

Setting up an expanded access/ compassionate use to evaluate candidate vaccines in the context of an outbreak?

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Building research readiness for a future filovirus outbreak.

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Outline

- Definition of ring vaccination
- Overview of Ring Vaccination
- Organization and implementation;
- ☐ Different approaches used during the response;
- □ Vaccine management;
- Lessons Learned



Definition of ring vaccination

Ring vaccination is a strategy:

- > contacts,
- > contacts of contacts
- > probable contacts of confirmed EVD cases.
- > 1970s (smallpox)



Two types of study:

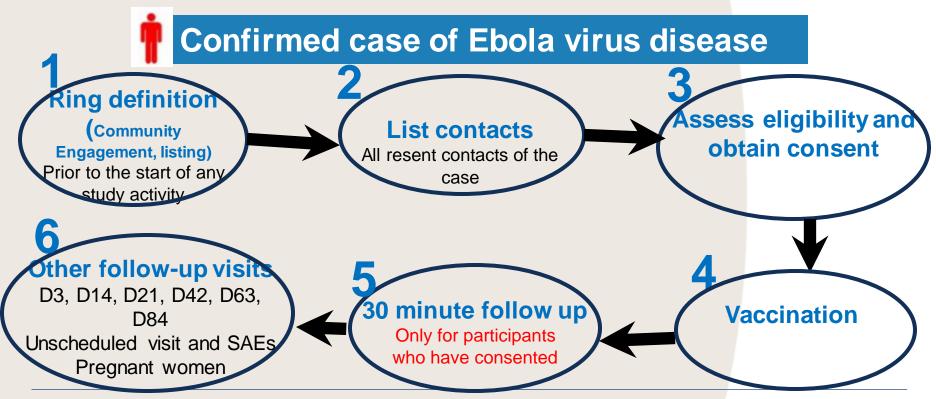
- Randomized trial "efficacy and safety of rVSV-ZEBOV" in Guinea (immediate and delayed vaccination);
- SAGE recommendation for the use of the unlicensed vaccine in the context of the epidemic on a "compassionate use protocol";
 - Limited global supply of unauthorized doses;
 - Sample size (undefined);
 - Quick implementation (Maximum 7 days)
 - Safety and efficacy
 - Implementation timeline (not defined)
 - Quick evaluation of vaccine candidate
 - Resources



Use of the experimental vaccine:

- >SAGE recommendations on the use of Ebola vaccines
- Protocol approved by the national regulatory authority and the ethics committee
- Informed consent of study participants
- Vaccination teams trained on GPC







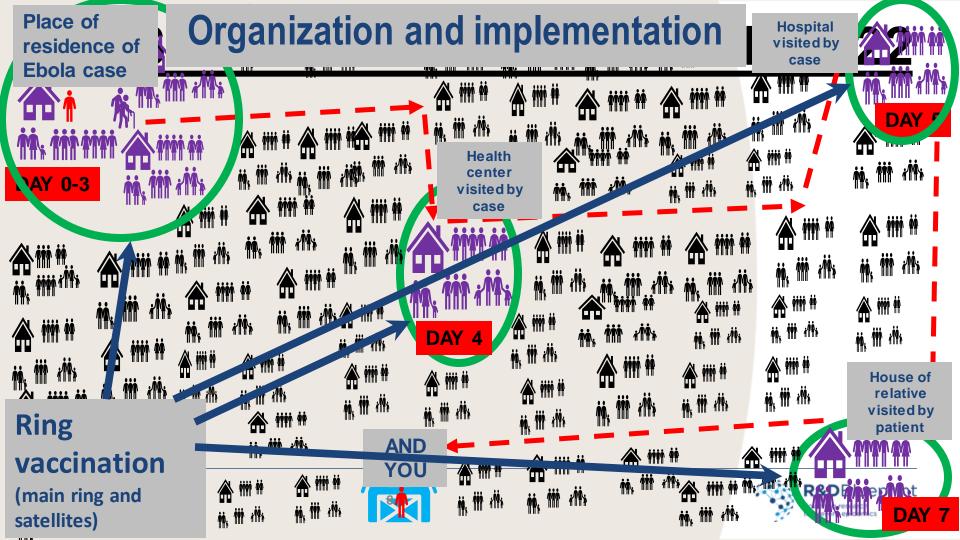


- 1.Enumeration of people at risk Surveillance and vaccination teams work together
- 2. Screening and eligibility Defining who is contact and contacts of contact
- 3. Group
 Informed
 consent. Time
 for Q&A
- 4. Individual signing of ICF Signature by vaccinee or by literate witness
- 5. Vaccination
 Vaccinate and
 encourage
 educate about
 side effects and
 adverse event
 reporting
- 6. 30mn post vaccination
 Participants wait 30 min in case of anaphylaxis
- 7.,Scheduled FU at D3, D21 etc. and SAEs

D3, D14, D21, D42, D63, D84, Unscheduled visit, pregnant women







Organization and implementation

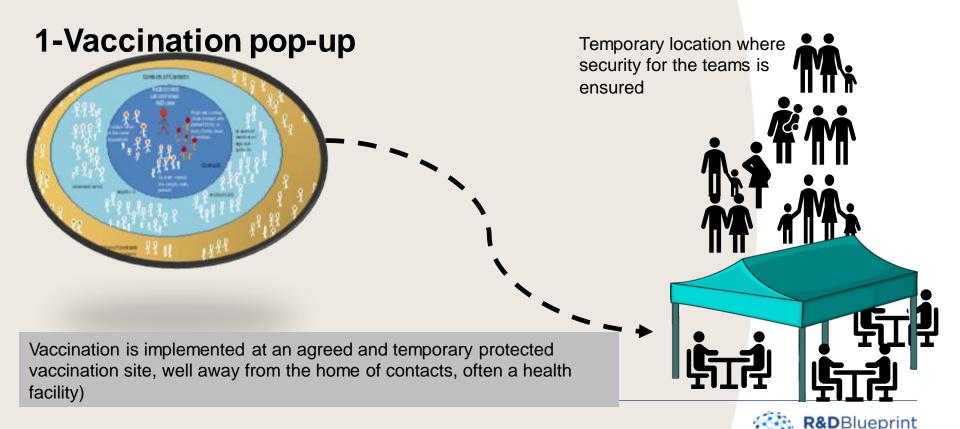
Eligible

- > 6 months and older
- Pregnant women after the first the 1st trimester
- > Breastfeeding women.

Ineligible

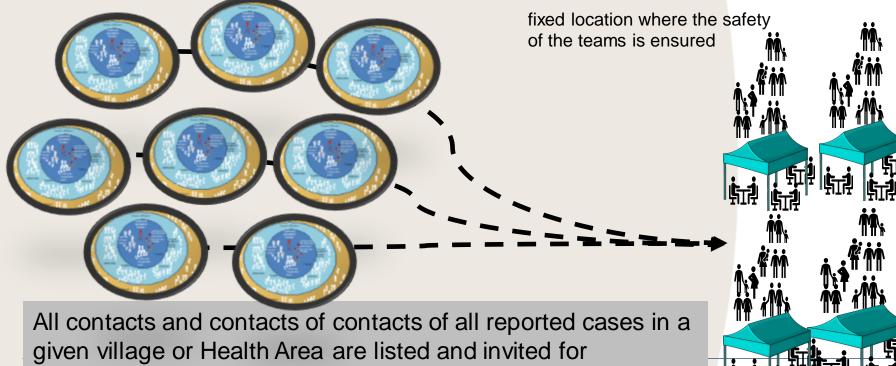
- ➤ History of EVD (declared or confirmed by the laboratory).
- > Pregnancy (before the first trimester).
- ➤ Previous administration of other experimental treatments within the last 28 days.
- ➢ History of anaphylaxis to a vaccine or vaccine component.
- >Serious illness that causes the person to be bedridden or requires hospitalization at the time of vaccination or after.

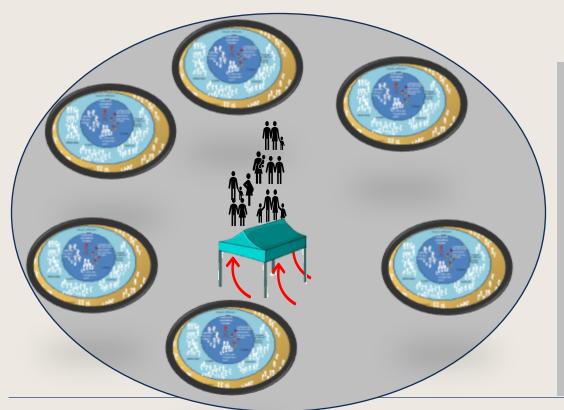




2-Targeted Geographical Area

vaccination simultaneously.



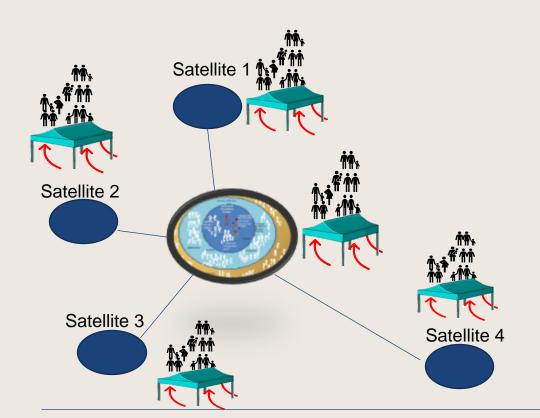


3-Mop up operations:

Fix teams in hostpots to catch up with contacts and contacts of contacts:

- 1st for cases in last 10 days
- 2nd for cases in last 21 days

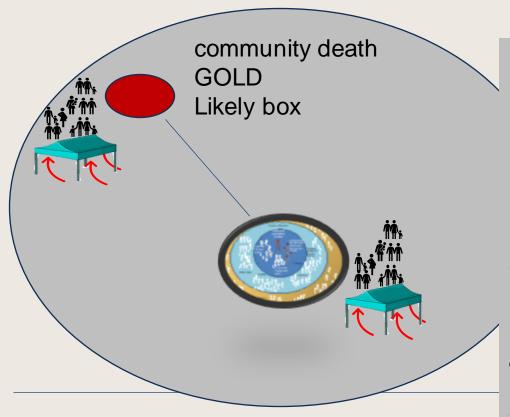




4-Several teams vaccinate around a case:

Simultaneous vaccination at all locations visited by cases since onset of symptoms (satellites)





5-Include people at risk around the deaths of probable cases or suspected cases (verified epi link): **Vaccinate** simultaneously within the framework of an existing ring

Vaccine management



Carbon dioxide gas(-80 to -60°C) From GVA to Country



Lessons Learned

- Research in the context of a health emergency (disease with epidemic potential) vaccine to help stop the spread of an epidemic;
- Innovative approaches depending on the context (targeted geographical vaccination, pop-up vaccination, Mob up operation, and simultaneous vaccination in all places visited by the index case),
- > Inclusion of children and pregnant women



Lessons Learned

- ➤ V. Preventive action in neighboring countries of the affected country as part of the preparation (J&J vaccination).
- Development of local competence (about 6000)
- Collaboration research and Response Teams



