & control strategy			Completion of draft cervical cancer prevention & control strategy		Draft Cervical Cancer strategy to Gavi

Q28. 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 website at: 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

Q29. 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, 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

HPV vaccines will be provided 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.

Q30. Please indicate how funds for operational costs requested in your budget in section 6 should be transferred by the Gavi Alliance (if applicable).

Funds are to be transferred through Unicef

8. 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.

UNICEF

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

9. Signatures

4.9 Government

The Government of Kenya 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 finds HPV vaccination is feasible (i.e. greater than 50% coverage of targeted girls within each strategy) and acceptable, Gavi will encourage and entertain a national application during the first or second year of the Programme. Application forms and guidelines for national applications are available at www.gavi.org. The data from the Demonstration Programme and timing of a national application are intended to allow uninterrupted provision of vaccine in the demonstration district and nationwide scale-up.

The Government of Kenya would like to expand the existing partnership with the Gavi Alliance 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 Kenya commits itself to improving immunisation services on a sustainable basis. The Government requests that the Gavi Alliance 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 Kenya 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 Kenya 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 Kenya 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 the Gavi Alliance as well as the Government of Kenya'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.

Q32. Please provide appropriate signatures below.

Enter 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		**Name**	
Date		**Date**	
Signature		**Signature**	

Q33. This application has been compiled by:

Enter the family name in capital letters.

Full Name	Position	Telephone	Email
Nakato JUMBA	Program Manager	+254724730347	ajnakato@gmail.com
Collins TABU	Epidemiologist	+254717333233	ctabu.epi@gmail.com
Henry MUINDE	EPI focal officer- Kitui County	+254722448700	henrymuinde@yahoo.com

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

Q34. We the members of the ICC, HSCC, or equivalent committee met on 8th September, 2015 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

Q35. In case the Gavi Secretariat has queries on this submission, please contact:

Enter family name in capital letters.

Name	Dr. Nakato JUMBA	**Title**	Program Manager
Tel no	020 5222815		
Fax no		**Address**	P.O. Box 43319- 00100 Nairobi
Email	ajnakato@gmail.com		
Mobile no	+ 254724730347		

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 cash support through a UN agency.