Executive Summary for SAGE Session on Ebola, Session 9 - Thursday, 25 October 2018

Current Ebola outbreaks and use of unlicensed candidate vaccines to respond to the outbreak

Background:

1- Epidemiology:

The 2014–2016 outbreak in West Africa was the largest and most complex Ebola outbreak since the virus was first discovered in 1976. There were more cases and deaths in this outbreak than all others combined. It also spread between countries, starting in Guinea then moving across land borders to Sierra Leone and Liberia. The virus causing the 2014–2016 West African outbreak belongs to the Zaire ebolavirus species.

Four measures have been in place to interrupt transmission of Ebola

I. infection control in health-care facilities and protection of health-care workers;
II. detection, management and isolation of patients;
III. surveillance (inclusive of back and forward contact tracing) and fever surveillance with rapid diagnosis and isolation; and
IV. community understanding with safe patient and body transport systems, safe burial and household/environmental decontamination

2- Additional measure to respond to Ebola - Vaccine development:

The major Ebola outbreak in West Africa has accelerated the development of a vaccine

Thirteen candidate Ebola vaccines (including monovalent, bivalent and multivalent candidates) have undergone or are currently undergoing clinical evaluation at different trial phases. Two vaccines were licensed, eight vaccines have completed or are in trials up to Phase I stage, two vaccines up to or in Phase II stage, and one vaccine has completed Phase III stage. Some vaccines are tested as single-dose regimen (Ad5-EBOV, ChAd3-EBOZ, rVSVΔG-ZEBOV-GP), while others include a priming and either homologous or heterologous boosting. When prime/boost regimens are tested, the interval between doses is at least 3–4 weeks.

Data on safety and immunogenicity are accumulating for all candidate vaccines under active clinical development. Trials have not reported serious adverse events definitely linked to any candidate vaccine. However, **safety profile** is still being characterized and additional safety information is being generated for children and special populations.

Session Objective:

To provide recommendations on the use of unlicensed vaccines and the anticipated impact of various vaccination strategies.

SAGE is requested to consider the following questions:

1- Is the current evidence sufficient for SAGE to adjust current recommendations regarding the use of Ebola vaccines in case of another Ebola outbreak? If yes, which recommendations can be proposed? And, what key data are missing?

2- what are the conclusions on the benefits and risk analysis of vaccination of pregnant women with rVSV-ZEBOV as part of Expanded Access/ Compassionate Use during Ebola outbreaks?

3- Are there remaining challenges that may prevent access to Ebola vaccines in future outbreaks, and, if yes, can SAGE make recommendations on how these might be addressed?

Session Summary:

1- the first presentation will be the on an overview of the epidemiology including an update of the current outbreak in DRC

2- the second presentation will provide an update on candidate Ebola vaccines: available data on R&D plans, immunogenicity, efficacy and safety, timelines for licensure and expanded access/compassionate use experience.

3. the third presentation will inform SAGE members on benefits and risk analysis of vaccination of pregnant women with rVSV-ZEBOV during outbreaks.

4- the forth presentation will provide projection on the impact of different Ebola candidate immunization strategies and targeted populations.

5- the chair of the WG will present the recommendations from the WG

Background Reading (Yellow Book and Web):

1- Ebola Vaccine development background doc

2- Interim SAGE recommendation for Ebola vaccines August 2018