Ebola virus disease

Frequently asked questions on compassionate use of investigational vaccine for the Ebola virus disease outbreak in Democratic Republic of the Congo

Updated 23 May 2018

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

An investigational vaccine called rVSV-ZEBOV has shown to be highly protective against Ebola virus infection. The rVSV-ZEBOV vaccine was studied in several trials that involved more than 16,000 volunteers in Europe, Africa and the United States, and it was found to be safe and protective against the Ebola virus. The vaccine consists of a vesicular stomatitis virus (VSV), which is an animal virus that causes flulike 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. Is the vaccine being used in the current Ebola outbreak in DRC?

- The current Ebola outbreak in DRC is caused by Ebola Zaire virus. The WHO Strategic Expert Advisory Group on Immunization (SAGE) recommended in 2017 that if an outbreak of Ebola virus disease is caused by the Zaire strain prior to the approval of the candidate vaccine, rVSV-ZEBOV vaccine should be rapidly deployed under ‘expanded access’ or ‘compassionate use’, with informed consent and in compliance with good clinical practice.
- The Ministry of Health – with support from WHO, Gavi, Médecins Sans Frontières (MSF), UNICEF and other health partners – is conducting ring vaccination of high-risk populations in affected health zones. A total of 7,560 doses of rVSV-ZEBOV vaccine from Merck have been sent by WHO to DRC to help stop of the current Ebola outbreak. Another 8,000 doses will be made available shortly.
- This is not a general vaccination campaign for the whole population of the affected area. It is a targeted vaccination that protects the affected population by vaccinating people at highest risk of infection.

3. In which locations will the investigational vaccine be used?
The use of the investigational vaccine in the current outbreak in DRC is planned initially for three locations – in Bikoro, Iboko and in Mbandaka, where laboratory confirmed Ebola patients have been reported. It will be expanded and implemented under a ‘ring vaccination’ strategy around each laboratory confirmed patient regardless of the location. As of today:

- MSF will support the Ministry of Health with the vaccination in Bikoro and Iboko.
- WHO will support the Ministry of Health with the vaccination in Mbandaka.

4. How will the investigational vaccine be administered?

The vaccination will be implemented under a ‘ring vaccination’ strategy which is a similar approach used to eradicate smallpox. 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:

- 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.
- 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.

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.

5. 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, social mobilizers, definers of the ring, doctor to assess the eligibility of those who should receive the vaccine, doctor who obtains written consent, vaccinator, an emergency doctor who evaluates the presence of adverse effects of the vaccine 30 minutes after it is administered and experienced logisticians. The steps for the ring vaccination are clearly defined. These include:

- The 1-2 trained local social mobilizers with the team leader for the ring vaccination team will visit the family and the neighbours of the Ebola virus disease confirmed patient and explain 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.
- 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 patient confirmed with Ebola virus (including those who may not be present in the community at the time of the visit of the ring definition team).
- The informed consent of each person eligible for the investigational vaccine is sought.
- The eligibility of the persons to be considered for the investigational
vaccine is assessed.
- The persons eligible for the investigational vaccine who have provided consent will be administered the vaccine.
- The persons vaccinated will be monitored by the doctor for 30 minutes immediately after being administered the vaccine.

6. Who will receive 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:

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

7. 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.

8. Will children, pregnant women and lactating women be vaccinated?

Under the current WHO protocol for the expanded access in DRC, children of below six years of age, pregnant women and lactating women will not be administered the vaccine. Pregnancy tests will be offered to women who are unsure of their pregnancy status. The reason for not providing vaccine to children under six years of age, pregnant women and lactating women is because of limited data on these subgroups. Available data from previous trials suggest that they might be indirectly protected by vaccinating the ring.

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, 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 visit all persons vaccinated on days 3 and 14 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. The serious adverse event (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 which has been established for the current investigational vaccination will be informed within 24 hours of knowledge of the event. 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 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:

- Separate (isolate) patients to prevent further spread at home or in the community,
- Early detection of new Ebola infections through close monitoring of contacts and separating them from other persons if they develop symptoms,
- Safely and respectfully bury the dead to reduce further spread of Ebola virus through contact with deceased.

1 Meeting of the Strategic Advisory Group of Experts on Immunization - conclusions and recommendations

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More about Ebola »

This page links all WHO technical and general information on Ebola virus disease.

For further information:
Fact sheet on Ebola virus disease

Frequently asked questions about Ebola

Meeting of the Strategic Advisory Group of Experts on immunization - conclusions and recommendations (Ebola vaccines)

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!)
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
The Lancet

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

WHO

This free online course offers decision-makers and frontline responders an overview of Ebola virus disease and access to e-PROTECT training, intended to help yourself and members of your team from contracting Ebola and prevent further transmission of the disease.

Access training

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