Approaches to Post Vaccination Monitoring

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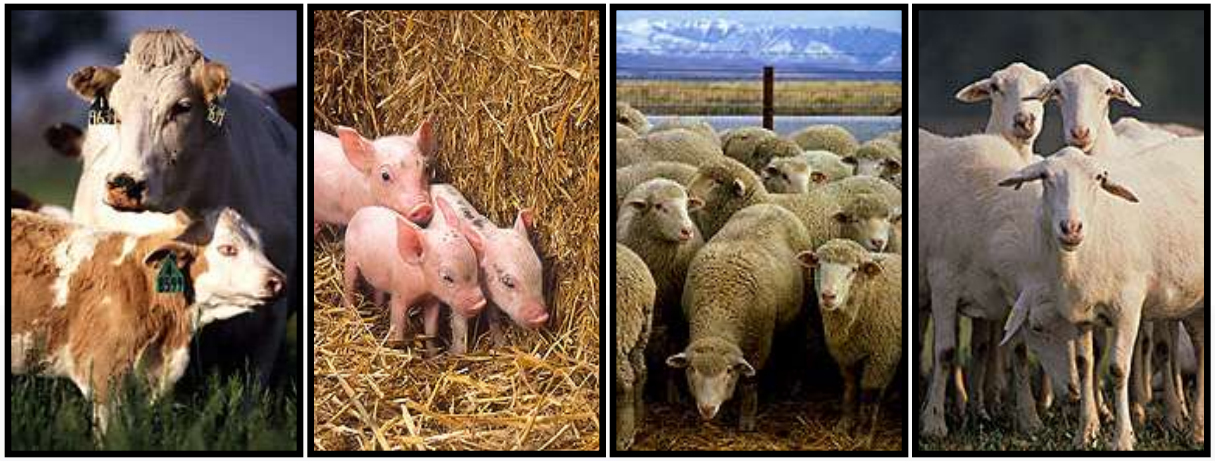

Why PVM?

- FAO supports developing countries with vaccine through funding parterns:
  - There is a need to follow up on the performance of the vaccine

- One of the most important components of FMD control is vaccination;
  - Vaccine cost $ 0.7-1.0/dose and vaccination is up to $ 0.7
  - Vaccination represents the highest cost of FMD control ~90% (12:1)
- Timely needed for global FMD control initiative
- Cost-benefits to vaccination = effectiveness of the vaccine
- Outbreaks have been reported in vaccinated animals
- Effectiveness of vaccine is complicated to measure because it is affected by a number of crucial elements

Goals and Outcomes

- Design PVM system to evaluate FMD vaccine effectiveness
  - Universal
  - Country/region - specific
- Publish guidelines for PVM with associated SOPs and protocols for field use
  - FMD specific
  - With modification, this can be used for other vaccines
- Identify cause(s) of vaccine inadequacy or failure for timely improvement of control program
- Evaluate vaccine performance and provide feedback to manufacturer
- Create field data for correlation between field protection and SP antibody titers

PVM working group (Jan 13, 2012)

virologists, diagnosticians, epidemiologists, statisticians, field vets

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PVM Milestones

- Feasibility study (360 degrees)
  - Manufacturer's specs ⇨ delivery ⇨ storage ⇨ vaccination ⇨post vaccination
  - Review existing PVMs
    - South America
    - China
    - South Africa
  - Develop guidelines; SOPs, protocol, training, task force
  - Peer review

- Proof of concept: pilot study in selected endemic countries
- Revision and finalization of the guidelines

PVM Prerequisite:

Elements contribute to vaccine effectiveness

- Vaccine quality including potency; low vs. high PD_{50}
- vaccine performance characteristics in relation to circulating virus strains, r-value..etc
- strategic vaccination dictated by epidemiological setting
- vaccine coverage
- age of vaccinates
- vaccine shelf-life

PVM Prerequisite: (continued)

Elements contribute to vaccine effectiveness

- vaccination program: cycle, time of the year and frequency
- Vaccine availability during campaign
- health condition of vaccinates
- vaccine storage at recommended temp (cold chain)
- training of vaccinators for proper vaccine delivery
- Vaccination campaign and taskforce for PVM

Parameters for PVM

- desired percent protection
- desired percent coverage of vaccinates

- Protective antibody titer to structural protein
  - Some published data showed strong correlation between in-vivo protection and virus neutralization test

- NSP at herd level
  - NSP best used in PCP stage 0 to determine FMDV prevalence at the country or regional level
  - In population vaccinated with pure vaccine, NSP can be used towards the end of PCP stage 3 to proof absence of virus circulation

Design of PVM

- serological surveillance:
  - population selection based on farming system
  - animal identification (retention of tags) for serological surveillance
  - sample collection post vaccination;
    - day post vaccination
    - sample size at standard error of 5% & ≥ 95% confidence interval,
  - dx assays to use for SP and NSP analysis
- Clinical and passive virological surveillance:
  - conduct regular field investigations for early detection and characterization of circulating virus isolates
- data analysis:
  - Prerequisite check list
  - Serological and virological surveillance

Summary

- **Needs:**
  - Develop PVM to become part of vaccination program
- **Challenges:**
  - Vaccine quality, availability and storage at optimum temp
  - Animal identification
- **Uncertainty:**
  - Country acceptance to implement
  - Transparency!!
- **Gaps:**
  - Vaccine quality control centers
  - Validated PVM screening tools
  - Producers awareness and incentives
- **Recommendation:**
  - Let's do it

Thank you for your attention