World Health Organization

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

R&DBlueprint

Powering research
to prevent epidemics

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.
https://www.who.int/news-room/events/detail/2018/04/23/default-calendar/plague-vaccines-workshop

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)

Time	Topic	Speakers
13:00 – 13:05	**Welcoming remarks**	Michael J Ryan Executive Director 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 Choprah (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)

Time	Topic	Speakers
15:50-16:10	**Assays challenges** o What assays could be used to assess immune protection against plague in animals and in humans? o What assay controls and/or standards would be needed to obtain reliable results with these assays? o Could any of these assays potentially be used for immune-bridging between animals and humans in an "animal rule" type approval? o What is the availability and deployability of these assays?	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?** WHO Workshop (2018) "Efficacy trials of Plague vaccines: endpoints, trial design, site selection"	Ira Longini (University of Florida, US)
16:20 – 16:40	**Phase 3 trial designs** – o What adjustments to the current recommendations are pertinent? o What opportunities for generating randomized evidence?	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** – o How to move forward with the implementation of phase 3 trials? o Which potential location for Phase 3 trials? o Can collaborations across at risk countries be possible/desirable	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

Time	Topic	Speakers
Session 4. Other critical actions to accelerate plague vaccines evaluation		
17:10 – 17:40	**Considerations on regulatory pathways'** o Can/should an accelerated pathway (e.g., conditional approval, accelerated approval, or animal rule) be used? o If yes, how could vaccine efficacy be confirmed?	Panel discussion moderated by Marco Cavaleri (EMA) Carla Cancino (DIGEMID, Peru) Daniel Etuko (NDA Uganda) Grant Munkwase (NDA, Uganda) Marie-Christine Bielsky (MHRA, UK) Pete Weina (CBER USFDA, US) Rubina Bose (DCGI, India) Yin Huajing (CDE NMPA, China) Li Yingli (CDE NMPA, China)
17:40-18:00	**Main conclusions and next steps**	Phil Krause (WHO)
18:00	**END OF MEETING**	