

Solomon Islands HPV DEMONSTRATION VACCINE SUPPORT

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

1. Country: Solomon Islands																
2. Vaccines Grant Number: 1516-SLB-19b-X Cash Support Grant Number: 1516-SLB-24a-Y																
3. Date of Decision Letter: 5 March 2014																
4. Date of the Partnership Framework Agreement: 29 April 2013																
5. Programme Title: HPV Demonstration Programme																
6. Vaccine type: HPV																
7. Preferred product presentation and formulation of vaccine: HPV Quadrivalent, 1 dose(s) per vial, LIQUID																
8. Programme Duration¹: 2015 - 2016																
9. Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement):																
<table><tr><td></td><td>2015</td><td>2016</td><td>Total²</td></tr><tr><td>HPV vaccines (US\$)</td><td>US\$133,000</td><td>US\$27,500</td><td>US\$160,500</td></tr><tr><td>Cash (\$)</td><td>US\$145,000</td><td>US\$25,000</td><td>US\$170,000</td></tr><tr><td>Total Programme Budget (US\$)</td><td>US\$278,000</td><td>US\$52,500</td><td>US\$330,500</td></tr></table>		2015	2016	Total ²	HPV vaccines (US\$)	US\$133,000	US\$27,500	US\$160,500	Cash (\$)	US\$145,000	US\$25,000	US\$170,000	Total Programme Budget (US\$)	US\$278,000	US\$52,500	US\$330,500
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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. This should be equal to the total of all sums in the table.

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	27,900
Number of AD syringes	29,400
Number of safety boxes	350
Annual Amounts (US\$)	US\$133,000

Cash support:

Cash Support by year	2015
Annual Amounts (US\$)	US\$145,000

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

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

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 the approval and disbursements of the future Annual Amounts. Further details can be found in the HPV Guidelines for Applications 2013.

Reports, documents and other deliverables	Due dates
1. A report of the evaluation of the HPV demonstration programme. 2. A copy of the approval by the local ethics committee, if a country determined that review and approval was required. 3. A report of the feasibility assessment of adolescent health interventions, with conclusions about what interventions are or are not feasible. 4. If an adolescent health intervention is identified for joint delivery with HPV vaccine, a description of the process by which the HPV vaccine delivery strategy will be modified and the steps required in planning and implementation with the district(s) and staff involved. 5. A summary of the activities completed and progress towards development of a national cervical cancer prevention and control strategy.	End of the first year (the first year starts when the first dose of the vaccine is administered).
6. Financial reports for the GAVI HPV demonstration programme covering the year ended, in form and substance satisfactory to GAVI.	Within 3 months of the end of each Country's fiscal year.
7. A summary report of year two delivery of HPV vaccinations, if not jointly delivered with adolescent health interventions. 8. If HPV was delivered jointly with adolescent health interventions, based on the year one feasibility assessment, an evaluation report of that delivery is required. 9. A copy of the developed or revised national cervical cancer prevention and control strategy.	End of second year (the first year starts when the first dose of the vaccine is administered and continues for twelve calendar months).

17. Financial Clarifications: The Country shall provide the following clarifications to GAVI*:

Signed by,
On behalf of the GAVI Alliance



Hind Khatib-Othman
 Managing Director, Country Programmes
 5 March 2014

NEW PROPOSALS IRC COUNTRY REPORT

GAVI Secretariat, Geneva, 7 – 22 November 2013

Country: Solomon Islands

1. Type of support requested

Type of support requested	Planned start date (Month, Year)	Duration of support	Vaccine presentation(s) (1 st and 2 nd choice, if applicable)
HPV demo project	March 2015	2 years	1 st : Quadrivalent (Gardasil) 2 nd : Bivalent (Merck)
MR campaign	May 2015	1 year	MR, 10 doses per vial, Lyophilised
Pneumococcal	January 2015	5 years	Pneumococcal (PCV13), 1 dose per vial, Liquid

2. In-country governance mechanisms (ICC/HSCC)

There is a functional ICC in place and it was actively involved in the preparation of the applications under review. It is composed of the leadership of the Ministry of Health and Medical Services (MoHMS), and WHO, PATH, UNICEF, AusAid and Australian Cervical Cancer Foundation (ACCF) serving as observers. Minutes of a meeting was provided. The frequency of meetings was not clear. Relevant in-country technical partners were included but no obvious CSO representation or participation.

It is commendable that as per the minutes provided, serious deliberations were conducted on the challenges of introducing new vaccines. The main weakness is the non-involvement of CSOs. It is not clear if a NITAG has been established.

The HPV Demo application mentions the involvement of the Anglican Church on Isabel Island and the involvement of faith-based schools in the two selected districts. The TAG is in place. It includes representatives of the MHMS, MoE, Ministry of Women Affairs, Adolescent Health officials and NGO officials. The high level leadership of the TAG by the Director of Disease Prevention and Control is commendable. Health statistics or SINU officials who will be leading the evaluation of the HPV Demo should be in the TAG.

3. Situation analysis (burden of disease and health system bottlenecks)

NVS and HPV Demo

The high burden of under-5 mortality due to pneumonia, meningitis and other diseases caused by pneumococcal bacteria is one of the main reasons for introduction of PCV13 vaccine into Solomon Islands National Immunisation Policy and Routine Vaccination Schedule. A 2012 outbreak of rubella in pregnant women has resulted in a recent increase in the incidence of CRS. The plan is now to replace the measles vaccine with MR both for routine immunisation and the catch-up campaigns. The target in the proposed 2015 MR campaign is age 12 months to 14 years. The burden of cervical cancer in Solomon Islands is well-described; it ranks as the second most frequent cancer. Age-standardised incident rate of 17.6/100,000 and mortality rate of 10.9/100,000 women (IARC Globocan 2008).

Solomon Islands successfully introduced Penta in July of 2008. Vaccination coverage is improving; measles (MCV1) coverage among one-year-old was 73% in 2011, and MCV1 coverage is supported by Measles SIA coverage of 90%. Pentavalent-3 (DPT-HepB-Hib) at 88% (2011) and reported DPT3 of 90% (2012). There is a history of successful mass vaccination campaign – the influenza vaccination of health workers in response to the H1N1 outbreak in 2009. The EPI system works but the EPI Review and EVM (both 2012) highlight significant challenges in planning and management, HR, supply, vaccine management and timely vaccination, cold chain, data quality and documentation. While these are being addressed with support from GAVI, WHO and UNICEF progress is slow. UNICEF plans to support a coverage survey in 2014 and is replenishing the cold chain. WHO will provide TA to strengthen surveillance. Other donors provide support to wider HSS through the health budget.

A list of lessons learned from past vaccination activities, along with mitigating interventions, was presented in the application. The HPV application discussed that, from watching other developing countries' experiences, Solomon Islands EPI realises the need for significant preparations in the form of HPV programme planning before national rollout and inclusion in existing immunisation systems.

4. Overview of national health documents

The NHP, cMYP, National EPI Review (2012), and EVM Assessment (2012) provide an appropriate situational analysis of the status of the immunisation programmes/health systems in the country. The proposal for new vaccine introduction is aligned with the national health documents. The high quality cMYP (2011-15) has evidence of recent revision to include the 2012 EVM findings and detail of cold chain improvements in 2013. The cMYP envisaged possible introduction of PCV in 2014, a further measles SIA in 2015 and planned introduction of MR into schedule. The cMYP and NHP cover 2011-2015 and did not envisage introduction of HPV in 2015-16. This will be reflected in a revised cMYP to be issued in 2015. The cMYP describes provision of integrated PHC services (Vitamin A, deworming) into MR campaigns.

The HPV pilot plans to leverage the existing TT vaccination programme in schools. The cMYP describes synergies between PCV and the MR campaign and other immunisation campaigns and broader health sector planning. PCV to be added to 6, 10 and 14 weeks immunisations. RCV was introduced in 2013.

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

NVS

The plan is to maintain the minimum co-financing requirement. The government, WHO, UNICEF and other partners will contribute to the co-finance of both PCV introduction and the MR campaign. Currently, there is no evidence of default in existing co-finance agreements. The country provides all of the financing of its routine vaccination programme except DPT-HepB-Hib; the government co-finances US\$ 0.4 per dose for DPT-HepB-Hib. The budget is well laid out and it is clear how much support is being requested from GAVI. No staff salaries are budgeted, although incentives are planned but not defined.

HPV Demo

The projected costs have been well outlined and are consistent with GAVI guidelines.

6. Gender and Equity

High levels of gender-based violence are acknowledged but no clear policy to address this was reported, except for the statement in the HPV Demo application that, “Data indicates there is no difference in vaccination coverage between boys and girls, preliminary discussions have extensively discussed methods that could be employed to educate the community as to why the HPV demo program is only delivering vaccines to girls”. The lack of gender differences in vaccination coverage is less convincing because it is also stated that, “To date no surveys have been conducted to look at wealth or sex differences in immunisation coverage”. Routine vaccination data is not disaggregated by sex and there is no plan to obtain sex disaggregated data. The presence of geographic inequities are acknowledged, there are mitigating measures built into the application e.g. local micro-planning, upgrade of cold store facilities

7. Specific comments related to requested support

NVS

New vaccine introduction plan

The PCV introduction will be phased-in starting January 2015. It will be added to the 6, 10, and 14 week vaccination windows. The targets are realistic and aligned with delivery plans and the phases of delivery. Procurement is via GAVI/UNICEF. There is plan for the training of staff and for community mobilisation for the introduction of PCV. The plan is to strengthen the usual preparations that the country does for the measles campaign

Preventive campaign

The plan is to replace the measles vaccine with MR. MR will now be part of the routine immunisation program. The campaign appears well designed to reach children who are in school and those who visit fixed sites and those who are reached by the mobile service. The weakness lies with finding out of school children, especially between age 5 and 14 years. There is a post-campaign evaluation plan.

Vaccine management and cold chain capacity

Solomon Islands has enough cold chain capacity to handle the MR campaign because it merely exchanges the space for measles vaccines. There is also sufficient capacity to store PCV and HPV vaccines. Vaccine wastage figures have been addressed in the proposal. The application has not shown how Solomon Islands has addressed the high and medium-priority recommendations made in the EVM.

Waste management

There is a good immunisation waste management process in the existing national immunisation program and there are plans to install more incinerators.

Data management and quality

A 2012 survey found it weak and suggested that training be done, as well as simplified reporting. The HPV vaccine is going to try to build on existing EPI practices, with further details developed “in the micro planning stage”. MR and PCV applications also mention this training.

AEFI

2012 national EPI review: no AEFI protocol at all levels. Suggested to develop national guidelines and conduct trainings. All applications state they will provide AEFI training for workers.

HPV Demo

Implementation strategy

A school-based strategy augmented by an outreach campaign for out-of-school girls is proposed in Honiara Town Council and Isabel districts. One is largely urban and relatively densely populated, while the other is rural and more sparsely populated. The choice of districts is satisfactory because it enables learning from both urban and rural sites.

The target group will change each year. For the first year, an initial multi-age (9-12 year olds) cohort is proposed, then single age (9 year olds) cohorts thereafter. They have argued for the efficiency of doing a multi-age cohort to catch all the 9 -12 year olds who are still in school in the first year of the demonstration. The age cohorts selected are satisfactory for achieving objective 1 and are in compliance with WHO target age. 8,050 girls are targeted in year 1 and 2,012 girls in year 2, a total of 10,062 girls by the end of the HPV Demo. This number sounds reasonable given the estimates derived from the MoE and estimates of the number of out of school girls. The number to be vaccinated each year is well within GAVI guidelines. The delivery of HPV to school girls is feasible and builds on a TT immunisation programme already present in the schools. The plan to reach the out-of-school girls was weakly and unconvincingly described. How will out of school girls be reached with a multi-dose vaccine regimen? An excellent and actionable timeline is proposed in the 2-year period.

Training, Community Sensitisation & Mobilisation Plans and Evaluation

The plan is to train EPI field staff, who routinely administer school-based vaccines to give HPV, and to train staff in outreach clinics. A communications strategy to sensitise teachers and the community, including church leaders, is provided—as are particular challenges identified and measures to address them. Solomon Islands National University (SINU), assisted by UNICEF in-country staff, is to lead the demonstration evaluation. A request was also made for an international expert supported by GAVI to provide technical assistance. SINU is a new university that has limited research experience. Nevertheless, giving the size of the project and with the support from UNICEF they should have the capacity to conduct the evaluation.

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

Adolescent health interventions: During year 1, a desk assessment of adolescent health interventions to 9-12 year olds is planned. They will use a local coordinator for 3 months to coordinate assessment activities. Solomon Islands should be congratulated for their plans to take advantage of the annual national family planning conference scheduled for September 2014, where an additional day will be scheduled to workshop the assessment of joint delivery of adolescent health interventions with key

participants. The coordinator will author the assessment report. No plans to test an intervention in year two are mentioned.

Development of Cervical Cancer Prevention and Control Strategy

A two year process is described, utilising an international consultant and the TAG and ICC to author the strategy of Comprehensive Cervical Cancer Prevention Programme, working with a senior local coordinator. Using online resources from WHO/PATH, consultation with stakeholders and experts, and desk reviews of programme reports will assist the consultant to synthesize the plan.

Linkages to immunisation outcomes, action plan for immunisation results and added value

There is a nationwide EPI programme for primary schools where every school is visited and integrated health services and vaccinations are given. This programme has been in place since the early 1970's. Additional training on HPV vaccine is an opportunity to reinforce the teaching of the primary school EPI workers on both vaccine and non-vaccine EPI components, such as waste management, data recording, and AEFI's. Solomon Islands have added a long time for training (11 months) from approval to first injection to try to maximize training and sensitisation.

Engagement of civil society, including for implementation

States have support of Australian cervical cancer groups, and the Victorian cytology registry has now agreed to process cytology samples (pap smears) free of charge.

Technical assistance needs

For HPV, Solomon Islands will need additional cervical cancer prevention strategists and have allotted finances to help pay. For MR, they will use WHO to help set up laboratory aspect of sentinel surveillance.

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

The cMYP is complete and good quality, as is the vaccine introduction plan and/or campaign operational plan and EVM.

9. Overview of the proposal

NVS (PCV and MR)

Strengths: Integration of PCV into routine vaccination and experience with measles SIA prepares Solomon Islands for the MR campaign.

Weaknesses: Many activities crammed into 2015.

Risks: Cold chain logistics and management.

Mitigating strategies: Compliance with EVM recommendations.

HPV Demo

Strengths: Strong leadership for the HPV Demo, feasible school-based strategy.

Weaknesses: Poorly described out-of-school strategy, inadequate involvement of CSO, improper dosing interval for dose #3 (5 months after dose 2 is proposed, but this should be 4 months after dose 2).

Risks: Cold chain logistics and management.

Mitigating strategies: Compliance with EVM recommendations and development of a tracking system for out-of-school girls

NOTE: GAVI HPV demonstration programme funding does not support a “catch up” round of vaccinations. You can test out these two strategies (9-12 together compared with 9 alone the following year) to learn by doing which strategy might work for country roll out. However, if you apply for country roll out, you could choose a delivery strategy to vaccinate 9-12 year olds together every 4 years, or a strategy to vaccinate a single cohort (such as 9 years old) annually, but you would not be able to do a “catch up” campaign.

10. Conclusions

NVS (PCV and MR)

Well delineated, organised application with high chance of success for PCV introduction into routine and MR Campaign.

HPV demo

Good chance to meet all three programme objectives, especially the delivery of vaccine/learn by doing. Strong use of timeline and pre-planning prior to first vaccine dose. Feel testing the two strategies for HPV delivery (9-12 at once, vs. 9 year old alone the next year) is well justified based on geography and transportation costs, and a true opportunity for another experience to “learn by doing”.

11. Recommendations

NVS (PCV and MR)

Recommendation: Approval with clarification

Clarifications:

- 1) Clarify that AEFI national guidelines have been developed and trainings have occurred.

HPV Demo

Recommendation: Approval with clarifications

Clarifications:

- 1) Timing of Dose #3 needs to be adjusted to reflect manufacturer’s recommendations (change to month 6, not month 7 as it is now planned).
- 2) Budget should be adjusted to take full advantage of GAVI support. The country should be made aware that they can ask for an additional US\$ 25,000 to be disbursed in year 2 exclusively if they decide to integrate vaccination with other ADH services.
- 3) Please 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.
- 4) GAVI HPV demonstration programme funding does not support a “catch up” round of vaccinations. You can test out these two strategies (9-12 together compared with 9 alone the following year) to learn by doing which strategy might work for country roll out. However, if you apply for country roll out, you could choose a delivery strategy to vaccinate 9-12 year olds together every 4 years, or a strategy to vaccinate a single cohort (such as 9 years old) annually, but you would not be able to do a “catch up” campaign.