HPV vaccines

Frequently Asked Questions
June 2012

APPLICATION REQUIREMENTS

1. GAVI has opened a window of support for human papillomavirus (HPV) vaccines?

In November 2011, the GAVI Alliance Board approved a new window of support for HPV and rubella vaccines, and subsequently in April a new application round opened for GAVI New Vaccines Support (NVS), with both of these vaccines now on offer to GAVI-eligible countries. The GAVI Secretariat has updated the NVS application guidelines and forms to include requirements specific to applications for HPV vaccines, and any country that is considering the introduction of HPV vaccines through GAVI should consult these resources. In addition to the guidelines, this document provides further details on the eligibility criteria and requirements to support successful applications for HPV vaccines.

2. How can a country receive GAVI support to introduce HPV vaccines?

There are two pathways through which a country may apply for HPV vaccines:

- **National introduction.** HPV vaccines may be introduced as part of a national strategy to prevent cervical cancer and other HPV-related deaths. The country must meet the eligibility requirements for national introduction (i.e. has demonstrated ability to deliver a complete multi-dose series of vaccines to at least 50% of the target vaccination cohort in an average size district, preferably comprising urban and rural areas, using a strategy similar to the one proposed for national HPV vaccine delivery). If the country does not meet these requirements, it may apply for support to implement a HPV demonstration project.

- **Demonstration project.** Countries that do not meet the eligibility criteria for national introduction of HPV vaccines will soon have the opportunity to apply for HPV demonstration projects. If approved, the project will enable the country to pilot HPV vaccine introduction in an average sized district and gather the data and information necessary to inform any subsequent decision-making on national introduction of HPV vaccines.

For both pathways, only countries with DTP3 coverage levels greater than or equal to 70%, based on the latest available WHO/UNICEF estimates, are eligible to apply.

3. How and when can countries apply for an HPV demonstration project?

GAVI support for HPV demonstration projects is intended to offer countries the opportunity to develop their capabilities in delivering a complete multi-dose series of HPV vaccines and gathering relevant data to inform the wider introduction of HPV vaccines. The successful implementation of a demonstration project will allow the country to submit an application for national introduction of HPV vaccines.

The protocol for HPV demonstration projects is currently being developed by GAVI and its technical partners, in consultation with a wide range of country and implementation stakeholders. The objective is to publish guidelines in Q3 2012, then to start accepting applications soon thereafter. GAVI will keep countries informed of the expected timeline and requirements for demonstration projects.

Please contact the GAVI focal point if your country would like to indicate interest in submitting a future application for a HPV demonstration project.

4. What is the application process for national introduction of HPV vaccines?

The following is a summary of the application process in 2012:

- Early June: Online application form is launched for submission of all NVS applications, including HPV and measles-rubella vaccines. This is the web site through which countries enter the information and upload documentation for their application.
- **31 August: Application submission deadline**
- 8-19 October: GAVI Independent Review Committee meeting to review NVS applications
- Early December: GAVI Board to consider and decide on IRC recommendations

5. What are the criteria that determine if a country will be eligible for support for national introduction of HPV vaccines?

In broad terms, in order to apply for GAVI support to introduce HPV vaccines, a country must meet the GAVI eligibility criteria for New Vaccines Support (WHO/UNICEF DTP3 coverage estimates above 70% and World Bank GNI per capita less than US$ 1,520; GNI data is reviewed and updated by the World Bank annually in July), and have demonstrated ability to deliver a complete multi-dose series of vaccines to at least 50% of the target vaccination cohort in an average size district (preferably comprising urban and rural areas) using a strategy similar to the one proposed for national HPV vaccine introduction.

To apply for national introduction of HPV vaccines, the country must:

- Identify a single year target vaccination cohort within the target population of 9-13 year old girls. If proposing a school-based delivery strategy, the country must also indicate the chosen school grade cohort for vaccination
- Provide a report on the costing analysis of the proposed delivery strategy or strategies and evidence of non-GAVI resources to support delivery.

If a country is proposing school-based delivery, the country should provide documentation that the Ministry of Education is a member of the Inter-agency Coordination Committee (ICC) and/or the Minister of Education's signature is also needed on the application.

Full details on the eligibility criteria can be found within the 2012 NVS application guidelines. Countries that cannot meet the criteria for national introduction of HPV vaccines will soon be invited to apply for HPV demonstration projects.

6. What is the link between the GAVI eligibility criteria of 70% DTP3 coverage and HPV vaccines? Isn't the target vaccination cohort different?

The DTP3 threshold of 70% (WHO/UNICEF estimates) is used by GAVI as an overarching eligibility filter for all countries that apply for any kind of new vaccines support. The DTP3 threshold is seen as a performance indicator for the routine immunisation system and services in a country, and the associated level of capacity to effectively manage vaccines and vaccine delivery to a target cohort.

It is true that HPV vaccines are targeted to adolescent girls and potentially via schools, however in terms of vaccine management, the same processes and principles as for other vaccines are equally applicable.

For example, for any GAVI supported vaccine, countries are expected to adequately manage vaccine procurement, supply chain, temperature monitoring, storage and transport capacities, and report regularly on progress against targets, stock levels, wastage rates and use of funds. The same requirements concern HPV vaccines and it is for this reason that the DTP3 threshold applies.

7. How can a country demonstrate its ability to deliver a complete multi-dose series of vaccines to at least 50% of the target vaccination cohort in an average size district?

Countries should provide data on the coverage achieved in a district where HPV has already been introduced, including details on how the vaccine was delivered, the schedule and strategies used, and the country experience in the lessons learnt from the activity. Data should include information on the target population, method of data collection, the source of the data, the number who started the multi-dose series and the number that received all doses. Supporting data may be provided from the WHO/UNICEF Joint Reporting Form (JRF), together with a detailed description.

PLANNING FOR NATIONAL INTRODUCTION

8. Our country is proposing to deliver the HPV vaccine through a health centre-based strategy. What supporting data is required?

Countries that choose to deliver the HPV vaccine through a health centre-based strategy will need to describe the health system and services for the target population, such as the number and type of health centres in the country. A description of other services for 9 to 13 year olds should be provided, as well as detailed information on other vaccinations delivered at the health centres. In addition, countries should provide a description of how the strategy will capture all the eligible girls in the target cohort, as well as any special considerations for marginalised or migrating populations.

Countries will need to provide data on the population of girls by age for the most recent year, including projections for the planned year of HPV vaccine introduction and sources for these total(s).

9. Our country is proposing to deliver the HPV vaccine through a school-based strategy. What supporting data is required?

The education system in the country must be described, including the number and type of schools in the country, the primary/secondary/tertiary arrangement, grades in each level, average age in each grade, the dates of the school year, school holidays and major examination periods.

All countries that choose to deliver HPV vaccines via schools must provide data on the proportion of girls of the target vaccination cohort who are enrolled in schools.

A minimum proportion of 75% girls in the target vaccination cohort should be enrolled in school. This can be demonstrated by providing data on the chosen age or grade cohort for vaccination (a single year cohort between the ages 9 to 13 years inclusive), the estimated number of girls in the targeted age or grade cohort, and a source for the enrolment data.

It will be useful to describe any other health services or health education to youth between the ages of 9 to 13 years. How effective was this? Has there been any independent assessment of these activities?

If a country is proposing school-based delivery, the country should also provide documentation that the Ministry of Education is a member of the Inter-agency Coordination Committee (ICC) and/or the Minister of Education's signature is also needed on the application.

10. How can we show that we will reach the girls who are not in school?

Supporting information should describe how the school-based strategy will capture girls not in school, e.g. will out-of-school girls be invited to join school-attending girls on the days of vaccination? Will separate outreach sessions be scheduled? Please describe frequency of services and plans to ensure effective delivery of all three doses to girls out of school, as well as any special considerations for marginalised or migrating populations.

11. Is it possible to propose the delivery of HPV vaccines through a mixed strategy, through a combination of both health centres and schools?

Yes, this is welcome. For such an application, please provide a complete description of the use of schools and health centres for the vaccine delivery strategy, as listed in questions 7-10 above.

12. What data can be provided on the cervical cancer burden in the country?

Where possible, national data sources are expected to be provided on the assessment of the cervical cancer burden, with a description of how and when the data collection was implemented. In the absence of such data, countries may report on Globocan data, available on the WHO HPV information centre web site at http://www.who.int/hpvcentre/en/

13. How do we demonstrate that a communication strategy is in place in the country?

Given that HPV vaccines are targeted to adolescent girls, countries will be requested to clarify how their plans for communication and social mobilisation reflect the unique needs of the programme, including key messages and mechanisms for reaching the priority audiences, the type and timing of activities to educate and raise awareness amongst the target population, their parents/guardians, the wider community, community leaders, etc. More information on developing a communication strategy is available from the web site www.rho.org

14. What detail is required in the costing analysis report for the delivery strategy?

A costing analysis report must also be provided for a country to submit a successful application. The report should provide data on the estimated total cost of the programme and evidence of non-GAVI resources to support delivery. Please also include by whom and when the costing analysis was completed. This costing analysis should be submitted in the online form with all other documentation.

15. Our country does not yet have a national strategy for cervical cancer prevention and control. Can we still apply for HPV vaccines?

Yes, a country is eligible to apply for support to introduce HPV vaccines even if it does not yet have a national strategy or roadmap to develop a strategy for cervical cancer prevention and control. Instead, a country will need to demonstrate its intentions to develop such a strategy to guide the implementation of a national cervical cancer prevention and control programme, which should include strengthening of existing health systems to improve access to primary and secondary prevention measures.

16. What other technical elements need to be addressed in an application for HPV vaccines?

The technical elements that are common to any new vaccine introduction also need to be addressed as a standard component of an application to GAVI for HPV vaccines. The elements which require detail are: cold chain equipment and logistics, waste management, vehicles and transportation, surveillance and monitoring, programme management, human resources and training, social mobilization, including an HPV vaccine communication strategy, and a new vaccine introduction plan.

17. What HPV vaccines are currently available to GAVI eligible countries? Can a country indicate a preference for either vaccine?

The two WHO-prequalified vaccines currently available to countries are:

- A bivalent vaccine, administered in a three-dose schedule at 0, 1 month and 6 months (2 dose vial)
- A quadrivalent vaccine, administered in a three-dose schedule at 0, 2 and 6 months (1 dose vial)

More information on these vaccines will be made available in the application form when it is launched in early June 2012. The online application form will request the country to rank their preference of vaccine presentation. If a case arises that the first preference of vaccine is in limited supply or not available in the short term, GAVI will contact the country and partners to explore alternative options. See section 3.3 of the 2012 NVS application guidelines for more information on vaccine preferences.

18. What other opportunities does HPV vaccination present for health interventions?

Successful HPV implementation can also serve to improve adolescent health by fostering synergies with other public health interventions such as HIV prevention, reproductive health, and nutrition. Accordingly, countries applying for national introduction are strongly encouraged to take this unique opportunity to provide other appropriate public health interventions targeting adolescents. Countries applying for the demonstration programme are required, and therefore financially supported through the programme, to assess the feasibility of integrating one or more adolescent health interventions with the delivery of HPV vaccine. The potential for delivering other interventions reinforces the importance of engaging groups from other fields that have not traditionally played a role in childhood immunisation.