BANGLADESH HPV DEMONSTRATION VACCINE SUPPORT

This Decision Letter sets out the Programme Terms of a Programme

1. **Country: Bangladesh**
2. **Vaccines Grant Number:** 1516-BGD-19a-X
   Cash Support Grant Number: 1516-BGD-24a-Y
3. **Date of Decision Letter:** 17 March 2015
4. **Date of the Partnership Framework Agreement:** 24 June 2013
5. **Programme Title:** HPV Demonstration Programme
6. **Vaccine type:** HPV
7. **Preferred product presentation and formulation of vaccine:** HPV Bivalent, 2 dose(s) per vial, LIQUID
8. **Programme Duration**[1]**:** 2015 - 2016
9. **Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement):**

	2015	2016	Total[2]
HPV vaccines (US$)	US$381,500	US$352,500	US$734,000
Cash ($)	US$333,500	US$25,000	US$358,500
Total Programme Budget (US$)	US$715,000	US$377,500	US$1,092,500

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.

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	2016
Number of HPV vaccines doses	80,500	74,300
Number of AD syringes	80,600	73,600
Number of safety boxes	900	825
Annual Amounts (US$)	US$381,500	US$352,500

Cash support:

Cash Support by year	2015
Annual Amounts (US$)	US$333,500

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.

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 copy of the approval by the local ethics committee, *if a country determined that review and approval was required.* 2. Three evaluation reports of the HPV vaccination demonstration programme: a. Post Introduction Evaluation (PIE) b. Coverage survey c. Costing analysis 3. A report of the assessment of adolescent health interventions, with conclusions about what interventions would be feasible for integration in year 2. a. If an adolescent health intervention is identified for joint delivery with HPV vaccine, the report should describe the identified intervention, the modified plans for Year 2, and the steps required for implementation with the district(s) and staff involved. b. If NO adolescent health intervention is identified for joint delivery with HPV vaccine the report should mention the reason why not. 4. A summary of the activities completed and progress towards the development of a national cervical cancer prevention and control strategy.	As soon as they become available, and at the latest by end of year 1 (the first year starts when the first dose of vaccine is administered, and continues for 12 months)
5. A financial and activity report of expenditures by the end of year 1.	End of year 1 (the first year starts when the first dose of vaccine is administered, and continues for 12 months)
1. If an adolescent health intervention is identified for joint delivery with HPV vaccine OR if the country substantially changed their delivery strategy: a. A new survey to measure the coverage of HPV vaccination and the coverage of the jointly delivered health intervention(s) and	End of Year 2 (the second year starts when the first dose of vaccine is administered to a new cohort, which is usually 12 months after the start of Year 1 and continues for twelve calendar months)

b. An updated micro-costing analysis of programme delivery costs. (Annex B) 2. If NO adolescent health intervention is identified for joint delivery with HPV vaccine in Year 2: A summary report of year 2 delivery of HPV vaccinations 3. A financial and activity report of expenditures in year 2. 4. A copy of the developed or revised national cervical cancer prevention and control strategy.	

17. Financial Clarifications: The Country shall provide the following clarifications to Gavi*: not applicable

18. Other conditions: Not applicable

On behalf of Gavi
Signed by,

Hind M. Khatib

Hind Khatib-Othman
Managing Director, Country Programmes
17 March 2015

Annex A

Independent Review Committee (IRC) Country Report

GAVI Secretariat, Geneva • 10-24 November 2014

Country: Bangladesh- HPV Demonstration Project

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1. Type of support requested

Type of support requested	Planned start date *(Month, Year)*	Duration of support	Vaccine presentation(s) *(1st and 2nd choice, if applicable)*
HPV	Feb 2015		HPV2-1st. HPV4-2nd

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

The ICC is active, with five meetings between May 2013 and May 2014. The ICC membership is comprised of MoHFW, MoF, WHO, UNICEF, World Bank, development partners (DFTAD, DFID, JICA, USAID) and civil society (BRAC, Rotary). The ICC discussed and endorsed this specific proposal on 1 Sept, 2014, with the only signature on the meeting notes being the Chair of the ICC. At this Sept, 2014 meeting, one representative from the department of education was present, and no reproductive health or cancer sector representatives. The MOE and MOH have signed off on the proposal. In the application, Bangladesh also supplies minutes from ICC meeting on 22 July, 2013 where the ICC "approved the decisions of the Scientific and Technical Committee of NCIP [National Committee for Immunisation Practices (NITAG equivalent)] for introducing HPV vaccine in District Demonstration Programme".

In the country HPV Demo application, names of proposed members of the TAG (to be formed) are given. The TAG will be chaired by an EPI physician who has expertise in immunisation and adolescent health. Broad, appropriate sector membership is proposed (MOE, Cancer control, Civil Society, Adolescent health, and Reproductive health, along with EPI representation). The proposal will be housed in EPI. Terms of reference for the TAG are well delineated.

3. Situation analysis – Status of the National Immunisation Programme

The immunisation programme enjoys strong government ownership, and has demonstrated high coverage of all antigens over many years (e.g. DTP3 coverage of 93%) with high regional (98% of districts achieving more than 80% coverage) and gender equity (less than 1% difference). The coverage for fully vaccinated children (FCV) has according to MoHFW/UNICEF survey data increased to 84%. Despite the high coverage, there are data quality issues with differences between the administrative and WUENIC 2013 data (e.g. 7% for measles, 11% for DTP3) and a low (1 star) grade of confidence for data quality.

Bangladesh is committed to improve routine activities in low performing districts. They have initiated micro-planning and conducted several trainings for vaccine delivery and monitoring.

Human resources remain a major area of concern in general. This application states that in Gazipur district, all the manager positions are filled but the main deficit is that 10% of the field worker posts are vacant. They state field workers are accustomed to the need to cover unfilled posts.

Bangladesh has gained experience from the MR campaign implemented in Jan/Feb 2014. The target group was a population of almost 53 million (9 month to 15 years old), and they were able to safely reach nearly 100% coverage and implement the campaign despite political tensions and roadblocks in the country in the weeks before the SIA. The few observed AEFI were well managed at different levels of the referral system and the AEFI expert committee met during the SIA to review the cases. NGOs supported MoHFW especially in urban areas, notably with social mobilisation activities.

Bangladesh's PCV application was approved in April 2012 and the introduction is expected in November 2014. IPV support was approved in April 2014 with an introduction date now in Q1 2015. A new HSS grant application is expected in early 2015.

4. Overview of national health documents

The cMYP spans 2011 to 2016 with a planned comprehensive update in June 2014. However this update was not available to reviewers. There is a section on introduction of new and underused vaccines but HPV introduction is not specifically reflected. The cMYP highlights principles to guide new vaccine introduction efforts to focus on *Quality and safety, maximal coverage, equity and gender equality.*

5. Equity

Bangladesh has a GII of .518 and ranks 111 out of 148 countries placing it in the lower third of the ranking. This indicates the poor status of women and girls. According to the EPI survey coverage in 2013, urban and rural immunisation coverage is roughly equivalent. There remains a challenge due to high migration of population. Coverage rates differ across wealth quintiles. The project will be based in Gazipur district where around 90% girls (above the national average of 87%) attend school. A particular challenge is "floating" population due to a large number of garment factories. The CES (2013) shows:

- Coverage = 83.7% in the upper quintile and 76.9% in the lowest quintile nationally.
- Fully vaccination coverage for male = 84% and female is 83%
- In Gazipur district fully vaccinated coverage is 74% male and 75% female

This proposal does not offer any specific idea for adding males in the adolescent health component, or sensitisation/outreach to male student prior to the start of HPV Demo project. Through the health education in schools, it seems this would be feasible.

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

Bangladesh is requesting above the Gavi allotted HPV Demonstration budget. They have proposed a larger target population (see below) and have calculated their Gavi funds (US$ 358,337) based on this larger target population. Within the budget proposed, they provide no unit costs. It appears that they may have overestimated the cost of some items (for instance, desk review of Adolescent Health intervention is budgeted for US$ 38,000, and coverage evaluation after year 1 is US$ 38,000), and underestimated the cost of drafting a national cervical cancer prevention and control strategy (US$ 9,740 seems low). They ask for $ 62,000 in cold chain, and $10,000 for other capital without detail as to what is needed. They have failed to supply budget and plans for post project evaluation.

7. Specific comments related to requested support

HPV Demo

Implementation strategy:

Cervical cancer burden: 29.8 per 100,000 women per year. Cancers are usually diagnosed in advanced stages, as there is scant access to screening and treatment of pre-invasive cervical disease.

Vaccination strategy: school–based primarily. For out of school girls: facility based and outreach. They have prior experience with this strategy for MR and TT, both used fixed (including schools) and outreach to vaccinate 15 year old adolescent girls, and both have achieved high coverage.

District choice: Gazipur, which has population of 3,746,584 with both urban and rural areas. Gazipur is geographically close to the EPI HQ in Dhaka and the district achieves high vaccine coverage. They chose this district after "careful assessment" of cold-chain capacity and delivery infrastructure, it gives an opportunity to target both urban and rural areas, and its proximity to Dhaka enables EPI HQ to assist and supervise.

Target group: They propose targeting all 10 year olds in the district, which is 32,952 in year one, and 33,403 in year two. This exceeds Gavi limit of 20,000 girls. They justify this by saying that all districts that are geographically close to Dhaka will have more than 20,000 girls and they do not want to take on the management to deliver and monitor far from their EPI center, nor do they think they can manage the tracking and delivery, especially to out of school girls, if the district is divided. Looking toward preparation for national rollout, which would be a cohort of 3-4 million girls, they state it would be "beneficial to demonstrate implementation of the HPV in one full district even though the target" exceeds the Gavi limit of 20,000 girls.

Delivery strategy: 90% of 10 year olds are in school. For school based, targeting grade 5, but unclear if will be looking for 10 year olds in other grades. They have health education days in schools regularly, and routine outreach sessions for vaccination taking place regularly in school, where "the school teachers act as volunteers" (eg Measles campaign). For out of school girls, fixed and outreach strategy is to be used. They state they will draw from prior experience gained through successful measles vaccination coverage and state they can cover the hard-to-reach females, many of whom are in garment factories. They plan to map the district and make a line list of all the 10 year old girls using outreach workers. The out of school girls will be vaccinated through the routine EPI fixed sessions and outreach sessions. On day prior to the planned routine session, field workers will inform the eligible girls to come to the upcoming session for vaccination.

Timeline:

Immunisation is planned in Feb 2015 to take advantage of school calendar, and to give first dose at beginning of school year, over two weeks followed by a 6 week campaign to vaccinate girls out of school. They will repeat this in 1 month for the 2nd dose, then at 6 months for the 3rd dose – wanting to keep all doses within the same school year. The timeline supplied is logical and complete, save a few areas of challenge: they have wisely planned a 6 month lead in for development of teams, materials, education, etc., but stated roll out date for vaccination is February 2015. They still have 5 months between dose 1 and dose 3 in 2nd year (instead of the recommended 6 months) and use 3 doses in timeline. It is likely that the timeline and number of doses were planned before WHO's recent recommendation which considers 2 doses, given 6 months apart, as comparable to the past 3 dose strategy.

Training, Community Sensitisation & Mobilisation Plans and Evaluation:

State will have nationwide education followed by district education. School teachers and officials will be a part of the training including AEFI surveillance. Widespread community advocacy and education with appropriate groups is planned.

Regarding challenges: The application states that devising messages for 10 year old girls may be "culturally challenging" to tell them that this vaccination is targeted to prevent sexually transmitted disease. Therefore, the message could be to prevent cervical cancers.

Lead project manager: Dr. Rahman who is the EPI programme Manager in Dhaka.

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

For the AHI: Currently, there is an ongoing preventive and promotive health intervention through the school health programme introduced in 20 districts, including the district of Gazipur, where all the primary schools are targeted, governmental and private, for health education and medical examination for eye, ENT, dental and nutritional problems. HPV vaccination will be preceded by health education on areas relevant for HPV infection and cervical cancer prevention, especially reducing behaviours that increase the risk of acquiring HPV infection, and information about the diagnosis and treatment of precancerous lesions and cancer. Introduction of HPV vaccination will be complimentary to the ongoing efforts on re-orienting the adolescent health interventions planned for this target group.

The TAG will advise and guide in all decision making related to the development of a comprehensive adolescent health intervention programme.

Cervical Cancer Control Strategy: They currently do not have a strategy but have named a group with appropriately broad representation to develop it. The lead person is not yet identified, but they state the group will have a meeting every 3 months, and they have laid out reasonable planning milestones. They state they will develop this strategy by March 2015, which is not realistic with the timing of this submission.

Cold chain and waste management

Cold chain review for the selected district reveals a shortage of 2,314 liters storage capacity for HPV vaccine storage during the HPV Demonstration Programme. They plan to purchase refrigerators, and have allotted for this in the budget. Waste management will be handled as per national policies, as will AEFI.

AEFI surveillance:

They have an independent AEFI committee and an existing surveillance system and protocol. Local and national managers will do the monitoring, including a MCH & Immunisation officer supported by Gavi/HSS support. States have used these same systems for nationwide rollouts, so feel comfortable using these systems for one district.

Engagement of civil society, including for implementation:

CSO development is not discussed for implementation, but is discussed for Objective 3.

Technical assistance needs:

Application mention the year one "lessons learned" analysis, but not the cervical cancer strategy or AHI or post vaccine programme evaluation.

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

Country has an EVM improvement plan and well organized cMYP. HPV demonstration project is not mentioned, but is such a small component compared to the entire routine immunisation picture and the comprehensive picture of immunisations in Bangladesh is favorable.

9. Overview of the proposal

Strengths:

1) well organized proposal;
2) school health program in place with previous experience with school vaccination;
3) functional outreach program;
4) Proposal targets both urban hard to reach, and rural populations;
5) Timeline is realistic (with few exceptions).

Weaknesses:

1) The system proposed to track all the out of school girls is quite labor intensive;
2) Unit costs not supplied;
3) Contradiction in what is stated in sensitisation vs. what is said in AHI for messaging 10 year olds regarding HPV as STI;
4) Did not discuss a risk mitigation strategy for negative publicity other than traditional AEFI mechanism;
5) No budget or discussion for mandated end of programme evaluation in year two;
6) No mention of consent/assent considerations in Bangladesh context.

Risks:

1) Budget requested and target group are over Gavi maximums;
2) Cervical cancer strategy development underfunded.

Mitigating strategies:

1) Reprogram budget;
2) Involve CSO's further;
3) Develop communication team and messaging that can be quickly deployed when needed for negative publicity.

10. Conclusions

Bangladesh has an excellent track record with immunisations, including reaching hard to reach groups, and is well positioned for this HPV demo program; all three objectives are likely to be met.

11. Recommendations

HPV Demo Bangladesh:

Approval with Recommendations

Recommendations for Bangladesh:

1) Please reconfigure timeline, including considering pushing back February, 2015 roll out, and correcting the months between doses.
2) Confirm number of doses per girl you will deliver. Bangladesh may want to consider the recent WHO recommendations with a two dose schedule, as this may offer advantages for delivery and cold chain needs.
3) Clarify whether cold chain needs are based on two doses or three doses per girl.
4) Need to clarify how and if you will identify and immunize in school 10 year old girls not in grade 5.
5) Clarify plans and funding for end of programme evaluation.
6) Work with Gavi on appropriate budget for partner technical assistance, coverage surveys and AHI desk review. Some of this technical assistance may be covered by the HPV Demo Business Plan.
7) Provide unit costs for budget expenditures for training, personnel, transport, education and outreach to ensure budgetary planning is realistic and feasible.
8) Devise messaging for pre HPV-vaccine sensitisation (eg not talking to 10 year olds about STI's) in context of what is said about messaging for AHI.
9) The communication strategies could be further strengthened by engaging the boys as secondary beneficiaries of HPV.
10) Similarly, consider conducting AHI for both males and females as principal of equity.
11) Please comment on whether there is any need for consent/assent considerations in Bangladesh context. If consent/assent is needed, provide plan for how this will occur.
12) Prior to vaccine delivery, develop a risk communication strategy and a plan on how to deploy quickly to mitigate negative publicity if it arises.

Recommendations for Secretariat:

1) Strongly recommend that target group be expanded to number requested by Bangladesh. It is considered that the proposal has high risk of failure, including difficulty finding and tracking out of school girls, if the district is fragmented to limit numbers.
2) Technical support is likely to be needed for cervical cancer prevention strategy.
3) Ensure that adequate funds are available for the 2nd year programme evaluation.