Mechanism for access to vaccine for use in Humanitarian Crisis
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Outline

• Background
• Goal & Objective
• Context:
  – Demand; trend and projection
  – Vaccines used
  – Registration requirements
  – Current mechanism in place
• Next steps:
  – Supply arrangements
• Process outline
Background

SAGE
- Oct 2015 “more guidance needed” …. “necessary to assess how activities can be carried out” …” stresses necessity to address access issues and call for more collaboration between WHO, Gavi, UNICEF, MSF, …. facilitate prompt provision of vaccines to the most vulnerable populations. ”
- April 2016, …. “continuous efforts in strengthening vaccination in humanitarian crises including further updating of field vaccination guides.”

During World Immunization Week 2016, partners such as UNICEF profiled the vaccination needs of conflict-affected children, noting that almost two-thirds of all unvaccinated children live in conflict affected countries
Goal & Objectives

Goal
To make progress towards reducing vaccine-preventable deaths in emergencies through scaled up vaccination services for crisis-affected populations and address the challenges to access affordable prices and availability in these situations.

Objectives

• Define the demand through collective quantitative data on the historical trend and determine a crude projection of vaccines for emergencies and humanitarian crisis (through CSOs and UNICEF)
• Access to affordable/low price for vaccine used in Humanitarian response
• Establishment of streamlined procurement process, and supply chain allowing timely response to emergencies
UNICEF disseminated a survey tool to immunization partners for data collection. The survey captured both quantitative and qualitative information to identify demand trend as well as challenges faced by different stakeholders.

Responses were cross-referenced with reports of humanitarian emergencies issued by UNOCHA.

Key considerations:
- Vaccines that already had mechanisms for global access for outbreaks were excluded (OPV, Measles containing and outbreak response vaccines such as YF, OCV, and Meningococcal A, C, W)
- Syria was analyzed separately in the historical demand
- Demand projection remains a challenge
Challenges related to supply of vaccines in Humanitarian Emergencies as per the outcome of survey

• **Production lead time:** frequently protracted contractual negotiations have been a bottleneck to securing supply in a timely manner

• **Price and affordability:** vaccine alone accounted for up to 80% of all expenses. UNICEF been able to access Gavi prices for most vaccines in Humanitarian context.

• **Regulatory Constraints:** Registration of vaccines in some countries vulnerable to humanitarian crisis, require advocacy on the acceptance of WHO-PQ in Humanitarian context.

• **Other Challenges:**
  – Sourcing and access to vaccines that are not routinely used and procured for EPI program (eg. Hep E),
  – Lack supply arrangement in place for some vaccine in non-Gavi countries (eg. PCV, Rota, HPV)
Countries that have received vaccines for humanitarian emergencies in the past 3 years as reported in the demand survey (Oct 2016)

Countries that are categorized as very high risk for humanitarian emergency by the overall INFORM risk index

- Liberia
- Mali
- Chad
- Sudan
- South Sudan
- Somalia
- Ethiopia
- Kenya
- Tanzania
- Uganda
- Rwanda
- Congo DR
Vaccine registration requirements

- 13 out of 25 countries that have been receiving the highest number of vaccines for humanitarian emergencies, require registration.
- Waiver for emergency could be explored, though more information and clarity needed on the process in emergency response.
- UNICEF will work with WHO, countries and suppliers to reduce bottlenecks in regulatory issues.
**Historical demand trend by antigen**

*(Excluding respond to Syria)*

- 1.4 Million doses delivered in 4 years with a peak in 2015
- PCV and Penta vaccines are the key drivers of the large volumes
- This also excluded antigens that are readily accessible e.g. MR, MMR, OPV

**Trend of demand for Humanitarian Emergencies, 2013-2016**

- DTP, Hib
- IPV
- Penta
- Hexavalent (Penta+IPV)
- PCV
- Yellow fever
- Cholera
The escalation of the Syria crisis situation is a reflection of the large demand for routine immunization programs that skews the 2016 data.
80% of demand is in the top 4 countries (CAR, Ethiopia, Lebanon and South Sudan)
• 6.5 million doses of vaccines have been delivered to Syria (excluding antigens that are easily accessible)
## Current context – Vaccines used in Humanitarian Response

<table>
<thead>
<tr>
<th>Vaccines currently under UNICEF Long Term Agreements</th>
<th>DTwP-Hib-HepB - Pentavalent</th>
<th>Same or similar price level to Gavi supported countries been accessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>DT/DPT/HepB</td>
<td>BCG</td>
<td></td>
</tr>
<tr>
<td>JE</td>
<td>MMR (LZ)</td>
<td></td>
</tr>
<tr>
<td>DT/DPT/HepB</td>
<td>DT/DPT/HepB</td>
<td></td>
</tr>
<tr>
<td>TT/Td</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccines with no arrangements for non-Gavi markets</th>
<th>PCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rota</td>
<td></td>
</tr>
<tr>
<td>HPV</td>
<td></td>
</tr>
<tr>
<td>Hep E</td>
<td>Has not been procured through UNICEF in the past</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emergency/outbreak response vaccine (contractual agreements for emergency response and/or stockpile)</th>
<th>OPV/mOPV</th>
<th>Managed through the GPEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPV/mOPV</td>
<td></td>
<td>Managed through the GPEI</td>
</tr>
<tr>
<td>Measles/MR</td>
<td></td>
<td>Managed in collaboration with MRI</td>
</tr>
<tr>
<td>Yellow Fever &amp; Meningitis</td>
<td></td>
<td>Managed through the ICG for response to outbreak</td>
</tr>
<tr>
<td>Oral Cholera Vaccine</td>
<td></td>
<td>Managed through the ICG for outbreak response; through the GTFCC for preventive campaign</td>
</tr>
</tbody>
</table>

*Special offers made by GSK and Pfizer for access to affordable prices for Humanitarian Response. Contractual arrangements are being put in place for streamlined access to vaccines.*
Current context -
Existing mechanisms for Emergency and Outbreak response

- **Measles and MR (MRI)**
  - 72 Hours
  - 1M doses Measles and 100K doses MR

- **Oral Cholera**
  - 96 Hours
  - LTA with 2 components: Preventive Campaigns and Emergency/Outbreak response

- **Yellow Fever**
  - 72 Hours
  - LTA with 2 components: Routine and Emergency/Outbreak response

- **Meningococcal A, C and W containing vaccines**
  - 72 Hours
  - LTA with 2 components: Routine and Emergency/Outbreak response

- **mOPV2** – post type 2 cessation outbreak response
- **IPV** – recommended use in outbreak response
- **bOPV** – sufficient availability to respond to outbreaks
Gavi Fragility and Immunisation Policy

**Purpose:** to improve coverage in countries with particularly challenging circumstances and protect immunisation systems and existing Gavi support in emergencies.

### Long-term fragility situations
- Country is eligible for Gavi support
  - Country has 4 of 7 exceptional circumstances identified within the framework
  - Secretariat develops country tailored approach including monitoring plan in collaboration with country and partners

### Short term emergency situations
- All Gavi supported countries (incl. transition)
  - Time-limited man-made or natural event that threatens immunisation system
  - Country may re-programme HSS, apply for additional HSS and vaccines if destroyed or need to cater for refugees.
  - Gavi determines implications and exceptions for policies and processes.

Guided by WHO's Framework for vaccination in humanitarian emergencies
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Next steps: Supply arrangement

• UNICEF to issue an Expression of Interest to invite industry’s engagement on vaccines with no supply arrangement for supply of antigens that are not readily accessible (currently on LTA) or that it is not accessible under current supply arrangements

• UNICEF to issue RFP based on the outcome of the EoI to establish supply arrangements for those vaccines in Humanitarian context and establish:
  – Time bound for non-routine vaccines (Hep-E)
  – Target bound for other vaccines
Processing a request for Vaccines in response to Humanitarian Crisis

• Submission of request for “validation body”
• Validation role and criteria:
  – Programmatic applicability and suitability
  – No duplication
  – Ensure rapid notification of all stakeholders
  – CSO capability and eligibility
  – Humanitarian context
• Supply availability: allocation criteria and prioritization
• Procurement/Order placement:
  – Directly by requesting CSO
  – Through UNICEF SD
• Shipment of vaccines
  – CSO and/or through supplier’s freight forwarder
  – UNICEF SD Global Freight forwarder
• Bi-annual review and assessment of demand