

## Frequently Asked Questions

# Compassionate Use of Ebola Vaccine in the context of the Ebola outbreak in North Kivu, Democratic Republic of Congo



### **1. Is there a vaccine for the Ebola virus disease?**

An investigational vaccine called rVSV-ZEBOV, which has shown to be safe and protective against the Zaire strain of the Ebola virus, is recommended by the Strategic Advisory Group of Experts on Immunization (SAGE)<sup>1</sup> for use in Ebola outbreaks caused by the Zaire strain of the virus, in the event where there is no licensed vaccine. The vaccine consists of a vesicular stomatitis virus (VSV), which is an animal virus that causes flu-like illness in humans. The VSV has been genetically engineered to contain a protein from the Zaire Ebola virus so that it can provoke immune response to the Ebola virus.

### **2. Has this vaccine been used before?**

This vaccine, although not commercially licensed, is being used under “expanded access” or what is also known as “compassionate use” in the ongoing Ebola outbreak in North Kivu. This vaccine was also used in the Ebola outbreak in Equateur in May-July 2018. In 2015, the vaccine was given to more than 16,000 volunteers involved in several studies in Africa, Europe and the United States where it was found to be safe and protective against the Ebola virus.

### **3. Why is the vaccine not given to everyone in the Ebola outbreak area?**

Although several studies have shown that the vaccine is safe and protective against the Ebola virus, more scientific research is needed before the vaccine can be licensed. The vaccine is therefore being used on compassionate basis, to protect persons at highest risk of the Ebola outbreak, under a “ring vaccination” strategy, which is similar to the approach used to eradicate smallpox.

### **4. How is the ring vaccination done?**

A ring vaccination tracks the epidemic, recruiting individuals at raised risk of infection due to their connection to a patient confirmed with the virus.

When a patient is laboratory confirmed, the definition of the ring is made as follow:

- I. Contacts are defined as individuals who, in the last 21 days, lived in the same household, were visited by the patient after they developed symptoms or visited the patient or were in close physical contact with the patient's body, body fluids, linen or clothes.
- II. Contacts of contacts are defined as neighbours, family, or extended family members at the closest geographic boundary of all contacts, plus household members of all high-risk contacts who do not live in the same locality as the patient.
- III. SAGE recommends vaccination of health care workers and frontline workers who may be in contact with Ebola patients.

The ring is not necessarily a contiguous geographic area but captures a social network of individuals and locations that may include dwellings or workplaces further afield, where the index patient spent time while symptomatic, or the households of individuals who had contact with the patient during the illness or after his or her death. Experience suggests that each ring may be composed of an average of 150 persons.

---

<sup>1</sup> <http://apps.who.int/iris/bitstream/handle/10665/255611/WER9222.pdf?sequence=1>

#### **5. Is participation in the ring vaccination voluntary?**

Yes. Participation in this “expanded access” or “compassionate use” of the Ebola vaccine is entirely free and voluntary. Each eligible person makes their own decision whether to participate or not and can withdraw at any time. Their rights will be respected. Disregard of whether the eligible person chooses to participate or not, it will not have an impact on their access to health services.

#### **6. Who are eligible for the vaccine?**

Each person to be considered for the expanded access of the vaccine will receive one dose of the vaccine. The persons to be considered include:

- i. Contacts, and contacts of contacts of confirmed Ebola virus disease patients (dead or alive),
- ii. Health care and frontline workers (local and international) in the affected areas, and
- iii. Health care and frontline workers in areas at risk of spread of the outbreak.

#### **7. Will children, pregnant women and lactating women be vaccinated?**

In North Kivu, the protocol approved by the National Regulatory Authorities and the Ethics Committee of the Democratic Republic of Congo considered the inclusion of children of above one year old for the ring vaccination. Pregnancy test is offered to women eligible for the vaccine but the test is not mandatory. Women who are pregnant are excluded from the vaccination.

#### **8. What is the composition of the vaccination team and how will they carry out the vaccination?**

Each vaccination team is trained and knowledgeable on Good Clinical Practices and comprises of a team leader, a social mobilizer, a definer of the ring, a doctor to assess the eligibility of those who should receive the vaccine, a doctor who obtains written consent, a vaccinator, an emergency doctor who evaluates the presence of adverse effects of the vaccine 30 minutes after it is administered and an experienced logistician. The steps for the ring vaccination are clearly defined. These include:

- i. A trained local social mobilizer with the team leader for the ring vaccination team visits the family and the neighbours of the Ebola confirmed patient and explains the process to potential participants on a one-on-one basis. If the ring vaccination is acceptable to them, the team member responsible for defining the ring will join the team.
- ii. The definition of the ring is made by 2 members of the vaccination team who are trained and will list all the contacts and contacts of contacts of a confirmed Ebola case (dead or alive), including persons who may not be present in the community at the time of the visit of the ring definition team.
- iii. The informed consent of each person eligible for the investigational vaccine is obtained.
- iv. The eligibility of persons to be considered for the investigational vaccine is assessed.
- v. The persons eligible for the investigational vaccine who have provided consent will be administered the vaccine.
- vi. The persons vaccinated will be monitored by a doctor for 30 minutes immediately after being administered the vaccine.

#### **9. Can the vaccine cause adverse effects and how will it be dealt with?**

Persons who receive the vaccine may develop adverse effects following the vaccination. In the Ebola vaccine study in Guinea in 2015, most adverse effects were typically mild. Vaccinated individuals most commonly reported headache, fatigue, muscle pain and mild fever.

All persons vaccinated will be advised to contact the vaccination team and they will also be visited at home by trained teams to assess their wellbeing. The vaccination team will follow up with persons vaccinated in the first two weeks after the vaccination.

**10. Is there a plan to deal with serious adverse events if it happens?**

There is a well-defined plan to deal with serious adverse events. In the event of a serious adverse event following vaccination, a medical doctor in the team will immediately visit the person and ensure that the person is appropriately cared for. Serious adverse events (death, life threatening conditions, hospitalization, leading to disability, congenital abnormality or if consider important by the doctor to lead to any of these) will be immediately notified to the national authorities, the Ethics Review Committee, WHO and the manufactures. An independent group of experts – the Data Safety Monitoring Board will be established at the national level where the expanded access of the Ebola vaccine is being introduced. They will be informed within 24 hours of knowledge of any serious adverse event following vaccination. One of their roles is determining whether the adverse event is related to the vaccination.

**11. Can a person vaccinated be infected with Ebola by the vaccine?**

The vaccine cannot cause the disease because there is no Ebola virus in the vaccine. The vaccine is manufactured according to international standards for vaccines.

If a person receiving the vaccine has been already infected with the Ebola virus before he/she is vaccinated, they could develop Ebola virus disease after they receive the vaccine. If they develop any symptom of illness, they should immediately contact the vaccination team.

Persons who receive the vaccine should continue to protect themselves from Ebola virus infection by not touching a patient's body (dead or alive), or bodily fluids, including blood, vomit, saliva, urine or feces. Personal items used by the patient like bedding and clothes may also be contaminated with Ebola virus and should be avoided.

**12. Is vaccination the main component of the Ebola outbreak control strategy?**

The use of investigational vaccine is one of the several components of the strategy to control the Ebola outbreak. Other important components include:

- i. Separating (isolating) patients to prevent further spread at home or in the community,
- ii. Early detection of new Ebola infections through close monitoring of contacts and separating them from other persons if they develop symptoms,
- iii. Safely and respectfully bury the dead to reduce further spread of Ebola virus through contact with deceased.
- iv. Systematically engage communities in the Ebola response.

**13. For how long can the vaccine protect a person from Ebola virus infection?**

We do not have sufficient data to say for how long the vaccine will protect a person from Ebola virus infection. Some studies suggest that persons who were given the Ebola vaccine can be protected for up to 12 months. More research is needed to look into the matter.

**For further information:**

**Strategic Advisory Group in Immunization Interim Recommendation on Ebola vaccine (August 2018)**

[http://www.who.int/immunization/policy/sage/Interim\\_recommendation\\_Ebola\\_vaccines.pdf](http://www.who.int/immunization/policy/sage/Interim_recommendation_Ebola_vaccines.pdf)

**Weekly Epidemiological Record: Meeting of the Strategic Advisory Group of Experts on immunization, April 2017 – conclusions and recommendations**

<http://apps.who.int/iris/bitstream/handle/10665/255611/WER9222.pdf;jsessionid=84A8710145124E5C537187BEFD46D5DC?sequence=1>

**Weekly Epidemiological Record: Meeting of the Strategic Advisory Group of Experts on immunization, April 2017 – conclusions and recommendations**

<http://apps.who.int/iris/bitstream/handle/10665/255611/WER9222.pdf;jsessionid=84A8710145124E5C537187BEFD46D5DC?sequence=1>

**WHO Ebola web page:**

<http://www.who.int/ebola/en/>

**Ebola virus disease fact sheet:**

<http://www.who.int/news-room/fact-sheets/detail/ebola-virus-disease>

**Frequently asked questions on Ebola virus disease:**

<http://www.who.int/csr/disease/ebola/faq-ebola/en/>

**Meeting of the Strategic Advisory Group of Experts on immunization - conclusions and recommendations**

**Ebola vaccines :**

<http://www.who.int/csr/resources/publications/ebola/sage-vaccines-2017/en/>

**OpenWHO Introduction to Ebola:**

<https://openwho.org/courses/knowledge-resources-ebola>

**The Lancet - Efficacy and effectiveness of an rVSV-vectored vaccine in preventing Ebola virus disease: final results from the Guinea ring vaccination, open-label, cluster-randomised trial (Ebola Ça Suffit!)**

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)32621-6/abstract](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)32621-6/abstract)

**The Lancet - Ring vaccination with rVSV-ZEBOV under expanded access in response to an outbreak of Ebola virus disease in Guinea, 2016: an operational and vaccine safety report**

<http://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2817%2930541-8/fulltext>

**The British Medical Journal - The ring vaccination trial: a novel cluster randomised controlled trial design to evaluate vaccine efficacy and effectiveness during outbreaks, with special reference to Ebola**

<https://www.bmj.com/content/351/bmj.h3740>