

<b>SUBJECT:</b>	<b>REVIEW OF GAVI SUPPORT FOR HPV VACCINE</b>
<b>Agenda item:</b>	12
<b>Category:</b>	For Decision
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## 1. Executive Summary

### 1.1 Rationale

- (a) Human papillomavirus (HPV) is the primary cause of cervical cancer, a disease which results in 266,000 deaths annually (GLOBOCAN 2012). There is a disproportionate burden in low and middle-income countries, where 85% of these deaths occur. Based on the latest available data, cervical cancer may now cause more deaths among women worldwide than childbirth.
- (b) The Gavi Board decided in November 2011 to open a funding window to support HPV vaccination in Gavi-eligible countries. This decision supported HPV vaccination through one of two pathways, depending on the country situation: either national introduction or a demonstration programme with limited geographic and target population scope. The latter approach was intended to facilitate "learning by doing" and allow less-experienced countries to prepare for a national scale-up (which required a second application to Gavi).
- (c) As of September 2016, 23 countries have implemented a demonstration programme, proving the feasibility of implementing HPV programmes in low income countries and generating globally applicable lessons. Three countries (Rwanda, Uganda and Honduras) have introduced HPV vaccination in their national immunisation programmes.
- (d) Overall, Gavi has achieved its goal to vaccinate 1 million girls by 2015. However, there is a risk that the Alliance will not meet the target of vaccinating 30 million girls by 2020, due to delays in national introductions. Lessons learned indicate that the demonstration programme design contributed to these delays in three primary ways. First, the high level of financial support provided for demonstration programmes and an emphasis on achieving high coverage rates did not encourage countries to test more cost-sustainable and programmatically effective delivery models to inform and prepare for

national introduction. Second, the national immunisation programme (NIP) often did not lead demonstration programmes, resulting in low programme ownership and prioritisation of HPV programmes. And third, Gavi's requirements (including the two-step application process and heavy evaluation requirements) made it complex for countries to progress from demonstration programmes to national scale-up.

- (e) The recent recommendation from SAGE (October 2016) to immunise multiple age cohorts of girls aged 9-14 years when the HPV vaccine is first introduced, offers an opportunity for Gavi to alter its current support model and accelerate HPV vaccine uptake. There is potential to increase the impact and cost-effectiveness of Gavi's HPV programme by providing wider primary protection, more rapid indirect herd effects and leveraging the operational efficiencies and economies of scale offered by broader age-range delivery.

## 1.2 Purpose

- (a) This paper describes proposed changes to Gavi's HPV programme design, which the Programme and Policy Committee (PPC) recommended to the Board at its meeting on 25-26 October 2016.
- (b) The Audit and Finance Committee at its meeting on 21 October 2016 noted that it had reviewed the financial implications of this and other potential funding decisions that may be considered by the Board and concluded that these decisions could be approved by the Board in accordance with the Programme Funding Policy.

## 1.3 Salient Features

- (a) The new programme design encompasses two strategic shifts to accelerate HPV vaccine introduction in Gavi-eligible countries:
  - (i) Allow countries to apply for a full-scale national introduction (with option of a phased roll-out) without requiring prior proof of experience in delivering HPV vaccines to adolescent girls.
  - (ii) Support countries to vaccinate a multi-age cohort of girls 9-14 years of age in the year of introduction if they choose to do so. Gavi would provide 100% of vaccine support and operational cost support of US\$ 0.65 per targeted girl for these additional cohorts, consistent with the level of operational support for other vaccines under the HSIS policy. This will partially fund activities required to reach additional cohorts and is designed to strike a balance between providing sufficient funding to achieve reasonable coverage and ensuring sustainability.<sup>1</sup>

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<sup>1</sup> For the base cohort, countries will continue to pay vaccine co-financing and will receive a Vaccine Introduction Grant (VIG). Countries will need to demonstrate how they will use the VIG and operational support to strengthen HPV vaccine delivery through routine immunisation, and be able to spend the funds over multiple years to use them for long-term strengthening of the programme.

- (b) The last financial forecast approved by the Board in December 2015 projected expenditure of US\$ 401 million for the HPV vaccine programme between 2016 and 2020 with a target of immunising ~30 million girls and averting ~600,000 deaths. The revised strategy would add an additional ~US\$ 72 million to the financial forecast during this period and enable Gavi to vaccinate an estimated ~40 million girls averting ~900,000 deaths. The Alliance will continue working actively to further increase the number of countries who choose to introduce HPV nationally to narrow inequalities in cervical cancer burden and prevention.
- (c) At its replenishment in 2015, Gavi forecasted that it would avert 5-6 million deaths 2016-2020 with total expenditure of US\$ 9.5 billion. Therefore, the revised HPV programme design would deliver a 5% increase in deaths averted by all Gavi programmes 2016-2020 for an incremental investment equivalent to 0.8% of projected expenditure. HPV is already one of the most cost effective vaccines in Gavi's portfolio and under this revised programme design, the cost per death averted would fall further from approximately ~US\$ 600 to ~US\$ 500.
- (d) Supply of vaccine will require planning, but can comfortably accommodate the increased demand. Successful implementation of the strategy may unlock the opportunity to access lower prices associated to higher volumes.
- (e) The new approach will require strong technical support and leadership across the Alliance. Therefore, HPV will be explicitly discussed during Joint Appraisals to shape the Targeted Country Assistance provided by in-country partners through the Partners' Engagement Framework (PEF). Partners and the Secretariat will enhance leadership on HPV within their organisations, strengthen coordination and improve knowledge sharing, especially from global/regional to national level.
- (f) Integration with adolescent health interventions will continue to be strongly encouraged. To facilitate this, the Secretariat is exploring partnerships with global organisations and initiatives. For example, Gavi recently agreed a partnership with Girl Effect to increase demand promotion and broader integrated health-seeking behaviours by adolescent girls and is exploring synergies with other initiatives such as the Global Fund, PEPFAR's DREAMS programme, and the Organisation of African First Ladies Against HIV/AIDS (OAFLA).

## 2. Recommendations

2.1 The Gavi Alliance Programme and Policy Committee recommended to the Gavi Alliance Board that it:

- (a) **Approve** that for HPV vaccine countries can apply:
  - (i) directly for national introduction, while maintaining the option of implementing a phased national introduction;
  - (ii) for support for multi-age cohort HPV vaccinations (9-14 years of age) in year one of introduction of the vaccine, including support for 100% of vaccine costs for the additional cohorts, and operational support of up to US\$ 0.65 per targeted girl of those cohorts.
- (b) **Note** that the additional funding associated with the above approval for the period 2016-2020 is expected to be approximately US\$ 72 million.

### Attachment

Appendix 1: Review of Gavi support for HPV vaccine: Report to the PPC, 25-26 October 2016, Doc 10

**SUBJECT: REVIEW OF GAVI SUPPORT FOR HPV VACCINE**

**Agenda item:** 10

**Category:** For Decision

**Authored by:** Anissa Sidibe, Stephen Sosler

## **Section A: Overview**

### **1. Purpose of this report**

- 1.1 This report proposes changes to the design of Gavi's HPV programme, building on lessons learned from implementation to date and reflecting anticipated recommendations from the Strategic Advisory Group of Experts on Immunisation (SAGE).
- 1.2 Two key changes are proposed to the design of the programme:
- (a) To allow countries to apply directly for national introduction, including the flexibility to implement a phased national introduction; and
  - (b) To support countries to immunise a multi-age cohort of 9-14 year-old girls in the first year of introduction, by funding the required vaccines and a portion of the operational costs.

## **Section B: Content**

### **2. Background**

- 2.1 Human papillomavirus (HPV) is the primary cause of cervical cancer, a disease which results in 266,000 deaths annually (GLOBOCAN 2012). There is a disproportionate burden in low and middle-income countries, where 85% of these deaths occur. Based on the latest available data, cervical cancer may now cause more deaths among women worldwide than childbirth.
- 2.2 Given the high efficacy of HPV vaccines in reducing cervical cancer, the Gavi Board decided in November 2011 to open a funding window to support HPV vaccination in Gavi-eligible countries. With the aim of bridging the gap in the use of HPV vaccines in high and low-income countries, Gavi worked with vaccine manufacturers to reduce the price of both available vaccines to less than US\$ 5 per dose in Gavi-eligible countries.

- 2.3 To-date, 23 countries have implemented a demonstration programme, proving that HPV vaccines can be successfully delivered in Gavi-eligible countries and generating useful lessons for countries and for Gavi's HPV programme. Two countries (Rwanda and Uganda) have introduced HPV vaccination in their national immunisation programmes and overall Gavi has achieved its goal to vaccinate 1 million girls by 2015. However, the pace of national introductions has been slower than anticipated and there is a risk that the Alliance will not meet the target of vaccinating 30 million girls by 2020 (see Annex F for forecast details).

### Gavi's Current HPV Vaccine Programme

- 2.4 Gavi's HPV programme currently has two application steps. Countries without experience delivering routine vaccines to young adolescents are required to conduct a demonstration programme to gain experience in vaccinating this age group. The demonstration programme is a "learn by doing" project that targets circumscribed geographic areas (districts) and a limited number of girls (< 15,000). The programme requires that countries evaluate HPV vaccination coverage, feasibility, acceptance, and costs, to make an informed decision regarding national introduction. The programme also requires that countries review options to integrate HPV vaccination with additional adolescent health services to enhance the efficiency and sustainability of these interventions. Finally, the programme encourages development of a comprehensive national cervical cancer prevention and control strategy with HPV vaccination as a primary prevention tool.
- 2.5 Once a country has completed and evaluated its demonstration programme, it becomes eligible to apply for support for national introduction. Countries that have already demonstrated the ability to deliver a multi-dose vaccine to at least 50% of a target population of 9–13 year old girls are not required to conduct a demonstration programme.

### Lessons learned from Gavi's HPV Programme

- 2.6 Demonstration programmes have allowed countries and external partners to gain significant experience in planning and budgeting for HPV, defining target populations and delivery strategies, developing community acceptance and consent procedures for adolescent services, designing and piloting new reporting forms and systems, coordinating with the Ministry of Education for school-based vaccinations, and using standardised evaluation tools. With consistent lessons derived from Gavi demonstration programmes and pilot projects elsewhere, the potential for further learnings from demonstration programmes is limited. See Annex A for further details on lessons learned.
- 2.7 Transition from demonstration programmes to national scale-up has been slower anticipated. In September 2016, Gavi held a consultation with vaccine experts, technical partners and representatives of national programmes to discuss the factors affecting country decisions to introduce HPV vaccine nationally and provide recommendations of how best to

overcome these barriers. This reviewed lessons learned from a number of sources, including Gavi's Full Country Evaluations, and identified three key challenges:

- (a) Demonstration programmes have not always been designed to inform or prepare for national introduction. They have often prioritised high coverage over testing cost-effective and sustainable strategies (partly due to Gavi's requirement to demonstrate the ability to achieve high coverage and the level of financial support provided). District selection was often based on convenience (e.g., more extensive routine vaccination coverage, higher performing infrastructure, and better education levels than national averages). And the small scale of the demonstration programmes has limited the relevance of lessons learned and data generated for national scale-up. As a result, they have not always equipped countries with a sustainable model or the necessary data to inform decision-making for national introduction.
- (b) EPI programmes have not always been leading or systematically engaged in demonstration programmes. As a result, they have not prioritised national introduction in their applications to Gavi. This has also undermined efforts to create a platform for integrated delivery of health services to adolescent girls.
- (c) Gavi's requirements have made it complex for countries to progress from demonstration programmes to national introduction. This includes the two-step application process and heavy evaluation requirements.

### Upcoming SAGE recommendation on immunising a multi-age cohort

- 2.8 The Ad-hoc expert consultation on implementation research of human papillomavirus (HPV) immunisation, held in August 2016 found that immunisation of a multi-age cohort results in wider primary protection and more rapid herd effects as well as offering opportunities for economies of scale in delivery potentially making programmes more resilient to unintended interruptions in vaccine delivery (see Annex C).
- 2.9 Based on these findings, the next meeting of the WHO's Strategic Advisory Group of Experts on Immunisation (SAGE), on 18-20 October 2016, is expected to recommend HPV vaccination of a multi-age cohort of 9-14 year old girls when countries first introduce HPV vaccine. Rwanda and Bhutan have already fully self-financed vaccine delivery while benefiting from donated vaccines for a multi-age cohort vaccination strategy when they introduced, and several other Gavi-eligible countries (e.g. Mozambique, Senegal, Tanzania, Zambia, Zimbabwe) are considering this strategy, but would likely be limited by financial constraints.

### **3. Gavi's HPV Programme Review Process**

- 3.1 Several of Gavi's Full Country Evaluations were in countries implementing HPV programmes. These evaluations identified many of the challenges described above. The Secretariat has also reviewed recommendations emerging from other sources including the a review of lessons learned by the London School of Hygiene and Tropical Medicine and PATH and a WHO report on scaling up HPV vaccine introduction (to be published).
- 3.2 The Secretariat convened several consultations with multiple stakeholders<sup>1</sup> to review and recommend changes to the design of Gavi's HPV programme, building on the recommendations of the recent WHO ad-Hoc Expert Consultation<sup>2</sup>.

#### 4. Proposed changes to Gavi's HPV programme

- 4.1 Two strategic shifts are being proposed to address the challenges and opportunities described above: (1) allow countries to apply directly for national introduction, and (2) fund multi-age cohort vaccinations upon introduction of the vaccine.

##### Strategic shifts

- 4.2 **Direct national scale-up/phasing:** Given the limitation of demonstration programmes described above, it is recommended that countries be able to apply for a full-scale national introduction without requiring prior proof of experience in delivering HPV vaccines to adolescent girls. The Alliance will work with countries to evaluate their capacity and whether a phased national introduction would be appropriate to balance programmatic and implementation challenges.
- 4.3 **Multi-age cohort in year one:** In line with the anticipated SAGE recommendation, it is recommended to extend Gavi support to offer countries the option to immunise a multi-age cohort of girls anywhere between 9 and 14 years old in the year of introduction. (see Annex E for details):
- (a) A catch-up will help protect more girls in the recommended age group due to wider primary protection. With this strategy, Gavi-supported HPV vaccines are projected to reach up to 40 million girls by 2020, assuming that countries immunise an additional three age cohorts on average (considering age of primary school completion) with average coverage of ~65%<sup>3</sup> (see Annex F for forecast details). This higher

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<sup>1</sup>First identified by the HPV sub-team in the first half of 2016 (meeting in May, Atlanta) and presented to the board in June 2016. Subsequently, a technical working group was brought together to review vaccine introduction costs for HPV national introduction and to estimate operational costs for multi-age cohort vaccinations. In September 2016 Gavi convened a consultative panel for a comprehensive two-day review of Gavi's proposed changes to the HPV programme (See Annex C for detail on participants and summary notes)

<sup>2</sup> Convened in August 2016 to review evidence on a range of HPV research and vaccination issues See Annex D for the minutes of the WHO Expert Consultation.

<sup>3</sup> Depending on adoption and coverage assumptions. Current coverage assumption is ~50-80% (average across all targeted cohorts)



initial number of girls vaccinated will also provide more extensive protection to the unvaccinated population, including boys, due to herd protection effect.

- (b) As a result of higher coverage and not considering herd (indirect) effects, Gavi's HPV programme would help avert an estimated ~900k deaths 2016-2020 through the multi-age cohort approach, compared to ~450k deaths averted through the single-age cohort approach. This is equivalent to an 8% increase in the total number of deaths averted by Gavi programmes<sup>4</sup> during this strategic period for an incremental investment equivalent to only 0.8% of projected Alliance expenditure<sup>5</sup>. This would make the HPV programme the second most cost-effective in Gavi's portfolio at a cost of ~US\$ 500 per death averted<sup>6</sup> (after pentavalent vaccine at ~US\$ 400 per death averted<sup>7</sup>). This is in part due to economies of scale from multi-age cohort vaccination (notably with school-based delivery), which takes advantage of activities such as social mobilisation and training conducted for the base cohort, as well as the presence of vaccination teams at a school.

4.4 The optimal strategy to vaccinate a multi-age cohort will depend on the particular country context (e.g., number of out-of-school girls, secondary school starting age, existing outreach capacity, etc.). Countries will therefore, have the flexibility to select the target group within the recommended age range, given the support available from Gavi. Gavi will need to consider the likelihood of the country achieving high coverage and sustainability before approving support. Countries will be encouraged to focus vaccination activities in primary schools due to higher enrolment rates and lower age of sexual debut. For those wanting to expand vaccination to secondary schools, a strong rationale and a case-by-case review will be conducted.

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<sup>4</sup> Deaths averted assumptions of all other programmes kept constant as per replenishment ask (2016-2020).

<sup>5</sup> HPV incremental investment of US\$ 72 million (cashflow basis- vs. Dec 15 Board) divided by US\$ 9.553 billion projected Alliance expenditure for 2016-2020 (October 2016).

<sup>6</sup> Raw model output from SDF12 modified using the death averted per FVP rate to adjust for new intro dates and increased cohort sizes. Assumes direct linear relationship between FVPs and deaths averted. Usual uncertainties apply generated by input data assumptions (burden, transmission, demographics)

<sup>7</sup> Source: Replenishment ask (2016-2020)

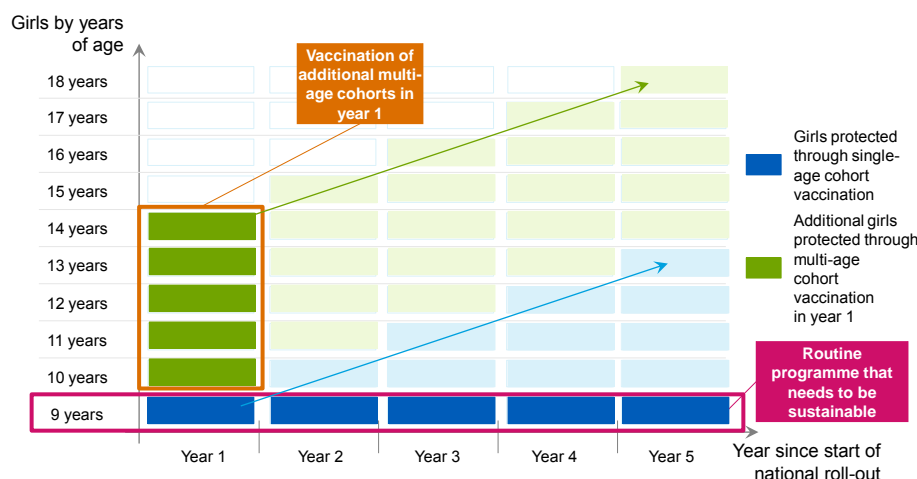


Figure 1: Scope of multi-age cohort vaccination

### Operational changes

- 4.5 **Evaluation requirements:** given the high vaccine cost and unique delivery challenges for the target population of HPV vaccine, countries will be required to conduct a Post-introduction evaluation (PIE) to evaluate the impact of the HPV vaccine introduction on the country's immunisation programme and to rapidly identify any problems needing corrective action.
- 4.6 **Reinforced technical assistance:** Recognising that technical support to countries should be tailored to their needs rather than a "one size fits all" solution, the redesign of the HPV programme proposes a new model of TA provision. This will enable countries to request Targeted Country Assistance a la carte from in-country partners through the Partners' Engagement Framework (PEF). Joint Appraisal discussions will include a stronger focus on HPV to help countries identify their specific TA needs. Support will be offered in a range of areas, including for example:
- Decision-making: support in advocacy, impact analysis, budget impact and costing analytics as well as support to facilitate NITAG review
  - Application process: support in the development of a sustainable implementation plan (selection of delivery strategy, communication / advocacy, training, etc.) and preparation of Gavi applications
  - Implementation: support in critical areas, e.g. – microplanning, social mobilisation, vaccination cards, registries, coverage monitoring system
  - Integration: identify opportunities for HPV integration with adolescent health interventions.
  - Evaluations: support for post-introduction evaluation, coverage surveys and costing analysis

- 4.7 **Enhanced leadership:** Leadership for the HPV programme will need to be reinforced across the Alliance to guarantee coordination and capability building at country level. Strengthened coordination between partners, concerted effort and a strong mechanism for knowledge sharing, from global/regional to national level, will be critical. At country level strong engagement and ownership of the EPI team will be important to assure integration with other programs and sustainability.

#### Financial support

- 4.8 **Maintain current support for base routine cohort:** Countries will continue to be eligible for standard vaccine support (with country co-financing) and a vaccine introduction grant (VIG) of US\$ 2.40 per targeted girl for the single-age cohort<sup>8</sup>. Experience from demonstration programmes and national roll-outs does not provide evidence suggesting that current VIG amounts should be modified (see Annex B for details).
- (a) Countries with phased introductions will receive the VIG for the full single-age cohort size according to their corresponding roll-out plan.
  - (b) The VIG is expected to cover costs such as social mobilisation, training, microplanning and other systems strengthening for introduction of HPV vaccine into national immunisation programmes for a one-age cohort.
- 4.9 **Additional support for multi-age cohort vaccinations in year one:** Countries will have the option to apply for additional support to vaccinate a multi-age cohort of girls aged 9-14 years old during the first year of introduction. Support would consist of:
- (a) 100% vaccine costs for additional age cohorts, in line with Gavi's support for wide age-range campaigns
  - (b) Operational support of up to US\$ 0.65<sup>9</sup> per targeted girl in additional age cohorts, aligned with current Gavi operational support under the HSIS policy. This will partially fund the additional activities required to reach additional cohorts including increased service delivery, transportation costs, and social mobilisation. The level of support has been set to balance providing countries while sufficient funding to achieve reasonable coverage with ensuring sustainability.
- 4.10 To ensure sustainability of the programme beyond the introduction year, countries will be required to submit budgets and financial plans with their application demonstrating they will fund the programme (especially

<sup>8</sup> As per the HSIS framework: <http://www.gavi.org/library/gavi-documents/policies/gavi-health-system-and-immunisation-strengthening-support-framework/>

<sup>9</sup> For low income countries, the amount will be up to US\$ 0.65 per targeted girl. Countries in preparatory transition phase (Phase 1) will be provided with up to US\$ 0.55 per targeted girl, and countries which have entered accelerated transition phase (Phase 2) up to US\$ 0.45 per targeted girl.

operational costs) after the year of introduction. In addition, guidance will be given to countries to reduce perverse incentives (e.g. per diem rates) and close monitoring of grant utilisation in accordance with Gavi's partnership framework agreement (PFA) will be in place. Countries will also need to demonstrate how they will use the VIG and operational support to strengthen HPV vaccine delivery through routine immunisation, and be permitted to spend the funds over multiple years to use them for long-term strengthening of their programme.

### Integration

- 4.11 Integration with adolescent health interventions and other disease-specific programmes will continue to be strongly encouraged including by providing technical assistance in this area. However, as integration adds complexity and may represent a risk in terms of HPV coverage when adolescent health platforms are weak, integration opportunities will need to be carefully assessed to ensure coverage is not negatively impacted.
- 4.12 Gavi is pursuing partnerships with a number of global organisations and private sector companies to advance the integration agenda and increase demand for health services and HPV vaccine among adolescent girls including, for example:
- (a) Organisation of African First Ladies Against HIV / AIDS (OAFLA): Working with OAFLA to reinforce commitment to HPV and advocate for adolescent girls' health to be systematically included in national, regional and global development agenda.
  - (b) Children's Investment Fund Foundation (CIFF) partnership: CIFF has committed US\$ 25 million Gavi's HPV programme. Integration opportunities could be considered with CIFF grantees focused on adolescent health, where Gavi and CIFF strategies align.
  - (c) Girl Effect: This new partnership aims to increase demand for HPV vaccination and to encourage broader integrated health-seeking behaviours by adolescent girls through social communications leveraging the Girl Effect brand. The budget for the project is US\$ 10 million and it is intended that Girl Effect and Gavi will each contribute approximately half of the costs. The Government of the Netherlands has indicated its commitment to match the contribution from Girl Effect by donating an equivalent amount directly to Gavi under the Matching Fund.
  - (d) PEPFAR's DREAMS aims to reduce new HIV infections among adolescent girls and young women in 10 sub-Saharan African countries. As these countries are also among those with highest HPV prevalence, Gavi is exploring integration of HPV with DREAMS key interventions including menstrual hygiene, body literacy, violence, and education.

- (e) Global Fund: Gavi is exploring opportunities to align investments with the Global Fund to finance sustainable interventions for adolescent girls and young women.
- (f) There could be potential synergies with other initiatives to reach adolescents including Family Planning 2020, UNICEF WASH and UNAIDS fast track to reduce HIV in adolescent girls. Discussions are also underway with the Global Partnership on Education on how to work together on this agenda.

### **Section C: Recommendations**

4.13 The Gavi Alliance Programme and Policy Committee is requested to recommend to the Gavi Alliance Board that it:

- (a) **Approve**, subject to confirmation by the Audit and Finance Committee that sufficient funding is available, that for HPV vaccine countries can apply:
  - i. directly for national introduction, while maintaining the option of implementing a phased national introduction;
  - ii. for support for multi-age cohort HPV vaccinations (9-14 years of age) in year one of introduction of the vaccine, including support for 100% of vaccine costs for the additional cohorts, and operational support of up to US\$ 0.65 per targeted girl of those cohorts.
- (b) **Note** that the additional funding associated with the above approval for the period 2016-2020 is expected to be approximately US\$ 72 million.

### **Section D: Risk implication and mitigation and Financial implications**

#### **5. Risk implication and mitigation strategy**

- 5.1 Countries may prioritise in-school girls in order to achieve high coverage faster, especially given the fact that multi-age catch-up initiatives require targeting older girls with lower school attendance rates. Risk will be mitigated by requiring a clear plan to reach out-of-school girls in the application and report on coverage achieved in this specific target group.
- 5.2 Countries may still be hesitant to apply for national introduction given long-term financial implications. To help address countries' concerns and facilitate that NITAGs and decision-makers have the data which they consider important to make an informed decision, including impact and financial analytics, technical assistance at the country level will be reinforced through the performance engagement framework.
- 5.3 Coverage may be different than expected, resulting in either in faster ramp-up that would require short term supply or slower ramp-up which would lead

manufacturers to lose confidence in the forecast. Regular monitoring will therefore need to be put in place with timely communication to manufacturers.

- 5.4 Countries may not be able to achieve high coverage levels among multiple cohorts due either to financial constraints or implementation challenges. The Alliance will enhance its support to countries and closely monitor implementation. This risk is partially mitigated by the fact that expected herd protection is higher with medium coverage levels (as shown in Annex E).
- 5.5 Countries may not be able to ensure effective coordination across relevant ministries for successful HPV vaccine national introduction. This risk will be mitigated by a reinforced application process that will require bringing relevant stakeholders around the table. Furthermore, within Gavi's HPV application form, countries will need to describe a clear accountability framework, including roles, responsibilities and coordination among relevant stakeholders (Ministry of Education, Ministry of Finance, Sexual Reproductive Health , Non-Communicable Disease, Adolescent Health, etc.).
- 5.6 As countries' primary focus will be to achieve high vaccine coverage, integration opportunities may be missed. To address this risk, Gavi will ensure that integration opportunities identified through global partnerships trickle down to the country level and, where relevant, additional technical support will be available to facilitate operationalization.

## 6. Financial implications

- 6.1 The revised strategy being proposed would add ~US\$ 72 million to the forecasted expenditure for HPV presented to the December 2015 Board for the period of 2016-2020. The total budgetary requirement would be ~US\$ 473 million<sup>10</sup>.
- (a) ~US\$ 252 million for the single-age cohort <sup>11</sup> , including ~US\$ 28.5 million VIG costs and ~US\$ 223.5 million vaccine costs for single-age cohort
- (b) ~US\$ 221 million for multi-age cohort, including ~US\$ 20.7 million operational costs and ~US\$ 200.5 million vaccine costs
- 6.2 Please note that additional volumes driven by multi-age cohort vaccinations may trigger price discounts, which have not been accounted for in the forecasted data.

<sup>10</sup> All figures presented on a cashflow year basis

<sup>11</sup> Including national introduction for the single-age cohort, demonstration programme, exceptional catalytic countries and India strategy

## **Appendix: Implications**

### **7. Impact on countries**

- 7.1 Eliminating the need to conduct a demonstration before national introduction will fast track the roll out HPV vaccines nation-wide. However, the amount of planning and resources required can potentially prove burdensome, particularly for countries with competing health priorities, weak health systems, limited resources or without HPV vaccination experience.
- 7.2 Gavi's additional operating and vaccine support for multi-age cohort vaccinations in year 1 will help countries extend protection to girls more quickly and benefit from herd immunity while rolling out HPV vaccinations through their routine programmes.
- 7.3 Some countries may still be hesitant to apply for national introduction due to the longer-term financial commitment. In this regard, Gavi and its partners' support will be critical in establishing both a realistic forecast of the financial requirements and reinforce advocacy efforts in order to facilitate decision-making.

### **8. Impact on Gavi stakeholders**

- 8.1 Gavi and its technical partners will need to engage with countries and provide technical assistance in a targeted and coordinated manner.

### **9. Impact on Secretariat**

- 9.1 Gavi's comprehensive support will require a corresponding increase in the need to oversee the strategy to ensure success at every stage. As such, there will be a need to increase the management capacity of the Secretariat to oversee and monitor this investment, which will be managed within Board-approved budget for 2017.
- 9.2 The Partnership Engagement Framework Budget, will need to reflect the needs for increased in-country support for the HPV Programme.

### **10. Legal and governance implications**

- 10.1 There are no legal or governance implications anticipated.

### **11. Consultation**

- 11.1 Consultations with stakeholders including some country representatives, technical experts, Alliance technical partners and the HPV sub-team were done through formal involvement in Steering Committee who provided guidance to the Technical Working Group or bilaterally. Please refer to point 4 on the process of consultation.

## **12. Gender implications**

12.1 HPV vaccine will be targeted at girls and the programme offers opportunities to increase impact on young girls, but also boys, through the impact of herd protection which can reduce genital warts and other cancers in male, as well as integration with other adolescent interventions that can be delivered to both.

### **Annexes (available on myGavi)**

- Annex A: Learnings from demonstration projects (presented by PATH at Gavi's HPV programme 2.0 consultation)
- Annex B: Review of introduction and operational costs for HPV vaccination programme (presented by WHO at Gavi's HPV programme 2.0 consultation)
- Annex C: WHO Ad-hoc expert consultation on implementation research of HPV – summary notes
- Annex D: HPV programme 2.0 consultation 6-7 Sept 2016 – attendees and summary notes
- Annex E: The additional impact of multi-year vaccination for 9-14 year old girls in Decade of Vaccine (DoV) countries (modeling analysis prepared by LSHTM to inform Gavi's multi-age cohort strategy)
- Annex F: Forecasted Financials and Impact