TPPs for pathogens as part of the emergency R&D agenda

Role for PDVAC as element of WHO Blueprint

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Gap in our processes identified: overseeing activities related to upstream vaccine R&D

• During the course of the high level WHO meetings on Ebola Vaccine Development, it was agreed that WHO would develop Ebola Vaccine Target Product Profiles.

• The target audience for this document are all those working to improve characteristics of currently tested ebola vaccines. The document is also aimed at those developing ebola vaccines that have not yet reached the clinic. This document will be finalised and published during Q4 2015.
Two use scenarios
Critical and preferred profiles

Reactive
Prophylactic
Process

Team B

PDVAC WG

Public Consultation

Finalised by Dec 2015
PDVAC Working Group

- Regulatory expertise in Africa:
- Vaccine implementation expertise in affected country:
- African ethics expertise:
- Industry expertise:
- Ebola science expertise:
- Modeling/epidemiology input
- WHO staff from vaccine development, regulatory, implementation responsibilities
- Consulted with programmatic suitability & prequalification teams within WHO
Key points: schedule

• 1 dose schedule highly preferred,
• For 2 dose schedules, homologous schedules are preferred to 2 dose heterologous prime-boost
• Time to onset of immunity key to reactive use scenario
Key points: efficacy

• Reactive use
  – Time to onset of immunity very important
  – Long duration of protection less important
  – Vaccines with modest efficacy could still be of value

• Prophylactic use
  – Higher efficacy threshold in critical profile
  – 2 dose schedules may be worthwhile if duration of protection is expected to be many years
Key points: stability

• Reactive use
  – In reality many products may be stored at -80°C for long periods in inter-emergency period
  – Guinea experience was that -80°C storage followed by 8 hours at 2-8°C was sufficient
  – Longer term storage and stability at higher temperatures eg -20 or 2-8 highly desirable
Key points: valency

• Monovalent Zaire acceptable in short term
• In medium term expectation is that vaccines will include Sudan and Marburg as a minimum together with Zaire.
• Bundibugyo inclusion desirable
TPPs on emerging pathogens

• TPPs are a higher risk product for WHO to develop, but more useful for developers: provide critical parameters

• TPPs when WHO wishes to provide more concrete guidance and products are more advanced

• PPCs when mandate/information for critical parameters are not yet available

• TPPs could be developed later for diseases where WHO starts with PPCs
Summary

• Ebola vaccine will be first TPP developed by WHO. ETA Dec 2015
• All are invited to comment
• MERS, ? Others to follow
• Wherever possible public consultation will be part of process
• In next emergency, faster TPP process will be used
Public consultation on WHO Ebola Vaccine Target Product Profiles

During the course of the high level WHO meetings on Ebola Vaccine Development, it was agreed that WHO would develop Ebola Vaccine Target Product Profiles to provide guidance on WHO’s critical and preferred profiles for Ebola Vaccines of two categories (please see draft document).

The target audience for this document are all those working to improve characteristics of currently tested Ebola Vaccines. The document is also aimed at those developing Ebola Vaccines that have not yet reached the clinic. This document will be finalised and published during Q4 2015.

The draft document is made available here for public consultation. Please send any comments on the attached comment form, with the name and affiliation by 2 October 2015. Comments may be submitted by individuals or organizations. These comments may be made available at a later date, and by submitting comments you are giving permission for the comments to be made publicly available.

WHO will finalise the Ebola Vaccine Target Product Profiles, after taking into account comments received.

Draft Ebola Vaccine TPPs
pdf, 411kb

Ebola Vaccine TPP comment form
pdf, 47kb

Send your comments to all three of the following email addresses; moorthyv@who.int, grubom@who.int and gsellp@who.int by 2 October 2015.