

# SAGE meeting: Ebola vaccines

## Introduction & questions for SAGE's consideration

**Fred Were**  
**Co-chair, Ebola vaccines Working Group**  
**SAGE meeting, 4 April 2019**



**R&D Blueprint**

Powering research  
to prevent epidemics

# SAGE interim recommendations on Vaccination against Ebola Virus Disease (EVD) – 20 Feb 2019

“Based on the empirical data available from DRC North Kivu province, and the preliminary results of modeling, SAGE concluded that the **currently recommended strategies for rVSV-ZEBOV-GP vaccine delivery, ring vaccination and geographic targeted vaccination, are effective**. The Ring + strategy will likely have a less marked impact on the number of new cases than that of the current recommended strategies, and it requires the vaccination of a larger number of additional people, several of them probably at low or no risk of EVD. The Ring + approach would be unlikely to provide added benefit over existing strategies and is therefore not recommended.”

# SAGE interim recommendations on Vaccination against Ebola Virus Disease (EVD) – 20 Feb 2019

"As SAGE noted previously, it is important to advance the clinical evaluation of other vaccines against EVD and to accrue additional information on their immunogenicity, safety and efficacy if possible. Noting the available data, SAGE recommends that **consideration is given to the use of any of these three above mentioned new vaccines to vaccinate HCWs and FLWs in the *neighboring areas* where there is a possibility of spread**. Such vaccination should be implemented as part of a randomised clinical trial and in compliance with GCP and informed consent. **Since these three new candidate vaccines are non-replicating or replication deficient, pregnant and lactating women should be included into the clinical trial protocols**. The protocols must include provisions for safety monitoring and for documentation of EVD cases among vaccinees, including follow-up of pregnant women and their offspring. Choice of vaccine should be undertaken by national authorities based on a transparent and evidence-based process. The WHO R&D Blueprint expert group on vaccine trials is asked to provide guidance on the design of such trials."

# SAGE interim recommendations on Vaccination against Ebola Virus Disease (EVD) – 20 Feb 2019

“If a confirmed case of Ebola (Zaire strain) is observed among the HCWs or FLWs vaccinated with one of these three candidate vaccine regimens, SAGE reiterated that the control of such an outbreak must include the use of rVSV-ZEBOV-GP using the ring vaccination, or the geographic targeted approach if necessary, as previously recommended by SAGE, in preference to these new candidate vaccines.”

**“SAGE stressed that in outbreak affected areas, HCWs and FLWs should continue to be offered the rVSV-ZEBOV-GP vaccine. Similarly, peacekeeping forces deployed to such areas should be offered the vaccine.”**

# SAGE interim recommendations on Vaccination against Ebola Virus Disease (EVD) – 20 Feb 2019

“In view of the severity of the outbreak and aligned with SAGE’s recommendation from October 2018, SAGE welcomes and supports the recent recommendation of the ethics committee of DRC to also authorize the vaccination of pregnant women in outbreak affected areas, using the currently recommended vaccination strategies, with the live-replicating rVSV-ZEBOV-GP vaccine with informed consent and in compliance with GCP. As recommended by the ethics committee, every effort must be made to collect data on the safety of the vaccine in these populations, including a documentation of the pregnancy outcomes. **SAGE advises that the use of rVSV-ZEBOV-GP vaccine in pregnant women currently remains limited to the EVD outbreak affected areas in DRC and should be continuously evaluated based on the emerging data on the safety and efficacy of the vaccine in this target population.** This careful review of the emerging safety data is needed to inform vaccine recommendations for future outbreaks.”

# SAGE interim recommendations on Vaccination against Ebola Virus Disease (EVD) – 20 Feb 2019

**"SAGE acknowledges the decision of the ethics committee of DRC to also proceed with vaccination of lactating women and children under 1 year of age given the ongoing outbreak and population risk.** SAGE is now reviewing the data, including modelling, in relation to the use of the vaccine in these populations and will provide an updated assessment as soon as is feasible."

# Questions for SAGE

1. Are the interim recommendations for Ebola vaccination strategies still valid?
2. Should lactating women and children less than 1 be included in the rVSV $\Delta$ G-ZEBOV-GP vaccination strategy in DRC?

# Today's session

Introduction & questions for SAGE's consideration	Fred Were Co-chair of Ebola WG
<b>Part 1: Ebola vaccination strategies</b>	
1.1 Update on outbreak epidemiology	Brett Archer WHE
1.2 Description of ring vaccination implementation in DRC and neighbouring countries	Abdourahamane Diallo Co-Field coordinator of the Expanded Access Ring Vaccination Protocol
1.3 Proposed recommendations regarding Ebola vaccination strategies	Helen Rees Co-chair of Ebola WG
1.4 Discussion	



# Today's session

## Part 2: Ebola vaccination of lactating women and infants below 1 year of age with rVSVΔG-ZEBOV-GP candidate vaccine and potential to assess other vaccines

2.1 Current SAGE recommendations regarding evaluation of other vaccines and ongoing plans	Ana Maria Henao-Restrepo Initiative for Vaccine Research, WHO
2.2 Outcomes of risk-benefit analysis of vaccinating lactating women and infants below 1 year of age with rVSVΔG-ZEBOV-GP candidate vaccine	Alejandro Costa Initiative for Vaccine Research, WHO
2.3 Proposed recommendations regarding Ebola vaccination of lactating women and infants below 1 year of age	Helen Rees Co-chair of Ebola WG
2.4 Discussion	