Application Form for Country Proposals

Providing approximately two years of support for an HPV Vaccination Demonstration Programme

Deadline for submission:1 May or 15 September 2014

Submitted by:

The Government of [Nepal]

Date of submission: [30/04/2014]

Please submit the Proposal using the form provided.

Enquiries to: proposals@gavialliance.orgor representatives of a GAVI partner agency. The documents can be shared with GAVI partners, collaborators and 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. Unless otherwise specified, documents will be shared with the GAVI Alliance partners and the general public.

1. Application specification

Q1a. Please specify for which type of GAVI support you would like to apply to.

Preferred vaccine Bilavent (GSK) or Quadrivalent (Merck) See *below*for more information	Month and year of first vaccination	Preferred second presentation[1]
[Bivalent (GSK)]	[May 2015]	[Quadrivalent (Merck]

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

[An initial report on multi-institution hospital- based cancer incidence data for Nepal was published in 2009 (Asian Pacific Journal of Cancer Prevention).The study was conducted to assess burden across a greater proportion of country with data from seven major hospitals where cancer is diagnosed and treated. Data of 4397 cancers were reviewed. Amongst the percentages of the various cancers in different hospitals, cervical cancer was the leading malignancy (21.4% of all cancers identified). Another study to show evidence of HPV subtypes linked with cervical cancer from cervical swabs from 44 histological confirmed invasive cervical cancer cases were obtained from two tertiary referral hospitals in Nepal. HPV types 16 and 18 were present in 70% of samples. In women, HPV subtypes 16, 18 (high risk types) is associated with 70% of cervical cancers and 6, 11 (low risk types) is associated with 90% of genital warts. By implementing bilvalent vaccine there will be better coverage of the high risk types (16, 18) associated diseases with HPV.

Also the cold chain space required for Kaski is 114 litres for HPV 2 dose (carton of 10 vials- 5.7cm3) and for Chitwan is 132 litres for HPV 2 dose (carton of 10 vials- 5.7cm3). The cold chain space for HPV 2 dose (bivalent) vaccine is more efficient than that compared to HPV 1 dose vaccine (quadrivalent) which has been illustrated in the graph below 18b. The Department of Drug Administration (DDA) as designed in 1979 as per the Drug Act: 2035 to convey the responsibility of National Regulatory Authority for regulation of drug products. Along with the WHO prequalified vaccine the national vaccine licensure through the DDA is needed for new vaccine introduction. Currently both quadrivalent and bivalent vaccines are not licensed for use with Department of Drug Administration (DDA) in Nepal. The DDA regulatory is in process for Bivalent (GSK)]

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 among women worldwide. It affects women relatively early in their midlives. The morbidity and mortality of women during the most productive years of their lives has a devastating effect on the well being of the family. Cervical cancer incidence rates vary from 1-50 per 100 000 females; rates are highest in Latin America and the Caribbean, sub-saharan Africa, Melanesia, and south-central and South –East Asia. Most cases of cervical cancer diagnosed in women aged>40 years.
In Nepal it is the commonest malignancy amongst women but there is limited data available on which subtypes of human papilloma virus (HPV) are associated with cancer in this population. Currently available are the quadrivalent (16, 18, 6 and 11) and bivalent (16 and 18) vaccines against HPV types, this evidence is of vital importance in obtaining further support for a vaccination programme.

An initial report on multi-institution hospital-based cancer incidence data for Nepal was published in 2009 (Asian pacific journal of cancer prevention).The study was conducted to assess burden across a greater proportion of country with data from seven major hospitals where cancer is diagnosed and treated. Data of 4397 cancers were reviewed. Amongst the percentages of the various cancers in different hospitals, cervical cancer was the leading malignancy (21.4% of all cancers identified).Another study to show evidence of HPV subtypes linked with cervical swabs from 44 histological confirmed invasive cervical cancer cases were obtained from two tertiary referral hospitals in Nepal. HPV type 16 and 18 were present in 70% of samples.
At the national level, a comprehensive approach to cervical cancer prevention and control benefits from being multidisciplinary. As this approach is made up of several key components ranging from community education, social mobilization, HPV vaccination, screening and treatment to palliative care, it is important to involve representatives from various disciplines and national health programmes such as immunization, reproductive health, cancer control and adolescent health.
The outcome of introducing the HPV demonstration programme plan in Nepal will be learning by doing through assessing potential successful HPV vaccine delivery strategies in order to generate evidence for decision making on national introduction of HPV vaccine in future, assess the feasibility of integrating other adolescent health interventions in the targeted age groups and setting up of information, education and communication (IEC) strategies for awareness and initiate national scale up for demand for HPV vaccines.]

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 inthe 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**	
	[2012] year	[2013] year	[2009] year	[2011] year
DTP 3	[90] %	[93] %	[92] %	[92] %

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.

[The survey data included in the table for 2009 is the National EPI coverage survey and in 2011 from Nepal Demographic and Health Survey (NDHS 2011)]

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

4. HPV vaccination ddemonstration 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.

Component	District 1 [Chitwan] name	District 2 (if applicable) [Kaski] name
Topography (% urban, % semi-urban, % rural, % remote, etc.)	[Type text], data source [Type text]	[Type text], data source [Type text]
Number and type of administrative subunits, e.g., counties, towns, wards, villages	[2 municipality & 36 VDCs], data source [HMIS]	[2 Municipality & 48 VDCs], data source [HMIS]
Total population	[613,071], data source [HMIS]	[532,748], data source [HMIS]
Total female population (%)	[318,490], data source [HMIS]	[276,869], data source [HMIS]
Total female population aged 9-13 years by age (% of total female population)	[38,118], data source [WPP 2012]	[33,137], data source [WPP 2012]
9 years	7,771	6,756
10 years	7,721	6,712
11 years	7,649	6,649
12 years	7,550	6,564
13 years	7,427	6,456
Number and type of public health facilities	[Hospital-1, PHC-4,HP-16, SHP-20]data source [HMIS]	[hospital-1, PHC-3, HP17], data source [HMIS]
Number and type of health workers in all district public health facilities	[Doctor, Public health officer, Health Assistant, Staff Nurse, AHW, ANM], data source [HMIS]	[Doctor, Public health officer, Health Assistant, Staff Nurse, AHW, ANM], data source [HMIS]
Number and type of private health facilities	[Medical colleges and nursing home], data source [DPHO]	[Medical colleges and nursing home], data source [DPHO]
Number and type of health workers in private health facilities in the district	[Doctor, Public health officer, Health Assistant, Staff Nurse, AHW, ANM] data source [DPHO]	[Doctor, Public health officer, Health Assistant, Staff Nurse, AHW, ANM], data source [DPHO]
Number and type of public and private primary and secondary schools	[Public and Private], data source [DPHO]	[Public and Private], data source [DPHO]
Estimate the number and percent of girls in school for each of the following ages:	[30,876 (81%)], data source [World bank]	[26,841 (81%)], data source [World bank]
9 year old girls	6,295	5,472
10 year old girls	6,254	5,437
11 year old girls	6,195	5,386
12 year old girls	6,116	5,317
13 year old girls	6,016	5,230
Estimate the number and percent of girls out of school for each of the following ages:	[7,242(19%)], data source [world bank]	[6,296 (19%)], data source [world bank]
9 year old girls	1,476	1,284
10 year old girls	1,467	1,275
11 year old girls	1,454	1,263
12 year old girls	1,434	1,247
13 year old girls	1,411	1,226

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

[The districts have been selected on based on the different regional locations. Chitwan is located in the central development region (CDR) where as Kaski is located in western development region (WDR). Chitwan is located in the flat lands (terai) whereas Kaski is located in the hilly region with distribution of urban and rural areas. Also these are accessible districts where proper monitoring and supervision can be carried out while implementing the HPV demonstration programme.] **Q7.** Please describe the operations of the EPI programme in the district(s) selected for the HPV vaccination demonstration programme.

Component	**District 1** [Chitwan]	**District 2 (if applicable)** [Kaski]
Number and type of administrative subunits (e.g. health facilities) used for routine vaccine delivery	[240]	[213]
Number and type of outreach sessions in a typical month used for routine vaccine delivery	[107]	[174]
DTP3 coverage	[73] %; year [2013]	[81] %; year [2013]
Polio3 coverage	[73] %; year [2013]	[81] %; year [2013]
Measles first dose coverage	[72] %; year [2013]	[69] %; year [2013]
Pentavalent 3 coverage	[73] %; year [2013]	[81] %; year [2013]
TT2+ (pregnant women)	[47] %; year [2013]	[61] %; year [2013]

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 EPI coverage for Chitwan for DPT3 coverage is 73%, MCV1 is 72%, TT+2 (pregnant women) 47%. There is one district cold store, three sub -store and five distribution centre.
The EPI coverage for Kaski for DPT3 coverage is 81%, MCV1 is 69%, TT+2 (pregnant women) 61%.there is one district cold store and eight sub-stores present in Kaski.
Even though EPI is one of the priority programmes of Nepal, there is need for more attention to ensure successful implementation of immunization programmes in these district; some of the logistics and technical recommendation at EVM progress report were;
Technical:

- There is clearly a need to enhance the capacity of the state vaccine store further for 2-80c to ensure storage of at least 3 months of working stock of all antigens. It is however advised to enhance the capacity to store more than 3 months of safety stock at the national level.
- A comprehensive plan for upgrading and strengthening of CC equipment at all level as discussed in the earlier section and condition of the current equipment.

Logistics:

- There should be sufficient supply of temperature recording notebooks other logistic forms, thermometers at all levels.
- In order to ensure sustainable operation, there is an imperative need to monitoring all repair and maintenance services.]

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.

[In 2012, Nepal conducted a successful MR campaign targeting 9 months to 15 years of age. The immunisation booths were mostly based in school settings for attaining high coverage of the campaign.

Q10. Please describe the potential challenges to access and delivery of 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.

[Some potential challenges during delivery of HPV vaccines:

- Where school enrolment of girls is high, school-based vaccination is a possibility; however different approaches are needed to reach girls not in school and who may be particularly vulnerable i.e. street children, migrants.
- Since HPV schedule recommends two to three doses, attracting young girls to repeatedly come to health facilities is likely to take special efforts.

Some of the challenges can be addressed in ways:

- Prior to the national introduction, the districts would be encouraged to pilot and assess vaccine delivery strategies in order to determine how to achieve affordable and high HPV vaccination coverage also,
- Safety of these vaccines needs to be closely monitored (AEFI monitoring) and needs reassurance of the community.
- Some of the challenges can be addressed by reaching girls with HPV vaccine with other health interventions.]

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.

[Although the national coverage for DPT3 vaccine is more than 90% for past 3 years, coverage is not uniform throughout the country. The coverage varies by geographical region, wealth quintile, education of mothers and urban versus rural. The vaccination generally is well accepted by every community. There is no difference in coverage between males and females.]

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 guidelines section 3.2). Countries are encouraged to use the resources in Annex A 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 guidelines section 3.2 for exceptions for large countries.

[The vaccine will be delivered to all girls aged 10 years of age born in the year 2005.]

Target population	**District 1** [Chitwan] name		**District 2 (if applicable)** [Kaski] name	
Who are the girls eligible for HPV vaccine based on the criteria set by the programme?	**Total eligible Year 1**	**Total eligible Year 2**	**Total eligible Year 1**	**Total eligible Year 2**
1. 10 year age female	N = 7721	N = 7721	N = 6712	N = 6712
TOTAL	7721	7721	6712	6712

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

[This targeted age group of cohort lies within the target population of 9-13 year old girls as recommended by WHO.]

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.

Please complete the table below for each district in the HPV vaccination demonstration programme.

Target age or grade	Year 1		Year 2	
Who are the eligible girls?	**N. of girls**	**Delivery strategy**	**N. of girls**	**Delivery strategy**
1.[All girls attending schools (aged 10)]	[11,691]	At schools	[11,691]	At schools
2. [All girls aged 10 not attending schools]	[2,605]	At routine fixed and outreach clinics	[2,605]	At routine fixed and outreach clinics
3. [All girls aged 10 in residing in heard to reach area]	[137]	Through mobile outreach by health workers	[137]	Through mobile outreach by health workers
TOTAL	[14,433]		[14,433]	

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 three fixed times a year, or continuous availability at vaccination locations, or week-long or month-long availability, etc.

[One HPV vaccination session for each ward in VDC of total 9 wards at two fixed times a year 2 doses: 0 and 6 months]

Q15. Please describe the mechanism or strategy for reaching all the target girls with three doses who were missed on the main vaccination days, specifying plans for reaching hard-to-reach or marginalized girls.

[The strategy for delivering the HPV vaccination programme will be using school based vaccination to reach those attending schools initially, adding HPV vaccination programme at fixed health posts and outreach clinics as required. The girls not attending schools will be vaccinated in the fixed and outreach clinics. The girls missed in the first HPV vaccination session will be vaccinated as new cohort at the planned second dose schedule.
Also carefully designed messages will be prepared to educate communities, parents, teachers, adolescents and other stake holders about HPV vaccine, HPV infection and cervical cancer and the availability of services to reach all targeted girls.]

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.

[The vaccines administered in the National Immunisation Programme (NIP), Nepal does not require obtaining parental or guardian consent.]

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 guidelines section 3.2, item 5).

[There will be prior distribution of IEC materials to inform the parents and guardians regarding the HPV vaccination programme.]

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.

[*Cold Chain System:* At present the cold chain facilities at the centre are adequate to maintain the current requirements but introduction of new vaccines and conducting supplementary immunization activities would require additional storage facilities. The current cold chain system includes a central cold store in Kathmandu, 6 regional cold rooms, 75 district cold rooms and sub centres at the peripheral level.

Vaccine Wastage: With geographical terrain with sparse populations and an immunization outreach delivery strategy to reach every targeted child in every corner of the country, vaccine wastage for some antigens is still high (BCG > 70% and measles > 50%. In consideration of the plan to introduce new and under used vaccines that are very expensive, the government is introducing new strategies with close monitoring to reduce vaccine wastage.

AEFI surveillance system: The AEFI surveillance system is in place in all 75 districts. Health staffs have been trained on AEFI reporting, recording and investigation. Serious AEFI cases are reported immediately investigated and causality assessment is carried. Non serious AEFI cases are reported on monthly basis. An independent AEFI committee has been formed at the national level and all serious AEFI cases are investigated and causality assessment is done by AEFI committee members.

Past experiences with introduction of new and underused vaccines: One of the objectives of the Government of Nepal as outlined in the comprehensive multiyear plan (CYMP 2011-2016) is to introduce new and underused vaccines based on evidence and financial sustainability. During last ten years, Nepal has introduced Hep-B monovalent vaccine into the NIP with GAVI support in November 2002. Monovalent Hep-B vaccine was replaced in a phased manner by tetravalent (DPT-Hep-B) in 2005 and expanded throughout the country by 2006. JE vaccine was introduced in 2008/2009 in high risk districts and Hib vaccine in 2009. The measles vaccine (MCV1) at 9 months was replaced with introduction of measles –rubella vaccine from June, 2013. The new and underused vaccine in the pipeline for introduction are pneumococcal conjugate vaccine (PCV-10), inactivated polio vaccine (IPV), measles rubella second dose (MRSD), HPV demonstration project and rotavirus vaccine. Immunisation related committees (NCIP, AEFI, ICC) are functional and in place to support rational decision making process. Annual EPI work plan are made every year following review of past year achievement, constraints and recommendations.

In addition as strongly recommended the country plans to use data and information from recent post introduction evaluations (PIE) to inform and provide evidence of vaccine delivery for the HPV demonstration programme.]

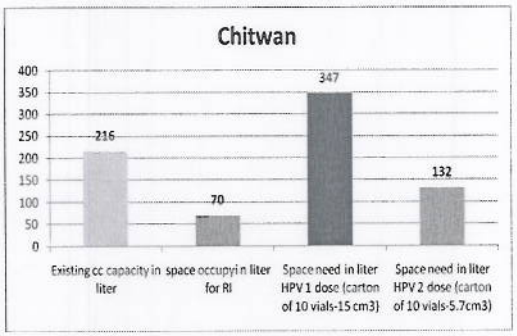
Q18a. Please describe the cold chain status for the selected district and the data source(s) for this information. Information such as the number of cold storage facilities, function and working order of the facilities, storage capacity (and any excess capacity), distribution mechanism for routine delivery 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.

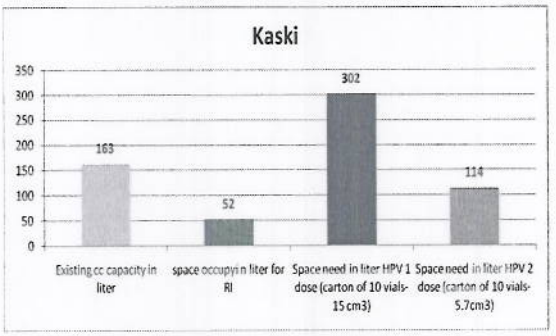
Component	**District 1** [Chitwan]	**District 2 (if applicable)** [Kaski]
Number and type of cold storage facilities	[9 (1 district cold store and 8 Sub-store]	[9 (1 district cold store, 3 sub -store and 5 distribution centre)]
Functioning and working order of the	[All]	[All]

facilities		
Storage capacity (any excess)	[216 litres]	[163 litres]
Distribution mechanism	[District to sub store to immunization centre]	[District to sub store or distribution centre to immunization centre]
Number and status of vaccine carriers	[PVC with 4 ice pack]	[PVC with 4 ice pack]
Number and status of icepacks (any shortages or excess)	[Type text]	[Type text]

Q18b. Additional district cold chain information if necessary:

[The graph below depicts the present cold chain capacity for each district (Chitwan and Kaski) and the increasing storage needed for HPV vaccine storage for 1 dose and 2 dose HPV vaccines. However the shortage will be felt so the plan needs to focus on the expansion of cold chain space in the district level and replacement of the old aged cold chain equipments.]





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.

[The GoN has allocated funds to support training for routine immunisation of around 8,000 health staffs in current FY (2014). Training of trainers has been completed to support training at district levels. Training and facilitator guidelines, presentations have been developed. The weak districts have been identifies to provide external support. The surveillance medical officers (SMOs) and trainers from regional training centre will be mobilised to ensure quality training during roll out of the HPV demonstration programme. The training includes use of practical sessions, PPP using audio visual system. There is plan to develop EPI training centres across the country. The Child health division will mobilise government, HPV TAG, non-government WHO and UNICEF staff for supervision of trainings and introduction of HPV. In addition to the trainings also review and planning meeting will be held at central and district level for smooth introduction of HPV demonstration programme.]

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	[Sensitisation, Immunisation,	[Info on cervical cancer, HPV vaccine benefits,	[Central and Regional

	Monitoring, Supervision]	safe injections, AEFI monitoring]	trainers, SMO]
Supervisors	[Sensitisation, Monitoring and supervision]	[Info on cervical cancer, HPV vaccine benefits, safe injections, AEFI monitoring]	[Central and Regional trainers, SMO]
Teachers	[Sensitisation, , Monitoring, Supervision]	[Info on cervical cancer, HPV vaccine benefits, safe injections, AEFI monitoring]	[District supervisors, health workers]
School officials	[Sensitisation, , Monitoring, Supervision]	[Info on cervical cancer, HPV vaccine benefits, AEFI]	[District supervisors, health workers]
District leaders	[Monitoring, Supervision]	[Info on cervical cancer, HPV vaccine benefits, AEFI]	[Central and Regional trainers, SMO]
Other:	[Type text]	[Type text]	[Type text]
Other:	[Type text]	[Type text]	[Type text]
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.

[HPV demonstration programme introduction will increase community awareness about cervical cancer and its prevention.

- Ensure proper information , education and communication (IEC) messages to educate communities, parents, teachers, adolescents and other stakeholders about the HPV vaccine, HPV infection and cervical cancer and the availability of the services.
- Educating men, including fathers and boys about HPV vaccines and cervical cancer is particularly important in this regard.
- Providing cervical cancer information to older women and mothers of the girls being offered vaccination is a potential way to involve parents.
- Prior dissemination of materials will be utilised for communication opportunity to educate parents and girls about adolescent health issues or cervical cancer screening.]

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.

Types of information or materials *(e.g., leaflet, poster, banner, handbook, radio announcement, etc.)*	**Audience receiving material** *(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, etc.; day of vaccination, two weeks before programme begins, etc.;)*
[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]

[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.

[Some of the potential barriers or risks to community acceptance are as follows:

- *Choice of delivery strategy for the HPV vaccination programme:* Effective, affordable and equitable delivery strategies to reach targeted age girls of age three times during a 6 month period are required. Where school enrolment of girls is high, school- based vaccination is a possibility; however, different approaches are needed to reach girls not in school and who may be particularly vulnerable (e.g. street children, migrants).
- *Communication:* Central education campaigns for vaccine introduction should be used to increase community awareness about cervical cancer and its prevention. Carefully designed messages are essential to educate communities, parents, teachers, adolescents and other stakeholders about the HPV vaccine, HPV infection and cervical cancer and the availability of services. Educating men, including fathers and boys, about HPV vaccines and cervical cancer is particularly important in this regard. Providing cervical cancer information to older women and mothers of the girls being offered vaccination is a potential way to involve parents. Also programmes can be quickly undermined by rumours and misinformation if the reasons for targeting girls only are not fully and sensitively communicated.
- *Monitoring and evaluation:* It is important to have strong systems in place to monitor HPV demonstration vaccination programme. Existing systems for monitoring vaccine coverage need to be adapted for HPV vaccines. As recommended by WHO a post-introduction evaluation (PIE) of an HPV vaccination programme should be undertaken 6-12 months after the vaccine has been introduced.

Considering some positive points that might be beneficial for programme implementation to promote acceptability.

- In the past Nepal Australian Cervical Cancer Foundation (NACCF) have conducted HPV vaccination in 7 districts of Nepal and has vaccinated approximately about 22,384 school girls aged 11-13 years during last 5 years (2008-2013). This experience and expertise could be relevant in planning and implementation the HPV demonstration programme.
- An opportunity exists to use the "Appreciative Inquiry" (AI) workshops to better organize the school based immunization as well as cervical cancer screening programmes to further strengthen the public confidence.]

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.

[Child Health Division, Department of Health Services, Nepal]

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.

[Type text]

4.5 Objective 2: Assessment of adolescent health interventions

Q23a. Please summarise the anticipated activities for the assessment of adolescent health interventions, such as planning milestones, stakeholder meetings, methodology for the

assessment, process for identifying a lead for this activity, and the process to involve the TAG in this work (see guidelines section 3.2, item 7).

[The anticipated activities for the assessment of adolescent health interventions with HPV demonstration programme:

- National adolescent sexual and reproductive health program (NASRH) activities of other agencies to be aligned with HPV demonstration programme.
- Incorporate ASRH indicators.
- Performance evaluation/appraisal.
- Identify innovative approach for IEC/BCC intervention and mainstreaming of IEC/BCC activities /materials with ASRH program.
- Involving and establishing links with youth clubs, child clubs, village child protection committees (VCPCs), NGOs and the private sector to expand and improve service delivery for adolescents.
- Other possible interventions through school health programs like preventive health check ups and services i.e. ENT, dental , deworming, HPV vaccination with Td vaccination, promotion of menstrual hygiene amongst adolescent girls , micronutrient supplementation i.e. Vitamin A]

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.

[Type text]

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 guidelines section 3.2, item 8).

[A comprehensive approach to cervical cancer prevention and control is made up of several key components. The primary prevention strategy involves HPV vaccination for girls of age 9-13 years. Some of the other activities involve community education, social mobilization, screening, and treatment to palliative care. It is important to involve representatives from various disciplines and national health programmes such as immunization, reproductive health, cancer control and adolescent health. In Nepal, the national cervical cancer prevention and control strategy guidelines was developed in 2010.The general objective aims at laying a foundation for achieving the implementation of cervical cancer control program in Nepal to reach the target population.
Specific objectives:

- Develop educational materials and messages to raise awareness on cervical cancer screening and prevention and develop outreach strategies.
- Identification of the service sites.
- To develop service providing strategy and outreach strategies.
- To establish referral system and follow up mechanism.
- To develop supervision and monitoring plans.
- To develop training strategy.
- To plan for integration of cervical cancer screening and prevention program into the national health policy/reproductive health programs.
- To establish network among key stakeholders in the country and abroad.

Along with these national objectives, the future cervical cancer screening and prevention (CCSP) in Nepal needs to align with the WHO comprehensive approach cervical cancer prevention and control.]

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.

[Type text]

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 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]
[Director General]	[SAH, Dr. L.L.]	[DoHS]
[Child Health Division]	[UPRETI, Dr. Shyam Raj]	[Immunisation]
[Family Health Division]	[REGMI, Dr. Kiran]	[Maternal and Women's Health]
[Logistics management Divs.]	[POKHRAEL, Dr. T. N.]	[LMD]
[Management Division]	[ACHARYA, Dr. B.]	[MD]
[MoHP]	[CHAND, Dr. P.]	[MoHP]
[WHO]	[BOHARA, Dr. Rajendra]	[IPD]
[UNICEF]	[K.C, Dr. Ashish]	[Child Health]
[WHO]	[PRADHAN, Ms. Latika Maskey]	[Maternal and Women's Health]
[WHO]	[GURUNG, Dr. Santosh]	[New Vaccines]
[NNCTR]	[SHAH, Dr. Aarati]	[NNCTR]
[NACCF]	[SHRESTHA, Dr. Surendra Bade]	[NACCF]

[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	[UPRETI, Dr. Shyam Raj]	[Child Health Division]	[Immunisation]

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 responsibilitie

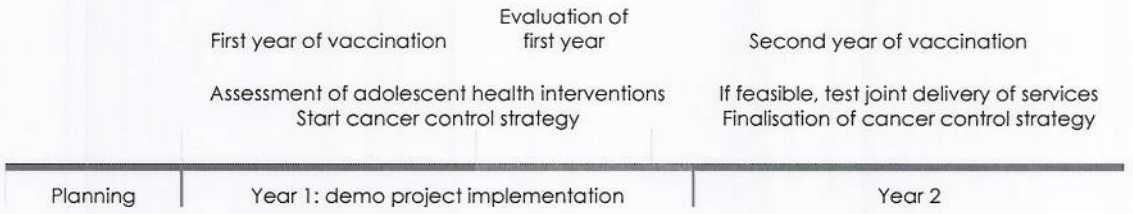
Enter family name in capital letters.

Name	[UPRETI, Dr. Shyam Raj]	**Title**	[Director]
Tel no	[977-9851088382]		
Fax no	[977- 1 4262263]	**Agency**	[Child Health Division]
Email	[drshyam@hotmail.com]	**Address**	[DoHS, Ministry of Health and Population, Teku, Kathmandu, Nepal]

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



Q28. Please draft a chronogram 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.gavialliance.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.gavialliance.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 must 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.
9 to and including 14 years Two doses each of 0.5 ml at 0, 6 months

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

[The HPV vaccination demonstration programme funding should be transferred to the government. Currently the calculation is made on two doses schedule (0,6 months) as recommended by the Strategic Advisory Group of Experts (SAGE) and EMEA (European Medicines Agency) for 9 to and including 14 years two dose schedule each of 0.5 ml at 0, 6 months can be considered.]

Calculating dose requirement HPV (single dose) ; YEAR 1				
For single dose (5% wastage rate i.e. WMF 1.05)				
District	Target population (10 yr female)	Vaccine required in 2 dose schedule (TP x 2x 1.05WMF)	Total vaccine required in doses with buffer stock (10%)	Total vaccine required in 2 doses vials with buffer stock (10%)
Chitwan	7721	16214	17836	8918
Kaski	6712	14095	15505	7752
Total	14433	30309	33340	16670

Calculating dose requirement HPV (single dose) ; YEAR 2				
For single dose (5% wastage rate i.e. WMF 1.05)				
District	Target population (10 yr female)	Vaccine required in 2 dose schedule (TP x 2x 1.05WMF)	Total vaccine required in doses with buffer stock (10%)	Total vaccine required in 2 doses vials with buffer stock (10%)
Chitwan	7721	16214	17836	8918
Kaski	6712	14095	15505	7752
Total	14433	30309	33340	16670

8. FiduciaryManagement Arrangements Data

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

The grant for HPV vaccination demonstration programme should be transferred to the government.

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 existing signed Aide Memoire derived from 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

9.1 Government

The Government of [Nepal] 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 second year of the Programme. Application forms and guidelines for national applications are available at www.gavialliance.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 nation-wide scale-up.

The Government of [Nepal] 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 HPVvaccination demonstration programme.

The Government of [Nepal] 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.

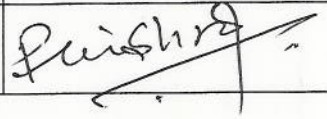
The Government of [Nepal] acknowledges that some activities anticipated in the demonstration programme could be considered research requiring approval by local ethics committees (e.g., collecting data from a random sample of parents of eligible girls for the HPV vaccine coverage survey). We acknowledge we are responsible for consulting and obtaining approval from appropriate local ethics committees (e.g., human subject protection committee or Institutional Review Boards) in our country, as required. By signing this application, the Government of [Nepal] 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 [Nepal]'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	[MISHRA, Dr. Praveen, Secretary, Ministry of Health and Population]	**Name**	
Date	30/4/2014	**Date**	
Signature		**Signature**	

The signature from the Ministry of Education will be uploaded shortly.

Q33. This application has been compiled by:

Enter the family name in capital letters.

Full Name	Position	Telephone	Email
UPRETI, Dr Shyam Raj	EPI Manager	977-9851088382	drshyam@hotmail.com
BOHARA, Dr Rajendra	National Coordinator, IPD/WHO	977-9851024615	boharar@searo.who.int
GURUNG, Dr Santosh	New Vaccine Officer, IPD/WHO	977-9851052724	gurungs@searo.who.int

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

Q34. We the members of the ICC, HSCC, or equivalent committee met on [27/04/2014] 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**. (attached document)

Enter the family name in capital letters.

Name/Title	Agency/Organisation	Signature
[Type text]	[Type text]	

Q35. In case the GAVI Secretariat has queries on this submission, please contact:
Enter family name in capital letters.

Name	[BOHARA, Dr Rajendra]	**Title**	[National Coordinator, IPD/WHO]
Tel no	[977-1-5260831 Ext 105]		
Fax no	[977-1-5260490]	**Address**	[Who-IPD , Chakupath, Kathmandu, Nepal]
Email	[boharar@searo.who.int]		
Mobile no	[977-9851024615]		

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 signed Aide Memoire derived from the FMA and countries currently receiving GAVI cash support through a UN agency.

GAVI ALLIANCE
GRANT TERMS AND CONDITIONS

Countries will be expected to sign and agree to the following GAVI Alliance terms and conditions in the application forms, which may also be included in a grant agreement to be agreed upon between GAVI and the country:

FUNDING USED SOLELY FOR APPROVED PROGRAMMES
The applicant country ("Country") confirms that all funding provided by the GAVI Alliance for this application will be used and applied for the sole purpose of fulfilling the programme(s) described in this application. Any significant change from the approved programme(s) must be reviewed and approved in advance by the GAVI Alliance. All funding decisions for this application are made at the discretion of the GAVI Alliance Board and are subject to IRC processes and the availability of funds.

AMENDMENT TO THIS PROPOSAL
The Country will notify the GAVI Alliance in its Annual Progress Report if it wishes to propose any change to the programme(s) description in this application. The GAVI Alliance will document any change approved by the GAVI Alliance, and this application will be amended.

RETURN OF FUNDS
The Country agrees to reimburse to the GAVI Alliance, all funding amounts that are not used for the programme(s) described in this application. The country's reimbursement must be in US dollars and be provided, unless otherwise decided by the GAVI Alliance, within sixty (60) days after the Country receives the GAVI Alliance's request for a reimbursement and be paid to the account or accounts as directed by the GAVI Alliance.

SUSPENSION/ TERMINATION
The GAVI Alliance may suspend all or part of its funding to the Country if it has reason to suspect that funds have been used for purpose other than for the programmes described in this application, or any GAVI Alliance-approved amendment to this application. The GAVI Alliance retains the right to terminate its support to the Country for the programmes described in this application if a misuse of GAVI Alliance funds is confirmed.

ANTICORRUPTION
The Country confirms that funds provided by the GAVI Alliance shall not be offered by the Country to any third person, nor will the Country seek in connection with this application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

AUDITS AND RECORDS
The Country will conduct annual financial audits, and share these with the GAVI Alliance, as requested. The GAVI Alliance reserves the right, on its own or through an agent, to perform audits or other financial management assessment to ensure the accountability of funds disbursed to the Country.

The Country will maintain accurate accounting records documenting how GAVI Alliance funds are used. The Country will maintain its accounting records in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of GAVI Alliance funds. If there is any claims of misuse of funds, Country will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against the GAVI Alliance in connection with any audit.

CONFIRMATION OF LEGAL VALIDITY
The Country and the signatories for the government confirm that this application is accurate and correct and forms a legally binding obligation on the Country, under the Country's law, to perform the programmes described in this application.

CONFIRMATION OF COMPLIANCE WITH THE GAVI ALLIANCE TRANSPARENCY AND ACCOUNTABILITY POLICY

The Country confirms that it is familiar with the GAVI Alliance Transparency and Accountability Policy (TAP) and will comply with its requirements.

ARBITRATION

Any dispute between the Country and the GAVI Alliance arising out of or relating to this application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either the GAVI Alliance or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The language of the arbitration will be English.

For any dispute for which the amount at issue is US$ 100,000 or less, there will be one arbitrator appointed by the GAVI Alliance. For any dispute for which the amount at issue is greater than US $100,000 there will be three arbitrators appointed as follows: The GAVI Alliance and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

The GAVI Alliance will not be liable to the country for any claim or loss relating to the programmes described in this application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. Country is solely responsible for all aspects of managing and implementing the programmes described in this application.

USE OF COMMERCIAL BANK ACCOUNTS

The eligible country government is responsible for undertaking the necessary due diligence on all commercial banks used to manage GAVI cash-based support, including HSS, ISS, CSO and vaccine introduction grants. The undersigned representative of the government confirms that the government will take all responsibility for replenishing GAVI cash support lost due to bank insolvency, fraud or any other unforeseen event.