Update on HPV vaccine introduction and programmatic perspectives

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SAGE Meeting, Geneva
24 October 2018
Presentation Outline

1. Where we are today:
   - Global status of HPV introduction, progress & challenges

2. What has been learned getting here:
   - What works; what does not work

3. Looking to the future:
   - Exciting developments and road ahead
WHO recommendations for HPV vaccination (2017)

- Primary target pop: girls 9-14 years
- 2 doses (6 months apart)
- No max interval (suggested not more than 12-15 months)
- If interval < 5 months, give another dose 6 months after 1st dose
- 3 doses if ≥15 years or immunocompromised

Multi-Age Cohort Vaccination (MAC)

- Vaccinate the entire 9-14 year girls cohort, when first introduced (Cost-effective)
- Also, 9–18 years; 3 doses if ≥15; (less likely to be cost-effective)

Economies of scale

Faster and greater impact

Resilience to supply interruptions
85 countries have introduced the HPV vaccine (as of Oct. 2018)

Only ~25% of 10 year old girls live in countries that have introduced the HPV vaccine.
Proportion of countries that have introduced HPV vaccine, by WHO region and WB income classification

Source: IVB Database as of 31 August 2018
Comparison of cervical cancer incidence in countries that have/have not introduced HPV vaccine (2017)*

<table>
<thead>
<tr>
<th>Size = 1,000 deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV vaccine introduced</td>
</tr>
<tr>
<td>HPV vaccine NOT introduced</td>
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</tbody>
</table>

*HPV immunization schedules and strategies — DRBackground paper for SAGE October 2018
Reported HPV vaccine coverage
Various ages and years, 2014-2016

27% of countries (n=14) ≥ 80%
25% of countries (n=13) < 50%

"Guess-Estimate" of Global Coverage of HPV in Girls 9-14yrs = 10% (2017)

Source: Brotherton & Bloem, 2017
Current HPV Vaccine Supply Landscape

- HPV4 (Gardasil) dominates market
- 2017 Est. Market Share:
  - HPV4: 50%
  - HPV9: 28%
  - HPV2: 20%
  - Unknown (HPV2/4): 2%
- 3 Products in advanced clinical development (bi- & quadri- valent)

Source: V3P/JRF, GVMM, UNICEF SD procurement volumes and Gavi shipments
### 2018 estimated vaccine dose distribution (in millions), by vaccination policy (n = 83 intro’d+11 projected)

<table>
<thead>
<tr>
<th>+Boys</th>
<th>+MAC</th>
<th># doses (%)</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>12.6m (40%)</td>
<td><strong>10 countries</strong>: Australia, Barbados, Brazil, Canada, Germany, Ireland, New Zealand, Switzerland, UK, USA</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>2.2m (7%)</td>
<td><strong>9 countries</strong>: Argentina, Austria*, Croatia, Czech Republic, Grenada, Italy, Israel, Norway, Panama</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>2.7m (8%)</td>
<td><strong>14 countries</strong>: Bahamas, Belize, Bhutan, Bolivia, Brunei Darussalam, Colombia, Cook Islands, Denmark, Iceland, Marshall Islands, Peru, Rwanda, Sweden, Zimbabwe</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>13.9m (44%)</td>
<td><strong>61 countries</strong>: Mix of Gavi (16), MICs (non-Gavi PAHO/UNICEF Procure)(15), MICs (self) (8), HICs* (22)</td>
</tr>
</tbody>
</table>

*Austria and Japan = 3 dose schedule*
HPV Supply & Demand

• Supply **not** sufficient to meet demand forecast until **2024** (then only with tight management and careful planning)

• Factors that could affect future supply/demand balance:
  – **Increase in capacity** does not materialise timely and in the expected size
  – **Pipeline products** do not reach market (or PQ) as forecasted
  – **Demand for 9 valent** increases substantially
  – Additional countries **extend immunization to boys**
  – Countries fail coordinating **Multi-Age Cohorts** (MACs) timelines
  – **Country introductions** and **coverage increases** do not occur as planned
Achievable: High HPV coverage with different strategies*

*HPV Vaccine Lessons Learnt. www.rho.org/HPV Lessons
Introduction guide for HPV vaccines & lessons learned from countries

WHO HPV resources: http://www.who.int/immunization/diseases/hpv/resources/en/
Challenges: Decision-Making

- Complex, time-consuming
- Coordination between EPI & Cancer Programmes
- Capacity of NITAGs
- Lack of awareness of disease burden
- Competing vaccine priorities
- Gavi co-financing commitments
Challenges – Price/Affordability

High price per dose and price variability -- $4.55 - $154.28 (2017)

Average non-Gavi UNICEF and self-procuring MICs prices 3X Gavi and ~1.5X PAHO

HIC prices highly varied; some paying less than the average MIC prices

PLUS delivery operations costs ranging $2-$8/dose (C4P Costing Tool)

Source: V3P, 2017 data
## Challenges: Acceptance/Hesitancy

<table>
<thead>
<tr>
<th>Country</th>
<th>Issue</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>CRPS</td>
<td>&lt;1% (2017)</td>
</tr>
<tr>
<td>France</td>
<td>MS</td>
<td>19% (2016)</td>
</tr>
<tr>
<td>Colombia</td>
<td>Anxiety-related reactions</td>
<td>13% (2017)</td>
</tr>
<tr>
<td>Denmark</td>
<td>POTS</td>
<td>36% (2017)</td>
</tr>
<tr>
<td>Ireland</td>
<td>POTS/CRPS</td>
<td>50% (2016/17)</td>
</tr>
</tbody>
</table>
**Call to Action: Towards Elimination of Cervical Cancer (WHA May 2018)**

**Vision:** A world without cervical cancer

**Goal:** Eliminate cervical cancer as a public health problem by reducing the incidence of cervical cancer to below 4 cases per 100,000 woman-years

**2030 Targets:**
- **90%** of girls fully vaccinated with HPV vaccine by 15 years of age
- **70%** of women screened with an HPV test at 35 and 45 years of age and all managed appropriately
- **30%** reduction in mortality from cervical cancer

The 2030 targets and elimination threshold are subject to revision depending on the outcomes of the modeling exercise (SAGE Oct 2018)
In summary....

• HPV vaccine in 44% countries but access in highest burden countries is lagging

• Good understanding/sharing of global lessons learned to achieve high coverage (although still working on how to calculate!)

• Supply shortage at least to 2024 – further exacerbated if MACs; boys; 9-valent; Will need to work in close collaboration with industry.

• Barriers/Challenges to introduction: Decision-making, Price/Affordability, and Acceptance/ Hesitancy

• New initiative Cervical Cancer Elimination – visibility, engagement of broad stakeholders, comprehensive approach, commitments, etc
WHO HPV Vaccine introduction
Clearing house

Visit each area for related resources:

- POLICY & DECISION-MAKING
  Informing national decision-making for HPV vaccine introduction
- PLANNING
  Planning for HPV vaccine introduction
- FINANCING
  Budgeting and financing for HPV vaccine introduction
- VACCINES & SAFETY
  Characteristics, presentations and safety profiles of HPV vaccines
- COMMUNICATION
  Communicating effectively using research-based approaches
- IMPLEMENTATION
  Delivering HPV vaccination programmes
- MONITORING & SURVEILLANCE
  Monitoring the coverage and impact of HPV vaccine programmes
- HPV partNERS
  Links to HPV partners and resources

http://www.who.int/immunization/hpv/en/
Resources for HPV vaccine implementation:

- What do health worker and teachers need to know?
- Is school ready for vaccination?
- Are informed consent procedures adapted for adolescents?
- Message and target of HPV communication plan? Crisis event planning?
- How to monitor HPV vaccination?
- Special vaccination cards for HPV?
- How to strengthen cancer registries?