

WHO R&D Blueprint novel Coronavirus (nCov)

Vaccine prioritization for clinical trials.

Appropriate WHO Confidentiality Undertakings were signed and submitted to WHO by all participating experts

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INTRODUCTION

The current global nCoV public health emergency underscores the need to accelerate the development of nCoV candidate vaccines. The Working Group for vaccine prioritization aims to provide aspirational guidance to vaccine developers from a public health perspective as well as to prioritize vaccine platform approaches and/or candidates to be considered for further development and potentially consider for latestage evaluation in the context of the global nCoV outbreak.

OBJECTIVES OF THE CONSULTATION

The objectives of this consultation were:

- 1. To review the current pipeline of candidate vaccines for nCoV
- 2. To review the current pipeline of candidate vaccines for other coronaviruses and discuss their value in protecting against the nCoV.
- 3. To make preliminary recommendations on whether the development of nCoV candidate vaccines should be prioritized over the development of other coronaviruses candidate vaccines.

This Consultation presents an initial step towards the evaluation of candidate vaccines against this novel Coronavirus. There are ongoing efforts to identify additional candidate vaccines and to expand the body of evidence available on each of the candidates.

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EXPERT PANEL AND DECLARATION OF INTEREST

WHO Declaration of Interest forms were completed and provided to WHO by all participating experts listed in the table below. Such DOIs were reviewed by the WHO Secretariat as par applicable WHO guidance. The following interests, if any, were declared: :

Chairperson: Marco Cavaleri

| Name | Confidentiality Undertakings; Assessments of Conflicts of Interest |
|----------------------|--|
| Marco Cavaleri | No conflict of interest declared |
| Ruben Donis | No conflict of interest declared |
| Josie Golding | No conflict of interest declared |
| Bart Haagmans | No conflict of interest declared |
| Robin Levis | No conflict of interest declared |
| Murray Lumpkin | No conflict of interest declared |
| Michael Parker | No conflict of interest declared |
| Stanley Plotkin | Consultant to pharmaceutical companies with potential interest in developing coronaviruses vaccines. |
| Anna Laura Salvati | No conflict of interest declared |
| Claire-Anne Siegrist | No conflict of interest declared |
| Peter Smith | No conflict of interest declared |
| Linfa Wang | No conflict of interest declared |
| Ralf Wagner | No conflict of interest declared |



OVERVIEW OF THE DELIBERATIONS

Participants noted that there is no licensed vaccine for nCoV or for other coronaviruses and no established immunological correlates of protection. Several candidate vaccines have completed Phase 1 clinical trials against SARS-CoV and MERS-CoV. Participants noted however that the clinical development status of the various SARS-CoV vaccines and the potential availability of candidate vaccine stocks remains unclear and needs to be assessed. It was mentioned that active developers seem to be focusing on engineering and advancing vaccines that include antigens from the new nCoV strain, although it was noted that they might not currently have the capacity to produce large-scale GMP materials.

Participants noted that, although there is some level of homology between the nCoV and SARS-CoV, and to a lesser extent MERS-CoV, there is currently insufficient information of cross-reactivity between nCoV and other coronaviruses. However, it was agreed that it would not be expected that antibodies from MERS-CoV vaccines based on the spike protein would be significantly cross-reactive. It was also considered that SARS vaccines, that were under development some years ago, might result in inadequate levels of cross-neutralising antibodies.

Participants recommended that, given current knowledge and vaccine development status, vaccine approaches targeting the novel coronavirus should be prioritized for further development over vaccine approaches targeting other coronaviruses in the context of the nCoV global outbreak, noting that the development of vaccines for other coronaviruses remains a public health priority.

Among the nCoV candidate vaccines, the information available on possible candidate vaccines and the nCoV epidemiology is very preliminary and the group felt that it is not possible to perform a proper prioritisation at this stage. Among the various platform technologies in the pipeline, nucleic acids (both mRNA and DNA) and viral vectored vaccine (e.g. MVA, VSV, Ad/ChAd) would represent in principle valid options for vaccine development, noting that some of the platforms may be easier and faster to

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