“Vaccination in acute humanitarian emergencies”

Guidance on the choice of vaccines and implementation of vaccination and update on the issue of access to vaccines.

Report of Vaccination in Humanitarian Emergency Situations meeting
Geneva, Switzerland
10-11 October 2016

Philippe Duclos
WHO, Immunization, Vaccines, Biologicals
Vaccination in acute humanitarian emergencies: A framework for decision making

The Strategic Advisory Group of Experts (SAGE) on Immunization stressed the need to develop guidance on use of vaccination in humanitarian emergencies in order to:

- Provide an evidence-based approach to assist decision-makers on the use or non-use of one or more vaccines.
- Foster agreement among stakeholders on which vaccines to use.

More needed! Repeated requests from SAGE and the WHA since 2015

- **October 2015 SAGE**
  - “…more guidance needed in relation to implementation of sustainable immunization in ongoing conflict or crisis among both internally displaced people and those who have become refugees in other countries.”
  - “…necessity to assess how immunization activities can be carried out in the context of response to humanitarian emergencies, ”
  - “called for strengthened collaboration between Gavi, UNICEF, MSF and other involved organizations to facilitate prompt provision of vaccines to the most vulnerable populations.”

- **April 2016 SAGE Meeting report**
  - “SAGE stressed the need for continuous efforts in strengthening vaccination in humanitarian crises including further updating of field vaccination guides.”

- **May 2016, 69th World Health Assembly**
  - “WHO should provide guidance for countries and partners on implementation of immunization programmes and immunization strategies during situations of conflict and chronic disruption.”
Vaccination in Humanitarian Emergencies: 2016 series of meetings

Cairo, January 2016

- Joint WHO HQ and EMRO meeting.
- Build on experience of EMR crisis-affected countries and on conclusions of previous EMR-AFR experience sharing meeting in Tunis in March 2014
- Aim to develop a guide on implementation of vaccination in humanitarian emergency and reflect on the use of the framework for decision making.

Geneva, June 2016

- Stakeholder meeting ”Vaccinating in humanitarian emergencies: identifying challenges and resolving barriers to timely supply of affordable vaccines in humanitarian crisis situations” jointly organized by MSF-WHO.

Geneva, October 2016
Meeting objectives

1. Agree on a package of documents/solutions to guide vaccination in humanitarian emergency including on the choice of vaccines and implementation of vaccination.

2. Develop a dissemination and communication plan to ensure availability and facilitate use of the package.

3. Agree on next steps to resolve barriers to timely supply of affordable vaccines in humanitarian crisis situation.
Vaccination in acute humanitarian emergencies: A framework for decision making

3-step approach to assess which vaccine(s) to use in the context of a humanitarian emergency.

- All potential vaccines (keep in mind routine if disturbed).
- Short term impact unless protracted crisis.

<table>
<thead>
<tr>
<th>Level of risk due to general risk factors</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of risk due to factors specific to the VPD</td>
<td>High</td>
<td>Definitely consider</td>
<td>Possibly consider</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>Definitely consider</td>
<td>Possibly consider</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>Do not consider</td>
<td>Do not consider</td>
</tr>
</tbody>
</table>

**STEP 1: Determine and grade risk of the VPD**
Is there an increased risk of the VPD? *(See Epidemiological Risk Assessment)*

**STEP 2: Assess vaccines & amenability to service delivery (e.g. mass campaigns/routine immunization services)*
Are relevant vaccines available in sufficient quantities; do the vaccine characteristics lend themselves the specific type of service delivery? *(See Vaccine Characteristics)*

**STEP 3: Assess contextual constraints and facilitators, alternative interventions and competing needs**
Is there political stability, security, adequate staff for mass campaigns & funding for vaccination, consensus between all key stakeholders, ethical consideration, etc.? *(See contextual Factors Chapter)*

Implement vaccination intervention

Monitor changes in disease patterns, risk factors, on-going alternative interventions, evolution of contextual barriers, and if indicated reassess from **STEP 1**
Vaccination in acute humanitarian emergencies: A framework for decision making

**STEP 1: Assessment of general risk factors and assessment of risk factors specific to the vaccine-preventable disease.**

<table>
<thead>
<tr>
<th>Level of risk due to factors specific to the VPD</th>
<th>Level of risk due to general factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Definitively consider</td>
<td>Definitely consider</td>
</tr>
<tr>
<td>Definitely consider</td>
<td>Possibly consider</td>
</tr>
<tr>
<td>Medium</td>
<td>High</td>
</tr>
<tr>
<td>Definitively consider</td>
<td>Definitely consider</td>
</tr>
<tr>
<td>Possibly consider</td>
<td>Do not consider</td>
</tr>
<tr>
<td>Low</td>
<td>Do not consider</td>
</tr>
<tr>
<td>Do not consider</td>
<td>Do not consider</td>
</tr>
<tr>
<td>Do not consider</td>
<td>Do not consider</td>
</tr>
</tbody>
</table>
Vaccination in acute humanitarian emergencies: A framework for decision making

- **STEP 2: Consideration of vaccine characteristics and amenability to the envisaged service delivery.**
  - Vaccine availability in sufficient quantities.
  - Time till protection.
  - Vaccine efficacy at full schedule and efficacy at less than full schedule as well as vaccine effectiveness.
  - Vaccine safety.
  - Storage and cold-chain requirements.
  - Implementation considerations.
Vaccination in acute humanitarian emergencies: A framework for decision making

STEP 3: Assessment of **contextual constraints** and facilitating factors.

- Ethical considerations.
- Political considerations.
- Security considerations.
- Human resources.
- Financial considerations.
- Alternative interventions.
- Add-on interventions.
- Research considerations.
Implementation guide: Outline 1

1. Introduction
   1.1 Purpose of the guide
   1.2 Target audience
   1.3 Definition of acute humanitarian emergency situation
... Implementation guide: Outline 2

2. Architecture of the response structure: Leadership, management, coordination and partnership

2.1 Establishment and activation of an Immunization Task Force
2.2 Establishment of the Operational Control Room
2.3 Interaction and coordination of the Immunization Task Force with the Health Cluster
2.4 Interaction and coordination of the Immunization Task Force with the sub-national and peripheral governance levels
2.5 Interaction and coordination of the Immunization Task Force with the NITAG
3. Planning and implementing of the immunization intervention

3.1 Decision on use of vaccines in humanitarian emergencies
3.2 Immunization programme assessment
3.3 Integration of immunization service delivery
3.4 Planning
3.5 Resource mobilization
3.6 Vaccine supply
3.7 Cold chain
3.8 Logistics
3.9 Demand-related intervention
3.9 Access
3.10 Immunization service delivery
3.11 Immunization schedule
... Implementation guide: **Outline-4**

4. Reporting and periodicity

5. Monitoring, evaluation and supportive supervision

6. Exit strategy and early recovery of immunization services

7. References

8. Annexes

   – Annex 1: Mapping of international entities active in supply of vaccines in humanitarian emergencies
   – Annex 2: Example of micro plans/micro plan framework
   – Annex 3: Country case studies
Vaccine Supply: Introduction of vaccines in accordance with the regulatory framework of the country.

- Timelines generally required by standard regulatory pathways not appropriate during emergencies.

- Specific alternative procedures can be considered in such cases. Options can include:
  - Waiving of registration requirements for vaccines supplied by the UN system, based on prequalification criteria for international supply and recognition of the assessment done by the prequalification team.
  - Waiving of registration requirements for vaccines produced and registered by countries with a functional NRA, based on WHO NRA benchmarking criteria.
  - Implementation of pathways for acceptance of the vaccines under emergency situation:
    - Reliance on other regulatory decisions for national registration.
    - Reliance on prequalification decisions through implementation of the collaborative procedure.
Vaccine Supply: Introduction of vaccines in accordance with the regulatory framework of the country.

- Preparedness required.
- Regulatory planning should include:
  - Identification of the key units and/or individuals responsible for establishing and revising emergency regulatory pathways.
  - Documentation of the roles, responsibilities and authority of these entities during preparedness planning and during the emergency.
  - Establishment of the regulatory decision options, the criteria to meet and the information required for decision making.
  - Establishment of the methods for communication of the regulatory disposition decisions, the responsible entity for communication and the recipient(s). These should include all affected parties involved in the vaccine introduction.
- Customs considerations for timely importation. Customs formalities should be mapped as part of preparedness planning with identification of mechanisms for accelerated clearance of emergency supplies.
Proposed mechanism to allow for access to vaccines at lowest price for use in humanitarian emergency situations in complement of already existing mechanisms

- In context of WHO Framework for Vaccination in Humanitarian emergencies…

- Fruitful collaboration among WHO-UNICEF, CSOs and industry have led to tentative development of a ‘Goodwill vaccine supply initiative’

- Mechanism is still under development…
Proposed principles and aims

- Ensure timely and affordable access to supply for humanitarian emergencies
- Complementary to existing mechanisms to ideally cover all antigens and all manufacturers. Eventually, all existing offers/options for timely and affordable access for humanitarian emergencies could be listed under this mechanism if appropriate for ease of use/management/coordination.
- Guarantee that vaccine will not be rerouted for use in routine under normal circumstances and only used under offer clause. Also guarantee appropriate and necessary use.
- Avoid interference with commercial strategy of companies
- Compassionate granting of lowest price to procuring organization
- Beyond CSOs
- Accommodate flexibility in the terms of offers
Process: 1- Coordination of requests

- Ensure no duplicate request
- Ensure rapid notification of all interested parties
- Ensure parallel kick start of relevant processes: e.g. check-in on registration of product, notification of manufacturers…

→ Opportunity to collect/collate data on demand
Process: 2- Verification of eligibility of request against offers.

2.1. Recipient/organization validation

• CSOs
  – Organization automatically eligible if:
    • Member of Global Health Cluster (HC) or HC observer status
    • UNICEF SD procures vaccine for this organization
  – If not desk audit and interaction with Immunization Task Force to determine status and appropriateness of request in the local context

• Beyond CSOs i.e. UN agency (such as UNICEF or UNHCR) or government, only other clauses apply to ensure restricted use to humanitarian purpose
Process 2 - Verification of eligibility request

2.2. Verification of humanitarian emergency situation (WHO, Emergency Operations)

- WHO graded emergency
- Humanitarian response plan
- Establishment of an immunization task force
- Displacement of populations?
2.3. Determination of appropriateness of the specific vaccine request (WHO, Immunization, Vaccines and Biologicals)

- Has the decision making framework been already applied with a positive conclusion (ITF, HC, government, partners)?

- If not then application of the framework by WHO/IVB (within 24-48 hours of request)
Thank you!
Definitions of acute humanitarian emergencies

- Occurrence of one or more of the following:
  - **Sudden unplanned displacement** of a large proportion of the population away from the community of habitual residence and into any settlement (refugee or internally displaced persons’ camps; host community; urban areas; other uninhabited areas), within the same country or across international borders.
  - Direct exposure of the civilian, non-combatant population to **new or exacerbated and sustained episodes of armed conflict**.
  - **Natural or industrial (including nuclear) disaster** resulting in temporary homelessness, disruption to critical public services (e.g. health care, water and sanitation, food deliveries, etc.), increased risk of injury and/or exposure to adverse weather conditions for a large proportion of the population.
  - **Sudden breakdown of critical administrative and management functions**, within the public and/or private sector, due to any reason, resulting in large-scale disruption of public health and related services (e.g. water and sanitation, housing).

- Crises can be of **short duration** or **protracted**
Humanitarian emergencies result in:

- Mass population movements and resettlement in temporary locations; overcrowding; economic and environmental degradation; impoverishment; scarcity of safe water; poor sanitation and waste management; absence of shelter; poor nutritional status as a result of food shortages; and poor access to health care.

- These risk factors place affected populations at risk of high morbidity and mortality from vaccine-preventable diseases.