Accelerating access to Ebola vaccines

From research to large-scale use

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World Health Organization
Ebola response roadmap: Situation report
3 December 2014

Sierra Leone

Liberia

Guinea

Number of cases

Cumulative deaths | Cumulative cases

Guinea

Sierra Leone

Liberia

0 2,000 4,000 6,000 8,000 10,000

Guinea 1,327 2,164

Sierra Leone 1,583 7,312

Liberia 3,145 7,635
Ebola vaccines under Preclinical evaluation

- HPIV-3 live attenuated Intranasal (two versions), NIAID (March/April 2015)
- Ebola recombinant nanoparticle with Matrix M adjuvant Novavax (1st quarter 2015)
- Oral adenovirus 5 Ebola vaccine Vaxart (1st quarter 2015)
- Ebola recombinant protein Protein Sciences (1st trimester 2015)
- Alternate rVSV Ebola vaccine Profectus (mid- 2015)

Description, developer (estimated date when clinical testing will start)

Jan 2015       June 2015       Dec 2015
Ebola vaccines under clinical evaluation in 2014

rVSV-ZEBOV
Recombinant vesicular stomatitis virus
It aims to induce EVD-specific immune responses.
NewLink Pharmaceuticals?Merck

ChAd3-ZEBOV
Chimpanzee adenovirus 3
It uses a chimpanzee adenovirus that does not grow, containing the gene for EVD surface protein.
GSK/NIAID

Ad26/Ad35/MVA
Johnson and Johnson Crucell

Ebola vaccine research and anticipated development timelines

(information available to WHO as of Dec 8, 2014)

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Expected date start enrollment

Expected date preliminary results would be available

ChAd3

rVSV

Ad26

World Health Organization
Matching vaccine supply to potential target populations

Anticipated number of doses of Ebola vaccine that would be released

Cumulative number of doses (thousands-log scale)

- All front line workers = 91,600
- All adults > 15 years of age = 12 million
- All population - 3 countries: 20 million

ChAd3, rVSV (1e6), rVSV (1e7), rVSV (5e7), Ad26
Ebola vaccines: WHO Oversight

**RESEARCH AND DEVELOPMENT PATHWAY**
Strategic and Technical Advisory Committee on Experimental Ebola Therapeutics and Vaccines (STAC-EE): Review of development plan, expert opinion on protocol design, and interpretation of data emerging from trials

**REGULATORY MATTERS**
WHO Advisory Committee on Regulatory Emergency Authorization of unlicensed Ebola Vaccines: Review of GMP, evidence on safety and efficacy, programmatic suitability. Time limited authorization for use

**SAFETY AND RISK ASSESSMENT**
WHO Ebola Vaccines Risk Assessment Group and WHO Global Advisory Committee on Vaccine Safety: Evaluation of safety data and opinion on potential risks and benefits.

**POLICY AND IMPLEMENTATION**
Strategic Advisory Group of Experts (SAGE): Review of evidence to inform policy considerations for large scale use, if appropriate
Task Force on Immunization (TFI): Operational implementation and monitoring in Africa
Ebola Vaccines - Key milestones

Planning for large-scale use including systems for vaccine financing, allocation and use.

- **Agreed protocols (including Phase 3) trials across sites**
- **Preparation started of sites for Phase 3 studies in Ebola affected countries**
- **Start of Phase 2 trials**
- **Start of Phase 3 trials in Ebola affected countries**
- **Initiation of Phase 1 trials for the two most advanced vaccines**
- **Initial safety and immunogenicity from most Phase 1 trials available**
- **Preliminary results vaccine efficacy available**
Accelerated efforts are underway to evaluate a number of Ebola vaccines. Preliminary results anticipated:

- **Phase 1 data:** Dec 2014
- **Phase 2 data:** 1st Quarter 2015
- **Phase 3 data:** 2nd to 3rd Quarter 2015

Analysis of anticipated supply and potential target populations suggest that doses would match demand as follows:

- **1st Quarter 2015:** Front line workers
- **3rd Quarter 2015:** Adults (older than 15 years of age or geographic target areas strategies)
- **2nd to 4rd Quarter 2015:** All populations in 3 worst affected Ebola countries

WHO has set in place the required oversight to ensure quality and compliance with ethical and regulatory matters, to develop policy recommendations and vaccine roll-out as appropriate.
"The vaccine is not the magic bullet.

But when ready, they may be a good part of the effort to turn the tide of this epidemic."
Thank you