Developing a research plan for Nipah Virus Disease

Vasee Moorthy MA MD PhD
August 2018
WHO/ICMR Meeting, Delhi
Phase 1 trials in High income settings

Phase 1 in Africa

Phase 2/3 in Liberia

Phase 3 in Guinea

Phase 2/3 in Sierra Leone

Interim Results from Ring Vaccination Trial

11 months
Norm for vaccines:
10-20 years from first phase 1 to safety and effectiveness information in relevant target populations to enable policy decisions
Ebola Consortia assembled from August 2014
Planning an efficacy study during an epidemic

- 23 Oct: WHO High level meeting
- Guinea working group formed
- 11 Aug: WHO Ethics Report
- 5 Nov: Ring design decided
- 5 Feb: Vaccine choice
- 23 Mar: Vaccination initiated
- 29-30 Sept: WHO Consultation on Ebola Vaccines
- Dec-Jan: Protocols / Financing
- 1 Jan: Start stability study
- 7 Aug: Last randomized ring vaccinated
- 31 Jul: Preliminary results
- 20 Jul: Interim analysis
- 1 Sept: Extension to Sierra Leone
- 90 rings
- 9 months
Preparing for the inevitable: the WHO R&D Blueprint

With more frequent travel, globalized trade and greater interconnectedness between countries, infectious disease outbreaks of international concern are becoming as inevitable as they remain unpredictable.
Towards a Global Coordination Mechanism

A. Improving coordination & fostering an enabling environment

B. Accelerating R&D processes

C. Developing new norms & standards tailored to the epidemic context
Various mechanisms for engaging with partners and key stakeholders

1) Global Coordination Mechanism

2) Bilateral Collaboration

3) Country and outbreak specific efforts while contributing to national research plan
Accelerating Research & Development Processes

A. Improving coordination & fostering an enabling environment

B. Accelerating R&D processes

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R&D Roadmaps
Prototype R&D roadmap: available for MERS-coronavirus

A roadmap for MERS-CoV research and product development: report from a World Health Organization consultation

Kayvon Modjarrad, Vasee S Moorthy, Peter Ben Embarek, Maria Van Kerkhove, Jerome Kim & Marie-Paule Kieny

As part of the World Health Organization (WHO) R&D Blueprint initiative, leading stakeholders on Middle East respiratory syndrome coronavirus (MERS-CoV) convened to agree on strategic public-health goals and global priority research activities that are needed to combat MERS-CoV.
Accelerating Research & Development Processes

A. Improving coordination & fostering an enabling environment

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Target Product Profiles

AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS
PLAN OF ACTION MAY 2016

World Health Organization
## Vaccine TPPs

<table>
<thead>
<tr>
<th></th>
<th>Circulation of draft TPP to Expert Working group for comments</th>
<th>Public consultation of draft TPPs</th>
<th>Final TPP published at WHO website</th>
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</thead>
<tbody>
<tr>
<td>Monovalent <strong>Ebola</strong> – reactive and preventive use</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Multivalent <strong>filovirus</strong> vaccine</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>Revised Zika</strong> virus</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>MERS Co-V</strong> vaccine TPPs</td>
<td>✓</td>
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<tr>
<td><strong>Nipah</strong> Virus vaccine TPP</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>Lassa</strong> Fever virus vaccine TPP</td>
<td>✓</td>
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Accelerating Research & Development Processes

A. Improving coordination & fostering an enabling environment

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AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS
PLAN OF ACTION MAY 2016

World Health Organization

Regulatory & Ethics Preparedness for Public Health Emergencies
Developing new norms & standards tailored to the epidemic context

A. Improving coordination & fostering an enabling environment

B. Accelerating R&D processes

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Trial design, endpoints, protocol development
Developing new norms & standards tailored to the epidemic context

- **A** Improving coordination & fostering an enabling environment
- **B** Accelerating R&D processes
- **C** Developing new norms & standards tailored to the epidemic context

Research data & sample sharing frameworks tailored to outbreaks
Summary points

Core principles of the R&D Blueprint include capacity development and maximising benefits for those in affected countries, timeliness, transparency, access for those most in need.

Collaboration greatly increases the utility of research in epidemics, and in preparedness phase.

Much more to do on ensuring critical information is shared in a timely and transparent manner.
OBJECTIVES OF THE PLAN

To advance readiness with surveillance, diagnostics and therapeutics

To expand the Nipah-related R&D capacity in the region (for Nipah and as preparedness for outbreaks)

To expand scientific knowledge about Nipah related to the recent outbreak and beyond

To identify areas/partners for long-term international collaboration
<table>
<thead>
<tr>
<th>AREAS OF WORK</th>
<th>Priority research is proposed:</th>
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<tr>
<td><strong>1. SURVEILLANCE, EPI, RISK FACTORS</strong></td>
<td>To improve and strengthen the surveillance system for early detection and response of Nipah virus outbreaks in X pilot areas. To ensure adequate capacity and expertise for rapid sequencing and early public sharing of Nipah sequences and analysis. To better understand the epidemiology and risk factors and the ecology of Nipah virus infection/disease.</td>
</tr>
<tr>
<td><strong>2. DETECTION</strong></td>
<td>To strengthen the capacities for safe handling and diagnosis of Nipah virus disease including laboratory capacity, quality assurance. Evaluation of candidate improved diagnostics.</td>
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<td>3. CLINICAL MANAGEMENT</td>
<td>4. To increase capacity to provide adequate standard of care and case management</td>
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<td>4. THERAPEUTICS DEVELOPMENT</td>
<td>5. To support tech transfer and GMP development of mAb</td>
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<td>5. SURVIVOR STUDIES</td>
<td>6. To conduct clinical, immunological and genetic characterization of survivors (samples very precious here)</td>
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<td>6. COMMUNITY ENGAGEMENT</td>
<td>7. To support community engagement activities in particular those aimed to understand risk behavior and risk management</td>
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<td>7. RESEARCH COORDINATION</td>
<td>8. To set up a sustainable mechanism in India to facilitate the coordination of the research efforts related to Nipah</td>
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### AREAS OF WORK

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<td><strong>8. THERAPEUTICS PROTOCOL DEVELOPMENT</strong></td>
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<td>9. To coordinate the design and support the prompt implementation of efficacy trials to assess candidate therapeutics for Nipah virus disease <em>(separate meeting, already advanced)</em></td>
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<td><strong>9. VACCINE OPERATIONAL USE CASE</strong></td>
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<td>10. To develop local perspective on requirements for a Nipah virus vaccine if it is to be useful <em>(explore feasibility of ring vaccination)</em></td>
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<td><strong>10. VACCINE PROTOCOL DEVELOPMENT</strong></td>
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<td><strong>11. DATA AND SAMPLE SHARING</strong></td>
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SHORT, MEDIUM AND LONG-TERM PRIORITIES

AGREE AREAS OF WORK, with SETS OF ACTIVITIES. These should break down into short, medium and long-term priorities for India and the region to better detect, prevent, control and treat Nipah virus infection and disease.
IMMEDIATE PRIORITIES OF THE PLAN

1. Therapeutics protocol pre-positioning
2. Surveillance/diagnostics
3. Key urgent capacity needs
4. Virtual distributed or central system for sample storage in each country

Each with concrete timelines, resources needed and agreed roles and responsibilities.