

Proposed recommendations regarding Ebola vaccination of lactating women and infants below 1 year of age

Helen Rees
Co-chair, Ebola vaccines Working Group
SAGE meeting, 4 April 2019



R&D Blueprint

Powering research
to prevent epidemics

Pregnant women and lactating women

Vaccination in pregnant women

- Based on a risk-benefit analysis, taking into account the difficult context of this outbreak, the WG reinforces the current SAGE recommendation that pregnant women in outbreak affected areas should be vaccinated as part of the ring strategy, with the live-replicating rVSVΔG-ZEBOV-GP vaccine, with informed consent and in compliance with Good Clinical Practice
- Notwithstanding the challenges, every effort should be made to follow these women up to monitor safety in mother and infant
- The WG was informed that DRC ethics committee has not yet approved vaccination in pregnant women

Vaccination in lactating women

- The WG considers the benefit of vaccination in lactating women is likely to outweigh the risk of vaccination for the woman and the unborn child
 - By including pregnant and lactating women in each ring, the number of vaccine recipients in the ring would increase with positive gains in herd immunity and further protection of children in the rings
- Despite foreseeable difficulties for follow-up, every effort should be made to monitor the safety of immunisation in vaccinated mothers and their infants
- Where possible, longer term monitoring in this group should be carried out to document any adverse effects
- The WG recommends to the manufacturers of all candidate Ebola vaccines to include pregnant and lactating women in clinical trials as early as feasible in the vaccine development process

Infants (under 1 year of age)

Consider extending vaccination to children above 6 months of age

- The WG recognizes the lack of safety data in children under 1 year old and safety concerns with live attenuated vaccines:
 - immaturity of infants' immune systems
 - inadequately developed haematoencephalic barrier
 - unknown potential interaction with other routine vaccines
 - difficulties of conducting quality safety monitoring in children aged less than 1 year
- The WG recommends that safety data on children aged 1-5 years should be compared to that of children aged 6-10 years to compare safety signals
- If possible, the WG recommends to collect data on the incidence of infection in children under 1 year old and the proportion of these infections where mothers were EVD positive

Consider extending vaccination to children above 6 months of age

- Given the risk of infection in children aged less than 1 year in the current outbreak in DRC, the WG recommends immunising infants above 6 months
- By including pregnant and lactating women in ring vaccination, infants between 0 to 6 months will receive some protection
- The WG recommends that manufacturers of candidate Ebola vaccines prioritize the development of a strategy to generate safety, immunogenicity and efficacy data for children aged less than 1 year as early as possible in the vaccine development process