IMPORTANCE OF QUALITY CONTROL OF FMD VACCINE

Ethel Chitsungo

Outline

- Introduction
- Quality Control Tests for FMD vaccine
- Development of FMD Reference Panel for East Africa
- Requirement for submission of FMD Vaccine for Quality Control at AU-PANVAC
- Conclusion

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Introduction

- FMD is an important constraint to livestock with impact on global trade.
- Vaccination is a critical component of FMD control
- Seven serotypes of FMDV (**O, A, C, SAT1, SAT2, SAT3, and Asia1**) and multiple subtypes are currently recognized
- Constant evolving of antigenic diversity of FMD virus require that vaccine strains **BE MATCHED** with field strains.
- Vaccine Production & Quality Control:
  - Requires high biocontainment facilities under appropriate biosecurity measures
  - Seed Virus Management (maintenance of genetic characteristics) to ensure consistency and efficacy of the vaccine.

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Introduction

- *Objective of QC:*
  - to guarantee vaccine purity, safety & efficacy
- *A good quality vaccine must be:*
  - **PURE:** Not contaminated with harmful pathogens
  - **SAFE:** for animal and human use (No adverse effects)
  - **EFFICACIOUS:** Possess Immunizing properties
  - **STORAGE CONDITION:** be consistent and should have defined Shelf life

Quality Control Tests for FMD vaccine

1. Sterility & Purity *(Demonstrate level of purification from NSPs for purified vaccine)*

2. Safety/Innocuity

- *Test in labs animals observed over 14 days.*
- *Innocuity on cell culture to determine the absence of infectious virus.*

3. Identity Testing (PCR, VNT) **:** To ensure that relevant strains are present.

4. **Stability test** – Oil emulsion stability

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Quality Control Tests for FMD vaccine

5. Efficacy testing

No regular matching of vaccine with the circulating field strains

Options available:

- *Vaccination & Challenge in animal hosts*:

Cons: high containment facility, expensive, time consuming

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Quality Control Tests for FMD vaccine

5. Efficacy testing

Serology tests (VNT) to correlate antibodies level and protection

Options available:

- Immunise with candidate vaccine. Test sera produced against field virus/from producer

Cons: Costly, naïve animal selection, time constraints and challenges with getting viruses

- Get serum from Producer and test against seed virus from producer or against a well-defined panel

Cons: Relies on information from producer

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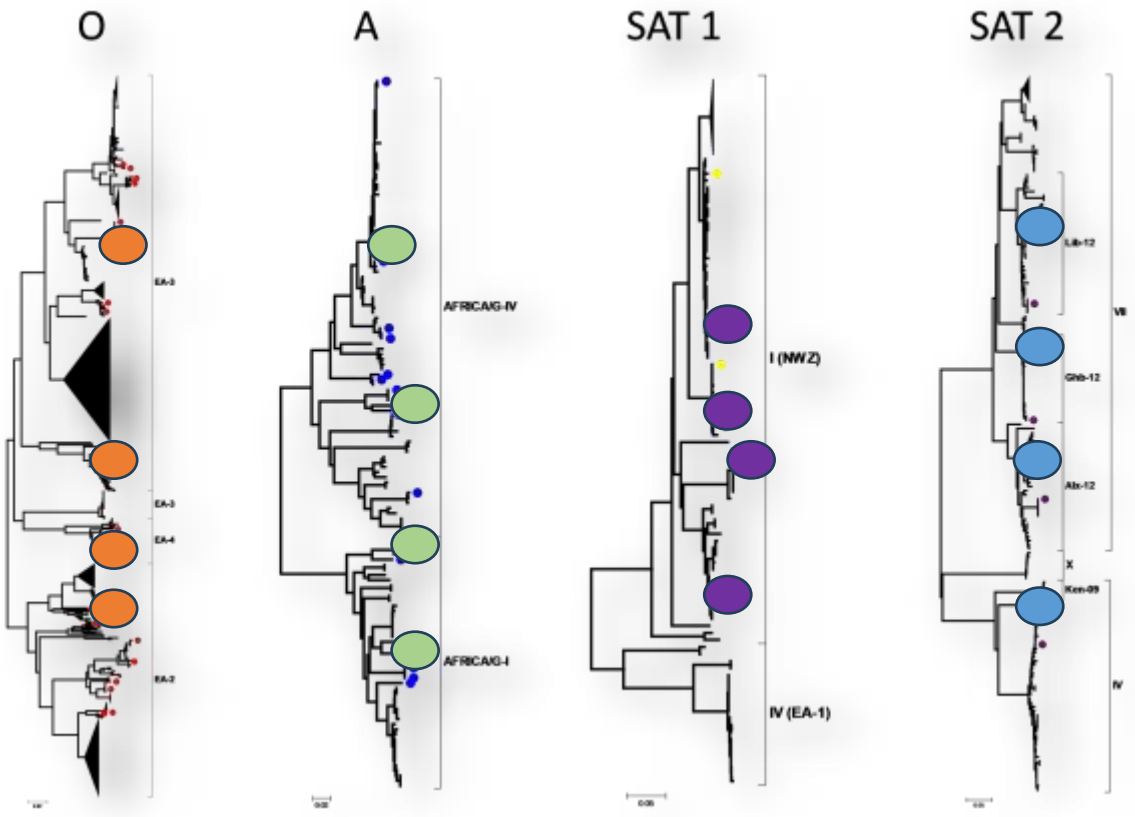
Reference Panels for Quality Control of FMD

Agend 2063 The Africa we Want



Selection of a panel of 16 FMD Viruses covering the genetic diversity circulating in **Eastern African countries** (**O**, **A**, **SAT1** & **SAT2**) **used for VNT**

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East African Region FMD Virus Panel

16 VIRUSES SELECTED

Serotype A	Serotype O	Serotype SAT 1	Serotype SAT 2
SUD/9/2018	ETH/4/2015	TAN/22/2013	ETH/16/2015
ETH/2/2018	ETH/9/2019	KEN/10/2013	KEN/19/2017
UGA/28/2019	ETH/30/2016	TAN/27/2012	EGY/1/2018
ETH/19/2019	KEN/4/2018	TAN/22/2014	ETH/11/2018

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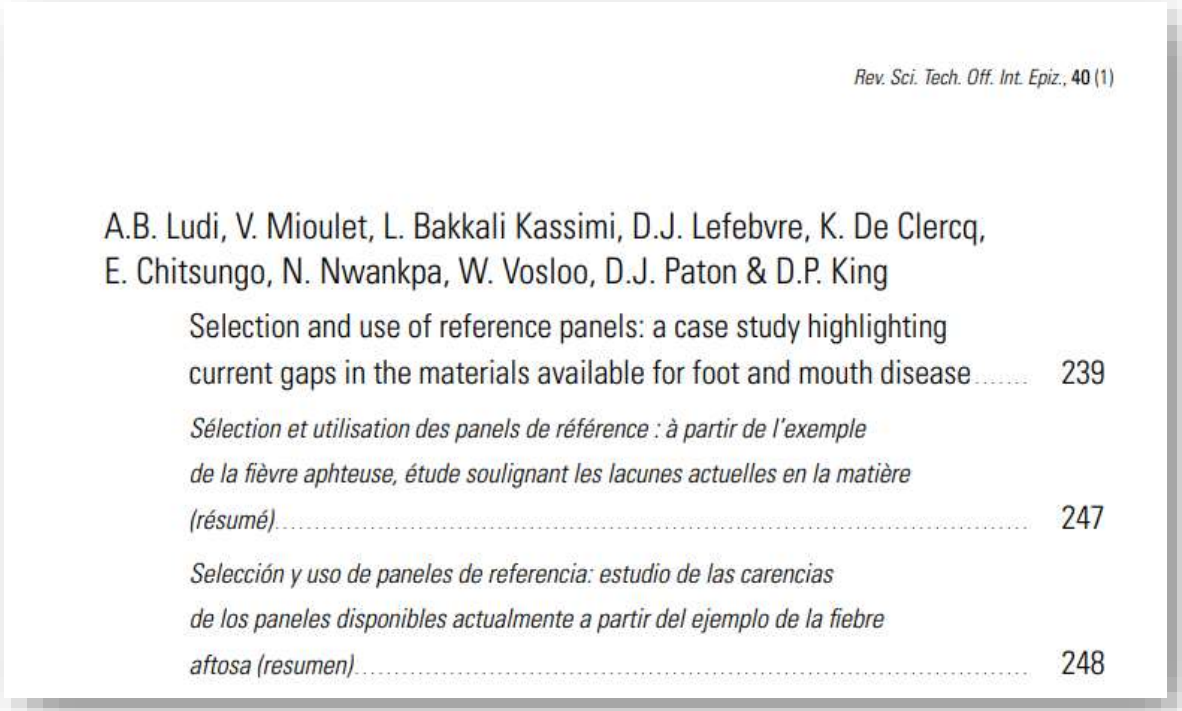
Publications on East African FMD Virus Panel

Publication 1 : 2021



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A.B. Ludi, V. Mioulet, L. Bakkali Kassimi, D.J. Lefebvre, K. De Clercq, E. Chitsungo, N. Nwankpa, W. Vosloo, D.J. Paton & D.P. King

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Article

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An antigen panel to assess the regional relevance of foot and mouth disease vaccines

Check for updates

David J. Paton[1] ✉, Ginette Wilsden[1], Clare FJ Browning[1], Efrem A. Foglia[2], Antonello Di Nardo[1], Nick J. Knowles[1], Jemma Wadsworth[1], Simon Gubbins[1], Ethel Chitsungo[3], Cisse Rahamatou Moustapha Boukary[3], Gelagay Ayelet[3], Charles S. Bodjo[3], Nick Nwankpa[3], Emiliana Brocchi[2], Santina Grazioli[2], Anna Ludi[1] & Donald P. King[1]

https://doi.org/10.1038/s41541-025-01128-7

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Future Direction

- Developing similar approach of FMD virus panel for:

Northern

Western

Central

Southern

- Exploration of guinea pigs as an alternative model for vaccine testing.

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Requirements for Testing FMD Vaccine at AU-PANVAC

- Vaccinal sera should be produced in cattle with no previous exposure to FMD virus
- Vaccine used should be the same as the final formulated vaccine
- Serum should be collected at day 0, day 21, and day 31 if a booster is given
- At least **5 individual cattle sera** should be submitted (not pooled)
- VNT Testing:
  - FMD virus Reference Panel will be used for vaccine directed to the East Africa.
  - For vaccines intended to use for other regions, vaccine manufacturers are encouraged to submit the viruses used for the vaccine formulation.

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VNT Interpretation for FMD Vaccine Batch Release at AU-PANVAC

- Individual sera titer **GREATER THAN 1/32 (1.5 log10)** will be considered as positive

- **80% (4/5 of sera)** meeting the above criteria will be used for FMD vaccine quality acceptance.

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Conclusion

- More reliable information on efficacy of vaccine obtained from using a well characterized panel

- Establishing panels of characterized reference FMD viruses and vaccine viruses for Africa is important.

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