Overview of HPV vaccine through UNICEF
In 2013, UNICEF began procuring HPV vaccine for countries supported by Gavi, and for middle-income countries (MIC) funding their national introduction.

HPV vaccine delivery programmes across low- and middle-income countries are still in early stages of development. Currently, there is no track record of Gavi demonstration projects translating to national introductions.

Total UNICEF procurement reached just over 4 million doses until Q3 2015. This is less than originally projected, on account of delayed country introductions and the WHO recommendation to reduce the HPV vaccine-dosing schedule from three to two doses.

Gavi has to date approved funding for smaller-scale demonstration projects in 25 countries and nationwide introductions for three countries. Demand is anticipated to increase significantly once Gavi demonstration programmes transition to nationwide introductions. Gavi expects ~17 countries to have introduced HPV vaccine nationally with Gavi support by end-2017.
UNICEF has so far awarded quantities under long-term arrangements (LTA) and ad hoc Purchase Orders (PO) against confirmed country demand. Additional **incremental awards** will be made as new country demand materializes and approval/timing for further introductions is confirmed.

**Supply available** from suppliers through UNICEF is sufficient to meet the currently projected demand funded by Gavi, for the tender period (2013-2017), as well as projected by MICs.

Demand from **self-funding countries** through UNICEF has so far been limited. UNICEF anticipates demand for this segment of countries to increase as additional countries consider HPV vaccine introductions. HPV vaccine **price remains a concern** for countries that are considering the long-term sustainability of financing programs for both self-financing MICs and Gavi-graduating countries.
High country demand for HPV vaccination support

- Almost 50% of eligible countries* are approved, the majority from Africa (n=23)
- Majority of countries did not have previous experience with HPV
- 8 countries expected to introduce by end of 2015 (1 National)
- 12-20 new applications expected by end of 2016, most for National support

*Analysis includes 16 countries eligible as of July 2015 based on the revision of the eligibility policy approved in June 2015
SDF v6 – GAVI supported nat. introductions (Sep 2012)

- 2014: Cameroon, Gambia, Kenya, Lao PDR, Malawi, Mauritania, Mozambique, Sao Tome & Principe, Solomon Islands, Rwanda, Uganda, Zimbabwe
- 2015: Benin, Burundi, Cote d'Ivoire, Ethiopia, Ghana, Kyrgyzstan, Madagascar, Nigeria, PNG, Senegal, Tanzania
- 2016: Bangladesh, CAR, Comoros, Nepal, Togo, Vietnam
- 2018: Cambodia
SDF v7 – GAVI supported nat. introductions (Feb 2013)

- 2014: Rwanda, Ghana, Kenya, Lao PDR, Madagascar, Malawi, Nepal, Rwanda, Uganda
- 2015: Benin, Burundi, Gambia, Gambia, Sao Tome & Principe
- 2016: Benin, Burundi, Gambia, Gambia, Sao Tome & Principe
- 2017: Bangladesh, Cameroon, Comoros, Cote d'Ivoire, Kyrgyzstan, Mali, Mauritania, Mozambique, Solomon Islands, Tajikistan, Tanzania, Uzbekistan, Togo, Vietnam
- 2018: Ethiopia, CAR, Cambodia, Nigeria, PNG
3 signifies 3 year demo assumed
* Approved for demo
SDF v9 – GAVI supported nat. introductions (Mar 2014)

3 signifies 3 year demo assumed
* Approved for demo

- Lao PDR*
- Madagascar*
- Malawi*
- Sierra Leone*
- Uganda
- Uzbekistan
- Rwanda
- Zambia
- Zimbabwe*
- Ghana*
- Tanzania*
- Togo³
- Solomon Islands
- Vietnam
- Nicaragua
- Tajikistan
- Nepal
- Cambodia³
- CAR
- Ethiopia³
- Comoros
- Mali³
- Cote d’Ivoire³
- Kyrgyzstan
- Mauritania³
- Nigeria³
- PNG
- Kenya*
- Bangladesh³
- Burkina Faso
- Cameroon³
- Niger*
- Sao Tome & Principe
- Senegal
- Nepal
- SPF - GAVI supported nat. introductions (Mar 2014)

1  8  3  11  9  >2018
**SDF v10 – GAVI supported nat. introductions (Oct 2014)**

- **2014**: Rwanda, Uganda, 1
- **2015**: 1
- **2016**: 16
- **2017**: 7
- **2018**: 7
- **>2018**: 7

*3 signifies 3 year demo assumed
* *Approved for demo
Bold = Gavi graduating country*
SDF v11 – GAVI supported nat. introductions (May 2015)

3 signifies 3 year demo assumed
* Approved for demo
Bold = Gavi graduating country

Rwanda
Uganda
Uzbekistan

2014
2015
2016
2017
2018
>2018

Burkina Faso
Cameroon
Gambia
Mozambique
Nepal
Niger

Ghana
Kenya
Lao PDR
Madagascar
Malawi

Burundi
Cote d'Ivoire
Ethiopia
Mali
Mauritania

Bangladesh
Benin
Comoros
Congo, DR
Djibouti
Eritrea
Erin
Guinea-Bissau
Kyrgyzstan
Liberia
Myanmar

Pakistan
Vietnam
Sao Tome & Principe
Togo

SDF v11 – GAVI supported nat. introductions (May 2015)

3 signifies 3 year demo assumed
* Approved for demo
Bold = Gavi graduating country
## Current status of HPV vaccine supply and demand

**UNICEF has so far awarded quantities under LTA in line with approvals for new Gavi-supported programs (2013–2017):**

<table>
<thead>
<tr>
<th>Manufacturer (Country)</th>
<th>Initial 2013 Awards (Doses)</th>
<th>Price per Dose</th>
<th>LTA Duration</th>
<th>Additional 2014 Awards (Doses)</th>
<th>Total Awards (Doses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlaxoSmithKline (Belgium)</td>
<td>180,800</td>
<td>$4.60</td>
<td>5 years</td>
<td>+253,300</td>
<td>433,300</td>
</tr>
<tr>
<td>Merck (USA)</td>
<td>2,440,800</td>
<td>$4.50</td>
<td>5 years</td>
<td>+624,480</td>
<td>3,065,280</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,620,800</strong></td>
<td><strong>$4.50</strong></td>
<td><strong>5 years</strong></td>
<td></td>
<td><strong>3,498,580</strong></td>
</tr>
</tbody>
</table>

In addition, UNICEF has awarded ad hoc Purchase Orders (PO) against confirmed country demand from self-financing MICs:

<table>
<thead>
<tr>
<th>Supplier Name</th>
<th>Receiving Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlaxoSmithKline (Belgium)</td>
<td>Cook Islands</td>
</tr>
<tr>
<td>Merck (USA)</td>
<td>Peru</td>
</tr>
<tr>
<td></td>
<td>Philippines</td>
</tr>
</tbody>
</table>
Gavi-supported HPV national introductions by 2020 – “one-off” countries

The following list of countries may apply for exceptional support for introduction of HPV*: Angola; Armenia; Azerbaijan; Bolivia; Congo Republic; Cuba; Georgia; Guyana; Honduras; Indonesia; Moldova; Mongolia; Sri Lanka; Ukraine.

- **Ten** of the one-time eligible countries have expressed interest (medium + high probability) in launching national HPV programs
  - **One** has already applied
- Can get support for **50% of the doses and VIG for 1 year or a two-year HPV vaccine demonstration programme**, if they introduce by 2017
- Must apply within 2016 for “one-off” support

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*Countries that have already introduced HPV vaccine nationwide through donations do not qualify for this exceptional opportunity to receive catalytic support from Gavi.*
Issues and Challenges – Way Forward

Significant forecast uncertainties:
HPV vaccine delivery programmes across LICs and MICs are still in early stages of development. Currently, there is no track record of Gavi demonstration programs translating to national introductions.

Competing priorities with other vaccine introductions (e.g. PCV, Rota, IPV) have led countries to shift to a 3-year demonstration duration or to delay national introduction.

HPV vaccine price remains a concern for countries that are considering the long-term sustainability of financing programs for both self-financing and Gavi-graduating countries.

Additional incremental awards will be made as new country demand materializes and timing for further introductions is confirmed.

A new tender is foreseen for Gavi demand to be issued during 2017 to cover the period beginning 2018 and beyond.

UNICEF will continue to assess country demand and identify actions to improve forecast accuracy, in addition to dialogue with manufacturers and follow the development of new products (e.g. 9-valent HPV vaccine).

UNICEF will continue to explore ways to improve access to affordable and timely supply of vaccines for MICs that self-finance their HPV vaccine purchases.
Overview of Japanese Encephalitis (JE) vaccine through UNICEF
Some Background – when it all started

• **2011:** The Gavi Board recommended opening a window for supporting JE catch up campaigns, subject to the pre-qualification of a suitable JE vaccine.

• **2013:** WHO pre-qualified a JE vaccine for pediatric use.

• **2014:** Gavi opened a window for country applications for catch up campaigns (1 dose schedule) for a target population aged 9 months, up to 15 years of age.

  The only UNICEF RFP for the procurement and supply of JE vaccine was launched in 2014 and resulted in a LTA valid until end of June 2016.

• **2015:** The 2016 JE Gavi Guidelines will soon be published.
• As of July 2015, 3 countries (Cambodia, Lao PDR and Nepal) have been approved for Gavi support of JE vaccine campaigns. Total awarded was of 10+ million doses.
Only includes estimated quantities for catch up campaigns (supported by Gavi).

**Need to secure enough supply** for up-coming Gavi supported catch-up campaigns from 2017 onwards.
**Challenges and Way Forward**

**Difficulty of demand quantification.** JE forecast accuracy has been a challenge and is subject to country application which have been slower than expected and has lowered demand.

**Number of available vaccines.** At the time of the 1st tender round in 2014, only one vaccine was pre-qualified for pediatric use.

**Prices.** The price differences among manufacturers are still high.

**Upcoming tender.** Precise timeline - in 2016 - still to be defined with partners.

**Process of forecast review commenced.** Periodic review will be conducted and adjustments on forecasted demands to become available to manufacturers on a timely manner.

**For Gavi demand for catch-up campaigns.** Upcoming tender to be in line with new JE application guideline.

**For routine JE immunization programmes.** Next tender will consider all JE WHO pre-qualified vaccines and pipeline and will establish contractual relationships with manufacturers to provide access to JE vaccine for routine immunization either after Gavi support or for fully self-financing MICs.

**Additional manufacturer(s) obtaining WHO pre-qualification during 2016-2017?** The new tender round will also be a tool to obtain updated information on pipeline producers and product innovation, and UNICEF encourages the participation of all manufacturers.

**CONCLUSION:** All vaccine manufacturers – both pre-qualified and pipeline producers – will be encouraged to participate in the tender exercise.
Supply and Market Update on JE available

Available at:

http://www.unicef.org/supply/index_82707.html

Japanese Encephalitis Vaccines Supply and Market Update

UNICEF provides a market informational note for Japanese encephalitis (JE) vaccines, highlighting current and projected demand, as well as anticipated supply availability during 2015-2020. JE vaccine programmes across low- and middle-income countries are in a formative stage. The timely delivery of supply is important given the seasonality of disease incidence, necessary timing of campaigns and the relatively limited shelf life of the JE vaccine procured through UNICEF.

Japanese encephalitis vaccines supply & market update - July 2015

Updated: 6 August 2015
Overview of Pneumococcal Conjugate Vaccines (PCV) through UNICEF
Current Status of PCV Supply situation - AMC

- 6 valid Supply Agreements with 2 suppliers: GSK and Pfizer (AMC)
- Supply is steady and in accordance with the Supply Agreements
- Availability of enough doses to support on-going programs
- No constraints in production or availability has been reported by manufacturers

<table>
<thead>
<tr>
<th>Company</th>
<th>Vaccine</th>
<th>Duration</th>
<th>Start</th>
<th>End</th>
<th>Present.</th>
<th>Doses</th>
<th>Courses</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlaxoSmithKline (Belgium)</td>
<td>PCV10</td>
<td>LTA – 15 years</td>
<td>2010</td>
<td>2024</td>
<td>2 ds</td>
<td>720,000,000</td>
<td>240,000,000</td>
</tr>
<tr>
<td>Pfizer (United States of America)</td>
<td>PCV13</td>
<td>LTA – 14 years</td>
<td>2010</td>
<td>2023</td>
<td>1 ds</td>
<td>740,000,000</td>
<td>246,000,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>1,460,000,000</strong></td>
<td></td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.
PCV procurement through UNICEF
Call for Supply Offer: Current situation

• The “AMC Offer Agreement” establishes that “a Call for a Supply Offer may be issued once per calendar year or more or less frequently if so decided by the GAVI Alliance in consultation with UNICEF”.

• The last Call for Supply Offers was issued in August 2012 with the conclusion of Supply Agreements in July 2013.

• Consultations among partners took place in 2015 to examine:
  • GAVI Strategic Demand Forecast (SDF) v10 and
  • the level of contracted supply through existing supply agreements,

As a result, the partners have agreed that there is no need for issuing a Call for Supply Offer in 2015 and that the currently contracted quantities suffice to meet the expected demand in the short term.

• Re-assessment of the situation in late 2015 for a possible Call for Supply Offer in 2016 based on
  • SDF v11 and
  • outcomes of the next rounds of GAVI applications,
Issues and Challenges

• Delays in country introductions - competing priorities between new vaccines, programmatic readiness, storage capacity and Vaccine registration

• Innovation: The introduction of new 4-dose vial presentations will require early planning, including assessment of country interest and introduction dates as well as addressing the issues of wastage.

• Product preference with the emerging MDV presentations remains uncertain and can impact demand forecast and product shares leading to supply constraints

• Prices of PCV for fully self-financing MICs are still very high compared with AMC prices
Way Forward

- Continue working with stakeholders to support the countries

- Work with countries, stakeholders and suppliers to manage the switch to MDV presentation

- Continue collaboration with manufacturer to meet countries demand – product registration in more countries will favour introductions

- UNICEF will continue to explore ways to improve access to affordable and timely supply of vaccines for MICs that self-finance their PCV purchases.

- PCV pipeline manufacturers are encouraged to register with the AMC Secretariat and to communicate with UNICEF SD to start a close follow-up on their vaccine developments.
Information available on the UNICEF website

http://www.unicef.org/supply/index_60990.html

AMC for Pneumococcal

The Advance Market Commitment for Pneumococcal Vaccine

On 12 June 2009, the Advance Market Commitment (AMC) for the supply of Pneumococcal Vaccine was launched. The Pneumo AMC has as its overarching goal the reduction of morbidity and mortality from pneumococcal diseases which represents the leading vaccine-preventable cause of death among young children.

The objectives of the Pneumo AMC are to:
• accelerate the development of vaccines that meet developing country needs;
• bring forward the availability of effective pneumococcal vaccines - through scaling up of production capacity to meet developing country vaccine demand;
• accelerate vaccine uptake - through predictable vaccine pricing for countries and manufacturers; and
• test the AMC concept for potential future applications.

The Pneumo AMC is geared to support the establishment of an annual manufacturing capacity of 200m vaccine doses to meet demand in countries supported by the GAVI Alliance. It is backed by a collective commitment from six donors (the governments of Italy, the United Kingdom, Canada, Russia, Norway, and the Bill and Melinda Gates Fund) to fund US$1.5b. Adding to this amount, both the GAVI Alliance and countries will contribute to the vaccine price, with GAVI projecting a funding requirement of US$2.7b from 2011-2015.

Key elements of the Pneumo AMC are the following:
• An initial price per dose of US$7.00 to be paid to the supplier

Earthquake in Nepal

Children in Nepal need your help. Please donate what you can today.

DONATE NOW
Overview of Rotavirus through UNICEF
- Ad hoc procurement in 2011
- LTAs in 2012
  - 2 WHO PQ vaccines;
  - GSK and Merck
- 32 countries have introduced with UNICEF/Gavi support
- LTAs valid 2012-2016
  - Country preference for one vaccine
  - LTAs have not been fully utilized
- Large country introduction anticipated
  - Insufficient supply currently available to support and sustain introduction countries with large populations
- 3 pipeline manufacturers anticipated by 2020
## Issues and Challenges – Way Forward

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Way forward</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Introduction delays due to training requirements</td>
<td>• Product presentation that does not require additional training requirements prior to country introduction</td>
</tr>
<tr>
<td>• Lower than expected uptake of program impacting LTA utilization (forecast accuracy)</td>
<td>• Close monitoring with partners to encourage country applications</td>
</tr>
<tr>
<td>• Cold chain requirements</td>
<td>• Vaccine innovation to support immunization delivery</td>
</tr>
<tr>
<td>• Delay in market entry of pipeline manufacturers</td>
<td>• Acceleration of market entry and WHO PQ</td>
</tr>
</tbody>
</table>
Way Forward – Future Tender

- **Strategic considerations**
  - Future demand expected from large countries
  - Need for diverse supplier base
  - Sustainability of programmes

- **Current LTA’s**
  - Validity 2012-2016 with option for extension by 1 year

- **Future Tender**
  - Planned in collaboration with partners
  - Tender objectives:
    - Accelerate use/early access
    - *Uninterrupted supply* that meets demand, including large countries
    - Ensure *appropriate* products that meet country needs
    - Affordable vaccine

Manufacturers are invited to update UNICEF on plans for licensure, manufacturing capacity and WHO PQ to allow planning for introduction
THANK YOU