



Application Form for Gavi NVS support

Submitted by
The Government of
Sri Lanka

Date of submission: **5 September 2016**

Deadline for submission:

- i. **9 September 2016**
- ii. 1st May 2015
- iii. 9 September 2015

Select Start and End Year of your Comprehensive Multi-Year Plan (cMYP)

Start Year

2016

End Year

2020

Form revised in 2016

(To be used with Guidelines of November 2015)

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

Gavi
GRANT TERMS AND CONDITIONS

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

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

AMENDMENT TO THE APPLICATION

The Country will notify the Gavi in its Annual Progress Report if it wishes to propose any change to the programme(s) description in its application. The Gavi will document any change approved by the Gavi, and the Country's application will be amended.

RETURN OF FUNDS

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

SUSPENSION/ TERMINATION

The Gavi 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 the Country's application, or any Gavi-approved amendment to the application. The Gavi retains the right to terminate its support to the Country for the programmes described in its application if a misuse of Gavi funds is confirmed.

ANTICORRUPTION

The Country confirms that funds provided by the Gavi shall not be offered by the Country to any third person, nor will the Country seek in connection with its 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, as requested. The Gavi 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 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 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 in connection with any audit.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the Country confirm that its application, and Annual Progress Report, are accurate and correct and form legally binding obligations on the Country, under the Country's law, to perform the programmes described in its application, as amended, if applicable, in the APR.

CONFIRMATION OF COMPLIANCE WITH THE Gavi TRANSPARENCY AND ACCOUNTABILITY POLICY

The Country confirms that it is familiar with the Gavi Transparency and Accountability Policy (TAP) and complies with the requirements therein.

USE OF COMMERCIAL BANK ACCOUNTS

The Country is responsible for undertaking the necessary due diligence on all commercial banks used to manage Gavi cash-based support. The Country confirms that it will take all responsibility for replenishing Gavi cash support lost due to bank insolvency, fraud or any other unforeseen event.

ARBITRATION

Any dispute between the Country and the Gavi arising out of or relating to its application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either the Gavi 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 languages of the arbitration will be English or French.

For any dispute for which the amount at issue is US\$ 100,000 or less, there will be one arbitrator appointed by the Gavi. 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 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 will not be liable to the country for any claim or loss relating to the programmes described in the 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 its application.

1. Type of Support requested

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

Type of Support	Vaccine	Start Year	End Year	Preferred second presentation[1]
Routine New Vaccines Support	HPV quadrivalent, 1 dose(s) per vial, LIQUID	2017	2017	

[1] Gavi may not be in a position to accommodate all countries first product preferences, and in such cases, Gavi will contact the country and partners to explore alternative options. A country will not be obliged to accept its second or third preference, however Gavi will engage with the country to fully explore a variety of factors (such as implications on introduction timing, cold chain capacity, disease burden, etc.) which may have an implication for the most suitable selection of vaccine. If a country does not indicate a second or third preference, it will be assumed that the country prefers to postpone introduction until the first preference is available. It should be noted that this may delay the introduction in the country.

[2] Gavi would appreciate feedback from countries on feasibility and interest of selecting and being shipped multiple Pentavalent vaccine presentations (1 dose and 10 dose vials) so as to optimise wastage, coverage and cost. Please refer to section 6.2.

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Annex 1.1 HPV quadrivalent, 1 dose(s) per vial, LIQUID

Table Annex 1.1 A Rounded up portion of supply that is procured by the country and estimate of relative costs in US\$

Table Annex 1.1 B Rounded up portion of supply that is procured by Gavi and estimate of relative costs in US\$

Table Annex 1.1 C Summary table for vaccine HPV quadrivalent, 1 dose(s) per vial, LIQUID

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Annex 2 - NVS Routine – Preferred Second Presentation

Annex 3 - NVS Preventive campaign(s)

Annex 4

Table Annex 4A: Commodities Cost

Table Annex 4B: Freight cost as percentage of value

Table Annex 4C: Accelerated transition phase - Minimum country co-payment per dose of co-financed vaccine

Table Annex 4D: Wastage rates and factors

Table Annex 4E: Vaccine maximum packed volumes

12. Banking Form

3. Executive Summary

Please provide a summary of your country's proposal, including the following the information:

- For each specific request, NVS routine support or NVS campaign :
 - The duration of support
 - The total amount of funds requested
 - Details of the vaccine(s), if applicable, including the reason for the choice of presentation
 - Projected month and year of introduction of the vaccine (including for campaigns and routine)
- Relevant baseline data, including:
 - DTP3 and Measles coverage data (as reported on the WHO/UNICEF Joint Reporting Form)
 - Target population from Risk Assessments from Yellow Fever and Meningitis A
 - Birth cohort, targets and immunisation coverage by vaccines
- Country preparedness
 - Summary of planned activities to prepare for vaccine launch, including EVM assessments, progress on EVM improvement plans, communication plans, etc.
 - Summary of EVM assessment and progress on EVM improvement plan
- The nature of stakeholders' participation in developing this proposal
 - Inter-Agency Coordinating Committee
 - Partners, including CSO involvement

National Advisory Committee on Communicable Disease, Ministry of health Sri Lanka, in its meeting held on March 2015, decided to introduce HPV vaccine into National Programme on Immunization as school based vaccine targeting children of 11 years of age from January 2017. For this introduction Ministry of Health Sri Lanka expect to request the GAVI support for new vaccine introduction (50% of vaccine cost for the initiation year) and implementation grant for the introduction (US\$ 420,000).

Introduction of HPV vaccination target population will be girls at 11 years of age that will come around 175,000 children per year. Sri Lanka expect to introduce HPV quadrivalent vaccine (single dose vial) in 2 dose schedule.

Country is having a good tract records of introduction of new vaccines to National Programme of Immunization with near 100% coverage within a short period of introduction.

Recently concluded EVM assessment reported adequate cold chain facilities at National, district and divisional levels for new vaccine introduction. EVM implementation plan recommended that some further improvement in cold chain management.

The NACCD agreed and endorsed to submit the proposal to get HPV new vaccine introduction support.

4. Signatures

4.1. Signatures of the Government and National Coordinating Bodies

4.1.1. Government and the Inter-Agency Coordinating Committee for Immunisation

The Government of Sri Lanka would like to expand the existing partnership with the Gavi for the improvement of the infants routine immunisation programme of the country, and specifically hereby requests Gavi support for:

HPV quadrivalent, 1 dose(s) per vial, LIQUID routine introduction

The Government of Sri Lanka commits itself to developing national immunisation services on a sustainable basis in accordance with the Comprehensive Multi-Year Plan presented with this document. The Government requests that the Gavi and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

Table(s) 6.2.4 in the NVS Routine section of this application shows the amount of support in either supply or cash that is required from the Gavi. Table(s) 6.2.3 of this application shows the Government financial commitment for the procurement of this new vaccine (NVS support only).

Following the regulations of the internal budgeting and financing cycles the Government will annually release its portion of the co-financing funds in the month of **January**.

The payment for the first year of co-financed support will be around **January 2017** for HPV quadrivalent, 1 dose(s) per vial, LIQUID.

Please note that this application will not be reviewed or recommended for approval by the Independent Review Committee (IRC) without the signatures of both the Minister of Health and Minister of Finance or their delegated authority. These signatures are attached as DOCUMENT NUMBER : 2 and 3 in Section 10. Attachments.

Minister of Health (or delegated authority)		Minister of Finance (or delegated authority)	
Name	Dr. Palitha MAHIPALA	Name	Mr P.B.S.C.Nonis
Date		Date	
Signature		Signature	

Proof of involvement of the Ministry of Education will also be required for HPV Routine Support. The Ministry of Education will either have to be involved in the ICC process (preferred option) and/or the Minister of Education (or delegated authority) must provide its signature. The signature is attached as DOCUMENT NUMBER : {0} in Section 10. Attachments.

Minister of Education (or delegated authority)	
Name	Mr. H.U.Premathilake
Date	
Signature	

This report has been compiled by (these persons may be contacted in case the Gavi Secretariat has queries on this document):

Full name	Position	Telephone	Email
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Dr. Deepa GAMAGE	Consultant Epidemiologist	+94 777 295 158	deepagamage@gmail.com
Dr. Paba PALIHAWADANA	Chief Epidemiologist	+94 777 291 441	paba@epid.gov.lk
Dr. SamithaGINIGE	Consultant Epidemiologist	+94 777 664 036	samithg@hotmail.com

4.1.2. National Coordinating Body - Inter-Agency Coordinating Committee for Immunisation

Agencies and partners (including development partners and NGOs) supporting immunisation services are coordinated and organised through an inter-agency coordinating mechanism (ICC, Health Sector Coordinating Committee (HSCC), or equivalent committee). The ICC, HSCC, or equivalent committee is responsible for coordinating and guiding the use of the Gavi NVS routine support and/or campaign support. Please provide information about the ICC, HSCC, or equivalent committee in your country in the table below.

Profile of the ICC, HSCC, or equivalent committee

Name of the committee	National Advisory Committee on Communicable Diseases (NACCD)
Year of constitution of the current committee	2016
Organisational structure (e.g., sub-committee, stand-alone)	Chairperson, Secretariat, Members
Frequency of meetings	quarterly

The Terms of Reference or Standard Operating Principles for the ICC, including details on the ICC membership, quorum, dispute resolution process and meeting schedules is attached as DOCUMENT NUMBER : 4.

Major functions and responsibilities of the ICC/HSCC:

In Sri Lanka , NACCD function as an integrated committee of the NITAG and ICC.

The main purpose of this advisory committee is to provide guidance to the Ministry of Health, Sri Lanka on prevention and control of communicable diseases in Sri Lanka.

Members must have specialist knowledge and expertise in designated areas and are appointed to the NACCD for the purpose of providing expert advice in relation to matters covered under the preview of the committee.

Major functions:

- Review national policies, strategies, priorities and plans for prevention, control, elimination and/or eradication of communicable diseases.
- Make recommendations on prevention, control, elimination and/or eradication of communicable diseases.
- Provide guidance on new vaccine introduction and Immunization schedule change
- Advise on monitoring & evaluation of prevention, elimination and/or eradication of vaccine preventable and other communicable diseases.
- Identify and advise on appropriate operational research on communicable diseases
- Advocate and promote linkages and liaise with global and regional bodies on communicable diseases

Please describe how partners have provided support in preparation of the proposal:

NACCD members discussed the importance of introduction of HPV in to National EPI shedule in March 2015.

Appointed an Expert Working Group on HPV consisted of all relevant experts (Chief Epidemiologist, Epidemiologists, Oncologists, Pathologists, Microbiologists, Community Physicians, National Cervical Cancer Screening Programme Manager, National Cancer Control Programme Manger, Veneriologists, Pharmacologists, Gynaecologists, Paediatricians, Physicians, School Health Programme Manager, representatives from Professional Colleges, few community representatives

Committee reviewed all relevant country disease burden, research findings, other country experiences, regional and global information on cervical cancer and HPV vaccines. Committee met with 3 occassions and developed a concept paper suggesting introduction of HPV vaccination into the National Immunization Programme, targeting girls of 11-12 year old, through school based Immunation programme. The Concept paper has been submitted to the NACCD and unanimously endorsed by NACCD held on June 2015.

Same sub committee was assigned to study the most suitable vaccine type to the country and appropriate implementation strategies to achieve maximum coverage.

The subcommittee recommended that quadrivalent HPV vaccine through school based programme.

NACCD members unanimously endorsed subcommittee decisions

4.1.3. Signature Table for the Coordinating Committee for Immunisation

We the members of the ICC, HSCC, or equivalent committee [1] met on the **04/03/2016** to review this proposal. At that meeting we endorsed this proposal on the basis of the supporting documentation which is attached. The minutes of the meeting endorsing this proposal are attached as Document number 5. The signatures endorsing the proposal are attached as Document number 6 (please use the list for signatures in the section below).

Please refer to Annex C of the 'Gavi HSS and NVS General Guidelines' for more information on ICCs.

Function	Title / Organisation	Name	Please sign below to indicate the attendance at the meeting where the proposal was endorsed	Please sign below to indicate the endorsement of the minutes where the proposal was discussed
Chair	Director General of Health Services	Dr. Palitha MAHIPALA		
Secretary	Chief Epidemiologist	Dr.Paba PALIHAWADANA		
Members	signatures with details attached	yes		

By submitting the proposal we confirm that the quorum has been met. **Yes**

The minutes from the three most recent ICC meetings are attached as DOCUMENT NUMBER : 7.

4.2. National Immunization Technical Advisory Group (NITAG)

Has a NITAG been established in the country ? **Yes**

We the members of the NITAG met on the **04/03/2016** to review this proposal. At that meeting we endorsed this proposal on the basis of the supporting documentation describing the decision-making process through which the recommendations were reached, attached as Document number 26.

4.2.1. The NITAG

Profile of the NITAG

Name of the NITAG	NACCD
Year of constitution of the current NITAG	2016
Organisational structure (e.g., sub-committee, stand-alone)	NITAG integrated to NACCD
Frequency of meetings	quarterly

Function	Title / Organisation	Name
Chair	Director General of Health Services	Dr.Palitha MAHIPALA
Secretary	Chief Epidemiologist	Dr. Paba PALIHAWADANA
Members	attached with details doc 8	

Major functions and responsibilities of the NITAG

In Sri Lanka , NACCD function as an integrated committee of the NITAG and ICC.

The main purpose of this advisory committee is to provide guidance to the Ministry of Health, Sri Lanka on prevention

and control of communicable diseases in Sri Lanka.

Members must have specialist knowledge and expertise in designated areas and are appointed to the NACCD for the purpose of providing expert advice in relation to matters covered under the preview of the committee.

Major functions:

- Review national policies, strategies, priorities and plans for prevention, control, elimination and/or eradication of communicable diseases.
- Make recommendations on prevention, control, elimination and/or eradication of communicable diseases.
- Provide guidance on new vaccine introduction and Immunization schedule change
- Advise on monitoring & evaluation of prevention, elimination and/or eradication of vaccine preventable and other communicable diseases.
- Identify and advise on appropriate operational research on communicable diseases
- Advocate and promote linkages and liaise with global and regional bodies on communicable diseases

In the absence of a NITAG, countries should clarify the role and functioning of the advisory group and describe plans to establish a NITAG. This document is attached as **(Document Number: 8)**

5. Immunisation Programme Data

5.1 Background information

Please complete the table below, using data from available sources. Please identify the source of the data, and the date. Where possible use the most recent data and attach the source document.

- Please refer to the Comprehensive Multi-Year Plan for Immunisation (cMYP) (or equivalent plan) and attach a complete copy (with an Executive Summary) as DOCUMENT NUMBER 9. Please attach the cMYP costing tool as DOCUMENT NUMBER 10.
- Please attach relevant Vaccine Introduction Plan(s) as DOCUMENT NUMBER : 12
- Please refer to the two most recent annual WHO/UNICEF Joint Reporting Forms (JRF) on Vaccine Preventable Diseases
- Please refer to Health Sector Strategy documents, budgetary documents, and other reports, surveys etc, as appropriate.
- Please refer to the attached risk assessments in the case of yellow fever and meningitis A mass preventive campaigns.

Please use the most recent data available and specify the source and date.

	Figure	Year	Source
Total population	20,966,000	2015	Department of censuses & Statistics
Birth cohort	334,821	2015	Register Generals Department
Infant mortality rate (per 1000)	9	2014	Family Health Bureau
Surviving infants ^[1]	331,808	2015	Family Health Bureau
GNI per capita (US\$)	3,191	2013	Central Bank Report
Total Health Expenditure (THE) as a percentage of GDP	3	2013	Central Bank
General government expenditure on health (GGHE) as % of General government expenditure	6	2014	central Bank

[3] Surviving infants = Infants surviving the first 12 months of life

5.1.1 Lessons learned

Routine New Vaccines Support

If new or under-used vaccines have already been introduced in your country, please give details of the lessons learned from previous introduction(s) specifically for: storage capacity, protection from accidental freezing, staff training, cold chain, logistics, coverage and drop-out rates, wastage rate, etc., and suggest action points or actions taken to address them. Please refer to previous Post Introduction Evaluations (PIE), if applicable. If they are included in the Introduction Plan, please cite the section only. If this information is already included in NVIP/POA, please reference the document and in which section/page this information can be found.

Lessons Learned	Action Points
country has introduced Pentavalent vaccine in 2008 and Live JE vaccine in 2009.	cold chain maintenance, staff training, logistics and achieving high coverage (>95%) has been successfully achieved soon after introduction

5.1.2 Health planning and budgeting

Please provide information on the planning and budgeting cycle in your country

Annual planning and budgeting cycle

Please indicate the name and date of the relevant planning document for health

Annual National Budget document 2015 : health component

Is the cMYP (or updated Multi-Year Plan) aligned with the proposal document (timing, content, etc.)

yes

Please indicate the national planning budgeting cycle for health

annual

Please indicate the national planning cycle for immunisation

annual

5.1.3 Gender and equity

Please describe any barriers to access, utilisation and delivery of immunisation services at district level (or equivalent) that are related to geographic, socio-economic and/or gender equity. Please describe actions taken to mitigate these barriers and highlight where these issues are addressed in the vaccine introduction plan(s).

All citizens have equitable access to free immunization services irrespective of socio-economic conditions, geographical distributions and gender

Discuss how equity issues (geographic, socio-economic and/or gender) are being taken into account in the design of social mobilisation and other strategies to increase immunisation coverage. Highlight where these issues are addressed in the vaccine introduction plan(s).

not seen and not applicable in Sri Lanka, All districts have achieved constant high immunization coverage for all antigens

However, in social mobilisation campaigns in new vaccine introduction, country take measures to convey messages in all three languages, publications are available in both sinhala and tamil in addition to English which could easily reach all citizens in all races

All immunization related messages are given in both sinhala and tamil in addition to English to reach all citizens in the country

Country is divided into provinces which has provincial health authorities including Consultant Community Physicians (Specialists) , district health authorities including Regional Epidemiologists (Medical Officers) and Medical Officers Maternal and Child Health (MO/MCH) who are responsible for provision of equitable services in their respective districts. Grass root level health staff of Medical Officers of Health (MOH) and their staff of Public Health nursing sisters , Public Health Inspectors and Public Health Midwives are providing house to house services at community level and no geographic area is left out in the country without receiving domiciliary services by Public Health Midwife. This shows how the equitable services providing immunization in the country

Schools are having School medical inspection (SMI) services providing at Grade 4, 7 and 10. immunization services are integrated with school health, means if need any immunization services to be provided same health staff who provides area community immunization services are responsible in providing SMI and necessary awareness and screening and follow up will be done through SMI service access in each school, Currently aTd vaccination (in Grade 7) is being given through schools and achieving >80% coverage for the denominator of children on roll in schools.

Country is having a past history of Rubella vaccination in Grade 8 and had achieved high coverage around

90%

HPV vaccination also can be provided through schools at Grade 6 with a gap of 6 months. after Grade 6 school transicion is less and same field health staff involved in immunization providing the school vaccination services it is easy to follow them up and vaccinate with the second dose

school drop out is very low in Sri Lanka till children reach Grade 10. Even though , few drop out children if any can be vaccinated through MOH conducted community clinics because the same staff in the area involved in school vaccination as well as the field level immunization services. These children and any children missed vaccination due to abscentism can be easily identified during domiciliary care provided by the area public health midwife

Please indicate if sex disaggregated data is collected and used in immunisation routine reporting systems.

This information is available at Divisional levels. Those were reviewed during Annual district and divitional level reviews

Is the country currently in a situation of fragility (e.g. insecurity, conflict, post-conflict, refugees/and or displaced persons and recent, current or potential environmental disaster, such as flooding, earthquake or drought or others)? If Yes, please describe how these issues may impact your immunisation programme, planning for introduction of routine vaccines or campaigns and financing of these activities.

Currently no such situation exists

Possible disaster situations

If available, please provide additional information and documents on subnational coverage data, e.g. comparing urban/rural districts or districts with highest/lowest coverage, etc.

not relevant

During conflict situation (even before 2009), Immunization services have been provided and continued. This has been proven by Immunization coverage surveys and sero surveys (Polio & measles) conducted in conflict affected districts after 2009.

Conflict situation was over in 2009. Since then , there was an organized resettlement programmes in the country and currently no refugee camps or displaced persons in the country. Country is functioning with normal health care infra-structure. All citizens has equal access to free healthcare situation.

In general country is not prone to large scale natural disasters. however, in any event of potential environmental disasters, countrydisaster contingency plans usually includes provision of Immunization services.

Country has well established time tested free healthcare delivery system which includes Immunization services with easy access through Public health services.

5.1.4 Data quality

Please attach a data quality assessment (DQA), report that has been completed within the previous 48 months with the most recently conducted national survey containing immunisation coverage indicators (DOCUMENT NUMBER: 27) and an immunisation data quality improvement plan (DOCUMENT NUMBER 28). If available, a progress report on the implementation of the improvement plan should also be submitted (DOCUMENT NUMBER: 11, DOCUMENT NUMBER: 28).

Please indicate what routine mechanisms to independently assess the quality of administrative data are in place, and if so what these mechanisms are and how they enable the country to track changes in data quality over time.

Quartely National Regional Epidemiologists' reviews: Regional Epidemiologists are appointed for all administrative districts. They are responsible for planning, implimentation, monitoring and evaluation of all activities of National Immunization programme at district level. Their activities are routinely reviewed quarterly

in these reviews and if gaps identified necessary timely actions will be taken. This reviews are conducted by National Immunization Programme managers and the team.

District reviews conducted by provincial and district authorities : District and Provincial level health authorities conduct monthly reviews in each district including immunization activity reviews to improve the system

Annual EPI reviews conducted by National EPI teams at district level : Detailed annual performances at Divisional (Medical Officer of Health) and grass root level (Public health Midwife level & Public Health Inspector-school vaccination) are reviewed in detail in the presence of all relevant key stakeholders. These reviews are conducted at each district by National, provincial and district health authorities. Gaps identified and timely recommendations and followup will be done accordingly

Field level EPI coverage surveys in selected districts: Field level coverage surveys are conducted periodically based on WHO recommended methodology

Please detail what household surveys have been conducted in recent years to independently assess immunisation coverage and equity, and describe any survey plans for the coming five year period.

EPI coverage survey: Nuwara Eliya -March 2016

EPI coverage survey in districts of Killinochchi and Mullaitivu: 2014

Plan to conduct further coverage survey in 2017

In all reviews we have observed equity in provision of immunization services to all social categories, and both sex categories. No any population is left out and no specific population categories identified with vaccine hesitancies or refusals. All antigens reviews have achieved very high coverages above 80%

5.1.5 HPV specific facts

Please demonstrate country's ability to deliver a complete multi-dose series of vaccines to at least 50% of a one-year cohort selected from the population of 9-13 year old girls the target vaccination cohort in at least one typical district using a similar strategy to the one proposed for HPV vaccine delivery. For each district, fill-in:

District Information	
Name of the district	covering whole country
Size of population of the district	
Describe how the district is divided into rural and urban areas:	country plan to introduce through National Programme on Immunization through Schools for 10-11 year old girls. Country has already demonstrated ability to achieve high vaccination coverage for Rubella vaccination and aTd vaccination through school based programme Vaccination programme implementation considered districts and divisions

Please specify what was the multi-dose vaccine used (HPV/TT/others)? What was the vaccination schedule?

BCG at birth

Pentavalent: 2,4,6 months

OPV :2,4,6,18 months and 5 years

IPV : 4 months

MMR: 9 months and 3 years

LJEV: 1 year

DPT: 18 months

DT: 5 years

aTd 12 years_ vaccine coverage achieved 87% in 2016 (JRF) Vaccine delivery is done by the area specific public health staff (Medical Officer of Health staff) involved in other immunization services in the area.

In Sri Lanka School Medical Inspection (SMI) services are available in which Immunization, vitamin treatment, Iron treatment, worm treatment are provided and children are screened for hearing, visual, cardiac or any other health issues and referrals and follow ups are being done.

HPV vaccination also can be integrated with the existing programme and plan to provide vaccination in Grade 6 in 2 dose schedule with a gap of 6 month in between. It is not difficult to identify children and vaccinate as after Grade 5, and by Grade 6 children moving between schools is minimal. In fact follow up of children with proper registration to identify them for the second dose is not difficult. If any absentees can be identified and vaccination can be provided from the Maternal and Child Health clinic at community level conducted by the same area specific public health staff (MOH staff). Public health midwife is doing field visits to provide domiciliary care and such children with possible drop outs can be easily identified and can be referred for HPV vaccination. Same procedure is carried out currently for aTd vaccination given in Grade 7 and has the past history of same procedure carried out for Rubella vaccination and achieved very high coverage of above 90%

TT: pregnancy

Describe the vaccination strategy used (school based, health centre based, mixed)? How was it carried out, who carried it out, who was the lead department/agency? What age/sex was the multi-dose vaccine delivered to? If it was school based, how many schools were targeted? Was it age based or grade based?

aTd 12 years: School based/grade based

target population: 345,000

In Sri Lanka well planned time tested School Medical Inspection Programme (SMI) is in place, covering all schools in the country including government and private schools. In SMI all children are screened in Grade 1, Grade 4 & in Grade 7 for their health status and Immunization status. If found any deficiency or defect. those

will be corrected.

SMI coverage in Sri Lanka is near 100%.

In Sri Lanka Primary education (<15 years) is mandatory and free education is available with easy access to all. In fact school enrolment rate is very high (>95%). Current school dropout rate is very low (<5%) by Grade 7.

What was the number of targeted population? What was the number in target population who started the multi-dose series? What was the number in the target population who received all doses?

aTd vaccination is given as a school based vaccination at grade 7 (12 years of age) . Missed children are provided vaccination at Field Immunization clinic at routine clinics.

target population in Grade 7 is 345,000

aTd is given as a single dose at 12 years of age as a component of National Immunization programme as intergrated programme with School Medical Inspection.

This activity is jointly coordinated at each level (National, district and divisional) by relevant authorities in the Ministries of Health and Education.

Vaccination is conducted at any time of the year, based on allocated targets for each areas (responsible by Medical Officer of Health and Educational authorities)

Individual cost estimations for separate vaccines have not been done. Curretly Immunization programme costing study is going on and results are not available yet. School based vaccination programmes as part of National Immunization programme is carried out as an integrated services of Maternal and child health services.

Please provide the source of data for estimation of the target population:

Target population is taken as number enrol at Grade 7 at both goverment and private schools.

Source of the target population is from School Medical Inspection Return and source for the return is from enrolment registers at each divisional levels.

If applicable, please detail what additional people beside the target population also received the vaccine:

not applicable

Table 5.1.5: (Please refer to WHO/UNICEF JRF)

Girl age	HPV 1st dose	HPV 2st dose	HPV 3st dose
9 years old			
10 year old			
11 year old			
12 year old			
13 year old			
14 year old			
15+ year old			
Unknown			

Was there an evaluation of the 'project'? If so, who performed it? Please provide a short summary of the evaluation methodology and/or provide the evaluation report if available (Document number No: 16). Please ensure this summary (and/or the attached report) includes a costing analysis of the proposed delivery strategy or strategies. Refer to section [10. Attachments](#).

not applicable, not done HPV demonstrattion project and plan to introduce as the National programme

5.2. Baseline and Annual Targets (NVS Routine Support)

Please refer to cMYP pages to assist in filling-in this section.

Number	Base Year	Baseline and Targets
	2015	2017
Total births	334,821	350,000
Total infants' deaths	3,013	2,800
Total surviving infants	331,808	347,200
Total pregnant women	5,288,000	5,300,000
Target population vaccinated with OPV3[1]	327,170	346,500
OPV3 coverage[2]	99 %	100 %
Target population vaccinated with DTP1[1]	327,552	346,500
Target population vaccinated with DTP3[1]	327,170	346,500
DTP3 coverage[2]	99 %	100 %
Wastage[3] rate in base-year and planned thereafter (%) for DTP	8	8
Wastage[3] factor in base-year and planned thereafter for DTP	1.09	1.09
Number of girls in the target cohort	167411	175000
Target population vaccinated with 1st dose of HPV	0	175,000
Target population vaccinated with the last dose of HPV	0	175,000
HPV quadrivalent coverage 1st dose	0 %	100 %
HPV quadrivalent coverage last dose	0 %	100 %
First Presentation: HPV quadrivalent, 1 dose(s) per vial, LIQUID		
Wastage[3] rate in base-year and planned thereafter (%)	0	5
Wastage[3] factor in base-year and planned thereafter (%)	1.00	1.05
Maximum wastage rate value for HPV quadrivalent, 1 dose(s) per vial, LIQUID	5 %	5 %
Target population vaccinated with 1st dose of MCV	329,726	348,250
MCV coverage[2]	99 %	100 %
Annual DTP Drop out rate [(DTP1 – DTP3) / DTP1] x 100	0 %	0 %

[1] Indicate total number of children vaccinated with either DTP alone or combined

[2] Number of infants vaccinated out of total surviving infants

[3] The formula to calculate a vaccine wastage rate (in percentage): $[(A - B) / A] \times 100$. Whereby: A = the number of doses distributed for use according to the supply records with correction for stock balance at the end of the supply period; B = the number of vaccinations with the same vaccine in the same period.

5.2.1 HPV specific targets

Single year cohort of girls to be vaccinated with HPV should be within the WHO-recommended target population of 9-13 years old girls

Please specify the source of data that was used to estimate the number of girls in target and reported in the above table under "Target population vaccinated with HPV"

Target age group is 11 years of age., 175,000 population, 2 vaccine doses

Source information - Register general of Births data

5.3. Targets for Preventive Campaign(s)

No NVS Prevention Campaign Support this year

5.4. Targets for One time mini-catchup campaign(s)

No One time mini-catchup campaign this year

6. New and Under-Used Vaccines (NVS Routine)

6.1. Assessment of burden of relevant diseases (if available)

If already included in detail in the Introduction Plan or Plan of Action, please cite the section only.

Disease	Title of the assessment	Date	Results
cervical cancer	National cancer registry data	2009	Number of new cases 879 ASR 8.7/100,000

6.1.1 HPV burden specific information

Has the country undertaken an assessment of the burden of cervical cancer? If so, describe the burden, and when and how the assessment was done. If not, countries may report on Globocan data (available on the WHO HPV information Centre website at <http://www.who.int/hpvcentre/en>).

Cervical cancer burden : new cases 879, ASR 8.7/100,000 women population (National Cancer Registry 2009)

HPV community prevalence among clinically normal women of 20-59 year age group (District of Gampaha, Sri Lanka) : 3.3%, HPV 16 and 18 among them: 1.2%

Risk attribution (PAR%): 69%

Describe the existing cervical cancer prevention and control activities.

Early detection by Pap smear screening, through community level Well Women Clinic programme

Has the country developed a roadmap or strategy for establishing or strengthening a national comprehensive approach to cervical cancer prevention and control? **Yes**

If Yes, please attach and refer to section [10. Attachments](#). (Document N°15)

If No, are there plans for the country to develop such a roadmap or strategy in the future? Please describe-when, who will be leading the development of the plan, and which agencies will be involved.

Guidelines are available with Cervical Cancer control programme and National Cancer Control Programmes, Ministry of Health

6.1.2 Delivery strategy for HPV vaccine

Please specify the chosen age cohort for HPV vaccination: **11 years old**

Please describe the HPV vaccination strategy and plan (when vaccinations will be scheduled, where vaccinations will be administered, who will do vaccinations, how will the vaccine logistics be assured, the plan to ensure all recommended doses are delivered, and plans for reaching girls who may be absent on the day of scheduled vaccinations, etc.)

Scheduled to start from January 2017 : Advisory Committee on Communicable Diseases which functions as NITAG has already taken a decision to start the HPV vaccination introduction in January 2017. Basic preparatory work in this regard has already been started. In fact we are not in a position change NITAG decision. However, Ministry component of remaining 50% of the vaccine procurement is in process.

two doses will be given in 6 months apart as part of school medical inspection including both government and private schools.

Through school based programme and absentees or if any dropouts (very low among 11 years in Sri Lanka) will be vaccinated at nearest field level Immunization clinics, in the similar way for other school based vaccines (aTd). After SMI, Public Health Inspectors are following up together with relevant Class teachers for absentees and refer them to Immunization clinics. Public Health Midwives are following them up at field level

home visits and if any drop outs also will refer to the nearest Immunization clinic for vaccination.

All vaccines given at school based programmes are available at all field/hospital Immunization clinics. Same Field level health staff is conducting relevant school programmes and vaccination data available with them for relevant updates required.

School based vaccinations are also carried out by divisional level Public Health Team headed by Medical Officer of Health in respective areas

Same teams will follow up with keeping records to deliver the 2nd dose

Main responsible person is Public health Inspectors (PHI) for the School Health and they work in close relationship with their respective area schools. In HPV vaccination plan to develop a separate Register to register children by Grade and by Class for each and every school. PHI will re-visit their respective schools after 6 months for relevant reminders for parents and measures will be taken to vaccinate for the 2nd dose. As the same area public health staff work as a team and visit schools it will not be difficult to identify children and vaccinate. In Sri Lanka usually Friday is expected to do work for School Medical Inspections and for school based vaccinations and it can be organized within the system to achieve high coverage for HPV

Irrespective of the strategy, provide a description of existing health services and/or health education currently being provided to young adolescents (both girls and/or boys) within the 9-13 year old age group and indicate and potential synergy by integrating with HPV vaccination:

a. For health services (this can include: what health services are provided, to which age/sex group, whether it's mandatory or voluntary, regularly or ad-hoc, in school or out of school, who provides these (government, NGOs), how often, what is the uptake in the community, how is it perceived by the community.)

Strategy of routine School Medical Inspection is existing in Sri Lanka for addressing health needs of school children. Health education for children, parents and teachers are integrated in the school medical inspection. AS a component of SMI all the children and parents are educated on health needs (Immunization, nutrition, hygiene, sanitations, referrals and follow up, dental care etc.,etc..) and address to relevant requirements.

Schools Immunization programmes are usually integrated in to School Medical Inspection which provide services to assess Nutritional status (Ht, Wt), screening for heart diseases, Vision, Hearing, skin diseases, congenital abnormalities, Dental screening, Immunization status (all included in the Child Health Development Record-Sri Lanka). Once HPV vaccination started, it also will be implemented as an integrated programme to SMI

educate and aware during home visits by Public Health Midwives

Public seminars integrated messages of cervical cancer screening for mothers and at the same time disseminate message to mothers to vaccinate girls of 11 years at Grade 6

b. For health education (this can include: the topic, whether it is national, sub-national, in school or out of school, who provides the education, how often, is it in the school curriculum, are there NGOs providing these? How is it perceived by the community? Has there been an evaluation and if so, how was it evaluated and what were the findings?)

Ministry of Health and Ministry of Education collaboratively plan to conduct HPV vaccination awareness and education

Please describe the communications and social mobilisation plan for the HPV vaccination strategy (what activities will be done to educate and raise awareness of the vaccination plan to the target population, their parents/guardians, the wider community, community leaders, groups of influence, etc.; who will provide this education and what materials will be used; how often will these activities occur vis-a-vis the proposed vaccination schedule.)

Communication and mobilization will be done using prevailing public health infrastructure, mass media and using other communication materials

- Awareness and training programmes will be conducted for all stakeholders (for both Health and Education Ministry authorities, National level, Provincial, District and Divisional level), involved in provision of immunization and school medical services at national level and at district level. This is

expected to improve the awareness and knowledge which required sensitizing and aware the community in gaining confidence and creating demand.

- Media seminars will be conducted at National level and at district level for enhancing dissemination of messages required for community awareness and gaining confidence of the public for HPV vaccination as well as to create demand among the public to accept HPV vaccination
- TV spots and media discussions will be conducted, newspaper articles, leaflets and other printed materials, video clips will be prepared and published to disseminate the message among the public in all 3 languages of English, Sinhala and Tamil, will be used through district level public health personnel in disseminating necessary messages in HPV vaccine introduction to the public.
- Combination of cervical cancer screening strengthening messages in which services are already existing for mothers, health education sessions at Antenatal clinics in health care institutions and maternal and child health clinics and Well Woman Clinics will be used in dissemination of messages to parents through health care personnel.
- Awareness and motivation will be done through Public Health Midwives during their home visits

Please select strategy that the country will choose to deliver the HPV vaccine: **School-based strategy**

School-based strategy

Describe the education system in the country:

INSTRUCTIONS

Description should include:

Primary/secondary/tertiary, grades in each category, majority age in each grade

Number of schools in the country (public/government schools, private school, or other categorization if possible and relevant for the country)

What is the school year (which month to which month)

When are the school holidays? (Approximated months, days if possible)

When are the major examinations? (Approximated month)

Sri Lanka is having free access to primary, secondary and tertiary education

Total number of Government schools in the country =10012, Private schools = 103 (2013)

Primary education is mandatory by law, All children have an equitable access to education,

School year starts from January and end in December

School holidays are 2 weeks to 1 month in months of April, August and December

Major examinations are held in August and December

Please specify whether girls will be vaccinated by selection of a **Specific age**

Table 6.1.2 a

Number of	Base year	Target year
	2015	2017
Target population of girls in chosen age	167,411	175,000
Girls of chosen age enrolled in schools	167,411	175,000

If girls are to be vaccinated by a specific **grade**, please specify grade and provide the below data relative to the target grade:

Table 6.1.2 b

Age of girls in grade	Number of girls in grade / age	% of girls in targeted population
8 years old	0	0
9 years old	0	0
10 years old	0	0
11 years old	0	0
12 years old	0	0
13 years old	0	0
14 years old	0	0
TOTAL girls 9-13 years old	0	0
TOTAL girls 14 years old and above	0	0
TOTAL	0	0

Note:

(1) To add new *Age of girls in grade*, click on the **New item** icon in the **Action** line. Use the **Delete item** icon to delete a specific *Age of girls in Grade*.

Please provide a source for the enrolment data (e.g., national statistics office, MOE, recent census, school registers, etc.)

Ministry of Education

total number estimated for grade 6 is 350,000.

How will the school-based strategy capture those girls not in school? (Will out-of-school girls be invited to join school-attending girls on the days of vaccination? Will separate outreach sessions be scheduled for them? Will existing outreach posts be used? Will out-of-school girls be asked to come to the local health center? Will vaccination nurses do home visits?)

In Sri Lanka primary education is mandatory, non school going rate is negligible, if any, vaccination will be provided through the field level immunization clinics

Public Health Midwives are doing field level services including field visits. Out of school girls will be identified (very low numbers) and referred for HPV vaccination at field clinics. 2nd dose will be delivered in the same way. Each Midwife is having a target population to be served around 3000.

If any, please describe special considerations to be made for marginalised or migrating populations?

no such marginalized populations

All populations at field level including if any social disadvantages are also under care of relevant grass root level field health care workers of Medical Officer of Health, Public Health Mid wife and Public Health Inspector. They are accountable for providing equal services for all.

Health center-based strategy

Sri Lanka strategy to deliver HPV vaccine does not include a "Health center-based strategy"

6.2. Requested vaccine (HPV quadrivalent, 1 dose(s) per vial, LIQUID)

As reported in the cMYP, the country plans to introduce HPV quadrivalent, using HPV quadrivalent, 1 dose(s) per vial, LIQUID.

When is the country planning to introduce this vaccine? **January 2017**

Please note that, due to a variety of factors, the launch date may vary compared to the date stipulated in the application. Gavi will work closely with countries and their partners to address these issues.

Please summarise the cold chain capacity (at central and other levels) and readiness to accommodate new vaccines, taking into consideration training, cold chain equipment and other logistical requirements. If cold chain expansion is required, state how it will be financed, and when it will be in place. The Independent Review Committee requires assurance that the cold chain is ready or will be ready for the routine introduction of the new vaccine, and evidence/plans need to be provided. All proposals that include Gavi- financing for cold chain equipment intended for vaccine storage shall need to procure equipment pre-qualified by WHO under their Performance Quality and Safety (PQS) program. The purchase of non-PQS equipment will only be considered on an exceptional basis, with justification and advance agreement from Gavi.

Recently conducted EVM assessment identified the adequacy of cold chain capacity for new vaccine of HPV introduction

No need of cold chain expansion at central level as well as district and divisional level

6.2.1. Co-financing information

The co-financing policy does not apply for this exceptional opportunity.

6.2.2. Specifications of vaccinations with new vaccine

	Data from		2017
Number of children to be vaccinated with the first dose	Table 5.2	#	175,000
Number of children to be vaccinated with the second dose	Table 5.2	#	175,000
Immunisation coverage with the second dose	Table 5.2	%	100%
Country share of total needs	Parameter	%	50.00%

6.2.3. Portion of supply to be procured by the country (and cost estimate, US\$)

		2017
Number of vaccine doses	#	229,700
Number of AD syringes	#	245,241
Number of re-constitution syringes	#	0
Number of safety boxes	#	0
Total value to be funded by the Country	\$	1,065,316

6.2.4. Portion of supply to be procured by Gavi (and cost estimate, US\$)

		2017
Number of vaccine doses	#	229,700
Number of AD syringes	#	245,241
Number of re-constitution syringes	#	0
Number of safety boxes	#	0
Total value of Gavi support	\$	1,065,315

6.2.5. New and Under-Used Vaccine Introduction Grant

Calculation of Vaccine Introduction Grant for the HPV quadrivalent, 1 dose(s) per vial, LIQUID

Year of New Vaccine Introduction	Girls in cohort (From Table 5.2)	Share per Girls in cohort in US\$	Total in US\$
2017	175,000	2.40	420,000

The Grant will be based on a maximum award of \$2.40 per girl in the birth cohort with a minimum starting grant award of \$100,000

Please describe how the Gavi Vaccine Introduction Grant will be used to facilitate the timely and effective implementation of critical activities in advance of and during the introduction of the new vaccine (refer to the cMYP and the Vaccine Introduction Plan).

Social mobilization, IEC, Advocacy for stakeholders at each level- National, District and Divisional and for public

Production of IEC materials

Training of health staff on vaccination, safety monitoring and

Cold chain quipment and maintenance

Vehicle and transportation

Surveillance and monitoring

Post introduction evaluation

Operational research on implementation

Stregthening of district level cold room facility

Please complete the 'Detailed budget for VIG / Operational costs' template provided by Gavi and attach as a mandatory document in the Attachment section.

Detailed budget attached as Document No. 22.

Where Gavi support is not enough to cover the full needs, please describe other sources of funding and the expected amounts to be contributed, if available, to cover your full needs.

Government of Sri Lanka

6.2.6. Technical assistance

Please describe any particular area(s) the Ministry would require technical assistance to support the introduction of HPV quadrivalent.

7. NVS Preventive Campaigns

No NVS Prevention Campaign Support this year

8. Procurement and Management

8.1 Procurement and Management of New and Under-Used Vaccines Routine

Note: The PCV vaccine must be procured through UNICEF to be able to access the price awarded by the Advance Market Commitment (AMC).

a) Please show how the support will operate and be managed including procurement of vaccines (Gavi expects that most countries will procure vaccine and injection supplies through UNICEF or PAHO's Revolving Fund):

Procure through UNICEF

b) If an alternative mechanism for procurement and delivery of vaccine supply (financed by the country or the Gavi) is requested, please document

- A description of the mechanism and the vaccines or commodities to be procured by the country
- Assurance that vaccines will be procured from the WHO list of pre-qualified vaccines, indicating the specific vaccine from the list of pre-qualification. For the procurement of locally-produced vaccines directly from a manufacturer which may not have been prequalified by WHO, assurance should also be provided that the vaccines purchased comply with WHO's definition of quality vaccines, for which there are no unresolved quality problems reported to WHO, and for which compliance is assured by a fully functional National Regulatory Authority (NRA), as assessed by WHO in the countries where they are manufactured and where they are purchased.

not applicable

c) If receiving direct financial support from Gavi (such as operational support for campaigns or VIG activities), please indicate how the funds should be transferred by Gavi.

Transfer to Ministry of Health account, Sri Lanka

d) Please indicate how the co-financing amounts will be paid (and who is responsible for this)

not applicable

e) Please describe the financial management procedures that will be applied for the management of the NVS direct financial support, including procurement.

As GAVI agreed to provide 50% of vaccine cost for the initiation year (2017)

Remaining 50% of the vaccine cost will be borne by the Government of Sri Lanka, This amount has been already included into the budget estimate of 2017,

f) Please outline how coverage of the introduced vaccine will be monitored, reported and evaluated (refer to cMYP and Introduction Plan)

HPV vaccine also introduced as a routine NIP vaccine and existing time tested vaccination monitoring and evaluation will be used

g) If applying for measles second dose, does the country wish to have the support in cash or in-kind? **N/A**

8.2 Procurement and Management for NVS Preventive Campaign(s)

No NVS Prevention Campaign Support this year

8.3 Product Licensure

For each of the vaccine(s) requested, please state whether manufacturer registration and/or national vaccine licensure

will be needed in addition to WHO prequalification and, if so, describe the procedure and its duration. In addition, state whether the country accepts the Expedited Procedure for national registration of WHO-prequalified vaccines.

Note that the necessary time for licensure should be factored into the introduction timeline and reflected in the Vaccine Introduction Plan or Plan of Action.

yes, In addition to WHO prequalification, registration with National Medicinal Drug Regulatory Authority is mandatory. Quadivalent HPV vaccine is already registered in the country and currently used in the private health sector

HPV vaccine single dose vial and 2 dose schedule both are registered in Sri Lanka for quadivalent vaccine

For licensure procedure in NMRA, Dossiers have to be submitted by the supplier or by the local agent to NMRA and reviewed by 3 independent experts. After that, their comments will be considered and reviewed by the Medicines Evaluation Committee of experts and decision will be taken for registration

For each of the vaccine(s) requested, please provide the actual licensure status of the preferred presentation and of any alternative presentations, if required.

HPV vaccine is already registered. In event of any alteration of presentation need to be re-registered

Registration of licensure issued for 3 years, and last updated for Quadivalent vaccine in 2016

Please describe local customs regulations, requirements for pre-delivery inspection, special documentation requirements that may potentially cause delays in receiving the vaccine. If such delays are anticipated, explain what steps are planned to handle these.

Medical Supplies Division of the Ministry of Health involved in clearance for vaccines without delay from customs

no such delays anticipated

Please provide information on NRA in the country, including status (e.g. whether it is WHO-certified). Please include points of contact with phone numbers and e-mail addresses. UNICEF will support the process by communicating licensing requirements to the vaccine manufacturers where relevant.

NRA is an independent statutory authority. WHO certified

current Chairperson: Prof. Lal Jayakody, jayakodyrl@hotmail.com

8.4 Vaccine Management (EVSM/EVM/VMA)

It is mandatory for countries to conduct an Effective Vaccine Management (EVM) assessment prior to an application for the introduction of a new vaccine. This EVM should have been conducted within the preceding **5 years**.

When was the EVM conducted? **July 2015**

Please attach the EVM improvement plan progress report (DOCUMENT NUMBER:21); and if not previously provided, please attach the most recent EVM assessment report (DOCUMENT NUMBER : 20,19,21) and the corresponding EVM improvement plan (DOCUMENT NUMBER : 19). The improvement plan should include a timeline, budget of committed resources for these activities and funding gaps, if any, as well as M&E indicators to monitor progress of implementation.

When is the next Effective Vaccine Management (EVM) Assessment planned? **January 2017**

8.5 Waste management

Countries must have a detailed waste management and monitoring plan as appropriate for their immunisation activities. This should include details on sufficient availability of waste management supplies (including safety boxes), the safe handling, storage, transportation and disposal of immunisation waste, as part of a healthcare

waste management strategy. Please describe the country's waste management plan for immunisation activities (including campaigns).

Divisional level vaccine waste will be destroyed mainly by burning at Medical Officer of Health level, who has the facility and routinely practising at the moment.

District level (Regional Medical Supplies Division) level utilise incinerator facility at the nearest hospitals

National level -incineration

9. Additional Comments and Recommendations from the National Coordinating Body (ICC/HSCC)

Comments and Recommendations from the National Coordinating Body (ICC/HSCC)

no additional comments

10. List of documents attached to this proposal

10.1. List of documents attached to this proposal

Table 1: Checklist of mandatory attachments

Document Number	Document	Section	File
Endorsements			
1	MoH Signature (or delegated authority) of Proposal	4.1.1	MoH_Signature.docx File desc: Date/time : 28/04/2016 06:56:50 Size: 18 KB
2	MoF Signature (or delegated authority) of Proposal	4.1.1	Dept_of_Public_Finance.pdf File desc: Date/time : 28/04/2016 06:47:14 Size: 304 KB
3	MoE signature (or delegated authority) of HPV Proposal	4.1.1	Signature_MoE.pdf File desc: Date/time : 29/04/2016 06:37:48 Size: 322 KB
4	Terms of Reference for the ICC	4.1.2	ACCD_TOR & conflict of Interest , final.docx File desc: Date/time : 28/04/2016 06:50:31 Size: 20 KB
5	Minutes of ICC/HSCC meeting endorsing Proposal	4.1.3	ACCD_Minutes_2016-03-04.pdf File desc: Date/time : 28/04/2016 06:57:37 Size: 332 KB
6	Signatures of ICC or HSCC or equivalent in Proposal	4.1.3	ACCD_signature_Attendance Sheet (1).pdf File desc: Date/time : 29/04/2016 05:03:56 Size: 4 MB
7	Minutes of last three ICC/HSCC meetings	4.1.3	ACCD_Minutes_2015.pdf File desc: Date/time : 29/04/2016 05:18:50 Size: 15 MB
8	Role and functioning of the advisory group, description of plans to establish a NITAG	4.2.1	ACCD_TOR & conflict of Interest , final.docx File desc: Date/time : 28/04/2016 07:02:38 Size: 20 KB
Planning, financing and vaccine management			
9	comprehensive Multi Year Plan - cMYP	5.1	Final_CYMP_2017 - 2021.pdf File desc: Date/time : 02/06/2016 01:07:28 Size: 377 KB

10	cMYP Costing tool for financial analysis	5.1	Final CYMP 2017 - 2021.pdf File desc: Date/time : 02/06/2016 01:09:10 Size: 377 KB
11	M&E and surveillance plan within the country's existing monitoring plan	5.1.4	M&E and surveillance plan .docx File desc: Date/time : 02/06/2016 01:05:55 Size: 23 KB
12	Vaccine introduction plan	5.1	HPV vaccine introduction plan Sri Lanka May 2016.doc File desc: Date/time : 29/05/2016 08:06:15 Size: 1 MB
15	HPV roadmap or strategy	6.1.1	road map_Human Papillomavirus.docx File desc: Date/time : 29/05/2016 08:06:58 Size: 891 KB
16	HPV summary of the evaluation methodology	5.1.6	HPV summary of the evaluation methodology.docx File desc: Date/time : 02/06/2016 01:05:06 Size: 19 KB
19	EVM report	8.3	EVM Report SriLanka_2015Final.docx File desc: Date/time : 28/04/2016 07:14:39 Size: 10 MB
20	Improvement plan based on EVM	8.3	EVM improvement Plan 2015.doc File desc: Date/time : 30/05/2016 07:05:37 Size: 23 KB
21	EVM improvement plan progress report	8.3	EVM Improvement plan Progress 2016.doc File desc: Date/time : 30/05/2016 07:06:39 Size: 35 KB
27	Data quality assessment (DQA) report	5.1.4	Data quality assessment report.docx File desc: Date/time : 29/04/2016 07:57:33 Size: 12 KB

Table 2: Checklist of optional attachments

Document Number	Document	Section	File
13	Introduction Plan for the introduction of RCV / JE / Men A / YF into the national programme	7.x.4	No file loaded
14	Annual EPI Plan with 4 year forward view for measles and rubella		No file loaded

17	Evidence of commitment to fund purchase of RCV for use in the routine system in place of the first dose of MCV	7.x.3	No file loaded
18	Campaign target population documentation	7.x.1, 6.x.1	No file loaded
22	Detailed budget template for VIG / Operational Costs	6.x,7.x.2, 6.x.2	VIG and Op Cost Detail estimate HPV vaccination Sri Lanka 2016 (1).xlsx File desc: Date/time : 30/05/2016 07:02:25 Size: 125 KB
23	Risk assessment and consensus meeting report for MenA. If the DPT was used instead, please include this.	7.1	No file loaded
24	National Measles (& Rubella) elimination plan if available		No file loaded
25	A description of partner participation in preparing the application	4.1.3	No file loaded
26	Minutes of NITAG meeting with specific recommendations on the NVS introduction or campaign	4.2	No file loaded
28	DQA improvement plan	5.1.4	No file loaded
29	Plan of Action for campaigns	7.1, 7.x.4	No file loaded
30	Other		EPI coverage survey Mullaitivu Killinochchi.pdf File desc: Date/time : 04/09/2016 11:24:35 Size: 483 KB
31	Evidence of self-financing MCV1	5.1.5	No file loaded

11. Annexes

Annex 1 - NVS Routine Support

Annex 1.1 - NVS Routine Support (HPV quadrivalent, 1 dose(s) per vial, LIQUID)

Table Annex 1.1 A: Rounded up portion of supply that is procured by the country and estimate of relative costs in US\$

		2017
Number of vaccine doses	#	229,700
Number of AD syringes	#	245,300
Number of re-constitution syringes	#	0
Number of safety boxes	#	0
Total value to be funded by the Country	\$	1,065,500

Table Annex 1.1 B: Rounded up portion of supply that is procured by Gavi and estimate of relative costs in US\$

		2017
Number of vaccine doses	#	229,700
Number of AD syringes	#	245,300
Number of re-constitution syringes	#	0
Number of safety boxes	#	0
Total value of Gavi support	\$	1,065,500

Table Annex 1.1 C: Summary table for vaccine HPV quadrivalent, 1 dose(s) per vial, LIQUID

ID		Data from		2017
	Number of surviving infants	Table 5.2	#	347,200
	Number of children to be vaccinated with the first dose	Table 5.2	#	175,000
	Number of children to be vaccinated with the second dose	Table 5.2	#	175,000
	Immunisation coverage with the second dose	Table 5.2	%	100%
	Number of doses per child	Parameter	#	2
	Estimated vaccine wastage factor	Table 5.2	#	1.05
	Number of doses per vial	Parameter	#	1
	AD syringes required	Parameter	#	Yes
	Reconstitution syringes required	Parameter	#	No
	Safety boxes required	Parameter	#	No
	Country share of total needs	Parameter	%	50.00%
gs	Gavi support	Parameter	%	50%
ca	AD syringe price per unit	Table Annexes 4A	\$	0.041
cr	Reconstitution syringe price per unit	Table Annexes 4A	\$	0
cs	Safety box price per unit	Table Annexes 4A	\$	0.005
fv	Freight cost as % of vaccines value	Table Annexes 4B	%	2.10%

Table Annex 1.1 D: Estimated numbers for HPV quadrivalent, 1 dose(s) per vial, LIQUID, associated injection safety material and related country budget (page 1)

		Formula	2017		
			Total	Government	Gavi
A	Gavi support	<i>Gavi support (gs)</i>	50.00 %		
B	Number of children to be vaccinated with the first dose	<i>Table 5.2</i>	175,000	87,500	87,500
C	Number of doses per child	<i>Vaccine parameter (schedule)</i>	2		
D	Number of doses needed	$B \times C$	350,000	175,000	175,000
E	Estimated vaccine wastage factor	<i>Table 5.2</i>	1.05		
F	Number of doses needed including wastage	$D \times E$	367,500	183,750	183,750
G	Vaccines buffer stock	<i>Buffer on doses needed = (D - D of previous year) x 25% Buffer on wastages = ((F - D) - (F of previous year - D of previous year)) x 25%, = 0 if negative result G = [buffer on doses needed] + [buffer on wastages]</i>	91,875	45,938	45,937
I	Total vaccine doses needed	<i>Round up((F + G) / Vaccine package size) * Vaccine package size</i>	459,400	229,700	229,700
J	Number of doses per vial	<i>Vaccine parameter</i>	1		
K	Number of AD syringes (+ 10% wastage) needed	$(D + G) \times 1.11$	490,482	245,241	245,241
L	Reconstitution syringes (+ 10% wastage) needed	$(I / J) \times 1.11$	0	0	0
M	Total of safety boxes (+ 10% of extra need) needed	$(K + L) / 100 \times 1.11$	0	0	0
N	Cost of vaccines needed	<i>I x vaccine price per dose (g)</i>	2,067,300	1,033,650	1,033,650
O	Cost of AD syringes needed	<i>K x AD syringe price per unit (ca)</i>	19,989	9,995	9,994
P	Cost of reconstitution syringes needed	<i>L x reconstitution price per unit (cr)</i>	0	0	0
Q	Cost of safety boxes needed	<i>M x safety box price per unit (cs)</i>	0	0	0
R	Freight cost for vaccines needed	<i>N x freight cost as of % of vaccines value (fv)</i>	43,342	21,671	21,671
S	Freight cost for devices needed	<i>(O+P+Q) x freight cost as % of devices value (fd)</i>	0	0	0
T	Total fund needed	$(N+O+P+Q+R+S)$	2,130,631	1,065,316	1,065,315

Note:Gavi vaccine support is limited to 50% of the required number of doses for the campaign, and a Vaccine Introduction Grant for the routine introduction.

Annex 2 - NVS Routine – Preferred Second Presentation

No NVS Routine – Preferred Second Presentation requested this year

Annex 3 - NVS Preventive campaign(s)

No NVS Prevention Campaign Support this year

Annex 4

Table Annex 4A: Commodities Cost

Estimated prices of supply are not disclosed

Table Annex 4B: Freight cost as percentage of value

Vaccine Antigen	Vaccine Type	2017
HPV quadrivalent, 1 dose(s) per vial, LIQUID	HPV	2.10 %

Table Annex 4D: Wastage rates and factors

The following table shows the wastage rates for routine and campaign vaccines, set for 2017.

Vaccine	dose(s) per vial	Maximum Vaccine wastage rate*		Benchmark Wastage Rate**
HPV bivalent, 2 dose(s) per vial, LIQUID	2	10 %	0 %	
HPV quadrivalent, 1 dose(s) per vial, LIQUID	1	5 %	0 %	
JE, 5 dose(s) per vial, LYOPHILISED	5	10 %	10 %	
Measles, 10 dose(s) per vial, LYOPHILISED in second dose	10	40 %	0 %	
Meningococcal A, 10 dose(s) per vial, LYOPHILISED	10	50 %	10 %	
MR, 10 dose(s) per vial, LYOPHILISED in second dose	10	40 %	15 %	
Pneumococcal (PCV10), 2 dose(s) per vial, LIQUID	2	10 %	0 %	
Pneumococcal (PCV13), 1 dose(s) per vial, LIQUID	1	5 %	0 %	
Rotavirus, 2-dose schedule	1	5 %	0 %	
Rotavirus, 3-dose schedule	1	5 %	0 %	
Yellow Fever, 10 dose(s) per vial, LYOPHILISED	10	40 %	0 %	
Yellow Fever, 5 dose(s) per vial, LYOPHILISED	5	10 %	0 %	

Comments:

* Source - WHO indicative wastage rates

** Source - Country APRs and studies, approved by WHO, UNICEF, and the Gavi Secretariat

Note: HPV demonstration project wastage rates are the same as for the national introduction of the vaccine

Table Annex 4E: Vaccine maximum packed volumes

Kindly note that this table is for reference purposes only and includes Gavi- and non Gavi-supported vaccines.

Vaccine product	Designation	Vaccine formulation	Admin route	No. Of doses in the schedule	Presentation (doses/vial, pre-filled)	Packed volume vaccine (cm ³ /dose)	Packed volume diluents (cm ³ /dose)
BCG	BCG	lyophilized	ID	1	20	1.2	0.7
Diphtheria-Tetanus	DT	liquid	IM	3	10	3	
Diphtheria-Tetanus-Pertussis	DTP	liquid	IM	3	20	2.5	
Diphtheria-Tetanus-Pertussis	DTP	liquid	IM	3	10	3	
DTP liquid + Hib freeze-dried	DTP+Hib	liquid+lyop.	IM	3	1	45	
DTP-HepB combined	DTP-HepB	liquid	IM	3	1	9.7	
DTP-HepB combined	DTP-HepB	liquid	IM	3	2	6	
DTP-HepB combined	DTP-HepB	liquid	IM	3	10	3	
DTP-HepB liquid + Hib freeze-dried	DTP-Hib	liquid	IM	3	10	2.5	
DTP-HepB liquid + Hib freeze-dried	DTP-HepB+Hib	liquid+lyop.	IM	3	1	22	

DTP-HepB-Hib liquid	DTP-HepB+Hib	liquid+lyop.	IM	3	2	11	
DTP-HepB-Hib liquid	DTP-HepB-Hib	liquid	IM	3	10	4.4	
DTP-HepB-Hib liquid	DTP-HepB-Hib	liquid	IM	3	2	13.1	
DTP-HepB-Hib liquid	DTP-HepB-Hib	liquid	IM	3	1	19.2	
DTP-Hib combined liquid	DTP+Hib	liquid+lyop.	IM	3	10	12	
DTP-Hib combined liquid	DTP-Hib	liquid	IM	3	1	32.3	
Hepatitis B	HepB	liquid	IM	3	1	18	
Hepatitis B	HepB	liquid	IM	3	2	13	
Hepatitis B	HepB	liquid	IM	3	6	4.5	
Hepatitis B	HepB	liquid	IM	3	10	4	
Hepatitis B UniJect	HepB	liquid	IM	3	Uniject	12	
Hib freeze-dried	Hib_lyo	lyophilized	IM	3	1	13	35
Hib freeze-dried	Hib_lyo	lyophilized	IM	3	2	6	
Hib freeze-dried	Hib_lyo	lyophilized	IM	3	10	2.5	3
Hib liquid	Hib_liq	liquid	IM	3	1	15	
Hib liquid	Hib_liq	liquid	IM	3	10	2.5	
Human Papilomavirus vaccine	HPV	liquid	IM	3	1	15	
Human Papilomavirus vaccine	HPV	liquid	IM	3	2	5.7	
Japanese Encephalitis	JE_lyo	lyophilized	SC	1	5	2.5	2.9
Measles	Measles	lyophilized	SC	1	1	26.1	20
Measles	Measles	lyophilized	SC	1	2	13.1	13.1
Measles	Measles	lyophilized	SC	1	5	5.2	7
Measles	Measles	lyophilized	SC	1	10	3.5	4
Measles-Mumps-Rubella freeze dried	MMR	lyophilized	SC	1	1	26.1	26.1
Measles-Mumps-Rubella freeze dried	MMR	lyophilized	SC	1	2	13.1	13.1
Measles-Mumps-Rubella freeze dried	MMR	lyophilized	SC	1	5	5.2	7
Measles-Mumps-Rubella freeze dried	MMR	lyophilized	SC	1	10	3	4
Measles-Rubella freeze dried	MR	lyophilized	SC	1	1	26.1	26.1
Measles-Rubella freeze dried	MR	lyophilized	SC	1	2	13.1	13.1
Measles-Rubella freeze dried	MR	lyophilized	SC	1	5	5.2	7
Measles-Rubella freeze dried	MR	lyophilized	SC	1	10	2.5	4
Meningitis A conjugate	Men_A	lyophilized	IM	1	10	2.6	4
Meningitis A/C	MV_A/C	lyophilized	SC	1	10	2.5	4
Meningitis A/C	MV_A/C	lyophilized	SC	1	50	1.5	3
Meningitis W135	MV_W135	lyophilized	SC	1	10	2.5	4
Meningococcal A/C/W/	MV_A/C/W/	lyophilized	SC	1	50	1.5	3

Meningococcal A/C/W/Y	MV_A/C/W/Y	lyophilized	SC	1	10	2.5	4
Monovalent OPV-1	mOPV1	liquid	Oral		20	1.5	
Monovalent OPV-3	mOPV3	liquid	Oral		20	1.5	
Pneumo. conjugate vaccine 10-valent	PCV-10	liquid	IM	3	1	11.5	
Pneumo. conjugate vaccine 10-valent	PCV-10	liquid	IM	3	2	4.8	
Pneumo. conjugate vaccine 13-valent	PCV-13	liquid	IM	3	1	12	
Polio	OPV	liquid	Oral	4	10	2	
Polio	OPV	liquid	Oral	4	20	1	
Polio inactivated	IPV	liquid	IM	3	PFS	107.4	
Polio inactivated	IPV	liquid	IM	3	10	2.5	
Polio inactivated	IPV	liquid	IM	3	1	15.7	
Rota vaccine	Rota_liq	liquid	Oral	2	1	17.1	
Rota vaccine	Rota_liq	liquid	Oral	3	1	45.9	
Tetanus Toxoid	TT	liquid	IM	2	10	3	
Tetanus Toxoid	TT	liquid	IM	2	20	2.5	
Tetanus Toxoid UniJect	TT	liquid	IM	2	Uniject	12	
Tetanus-Diphtheria	Td	liquid	IM	2	10	3	
Yellow fever	YF	lyophilized	SC	1	5	6.5	7
Yellow fever	YF	lyophilized	SC	1	10	2.5	3
Yellow fever	YF	lyophilized	SC	1	20	1.5	2
Yellow fever	YF	lyophilized	SC	1	50	0.7	1

12. Banking Form

In accordance with the decision on financial support made by the Gavi, the Government of Sri Lanka hereby requests that a payment be made via electronic bank transfer as detailed below:

Name of Institution (Account Holder):	Ministry of Health , Sri Lanka		
Address:	385, Rev. Baddegama Wimalawansa Thero Mawatha,		
City Country:	Colombo 10, Sri Lanka		
Telephone no.:	+94 112694033	Fax no.:	+94112693866
	Currency of the bank account: LKR		
For credit to:			
Bank account's title:	Ministry of Health, Sri Lanka		
Bank account no.:	7040238		
Bank's name:	Bank of Ceylon, Thaprobane Branch, No 61, Hospital Lane, Colombo 01		

Is the bank account exclusively to be used by this program? False

By who is the account audited? Secretary of Health

Signature of Government's authorizing official

		Seal
Name:	Mr. Anura Jayawickrama	
Title:	Secretary Health, Sri Lanka	
Signature:		
Date:	29/04/2016	

FINANCIAL INSTITUTION		CORRESPONDENT BANK (In the United States)	
Bank Name:	Bank of Ceylon		
Branch Name:	Thaprobane Branch		
Address:	No. 61, Hospital Lane,		
City Country:	Colombo 01, Sri Lanka		
Swift Code:	BCEYLK LX		
Sort Code:			
ABA No.:			
Telephone No.:	+94112422267		
FAX No.:	+94112422267		

I certify that the account No 7040238 is held by Ministry of Health at this banking institution

The account is to be signed jointly by at least 2 (number of signatories) of the following authorized signatories:

1	Name:	Mr. Anura Jayawickrama
	Title:	Secretary, Ministry of health, Sri Lanka
2	Name:	Dr. Palitha Mahipala
	Title:	Director General of Health Services
3	Name:	Mr.S. R. Rajapaksha
	Title:	Chief Accountant

Name of bank's authorizing official	
Manager, Bank of Ceylon	
Signature:	
Date:	4/29/2016 12:00:00 AM
Seal:	

