Dr. S. R. Upreti
Director, Child Health Division
Ministry of Health, Royal Government of Nepal
Kathmandu
Nepal

12 December 2014

Government of Nepal's Proposal to Gavi, the Vaccine Alliance

Dear Dr. Upreti,

I am writing in relation to Nepal's proposal to Gavi, the Vaccine Alliance, for New Vaccines Support (NVS) for HPV Demonstration Programme and Measles Second Dose which was submitted to the GAVI Secretariat in May 2014.

In July 2014 your application was reviewed by the GAVI Independent Review Committee (IRC) which recommended "Approval with Clarifications" of your application.

We have since received your response to these clarifications, which was deemed satisfactory. Consequently, I am pleased to inform you that Gavi, the Vaccine Alliance approved Nepal's application for GAVI support as in the attached Decision Letter and IRC report.

Please do not hesitate to contact my colleague Raj Kumar rajkumar@gavi.org if you have any questions or concerns.

Yours sincerely

Hind Khatib-Othman
Managing Director, Country Programmes

Appendix A

Nepal HPV DEMONSTRATION VACCINE SUPPORT

This Decision Letter sets out the Programme Terms of a Programme.

1. **Country: Nepal**
2. **Vaccines Grant Number:** 1516-NPL-19a-X
   Cash Support Grant Number: 1516-NPL-24a-Y
3. **Date of Decision Letter:** 12 December 2014
4. **Date of the Partnership Framework Agreement:** 22-08-2014
5. **Programme Title:** HPV Demonstration Programme
6. **Vaccine type:** HPV
7. **Preferred product presentation and formulation of vaccine: HPV Bivalent, 2 dose(s) per vial, LIQUID**
8. **Programme Duration[1]: 2015 – 2016**
9. **Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement):**

	2015	2016	Total[2]
HPV vaccines (US$)	US$154,000	US$139,000	US$293,000
Cash ($)	US$199,000*	US$25,000**	US$224,000
Total Programme Budget (US$)	US$353,000	US$164,000	US$517,000

*This amount is to cover vaccination implementation expenses for **both** 2015 and 2016.
Planning and use of funds in 2015 should spread the funds across two years and take into account that no additional budget will be disbursed in 2016 for vaccine implementation activities.

**Conditional to country having completed Adolescent Health integration assessment AND to country choosing to implement one or more integrated deliveries of health services together with the vaccine. The 25.000 are designed to cover the cost of a new coverage survey.

10. **Vaccine Introduction Grant:** Not applicable

[1] This is the entire duration of the programme.
[2] This is the total amount endorsed by GAVI for the entire duration of the programme.

a. If an adolescent health intervention is identified for joint delivery with HPV vaccine, the report should describe the identified intervention, the modified plans for Year 2, and the steps required for implementation with the district(s) and staff involved. b. If NO adolescent health intervention is identified for joint delivery with HPV vaccine the report should mention the reason why not. 4. A summary of the activities completed and progress towards the development of a national cervical cancer prevention and control strategy.	
5. A financial and activity report of expenditures by the end of year 1.	End of year 1 (the first year starts when the first dose of vaccine is administered, and continues for 12 months)
1. If an adolescent health intervention is identified for joint delivery with HPV vaccine OR if the country substantially changed their delivery strategy: a. A new survey to measure the coverage of HPV vaccination and the coverage of the jointly delivered health intervention(s) and b. An updated micro-costing analysis of programme delivery costs. (Annex B) 2. If NO adolescent health intervention is identified for joint delivery with HPV vaccine in Year 2: A summary report of year 2 delivery of HPV vaccinations 3. A financial and activity report of expenditures in year 2. 4. A copy of the developed or revised national cervical cancer prevention and control strategy.	End of Year 2 (the second year starts when the first dose of vaccine is administered to a new cohort, which is usually 12 months after the start of Year 1 and continues for twelve calendar months)

17. Financial Clarifications: The Country shall provide the following clarifications to GAVI*: Not applicable.

**Failure to provide the financial clarifications requested may result in GAVI withholding further disbursements*

18. Other conditions: Not applicable.

Signed by,

On behalf of the GAVI Alliance

Hind Khatib-Othman
Managing Director, Country Programmes
12 December 2014

11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):[3]

Vaccines:

Type of supplies to be purchased with GAVI funds in each year	2015
Number of HPV vaccines doses	35,300
Number of AD syringes	35,300
Number of safety boxes	400
Annual Amounts (US$)	US$154,000

Cash support:

Cash Support by year	2015
Annual Amounts (US$)	US$199,000

12. Procurement agency: UNICEF

13. Self-procurement: Not applicable

14. Co-financing obligations: Not applicable

15. Operational support for campaigns: Not applicable

16. Documents to be delivered for future disbursements: The Country shall deliver the following documents by the specified due dates as part of the conditions to this approval and to disbursements of the future Annual Amounts. Further details and report template forms can be found in the HPV Demo Application Guidelines and its Annexes (http://www.gavi.org/Library/Documents/GAVI-documents/Guidelines-and-forms/Gavi-human-papillomavirus-for-demonstration-programme-guidelines-2015/).

Reports, documents and other deliverables	Due dates
1. A copy of the approval by the local ethics committee, *if a country determined that review and approval was required.* 2. Three evaluation reports of the HPV vaccination demonstration programme: a. Post Introduction Evaluation (PIE) b. Coverage survey c. Costing analysis 3. A report of the assessment of adolescent health interventions, with conclusions about what interventions would be feasible for integration in year 2.	As soon as they become available, and at the latest by end of year 1 (the first year starts when the first dose of vaccine is administered, and continues for 12 months)

[3] This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.

Appendix B

Nepal VACCINE SUPPORT – MEASLES RUBELLA

This Decision Letter sets out the Programme Terms of a Programme.

1. **Country: Nepal**
2. **Grant Number:** 1516-NPL-09a-X / 15-NPL-08d-Y
3. **Date of Decision Letter:** 12 December 2014
4. **Date of the Partnership Framework Agreement:** 22-08-2014
5. **Programme Title:** NVS, Measles second dose, Routine
6. **Vaccine type:** Measles-Rubella
7. **Requested product presentation and formulation of vaccine:** Measles Rubella, 10 dose(s) per vial, LYOPHILISED
8. **Programme Duration[4]: 2015 - 2016**
9. **Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):**

	2015	2016	Total[5]
Programme Budget (US$)	US$348,500	US$367,500	US$716,000

10. **Vaccine Introduction Grant:** US$546,500 payable up to six months before the introduction.
11. **Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):[6]**

Type of supplies to be purchased with GAVI funds in each year	2015
Number of doses of vaccines for Measles Second Dose	902,700
Number of AD syringes	674,300
Number of re-constitution syringes	99,300
Number of safety boxes	8,525
Annual Amounts (US$)	US$348,500

12. **Procurement agency:** UNICEF
13. **Self-procurement:** Not applicable.
14. **Co-financing obligations:** Not applicable
15. **Operational support for campaigns:** Not applicable

[4] This is the entire duration of the programme.
[5] This is the total amount endorsed by GAVI for the entire duration of the programme.
[6] This is the amount that GAVI has approved.

16. **The Country shall deliver the following documents by the specified due dates as part of the conditions to the approval and disbursements of the future Annual Amounts:** The Country shall deliver the following documents by the specified due dates as part of the conditions to the approval and disbursements of the future Annual Amounts.

Reports, documents and other deliverables	Due dates
Annual Progress Report or equivalent	To be agreed with GAVI Secretariat
Annual Progress Report 2014	15 May 2015

17. **Financial Clarifications:** The Country shall provide the following clarifications to GAVI*: Not applicable

**Failure to provide the financial clarifications requested may result in GAVI withholding further disbursements*

18. **Other conditions:**

Country has presented an official request to GAVI and UNICEF SD to switch from measles vaccine to measles- rubella vaccine for the routine measles second dose with country funding for the equivalent cost of the Rubella component. As such, country will make the required payments to UNICEF SD as indicated in the table below.

	2015	2016
Number of doses of vaccines for Measles Second Dose approved by GAVI	902,700	910,600
Amount for vaccines approved by Gavi in US$ (excluding freight and insurance).	$270,810	$291,392
Number of doses of Measles-Rubella vaccine that can be purchased with Gavi support	468,529	477,692
Number of doses of Measles-Rubella vaccine to be funded by country	434,171	432,908
Amount for Measles-Rubella vaccines to be funded by country (excluding freight and insurance).	$250,951	$264,074

Country understands that vaccines will be purchased only after receipt of full payment of the respective amounts due from Country and Gavi to the procurement agency for the number of doses as indicated in this Decision Letter. In the event that country wishes to revert to measles vaccine, country should inform UNICEF and GAVI immediately in order to agree on an appropriate arrangement.

Hind H. Khatib

Signed by,

On behalf of the GAVI Alliance

Hind Khatib-Othman
Managing Director, Country Programmes
12 December 2014

Independent Review Committee (IRC) Country Report

GAVI Secretariat, Geneva • 23 June – 4 July 2014

Country: NEPAL

Type of support requested: NVS

Vaccines requested: Measles Rubella

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1. Type of support requested

Type of support requested	Planned start date *(Month, Year)*	Duration of support	Vaccine presentation(s) *(1st and 2nd choice, if applicable)*
MSD	February 2015	December 2016	10-dose/vial LYOPHILISED
HPV Demo	May 2015	May 2017	1st Bivalent GSK
			2nd Quadrivalent Merck

2. In-country governance mechanisms (ICC/HSCC) and participatory proposal development process

Signatures from the Minister of Health were provided for both the MSD and HPV applications. In addition, a signature from the Minister of Finance was provided for the MSD application and the Minister of Education for the HPV Demo application.

A comprehensive list of the major functions and responsibilities of ICC was provided with the application. Although a formal membership list for the ICC was not included, minutes from the last four ICC meetings held in May 2013, Sept 2013, March 2014, and April 2014 were provided and each set of minutes included a list of meeting participants. The ICC includes membership from various government departments, UNICEF, USAID, WHO, NHSSP, Sabin Vaccine Institute and Rotary International. The applications for both MSD and the HPV demo project were discussed during the ICC session held on April 27, 2013. In addition to regular member attendance, there was high-level representation from the Ministry of Education (Under Secretary). Both proposals were fully endorsed and signatures of all attendees were provided.

The Nepal National Committee on Immunisation Practices (NCIP) functions as the NITAG in Nepal, and has been in place since 2009. The NCIP Charter that includes TORs and membership was included with the application; NCIP has been found to be compliant with WHO standards for NITAGs. The application indicates that a NITAG meeting was held in Oct 2013, during which the recommendation for the introduction of MSD into the routine immunisation programme at 15-18 months was made. NCIP recommended that the MR vaccine should be used for both the first and second dose of MCV.

The country provided a membership list for the HPV Demo TAG that includes EPI, ICC, Child Health, Maternal & Women's Health, WHO, UNICEF and NGOs. Of note, individuals from Cancer Control and Education were not

included in the submitted TAG membership list. However, MOE was present at the ICC meeting that approved the HPV Demo Project. The TAG will be chaired by EPI, Child Health Division.

3. Situation analysis – Status of the National Immunisation Programme

Nepal is a low-income country with a population of approx. 28 million and GNI per capita of US$ 700. The EPI was initially established in 1979 in 3 districts, providing two antigens (BCG & DPT). By 1989, the programme expanded to all 75 districts, providing the six traditional antigens. Currently, the NIP provides BCG, Penta, OPV and MR to children less than one year of age, Td vaccine to pregnant women, and JE vaccine to children 12-23 months of age in 31 post JE campaign high-risk districts. In addition to the current application for MSD and HPV Demo, the country has plans to launch IPV in Sept 2014 and PCV10 in Nov 2014.

Official country estimates in 2012 was 90% for DTP3 and 86% for MCV1, in line with WUENIC estimates. For 2013, the country has experienced increases for both DPT3 at 93% and MCV1 at 88%. The last immunisation survey in the country was the NDHS survey in 2011; the survey estimated DPT3 coverage of 92% and MCV1 of 88%.

A data quality self-assessment (DQSA) analysis of 25 districts was carried out in 2013, implemented by respective regional health directorates for each of the five regions. Some of the key findings included: satisfactory data accuracy ratio (though majority of districts experienced under reporting of given services); poor evidence of using immunisation data for correction; satisfactory retention of immunisation cards until the child receives penta (>80% children in 16 districts have immunisation card). A Lot Quality Assurance Sampling (LQAS) survey was carried out in 7 districts in Nepal, June 2013. Some of the key findings were: improved Immunisation Card Retention Rate (average rate 45%); penta coverage of 96%, complete immunisation rate of 91%, partial immunisation of 8%, and children receiving no immunisation was only 1%.

The government of Nepal has implemented several initiatives to strengthen routine immunisation: RED micro planning, capacity building trainings, celebration of immunisation months, mobilisation of local community, ownership and resources using appreciative inquiry approach and BCC activities. Nepal has also developed an "intensification of routine immunisation plan of action" to strengthen immunisation. The country provided some lessons learned from previous introductions including: the importance of training staff on vaccine management; proper dissemination of IEC materials and advocay meetings at all levels; lower vaccine coverage when vaccine given after one year of age; and the need to reduce vaccine wastage rates. Action points to address these issues have been developed.

4. Overview of national health documents

The time period of the cMYP (2011-2016) is in line with the current application, is linked to broader health sector planning, and provides an adequate situational analysis of the status of the immunisation programme in the country. The document has been updated in some but not all sections to reflect introduction of MRSD into the routine immunisation programme. No mention is made in the cMYP regarding synergies with vaccination and other health interventions such as vitamin A supplementation.

5. Gender and Equity

GII	0.48
GII Rank	102/148
MMR	170/100,000

MSD

The application provides disaggregated data on geographical, wealth and gender equity data and points out the disparities in immunisation in wealth quintiles, maternal education, rural or urban residence, and geographical areas. Moreover, the proposal provides solutions in the form of strengthening access through mobile camps and regular outreach clinics and through immunisation months. Advocacy, social mobilisation and BCC are proposed to address

equity issues. DoHS (HMIS) is piloting collecting immunisation data aggregated by sex, caste, and ethnicity in a few districts. Currently, sex disaggregated data is collected through the DHS survey.

HPV Demo

Child marriage of 41% and is linked to cervical cancer. Any HPV proposal scores high on gender equity since it addresses morbidity and mortality of women. The country has a good DTP3 coverage but there are disparities related to wealth quintile, geographical location, urban/rural, and maternal education. 90% of the population lives in rural areas. It is interesting to note that TT coverage is very low in both the districts (47% and 63%) in which the HPV Demo project will occur. It is unclear whether this represents low status of women or the services provided to them. As for the representation of youth, national adolescent sexual and reproductive health agencies will be aligned with HPV demonstration programme, along with involving and establishing links with youth clubs, child clubs, village child protection committees (VCPCs).

6. Proposed activities, budgets, financial planning and financial sustainability

Nepal is applying for GAVI support for the introduction of MSD, with the duration of support 2015-2016, in-line with the current cMYP. The estimated cost for MSD vaccine and supplies, inclusive of buffer stocks and wastage is US$ 654,966 for the two-year period. The total operational costs for MSD introduction have been estimated as US$ 599,040. The total amount of funds requested for the GAVI VIG is US$ 546,163. The government plans to contribute US$ 52,887 to the operational costs of MSD introduction, amounting to approximately 10% of the total operational budget, with no remaining funding gaps indicated. 47% of the GAVI VIG has been allocated to "planning and preparations", 29% to other trainings and meetings, and 11% to cold chain equipment.

Nepal funds all traditional vaccines and co-financing obligations for GAVI funded vaccines have been met. Co-financing is not required for MSD vaccine; however, the government is expected to cover the additional costs for the use of MR vaccine above the cost of single antigen measles vaccine. The country has committed to cover this additional cost since it will be using MR for both doses of MCV.

For the HPV Demo, the country is requesting VIG or US$ 164,279 for year 1 and US$ 59,639 for year 2, in line with GAVI entitlements. The projected cost for the evaluation component was flagged as a concern; only US$ 404 has been allocated to this important component of the demo project. The country should increase this figure or provide justification to GAVI for this very low allocation. In addition, there are errors in the "full costs/needs for NVI column of the budget tables". For three cost categories, years 1 and 2 do not add up to the full costs/needs.

7. Specific comments related to requested support

MSD

New vaccine introduction plan

Nepal has developed a National Measles Elimination and Rubella/CRS Control Strategic Plan (2014-2018), with the goal to achieve measles elimination and rubella/CRS control by end of 2018. By end 2015, the country aims to reduce measles mortality by at least 95% compared with 2000 estimate and to reduce measles incidence to <5 cases per million populations. The country has witnessed significant reductions in the number of measles cases in the last decade: measles cases dropped from approximately 12,000-13,000 cases in 2003/04 to less than 1,000 cases in the last three years.

To achieve global measles control and elimination goals, WHO recommends reaching all children with two doses of measles containing vaccine (MCV) when the national coverage of MCV1 is ≥80% for the last three years; Nepal has achieved this milestone. Therefore, the NCIP recommended the introduction of MSD into the routine immunisation programme using MR vaccine at 15-18 months. The country plans to introduce MRSD into the routine EPI schedule starting Feb 2015. The country is targeting 79% coverage for MCV2 over the next three years; this is a reasonable target given the coverage for MCV1 in 2013 was 88%. The country does not indicate plans to link to other child health programming/interventions or to use the MCV2 visit to review the child's immunisation record and "catch-up" missed

doses of other antigens. In addition, potential synergies with the upcoming introductions of IPV (Sept 2014) and PCV (Nov 2014) were not discussed.

The country replaced single antigen measles vaccine given at 9 months with MR in July 2013, after a successful phased MR catch-up campaign in 2012 targeting children 9mo-15 years. A total of 9,685,099 children were vaccinated during the MR campaign, achieving 100% coverage. A follow-up MR SIA is scheduled for 2016 and will target children 9 months to less than 5 years. This is in line with WHO recommendations that follow-up SIAs should be conducted until 90-95% vaccination coverage has been achieved with **both** MCV1 and MCV2 for a period of three years.

The Department of Drug Administration (DDA) functions as the NRA in Nepal. All new vaccines are required to be WHO prequalified along with national vaccine licensure through the DDA. Nepal will use the MR vaccine in 10-dose vial plus diluents presentation, which is already licensed in Nepal. Vaccines will and supplies will be procured through UNICEF SD.

Measles-rubella surveillance was integrated with AFP surveillance in 2003. Case-based surveillance for measles-rubella has been expanded and includes more than 300 sites throughout the country. All suspected measles-rubella outbreaks are reported, investigated and laboratory specimens are collected for serological confirmation. Plans to establish sentinel surveillance for CRS are underway. In addition, a rubella seroprevalence study was conducted in 2009; no plans were provided for conducting future rubella seroprevalence studies.

Advocacy meetings highlighting the significance of MRSD and routine immunisation will be held at central, regional and district levels involving professional organizations, public-private organizations and media. Advocacy and IEC materials will be developed and distributed at all levels targeting local communities, religious leaders, political leaders and parents and mass media will be used to disseminate key messages. Operational research will be carried out to investigate perceptions of parents, medical professionals, media and other key stakeholders on new vaccine introductions and based on findings corrective measures will be implemented to support the new vaccines introduction.

The government has allocated funds to support training of around 8,000 health staff in the current financial year. Training of trainers has been completed to support training at district levels and training and facilitator guidelines and presentations have been developed. Weak districts have been identified and will be provided with additional support. Surveillance officers and trainers from the regional training centers will be mobilised to ensure quality training. The Child Health Division will also mobilise government, non-government WHO and UNICEF staff for supervision of trainings and introduction of MRSD.

Monitoring of the introduction of MRSD will be conducted as per the existing MoHP reporting and monitoring system for all immunisations. The logistics management information system (LMIS) monitors vaccine stocks at all levels. The MoHP has a health management information system (HMIS) in place for recording, reporting and monitoring of immunisation coverage data, dropout, wastage rate and AEFIs. The HMIS provides feedback to each division and concerned partners on a quarterly basis. Each district organises quarterly performance review meetings of all health facilities at district level. The Management Division organises annual review meetings at regional level and a national review at central level. In addition, the country plans to conduct a Post Introduction Evaluation 6-12 months after vaccine introduction.

AEFI surveillance system is in place in all 75 districts. Health staff have been trained on AEFI reporting, recording and investigation. Serious AEFI cases are reported immediately, investigated and causality assessment is carried out. Non-serious AEFI cases are reported on monthly basis. An independent AEFI committee has been formed at national level and all serious AEFI cases are investigated and causality assessment is conducted.

Vaccine management and cold chain capacity
The cold chain system in Nepal comprises a central store with $55m^3$ of net storage capacity, 6 regional cold rooms, and refrigerators at 75 districts and service delivery locations. Nepal conducted EVM in December 2011. Results were mediocre with an EVM aggregate score of 57.5%. Maintenance was weakest at 48%, and storage capacity strongest at 73%. A detailed and well laid out EVM implementation plan based upon the 2011 assessment shows that more than 75% of listed actions for improvement are either complete or in progress.

The present cold chain capacity at the central store is sufficient to accommodate all vaccines inclusive of PCV10 scheduled for introduction by 2015. However, if Rota is introduced in 2016 this will cause a shortfall in storage capacity. The exact shortfall will be determined in the next EVMA scheduled for Q3 2014. Nepal also prepared a cold chain replacement plan for 10 years (2010-2020) that apparently shows Nepal has enough space for introduction of MSD vaccine (The plan was not made available to the IRC). The Government is currently updating the inventory of all cold chain equipment from central to district level. Based on need for additional space for each district, an updated replacement plan will be developed and implemented based on urgency. The government is taking serious steps to strengthen its cold chain system at all levels. HSS support to Nepal through the pool fund terminated in 2013. The GAVI HSS application targeted for submission in Sept 2014 is focused on expansion of vaccine sub stores below the district level and replacement of old aged cold chain equipment with completion targeted by 2016.

The HPV Demo in a 2 dose bivalent presentation will be administered in 2 pilot zones, Kaski and Chitwan. 132L of Capacity and 114L are required in Chitwan and Kaski respectively. There are no storage capacity issues at either of these locations. For the HPV Demo Project, US$ 18,000 is earmarked in the budget in Year 1 to procure 4 WHO/PQS approved refrigerators and US$ 3,750 is earmarked each year to support waste management. Additionally, US$ 3,000 for each year has been allocated for cold chain support. The level of GAVI support requested is deemed reasonable. The IPV VIG earmarks US$ 56,000 for cold chain support in the form of maintenance. Government contribution would be an additional US$ 30,000. The MSD Application earmarks US$ 72,576 for Cold Chain equipment that includes a request from GAVI in the amount of US$ 62,208.

No significant supply chain issues relating to the HPV demo in Chitwan and Kaski districts are anticipated. Also, given the good temperature stability of measles vaccine, no major issues are anticipated related to MSD introduction except that the IRC would like to better understand the supply chain capacity at the service delivery level.

Waste management
Used syringes and needles are collected in safety boxes. While some sites dispose of waste through incinerators, primarily disposal is through open-pit burning and burying. The application indicates that the government has plans to explore additional methods of waste disposal.

HPV Demo

Implementation strategy

The country provides multi-institution hospital-based cancer incidence data published in 2009 to justify introduction of HPV. Data was collected from seven major hospitals in Nepal where cancer is diagnosed and treated and found that cervical cancer was the leading malignancy, comprising 21.4% of all cancers identified. Another study was done to provide evidence of the HPV subtypes linked to cervical cancer cases from two tertiary referral hospitals; HPV types 16 and 18 were present in 70% of all cervical cancers and 90% of all genital warts. The main justification provided for choice of the bivalent over the quadrivalent was the reduced cold chain requirements with the bivalent.

The country states that neither the bivalent or the quadrivalent vaccine are licenced with the DDA. In addition to WHO prequalification, DDA licencing is requirement in Nepal. The country has initiated the process for licensing of the bivalent vaccine. Despite the lack of licensing, the Nepal Austrailian Cervical Cancer Foundation conducted HPV

vaccination in 7 districts, vaccinating approximately 22,384 girls aged 11-13 years from 2008-2013. The country indicates that it will investigate lessons learned from this process to inform the HPV Demo Project.

The country has selected the districts of Chitwan and Kaski for the HPV Demo Project. The districts were selected based on their different regional locations; Chitwan is located in the central development region in the flat lands, whereas Kaski is located in the hilly, western development region. Both regions are accessible districts, which the country has cited as important for enabling good monitoring and supervision during the HPV demo implementation. The two regions have similar population size, public health facilities and number and types of schools. DTP3 coverage is 73% in Chitwan and 81% in Kaski. The selection of districts for the HPV Demo is adequate, however, the country may have benefited from selecting a district that was less accessible.

The bivalent vaccine will be delivered to all girls 10 years of age, using in a two-dose schedule at 0 and 6 months (May and Oct), in line with recent WHO SAGE recommendations. This translates to 7,721 girls in Chitwan and 6,712 girls in Kaski each year for a period of 2 years. The application indicates that there is no legal requirement to obtain parental/guardian consent for adolescent vaccination in Nepal. However, IEC materials will be provided to parents prior to HPV vaccination.

The country has identified three delivery strategies for HPV vaccine:

1. School Based: All girls aged 10 attending schools (N=11,691/year; 81%)
2. Routine fixed and outreach clinics: All girls aged 10 not attending school (N=2,605/year; 18%)
3. Mobile outreach by HCWs: All girls aged 10 residing in hard to reach areas (N=137/year; 1%)

Inclusion of a strategy for hard to reach areas is a strength, as this has often been neglected in previous HPV demo applications. However, no details were provided in the application on the mobile outreach strategy to be used in hard to reach areas. Girls missed at the first HPV school vaccination session in the month of May will be vaccinated as new cohort during the second dose schedule in Oct. In addition, the timeline of activities indicates that mop-up activities will be conducted after each round of vaccination. HPV vaccination will also be added to fixed health posts and outreach clinics to reach girls not in school. The timeline includes adequate preparation time prior to delivery of the first dose, and the implementation of all activities within the 2 years of the project appears feasible.

Training, Community Sensitisation & Mobilisation Plans and Evaluation

Specific training plans for HPV Demo implementation were not provided in the application. A generic description of training for FY 2014 was provided that indicates training of trainers has been completed to support training at the district level and that SMOs and trainers from the regional centers will be mobilised to ensure quality training during the rollout of HPV demo. In addition, government, HPV TAG, NGO, WHO, and UNICEF stall will be mobilised to provide supervision of trainings and introduction of HPV. No mention was made regarding the need to train school health workers or additional staff to vaccinate in schools.

Community awareness will be generated throught the development of IEC materials targeted at communities, parents, teachers and other relevant stakeholders regarding HPV infection, HPV vaccine, and cervical cancer and the availability of services. A particular focus will be given to educating men, including fathers and boys, as well as older women and mothers of girls being offered vaccine. Communication materials will also be used to educate parents and girls regarding AHIs and cervical cancer screening. The proposal did not mention plans to conduct formal assessments of their IEC activities or assessments to determine reasons for not getting vaccinated etc. (e.g. qualitative research; cross-sectional survey). This is a missed opportunity to learn by doing during the demonstration project.

The application indicates two key potential barriers/risks worth highlighting:

- Reaching girls in areas where school enrollment is not high will require different approaches. These populations may be particularly vulnerable i.e. street children and migrants.
- Potential concern regarding rumors and misinformation and the need to develop carefully tailored communication messages.

The Child Health Division of the Department of Health Services has been identified as the lead agency to conduct the evaluation on the coverage, acceptiblity, feasibility and costs after the first round of vaccination. There is concern regarding the very low amount of funding allocated to evaluation (US$ 404).

Assessment of adolescent health interventions and the development of Cervical Cancer Prevention and Control Strategy

Some possible adolescent health interventions (AHI) identified were school health programmes such as preventive health checkups and services, ENT, dental, deworming, Td vaccination, promotion of menstrual hygiene amongst adolescent girls and micronutrient supply. The appropriateness of these AHIs will be determined during TAG meetings and the assessment of possible AHIs will be done immediately after the implementation of dose 2 in Oct 2014. This is in line with GAVI guidance that year one be used to conduct a "desk review" of possible AHI. Anticipated activities for the assessments include:

- Aligning activities of the national adolescent sexual and reproductive health programme with HPV demo and incorporation of ASRH indicators
- Involving and establishing links with youth clubs, child clubs, village child protection committees, NGOs and the private sector
- Investigating the use of school health programmes to deliver AHIs

The Nepal Cervical Cancer Prevention and Control Strategy was developed in 2010. Most of the objectives in the strategy are focused on awareness, monitoring, training and referral sites; there is no focus on the primary prevention strategy through HPV vaccination. The country has indicated that the preliminary report from the evaluation of HPV demonstration project will guide the TAG, which will include experts from relevant fields of cancer control, non-communicable diseases and gynecology, to further advise on the revision of the national cervical cancer prevention and control strategy. No further details were provided on methodology for the revision.

8. Country document quality, completeness, consistency and data accuracy

The cMYP (2011-2016) is aligned with Nepal Health Sector Programme-II. All mandatory documents were submitted and there is relatively good consistency between proposal documents.

9. Overview of the proposal

Strengths:

- Government finances all traditional vaccines and co-financing obligations have been met.
- Country has developed national measles elimination & rubella/CRS control strategic plan with clear goals and targets.
- Country conducted a successful MR catch-up campaign with very high coverage in 2012, followed by replacement of single antigen measles vaccine with MR in 2013.
- A follow-up MR SIA is planned for 2016, in line with WHO recommendations.
- Case based surveillance system for measles and rubella is in place and the country plans to introduce sentinel surveillance for CRS. A rubella seroprevalence study was conducted in 2009.
- Communication strategy for the HPV Demo has component to target men in the community, particularly fathers and boys.

Weaknesses:

- Opportunities to link with other child health programming/interventions during the 15-18 month visit for MCV2 were not indicated.
- Potential synergies with upcoming IPV and PCV introductions and MRSD were not discussed.
- No plans indicated for periodic rubella seroprevalence studies to monitor the impact of vaccination and changes in age specific or sex specific rubella prevalence.
- Concerns regarding country response that obtaining parental/guardian consent for HPV vaccination of 10 yo girls is not required in Nepal; no legal basis was provided to support this response and there was no analysis/discussion regarding potential issues that may arise from this policy decision.
- Plans for formal assessments of IEC activities and reasons for not getting vaccinated, prior to the initiation of HPV vaccination were not included in the application.
- Cancer Control and Education are not represented in the current TAG membership list.
- Process and methodology to revise the 2010 cervical cancer and prevention and control strategy was not provided.
- Details on mobile outreach strategies for hard to reach populations were not included in the application.

Risks:

- Capacity of the country to introduce multiple new vaccines in 2014/15 (IPV, MSD, HPV Demo and PCV10) in the span of 6 months.

Mitigating strategies:

- Strong support of in-country partners
- Ensure both Cancer Control and Education representation on the TAG. MOE was in attendance at ICC meeting approving HPV Demo application
- Consider conducting formal assessments of IEC activities and reasons for not getting vaccinated, prior to HPV Demo to start date and adapt communication strategy as required

10. Conclusions

The application for MSD met all mandatory requirements and no major issues were identified. The country provided a feasible HPV Demo Project application that addressed the three primary objectives, with comments as outlined in the below recommendations section.

11. Recommendations

NVS (MSD):

Recommendation:

Approval with Comments

Comments:
1. Provide an updated cold chain inventory report and submit an analysis of net storage capacity given the introduction of 3 new vaccines plus HPV Demo over a 6-month timespan.
2. Consider potential synergies between MRSD introduction and upcoming introductions of PCV10 & IPV.

HPV Demo:

Recommendation:

Approval with Comments

Comments:

1. Confirm inclusion of appropriate representatives from Cancer Control and Education on the HPV TAG.
2. Modify budget to include a more realistic estimate for the cost of the evaluation component or provide justification for the existing low figure.
3. Submit detailed plans for mobile outreach strategies targeting hard to reach populations.
4. Ensure that if you are conducting activities that might be deemed research, you seek the appropriate ethical approvals based on your national guidelines, and if applicable, submit a copy of the approval letter with year 1 deliverables.