Plague vaccines
What R&D progress has been achieved and how can we accelerate development of a vaccine?

Thursday 12 October 2023
13:00 – 18:00pm Central European Time

Agenda
BACKGROUND

Plague is an infectious disease caused by Yersinia pestis, a zoonotic bacterium, usually found in small mammals and their fleas. As an animal disease, plague is found in all continents, except Oceania. There is a risk of human plague wherever the presence of plague natural foci (the bacteria, an animal reservoir and a vector), and the human population co-exist. There are large plague reservoirs in African, Asian, and South American continents; but since the 1990s, most human cases have occurred in Africa.

https://www.who.int/news-room/fact-sheets/detail/plague

https://www.who.int/publications/i/item/9789240015579

The WHO mapping tool currently includes 21 plague vaccine candidates under development. Three of these vaccines have completed Phase 2 clinical trials.

https://www.who.int/publications/m/item/landscape-of-plague-vaccine-candidates

A WHO Plague Vaccine Target Product Profile (TPP) was developed to provide the public health perspective to vaccine developers.

https://www.who.int/publications/m/item/who-target-product-profile-for-plague-vaccines

In 2018, WHO convened experts in epidemiology, preclinical and clinical vaccine evaluation, regulatory affairs, statistics, and mathematical modelling, in a workshop to discuss plague vaccine efficacy trials. Based on the available scientific evidence as well as on lessons learned from the public health response to plague outbreaks, the workshop defined generic principles to best design, conduct and analyse vaccine trials against plague.


WHO is organizing an open expert consultation on Thursday 12 October 2023 (13:00 -18:00 CET) to discuss progress made towards Plague candidates vaccine development and evaluation. During this forthcoming consultation, global experts will present recent epidemiology updates, then review the evidence from developmental vaccine studies to enumerate knowledge gaps and outline research priorities related to plague vaccines.

The specific objectives of the consultation are to:

- Review the epidemiological situation.
- Review salient animal models and immunology of protection against plague
- Discuss the developmental progress of plague vaccines in the pipeline.
- Review scientific approaches for their clinical evaluation.
- Identify knowledge gaps and research priorities.

Registration link: https://who-e.zoom.us/webinar/register/WN_r-Cb4ASDSdqE0YEmK_3JUg

Background documents, agenda and presentations will be uploaded here:
https://www.who.int/news-room/events/detail/2023/10/12/default-calendar/global-consultation-on-plague-vaccines
**Chairperson: Dr Marie Paule Kieny (Medicines Patent Pool and DNDi)**

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speakers</th>
</tr>
</thead>
</table>
| 13:00 – 13:05   | **Welcoming remarks**                                     | Michael J Ryan  
WHO Health Emergencies programme |  
| 13:05 – 13:10   | **Objectives of the consultation**                        | Chairperson                                                             |

**Session 1. Epidemiological situation**

| 13:10 – 13:50   | **WHO Regions overview of current epidemiological situation**  
(5 minutes each) | African Region - Reena Hemendra Doshi  
Americas Region - Ana Riviere Cinnamond  
Eastern Mediterranean Region – Chiori Kodama  
European Region – Richard Pebody  
Southeast Asia Region - Gyanendra Gongal |
| 13:50 -14:00    | Questions for clarification                              | Moderated by Chairperson                                                 |

**Session 2. Candidate vaccines landscape**

| 14:00 – 14:10   | **Overview of all candidate vaccines in the pipeline**  
(preclinical and clinical phase) | Ashok Chopra (UTMB, US) |
| 14:10 – 14:50   | **Brief update of vaccines undergoing clinical evaluation**  
(5 minutes each)  
To include summary of existing animal and human efficacy/immunogenicity data | 1. rF1V Vaccine with CpG 1018 (Phase 2) Wai Kwan Chung (JPM CBRN Medical) and Ouzama Henry (Dynavax)  
2. F1 antigen and recombined V antigen (F1+rV) (Phase 2b) Jingxin Li, Master, Jiangsu Provincial CDC  
3. Live plague vaccine EV 76 NIIEG Uyanga Baasandagva (National Centre for Zoonotic Diseases, Ulaanbaatar, Mongolia)  
4. Flagellin/F1/V (Phase 1) National Institute of Allergy and Infectious Diseases (NIAID) - TBC |
| 14:50 – 15:00   | Questions for clarification                              | Moderated by Chairperson                                                 |

**Session 3. Candidate vaccines evaluation considerations**

| 15:00 – 15:10   | **WHO Plague vaccine Target Product Profile** | Ximena Riveros Balta (WHO) |
| 15:10 – 15:20   | **Animal models challenges**  
How to evaluate response after infection and vaccination | Judith A Hewitt (NIAID,US) |
| 15:20 – 15:50   | **Animal models and immunology**  
o Which animal models could potentially predict human outcomes?  
o Which immune markers are most likely to be useful in predicting human outcomes?  
o Which immune markers may be useful in immunobridging to support an animal-rule type approval? | Panel discussion moderated by Simon Funnell (UKHSA)  
Andrey Anisimov (State Research Center for Applied Microbiology, Russia)  
Roger D Pechous (University of Arkansas for Medical Sciences, US)  
Roy Barnewal (Amplify Bio, US)  
Ruifu Yang (Beijing Institute of Microbiology and Epidemiology, China) |
<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speakers</th>
</tr>
</thead>
</table>
| 15:50-16:10   | Assays challenges                                                    | Panel discussion moderated by Diane Williamson (Defence Science and Technology Laboratory, Porton Down, UK)  
Christian Demeure (Ins. Pasteur, France)  
Neil Almond (NIBSC, UK)  
Shailendra Kumar Verma (La Jolla Inst., US) |
|               |                                                                      |                                                                                                                                                                                                           |
| 16:10 – 16:20 | Trial designs - Where did we leave the conversation?                 | Ira Longini (University of Florida, US)                                                                                                                                                                    |
| 16:20 – 16:40 | Phase 3 trial designs –                                              | Panel discussion moderated by Phil Krause (WHO)  
André Machado de Siqueira (FiOCRUZ, Brazil)  
Andrew Pollard (University of Oxford, UK)  
Aparna Mukherjee (ICMR, India)  
Ira Longini (Univ. of Florida, US)  
Javier Pizarro Cerda (Inst. Pasteur, France)  
Tom Fleming (Univ. of Washington, US) |
| 16:40 -17:00  | Phase 3 trial implementation –                                      | Panel discussion moderated by Placide Mbala (INRDB, DRC)  
Julius Lutwama & Linda Atiku (UVRI, Uganda)  
Karim Pardo (Universidad Peruana Cayetano Heredia, Perú)  
Mihaja Raberahona (University of Antananarivo, Madagascar)  
Monil Singhai (National Centre for Disease Control, India) |
| 17:00 – 17:10 | Prioritizing vaccines to be assessed in Phase 2b/Phase 3 trials      | Mike Levine (Univ. of Maryland, US)  
Chairperson WHO Technical Advisory Group on candidate vaccine prioritization                                                                                                                                  |
## Session 4. Other critical actions to accelerate plague vaccines evaluation

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>17:10 – 17:40</td>
<td><strong>Considerations on regulatory pathways’</strong></td>
<td>Panel discussion moderated by Marco Cavaleri (EMA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carlo Cancino (DIGEMID, Peru)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Daniel Etuko (NDA Uganda)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Grant Munkwase (NDA, Uganda)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marie-Christine Bielsky (MHRA, UK)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pete Weina (CBER USFDA, US)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rubina Bose (DCGI, India)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yin Huajing (CDE NMPA, China)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Li Yingli (CDE NMPA, China)</td>
</tr>
<tr>
<td>17:40-18:00</td>
<td><strong>Main conclusions and next steps</strong></td>
<td>Phil Krause (WHO)</td>
</tr>
<tr>
<td>18:00</td>
<td><strong>END OF MEETING</strong></td>
<td></td>
</tr>
</tbody>
</table>