Integrating vaccine research into the outbreak response: *Lessons learned from ring vaccination strategy during EVD outbreaks.*

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Building research readiness for a future filovirus outbreak.
20-22 February 2024, UGANDA
Ring vaccination use in EVD epidemics

Successive Ebola Virus Disease (EVD) epidemics with use of ring vaccination

2014-2016

Guinea
Sierra Leone

2018
Equateur, DRC

2018-2020
Eastern DRC
Uganda

2020
DRC, Equateur

2021
N’zérékoré, Guinea
North Kivu, DRC
North Kivu, DRC

2022
Equateur, DRC

RESEARCH: Expanded access / compassionate use protocol

Licensed doses
Integrated vaccine research into EVD outbreak response

Background from 2014-2016

- **High quality** clinical trial using mobile teams can be done in a **context of an outbreak** like EVD
- Local staff use is not a choice but imperative! (90% local staff in Guinea)
- The **ultra cold chain** can be used in very remote areas
- Use of an **unlicensed vaccine with efficacy data** in outbreak response is feasible → Covid-19
- Expanded access/compassionate use can be used for safety monitoring and to further document efficacy and effectiveness
Integrated vaccine research into EVD outbreak response

Method

• Ring vaccination trial protocol → ICH/GCP compliance.
  ✓ Written informed consent CCCs
  ✓ Clear inclusion and exclusion criteria etc.
  ✓ Appointment of Principal Investigator (local PI)
  ✓ Study duration → Outbreak

• WHO/Country → EC, IRB & RA approval
• Local staff training (GCP and Protocol & SOP)
• Support from Clinical trials experts
Method/ Solidarity against Filovirus RCT protocol.

Confirmed Filovirus disease case
(recently reported by MOH/WHO)

Rapid definition of ring and seeking consent
(list of all contacts of the case)

Random assignment of the ring

Immediate vaccination of consenting contacts

Delayed vaccination of consenting contacts

Monitoring of safety & confirmed cases

Monitoring of safety & confirmed cases

Comparison of confirmed case rates
Method/ Coordination of the Trial Activities

Ring vaccination base  
(Field coordinator)

Teams

Team leader

Logistics and supplies (Field Logisticians)

Community engagement team / Community consent

Ring definition

Listing of contacts

Inform consent

Eligibility Criteria

Vaccination

Vaccinate the participants

Follow up

30mn, day7, day21 etc.
Method/ Example of team coordination from TOKOMEZA trial

- **SPONSORS**
  - WHO Tech Support
  - Principal Investigator (PI)
  - Sub-Investigators
  - Support team (Base): Pharmacist, IPC, Administration, Finance, Data Manager, Lead CE, Lead Logisticians

- **Team Lead**
  - Field Supervisors
  - Trial Manager/ Field Co
  - Vaccinators
  - Safety/Care Physicians
  - Follow up team
  - Field Logistician

- Community Engagement & Rind definition officers
  - Eligibility /Consent ICF & call Randomization officers
A lab-confirmed filovirus case reported!

1. Engage community
   Before any trial activity starts

2. List contacts
   All recent contacts of the case

3. Assess contacts eligibility & seek consent
   CLOSE RING

4. Randomize RING
   Vaccination Now or 21 days later

5. Vaccinate + 30 minutes follow up
   ONLY consented ring members

6. FU visits at home
   on days 7, 14 and 21
Method/ Field Vaccination Procedures

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
Outcome/ Readiness of vaccine research integrated into EVD outbreak responses since 2016

Over 2,243 rings defined and vaccinated, covering 91% (3,526/3,885) of EVD cases from 2016 to 2022
Outcome/ Local capacity building across EVD outbreaks affected countries

- We have built 179 field teams and trained more than 2500 local HCWs with the basics of GCP and ring vax SOPs across those successive EVD outbreaks in 111 districts in the affected areas.

<table>
<thead>
<tr>
<th>Country</th>
<th># of field team trained and used</th>
<th># of Health Zones or Districts covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guinea 1st EVD outbreak</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>DRC 09th EVD outbreak</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>DRC 10th EVD outbreak</td>
<td>95</td>
<td>68</td>
</tr>
<tr>
<td>Uganda 2019</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>DRC 11th EVD outbreak</td>
<td>46</td>
<td>20</td>
</tr>
<tr>
<td>DRC 12th EVD outbreak</td>
<td>14</td>
<td>4</td>
</tr>
<tr>
<td>Guinea 2nd EVD outbreak</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>DRC 13th EVD outbreak</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>179</strong></td>
<td><strong>111</strong></td>
</tr>
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</table>
Some Key Lessons learned

• **Building local staff capacity** is crucial, highlighting preparedness in resource-challenged countries, as seen in Uganda in 2019.

• Early assessment of vaccine safety is vital for pregnant women, breastfeeding women, and infants aged 6 months and above.

• Research activities involve **strategic communication**, training vaccinators, prioritizing **healthcare worker education**, and using diverse media.

• Include **local traditions, customs, and authorities** in the communication strategy, collaborating with local leaders and addressing rumors through various channels.

• Continuously **adapt the implementation strategy** based on field conditions, incorporating **innovative approaches** and empowering **local healthcare workers**.

• Tailor the communication **strategy to each country** and **community**, recognizing the unique differences among vaccine beneficiaries.
Conclusion

- Over **370,000** individuals have received vaccinations with unlicensed doses, research integrated into Ebola outbreak response.

- Ring vaccination is an **effective vaccine research strategy** to prioritize high-risk individuals when vaccine supplies are constrained.

- **Successful** vaccination strategies hinge on **stakeholder engagement**.

- **Lessons from Ebola** ring vaccination offer **valuable insights** for developing vaccine research guidelines and strategies for other interventions during outbreak, including COVID-19, Monkeypox, Marburg, etc.

The PI, Professor J. J. Muyembe with WHO ring vaccination experts in Beni Health Zone/North Kivu /DRC, 2019.
THANK YOU FOR YOUR ATTENTION

Dr. M. J. Ryan visiting and supporting field team in VISIKI/LIDE Health Area /North Kivu /DRC, 2019