Update with the development of Ebola vaccines and implications to inform policy recommendations

Conclusions and recommendations

Helen Rees, Co-chair, Ebola WG
SAGE meeting, 25–27 April 2017

Considerations (1)

✓ 12 candidate vaccines underwent or are actively undergoing clinical development at different trial phases.

✓ The Phase 3 trial for rVSVΔG-ZEBOV-GP in Guinea reported clinical efficacy and effectiveness and rVSVΔG-ZEBOV-GP candidate vaccine with efficacy data was granted access to the Priority Medicine by the EMA and Breakthrough Therapy designation by the US FDA.

✓ A prime/boost candidate vaccine based on rVSV- and Ad5- vectored components (GamEvac-Combi) is licensed in its country of origin (Russia)

Considerations (2)

✓ The rVSV∆G-ZEBOV-GP candidate and a prime/boost Ad26.ZEBOV/MVA-BN-Filo candidate vaccine have submitted EUAL documentation to WHO.

✓ Potentially, various licensure pathways exist for candidate vaccines to obtain licensure.

✓ The WHO Secretariat is implementing the work plan of the R&D Blueprint for Action to Prevent Epidemics

1. Are there **remaining challenges that may prevent access** to Ebola vaccines in future outbreaks? If yes, can SAGE make recommendations on how these might be addressed?

Proposed recommendations

- Recognition of momentous progress made in the development and evaluation of several vaccine platforms against Ebola and other filoviruses

- Intensification of efforts in reaching a consensus and clarity on specific aspects of regulatory pathways that would allow the development and registration of candidate Ebola vaccines; facilitation by Secretariat regulatory convergence through development of WHO Guidelines for Ebola vaccines evaluation

World Health Organization

Proposed recommendations

- Encouragement to developers to engage relevant NRAs, in particular, national and regional regulatory agencies/structure of African countries.

- Submission of additional data on the GamEvac-Combito apply for WHO prequalification status

World Health Organization

2. Is the current evidence sufficient for SAGE to make recommendations regarding the use of Ebola vaccines (e.g. rVSV and the Russian vaccine) in case of another Ebola outbreak (prelicensure and/or post licensure)?

- o If yes, which recommendations can be proposed?
- o If not, what key data are missing?

Proposed recommendations (1)

- Should an EVD outbreak occur, rVSV∆G-ZEBOV-GP candidate vaccine should be deployed under Expanded Access framework and in ring vaccination adapted to social and geographic conditions of the outbreak and affected areas

- Insufficient evidence to recommend pre-emptive vaccination of health-care workers (HCW). Need for additional sociological knowledge on acceptability of vaccines used pre-emptively among HCW and modelling work on benefits of pre-emptive HCW immunisation

Proposed recommendations (2)

- Insufficient to recommend pre-emptive mass immunisation of general population because of the still partial knowledge on the vaccine immunogenicity, efficacy, safety, and acceptability as well as the unpredictability of where Ebola may emerge next

- Once one or more Ebola vaccines are licensed and prequalified, a mechanism for stockpiling should be put in place to ensure prompt and equitable access. Gavi Board has already committed to purchase 300,000 doses.

- Mathematical modelling should further refine size and composition requirements.

Proposed recommendations (3)

- Take all opportunities to generate or expand evidence base that can broaden the indication and increase the acceptability of Ebola vaccination, including on:
    - Safety, immunogenicity and efficacy of candidate vaccines in special population groups
    - Vaccination perception and acceptability
    - Messaging and communication strategies in the event of an outbreak.

Thank you