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
Overview of Ring Vaccination

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
Overview of Ring Vaccination

1. Ring definition
   (Community Engagement, listing)
   Prior to the start of any study activity

2. List contacts
   All recent contacts of the case

3. Assess eligibility and obtain consent

4. Vaccination

5. 30 minute follow up
   Only for participants who have consented

6. Other follow-up visits
   D3, D14, D21, D42, D63, D84
   Unscheduled visit and SAEs
   Pregnant women

Confirmed case of Ebola virus disease

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Overview of Ring Vaccination

1. Enumeration of people at risk
2. Screening and eligibility
3. Group informed consent
4. Individual signing of ICF
5. Vaccination
6. 30mn post vaccination
7. Scheduled FU at D3, D21 etc. and SAEs

Surveillance and vaccination teams work together
Defining who is contact and contacts of contact
Time for Q&A
Signature by vaccinee or by literate witness
Vaccinate and encourage educate about side effects and adverse event reporting
Participants wait 30 min in case of anaphylaxis

D3, D14, D21, D42, D63, D84, Unscheduled visit, pregnant women
Organization and implementation

Ring vaccination (main ring and satellites)

Place of residence of Ebola case

Hospital visited by case

Health center visited by case

Day 0-3

Day 4

Day 5

Day 7
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.
Different approaches used during the response

1-Vaccination pop-up

Vaccination is implemented at an agreed and temporary protected vaccination site, well away from the home of contacts, often a health facility.

Temporary location where security for the teams is ensured
All contacts and contacts of contacts of all reported cases in a given village or Health Area are listed and invited for vaccination simultaneously. Different approaches used during the response 2-Targeted Geographical Area
Different approaches used during the response

3-Mop up operations:
Fix teams in hotspots 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)
Different approaches used during the response

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
- Main storage (-80 to -60°C)
- Transport to the Zone and the health structure
- Arteck (-80 to -60°C)
- PCM Accumulators
- CryoQ +2 to +8°C
- Vaccination site storage and transport
- 5/30/202
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
Thank you