World Health Organization

Target Product Profiles for Rift Valley Fever Virus Vaccines

tpp-rift-valley-fever-vaccines-draft3-0pc.pdf

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RD Blueprint for Epidemics

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R&D Blueprint

Powering research to prevent epidemics

TPP content

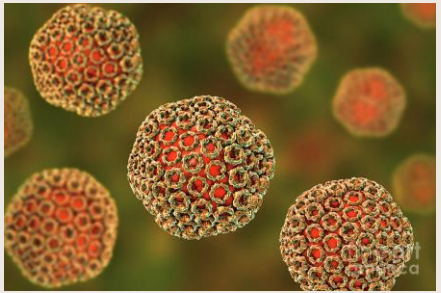
Developed through a consultation process

1. **Human** vaccine for **reactive/emergency** use to prevent disease
   - In populations experiencing outbreaks or geographically close to an outbreak

2. **Human** vaccine for **long-term protection** for persons at high risk of infection
   - **Handling animal tissues** (slaughtering or butchering, assisting with animal births, veterinary procedures, disposal of carcasses or fetuses.
   - **High-risk occupational groups**: herders, farmers, slaughterhouse workers, veterinarians.

3. **Animal vaccine** – prevention of RVFV among ruminants and from ruminants to humans

Describes **optimal** and **minimally** acceptable target



Human vaccines – outbreaks settings with rapid onset of immunity

Vaccine characteristic	Optimal Target	Minimally Acceptable Target
Indication for use	Active immunization of **at-risk persons** in an ongoing outbreak, prevention of RVF to be used with other control measures	
Target population	People in areas of outbreak, including **pregnant women** Those in contact with infected animals or tissues from infected animals, including consuming milk and handling raw meat products	People in areas of outbreak Those in contact with infected animals or tissues from infected animals including consuming milk and handling raw meat products.
Safety/reactogenicity	Highly favourable benefit/risk profile Mild and transient AE	Benefits outweigh safety risks LAV that may allow reassortment **not** indicated in an outbreak.
	No LAV unless reassortment is excluded	

Vaccine characteristic	Optimal Target	Minimally Acceptable Target
Efficacy	90% efficacy in preventing lab-confirmed disease detection of live RVFV, RNA, or IgM against-RVF Rapid onset of Immunity less than 2 weeks Characterize the immune response including humoral and cellular immune response	70% efficacy in preventing lab confirmed disease detection of live RVFV, RNA, or IgM against-RVF Rapid onset of Immunity less than 3 weeks
Dose regimen	Single dose	No more than 2 doses, short interval (less than 3 weeks) Some protection after first dose
Duration of protection	At least 1 year Could be inferred from immune kinetics and documentation of breakthrough cases	6 months

Vaccine characteristic	Optimal Target	Minimally Acceptable Target
Route of administration	Injectable (IM. ID or SC) Standard volumes Needle-free delivery	Injectable (IM. ID or SC) Standard volumes
Coverage	Protection against all RVFV lineages against any RVFV strain likely to cause infection	
		Heterologous vaccine could be considered if partial protection is demonstrated
Stability and storage	Shelf life 5 years at 2 – 8 C Data on thermostability at higher temperatures	Shelf life 12 months at -20 C At least 1-month stability at 2-8 C
	Need for preservative is determined and issues addressed VVM: proof of feasibility and intent to use in the primary container	

Vaccine characteristic	Optimal Target	Minimally Acceptable Target
Co-administration	co-administered without affecting safety and efficacy of either vaccines	Stand alone
Presentation	liquid product in mono-dose or multi-dose presentations Maximal dosage volume of 0.5 mL. Multi-dose presentations should be formulated, managed and discarded in compliance with WHO's multi-dose vial policy.	Liquid or lyophilized product in mono- dose or multi-dose presentations maximal dose volume of 1.0 mL. Multi-dose presentations should be formulated, managed and discarded in compliance with WHO's multi-dose vial policy. Lyophilized vaccine accompanied by paired separate vials of diluent.
Registration and pre-qualification	WHO pre-qualified according to the process outline in the Procedures for assessing the acceptability of vaccines purchases by UN agencies.	

Human vaccines – long-term protection of persons at high ongoing risk

Vaccine characteristic	Optimal Target	Minimally Acceptable Target
Indication for use	Active immunization of **at-risk persons** including those working with potentially infected animals (herders, farmers, slaughterhouse workers and veterinarians)	
Target population	Persons at high ongoing risk of RVFV infection: handling of animal tissue during slaughtering or butchering, assisting with animal births, conducting veterinary procedures, or involved with the disposal of carcasses or fetuses. High risk occupational groups include herders, farmers, slaughterhouse workers and veterinarians.	
	Pregnant women	
Safety/reactogenicity	Comparable to WHO routine vaccines Highly favourable risk-benefit profile Only mild, transient AEs No SAEs including in immunocompromised	Benefits clearly outweighs safety risks Primarily mild, transient health effects rare SAEs

Vaccine characteristic	Optimal Target	Minimally Acceptable Target
Efficacy	90% efficacy in preventing lab-confirmed disease detection of live RVFV, RNA, or IgM against-RVF Characterize the immune response including humoral and cellular immune response	70% efficacy in preventing lab confirmed disease detection of live RVFV, RNA, or IgM against-RVF
Dose regimen	Single dose	No more than 2 doses, short interval
Duration of protection	5 years or more which can be maintained by booster doses	3 years which can be maintained by booster doses

Vaccine characteristic	Optimal Target	Minimally Acceptable Target
Route of administration	Injectable (IM. ID or SC) - Standard volumes	
Coverage	Protection against all RVFV lineages A - O	Protection against any RVFV strain likely to cause infection
Stability and storage	Shelf life 5 years at 2 – 8 C Data on thermostability at higher temperatures Not damaged by freezing. Delivered by Controlled temperature chain	Shelf life 12 months at -20 C And 6 months at 2-8 C
	Need for preservative is determined and issues addressed VVM: proof of feasibility and intent to use in the primary container	

Vaccine characteristic	Optimal Target	Minimally Acceptable Target
Co-administration	co-administered with licensed vaccines for same age and population groups without impact on immunogenicity or safety of either vaccines	Stand alone
Presentation	liquid product in mono-dose or multi-dose presentations Maximal dosage volume of 0.5 mL. Multi-dose presentations should be formulated, managed and discarded in compliance with WHO's multi-dose vial policy.	Liquid or lyophilized product in mono-dose or multi-dose presentations maximal dose volume of 1.0 mL. Multi-dose presentations should be formulated, managed and discarded in compliance with WHO's multi-dose vial policy. Lyophilized vaccine accompanied by paired separate vials of diluent.
Registration and pre-qualification	WHO pre-qualified according to the process outline in the Procedures for assessing the acceptability of vaccines purchases by UN agencies.	

THANK YOU

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