Defining characteristics of next generation cholera vaccines – programme of work

PDVAC Meeting
Geneva, 22 June, 2017

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Scope

- Brief background on the landscape of next generation cholera vaccines
- Programme of work planned by WHO, MSF and other global partners
  - proposed engagement with PDVAC

The following will not be covered:
  - currently licensed oral cholera vaccines and use
    - 5 killed, whole-cell vaccines; 3 WHO PQ’d; **Shanchol and Euvichol available through the global OCV stockpile**
    - 1 live attenuated vaccine
  - policy recommendations for OCV use
  - cholera control activities in general
## Overview of pipeline (as at mid-2016)

*(selected candidate product characteristics)*

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>University of Gothenburg candidate</th>
<th>Johns Hopkins University candidate</th>
<th>Finlay candidate C7258 strain</th>
<th>Vibrio cholerae 638</th>
<th>CholeraGarde</th>
<th>VA1.3 and VA1.4 Indian government candidates</th>
<th>IEM108 Chinese CDC candidate</th>
<th>OSP conjugated Harvard candidate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platform</td>
<td>Killed <em>Vibrio cholerae</em></td>
<td>Killed <em>Vibrio cholerae</em></td>
<td>Killed <em>Vibrio cholerae</em></td>
<td>Live attenuated <em>Vibrio cholerae</em></td>
<td>Live attenuated <em>Vibrio cholerae</em></td>
<td>Live attenuated <em>Vibrio cholerae</em></td>
<td>Live attenuated <em>Vibrio cholerae</em></td>
<td>Conjugated</td>
</tr>
<tr>
<td>Strain / Antigen</td>
<td><em>Vibrio cholerae</em> O1 (Hikojima)</td>
<td><em>Vibrio cholerae</em> O1 (Inaba and Ogawa)</td>
<td><em>Vibrio cholerae</em> O1 (Ogawa)</td>
<td><em>Vibrio cholerae</em> O1 El Tor Ogawa</td>
<td><em>Vibrio cholerae</em> O1 El Tor Inaba Peru 15 (CT and recA deletion + motility deficient)</td>
<td><em>Vibrio cholerae</em> O1 El Tor Inaba (non-toxigenic strain)</td>
<td><em>Vibrio cholerae</em> O1 El Tor Owaga (CTX deletion)</td>
<td><em>V. cholerae</em> O1 Inaba strain PIC018 OSP and a recombinant heavy chain fragment of tetanus toxin (OSP-rTTHc).</td>
</tr>
<tr>
<td>Administration Route</td>
<td>Oral</td>
<td>Oral</td>
<td>Oral</td>
<td>Oral</td>
<td>Oral</td>
<td>Oral</td>
<td>Oral</td>
<td>Injectable</td>
</tr>
<tr>
<td>Formulation</td>
<td>TBD</td>
<td>TBD</td>
<td>Coated capsule</td>
<td>Liquid</td>
<td>Lyophilized</td>
<td>TBD</td>
<td>TBD</td>
<td>Lyophilized</td>
</tr>
<tr>
<td>Development status (2016)</td>
<td>Animal studies</td>
<td>Animal studies</td>
<td>Animal studies</td>
<td>~Phase 2/3</td>
<td>Phase 2</td>
<td>Phase 2</td>
<td>Animal studies</td>
<td>Animal studies</td>
</tr>
</tbody>
</table>

*Courtesy of F Luquero (Epicentre)*
Background: challenges with current OCVs

- Increased use of OCV in emergency and endemic settings
- Yet barriers against achieving full public health benefits at global level, including:
  - cost (1 person fully vaccinated costs approx. $6)
  - availability (supply) compared to needs (demand)
    - complex production → limited production volumes
  - logistical constraints
    - 2 dose schedule, not easy to complete within recommended 14 days
    - relatively high packing volume (increased storage space, transportation costs)
    - cold chain requirements (delivery to remote areas costly and complex)
- March 2016: MSF-hosted meeting with WHO and other global cholera stakeholders/partners
  - draft TPP developed
Update and expand landscape review of pipeline
  • all candidate vaccine platforms

Consultation in Q4 2017 (co-hosted by WHO, MSF)
  • Objectives (DRAFT):
    – define preferred characteristics of the next generation cholera vaccine(s) to meet public health needs
    – discuss bottlenecks in the development process of current candidates and propose solutions
    – identify candidate(s) to be promoted; define research and development framework for identified candidates
  • Scope:
    – 2-day meeting (tentatively mid-late Nov)
    – candidate vaccine developers/manufacturers (shortlist?), researchers, implementers, donors
    – vet/validate draft “TPP”; potentially post the final draft TPP/PCC for broader public comment
  • Outcome: final TPP/PCC (early 2018)
“Questions” to PDVAC

1. PDVAC participation in consultation and review of draft TPP/PPC
   • we propose nomination of 1-2 PDVAC members as leads (~next 6-8 months)

2. PDVAC endorsement of final TPP/PPC
   • PDVAC process for final endorsement?
Coordination of planned work involves:

- MSF (M Serafini, F Luquero)
- WHO IHM/High Threat Pathogens (D Legros, L Pezzoli)
- WHO/IVB/Initiative for Vaccine Research (J Hombach)