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# Technical Insights on FMD Surveillance and PVM in Accordance with the WOAH Code

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THE Pirbright INSTITUTE

PVS Public-Private Partnership (PPP) Targeted Support Workshop for development of FMD free zones in India, New Delhi, 15-17 September 2026

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# Overview

- Surveillance concepts for FMD
- Outbreak investigation and virological surveillance
- NSP serosurveys to substantiate freedom from infection in vaccinated animals
- Serosurveys of population immunity in vaccinated animals
- Emergency preparedness

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# Zonal or Compartmental Freedom

- Implies continuing threat from other parts of the country
  - Livestock separation is critical
- Important to understand the nature of this threat
  - The types of viruses
  - The opportunities for virus incursions

Surveillance strategies employed for establishing and maintaining a compartment should identify the prevalence, distribution and characteristics of FMD outside the compartment (10km rule)

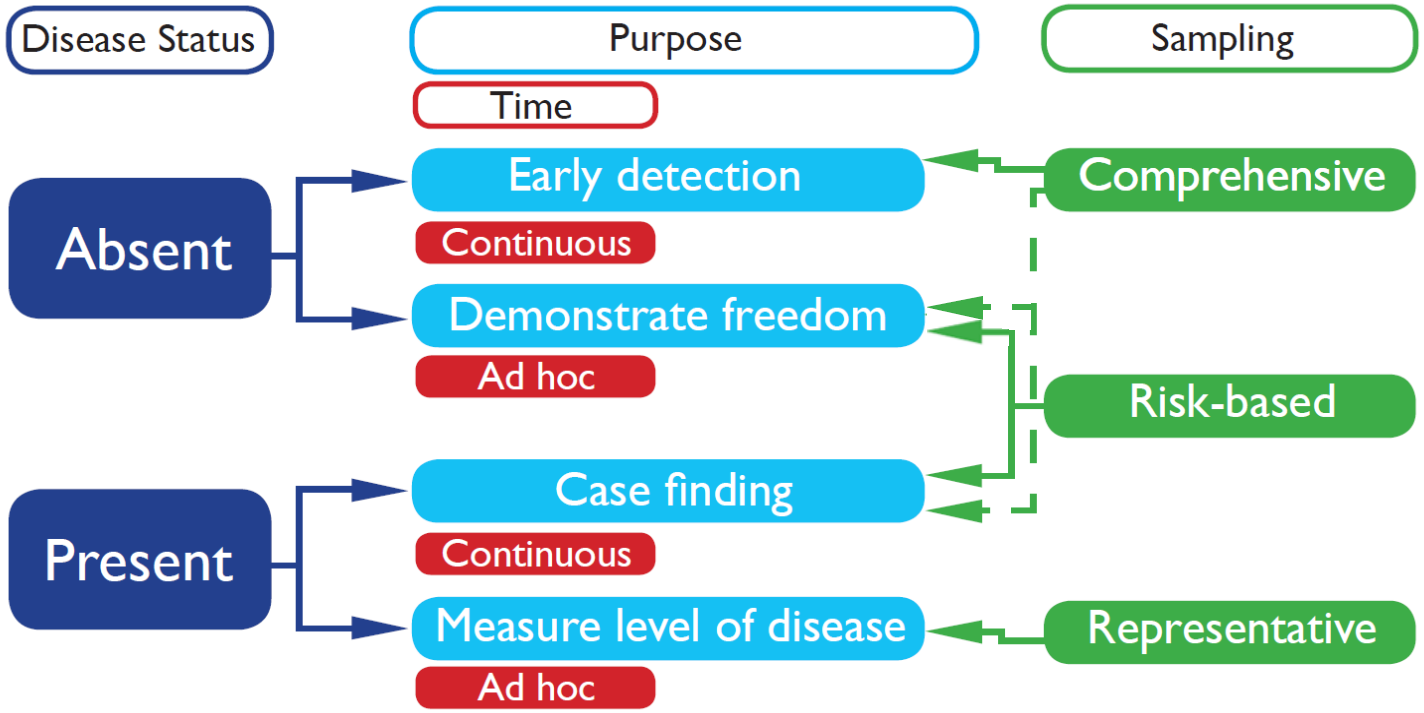
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# Surveillance

*Modified from Manual of Basic Animal Disease Surveillance*

*Dr. Angus Cameron*

The requirements for different surveillance purposes are summarised in the figure below.



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# Laboratory support

- Capacity and capability
- Proximity/connectivity
- Quality assurance and Proficiency testing
- Biosecurity



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# Early warning/detection

- High awareness and buy-in
- Throughout livestock value chain
- Sampling and testing procedures
- Availability of expert assistance
- Rapid detection and reporting

## UK 2001

| Date | Event | Cumulative infected premises in country | Cumulative infected counties |
|---|---|---|---|
| 19 Feb 2001 | First suspected outbreak | 48 | 15 |
| 20 Feb 2001 | First outbreak confirmed | 57 | 16 |
| 23 Feb 2001 | National Movement Ban | 119 | 23 |

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# Surveillance programmes must be well documented

- Purpose
- Design
- Implementation
- Findings
- Follow-up



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# Outbreak Investigation: what, when, why, where else



- Is it FMD and if so what serotype and strain and how related to others
- How long has infection been present (lesion ageing)
- What is the attack rate and when was the last vaccination (vaccine breakdown?)
- What were the risk factors for introduction and spread
- **Tracing – epidemiological skills and support from traceability systems**

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Oldest lesion

# Infection and risk timeline prepared in excel

| | 15-Mar | 16-Mar | 17-Mar | 18-Mar | 19-Mar | 20-Mar | 21-Mar | 22-Mar | 23-Mar | 24-Mar | 25-Mar | 26-Mar | 27-Mar | 28-Mar | 29-Mar | 30-Mar | 31-Mar | 01-Apr | 02-Apr | 03-Apr | 04-Apr | 05-Apr | 06-Apr | 07-Apr | 08-Apr |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clinical/days | -17 | -16 | -15 | -14 | -13 | -12 | -11 | -10 | -9 | -8 | -7 | -6 | -5 | -4 | -3 | -2 | -1 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Infection | | | | | | | | | | | | | | | | | | | | | | | | | |
| Transmission | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | Vaccinations | | | | Cow sold | | AI technician | | | Visited farmer | | | Son's visit | OI |
| | | | | Milk Daughter's friend | Milk Daughter's friend | Milk Daughter's friend Heifer purchase | Milk Daughter's friend | Milk Daughter's friend | Milk Daughter's friend | | | | | | | | | | | | | | | | |
| | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk | Milk |

| Date | Tracing | Additional information |
|---|---|---|
| Every day | Milk collection | Mostly follows set route. ~4 other local farms are visited each day, some before and some after this one. |
| 18-23rd March | Daughter's friend visits | Friend comes from farm with livestock. Children help look after goats. |
| 20th March | Market | Purchased an in-calf heifer |
| 26th March | Vet | Vaccinated cattle |
| 30th March | Cow sold | To local butcher |
| 1st April | AI technician | Served one cow. Visited two other farms same day - one before and one after. |
| 4th April | Visited other farmer | Visited a farmer friend, around 10km away. |
| 7th April | Visit | Famer's son visted and returned to his own farm and livestock |

Then rank risks
And follow-up with other enquiries

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**Outbreak investigation is more than looking for clinical signs and sampling**

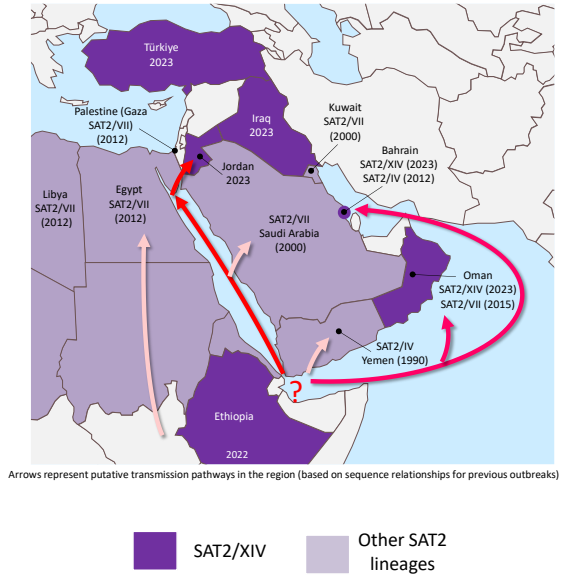
Detective work needs an enquiring and open mind, good rapport with farmers and careful and systematic questioning and recording, **but above all the desire to find out more**

If not regularly performing this type of work, lesion ageing cards, **checklists/forms**, and photographs are very useful

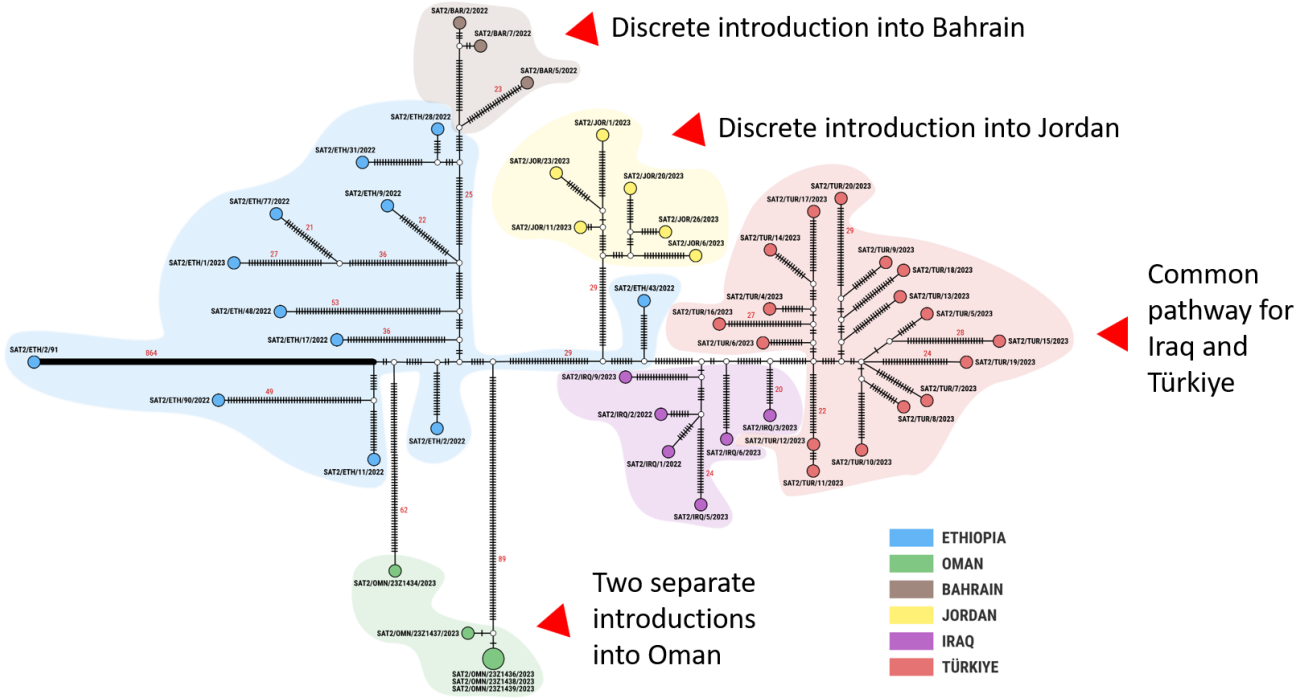
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# Virological surveillance and phylogenetics

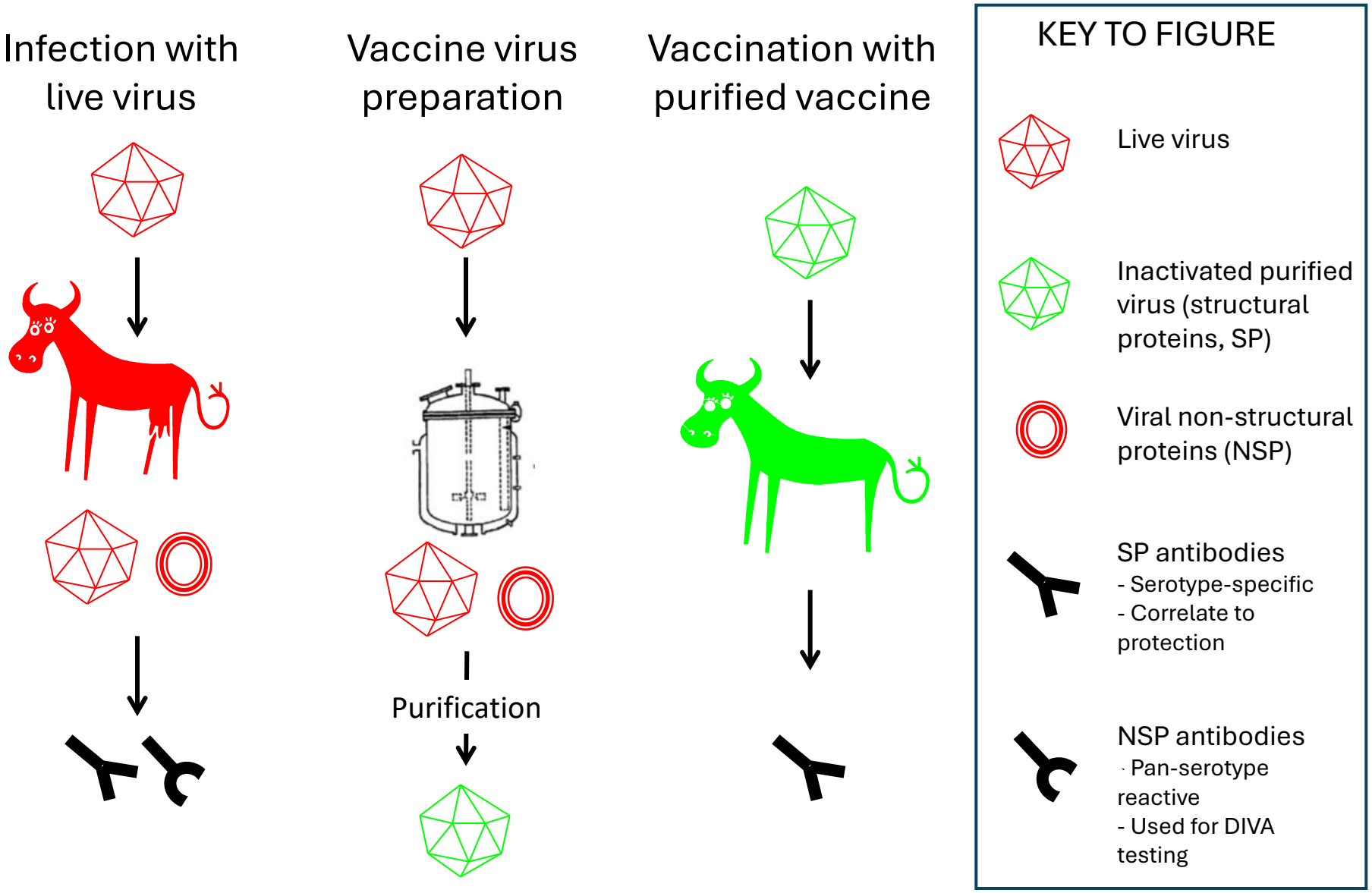
- Virus recovery from cases – acute/carriers
- Other sources: milk, nasal swabs, environment
- Relevance to free zones and compartments
- **Vaccine suitability**
- **What is the source or sources of continuing infections in India**



Arrows represent putative transmission pathways in the region (based on sequence relationships for previous outbreaks)



# FMD Serology: SP/NSP tests and the DIVA principle



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# Substantiating FMD freedom with vaccination

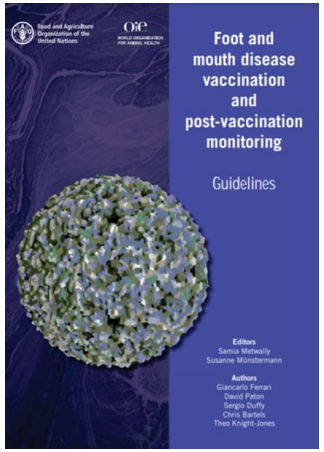
## NSP serosurveys

- To substantiate absence of undisclosed infection where vaccination may mask clinical signs

New Guideline Being Developed by WOAH

## Evidence that vaccination has been implemented effectively is one of the best guarantees against virus transmission

- Vaccine, vaccination strategy and campaigns
- Information on coverage achieved and on population immunity (SP serosurveys)




**These surveys are common source of problems in freedom dossiers**

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# Serosurveys for undisclosed infection

## NSP serosurveys

- To substantiate no evidence of FMDV transmission during the past 12 months
- Two stage sampling design informed by known test sensitivity and specificity
- Young animals sampled to reduce false positive results due to vaccination
- Can delay testing beyond immediate post-vaccination period
- Follow-up of all seroreactors to exclude possibility of infection
  - Number and strength of reactors after repeat testing
  - Clinical and epidemiological investigation
  - Resampling and testing for NSP antibodies
  - Probang sampling and testing
  - Clustering – within and between units
- Summary results for all seroreactor epidemiological units

**WOAH Manual:** Vaccine purity testing for antibody against NSP

- FMD antigens used to formulate vaccines that may be used in these circumstances should be purified to reduce the NSP content.
- Provide supporting documentation from manufacturer as part of the licensing procedure.
- At least eight cattle should be booster vaccinated at 28–30 days after first vaccination and tested for purity 28–30 days later. Up to one reactive animal at 28–30 days post-booster vaccination could be accepted.

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# Preparation for NSP serosurvey to substantiate freedom from infection

- **Descriptive analysis** of susceptible livestock and holdings to define epidemiological units and decide on and justify stratification of zone or country
- **Two stage design** – primary and secondary sampling units (PSU = epidemiological unit and SSU = animals)
- **Random v risk-based design**
- Decide on **design prevalence** for each, e.g. PSU: 1%, SSU: 5-10%, both at 95% confidence
- Decide on **test system**, e.g. sample, NSP test, NSP retest, clinico-epi follow-up with resampling (paired serology and serial probang testing)
- Establish **Se/Sp at PSU and SSU level** – e.g. PSU: 95%/100% and SSU: 90%/100%
- Establish **system** – roles, methodology, training, timing



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# Preparation for NSP serosurvey to substantiate freedom from infection

**Selection of PSUs** - representation (+/- stratification based on herd size) and sampling system, extras (total PSUs ~330 / stratum for 1% design prevalence)

→

**Plotting the initially selected PSUs on a map**, alongside the distribution of all other epidemiological units in the reference population, is a useful step to check for any geographical gaps in coverage.

→

**Selection of SSUs** – age (6- 18 months preferred), vaccination status, randomisation procedure, feasibility (total SSUs ~7000 / stratum for 10% design prevalence)

↓

Prepare **table to show sample numbers required according to PSU size**, with minimum (e.g. 10-20 according to PSU size)

→

**Pre-visit PSUs** – awareness, suitability, possible non-vaccination, modification

→

**Where insufficient animals are present on small holdings** to meet the calculated sample size, additional animals can be selected from neighbouring premises that are epidemiologically related

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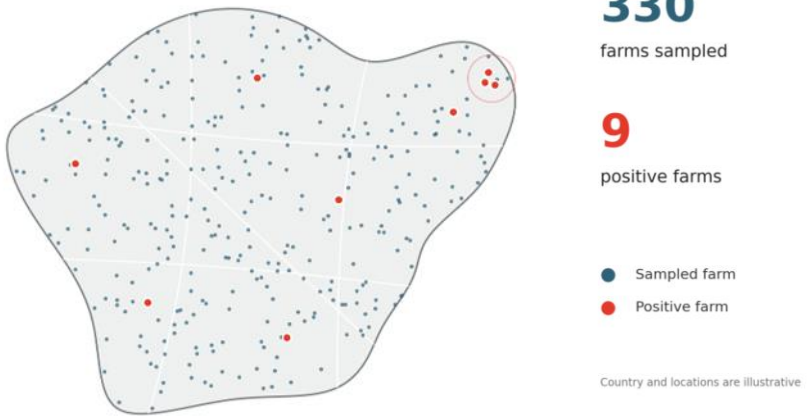
# Conducting NSP serosurvey to substantiate freedom from infection

| Visit | Data | Animal ID | Test | Review | Revisit +ves |
|---|---|---|---|---|---|
| Visit to PSUs to collect samples and metadata | Metadata: age, sex, vaccinations, origin | Individually identify each sampled animal and ensure it remains in the holding until negative NSP test results are confirmed | Test samples promptly with retest of initial positives for confirmed result | Review strength and clustering of confirmed positives. Numbers will depend on vaccine purity, but expectation that most will be singleton reactors | Revisit all PSUs with confirmed positives – clinico-epidemiological investigation, resampling and NSP retesting, probangs (e.g. serial testing of seropositives: x3 over 15 day period) |

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# Data Analysis, Interpretation and Presentation

- Provide a **systematic description of the sampling process and results**
- **Summarise results according to WOAH recommendations and conclude on confidence established**
- **Tables listing each PSU surveyed**, the number and species of susceptible animals present, the number of animals sampled, and their test results (distinguishing initial screening test and any confirmatory test results), along with the date of the farm visit and the final classification of the unit.
- **Maps** of the survey area indicating the locations of all epidemiological units in the target population, highlighting which units were sampled and marking those that had any positive reactors.
- **Review NSP test specificity** from overall results



# Vaccination coverage

The **% of holdings/animals** in which vaccination has been carried out in the defined target population

**Results should be stratified** to account for differences between campaigns, species, ages of animals and regions, and to avoid double counting.

The **required coverage** to stop transmission depends on the opportunities for virus spread and the protective effect of vaccination but should approach 100% of eligible herds and 100% of eligible animals

**Monitoring coverage is synergistic with population immunity studies**

Whether or not transmission is blocked by vaccination depends upon:

- The proportion that are vaccinated (f)
- How rapidly the virus spreads ($R_0$)
- How well the vaccine blocks transmission (h)

**Table 1. The relationship between rate of transmission in the population and vaccination coverage needed to halt virus spread ($f \times h = 1 - 1/R_0$)**

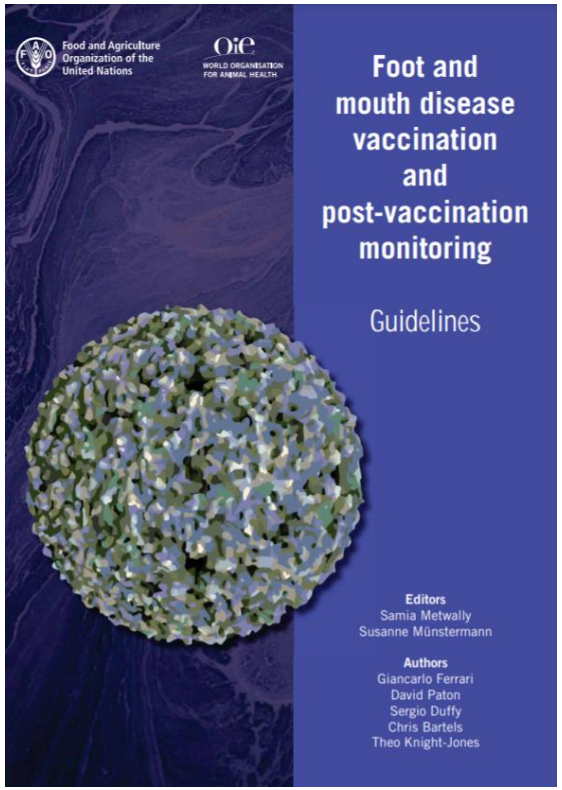
| Initial rate of spread ($R_0$) | Proportion of animals that must be vaccinated *(f)*, assuming vaccination is 100% effective *(h)* | Proportion of animals that must be vaccinated *(f)*, assuming vaccination is 75% effective *(h)* |
|---|---|---|
| 2.5 | 60% | 80% |
| 4 | 75% | 100% |
| 5 | 80% | Impossible* |
| 6.7 | 85% | Impossible |
| 10 | 90% | Impossible |
| 20 | 95% | Impossible |

* Impossible to eliminate infection even by vaccinating the whole population

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# Vaccination records

- Accurate estimation of vaccination coverage requires a clear definition of the reference population
  - the **number of holdings**
  - and the **number of animals within** those holdings.
- **Central and local** vaccine holding centre records of vaccine batch receipts and dispatches
- **Digital records linked to those of farms and animals greatly simplify data retrieval and analysis**
- **Verification and analysis** including timeliness of campaigns
- *When setting out the findings from vaccination coverage surveys, it is important to **clearly explain** the populations under study, the selection of targeted and eligible animals (Ferrari et al 2016) the methodology for data collection and analysis and the interpretation in relation to the expected results.*



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# Value of population immunity studies

- Measure overall immunity achieved through vaccination
- Identify heterogeneity in immune protection
- Support corrective actions, such as targeted revaccination
- Indicate need to investigate underlying causes of poor performance

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# The correlation between serology and protection

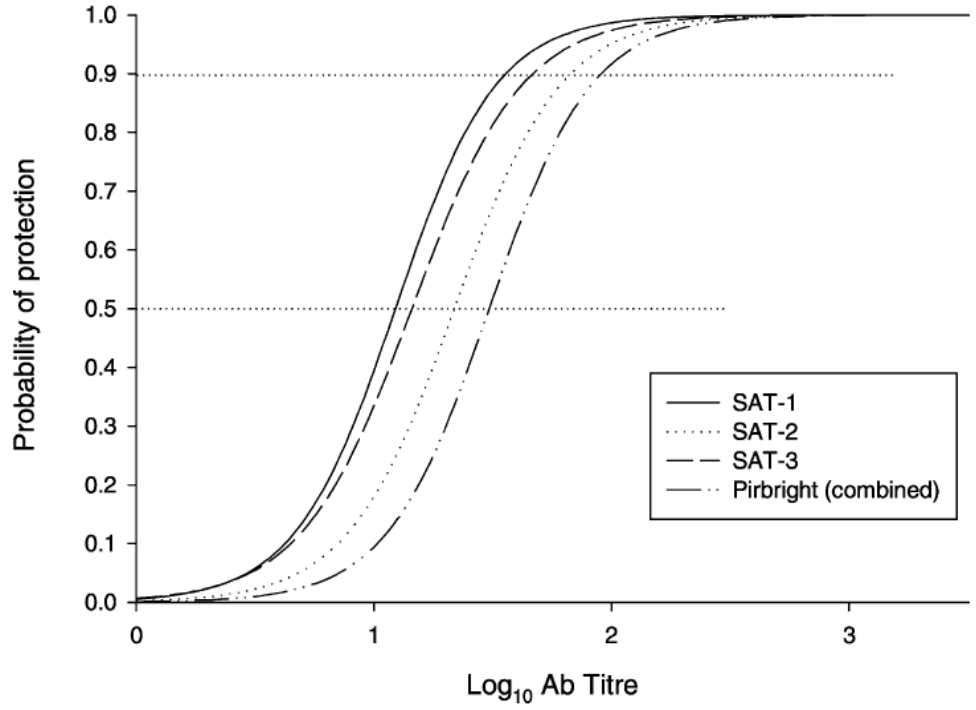



Fig. 2. The best fitting models to four different subsets of the data.

Live challenge tests in support of registration can establish serological correlates of protection

Subsequent vaccine batch release can be based on immunogenicity studies to see if vaccines elicit the Ab threshold indicative of the desired level of protection ("**vaccine batch release sera**")

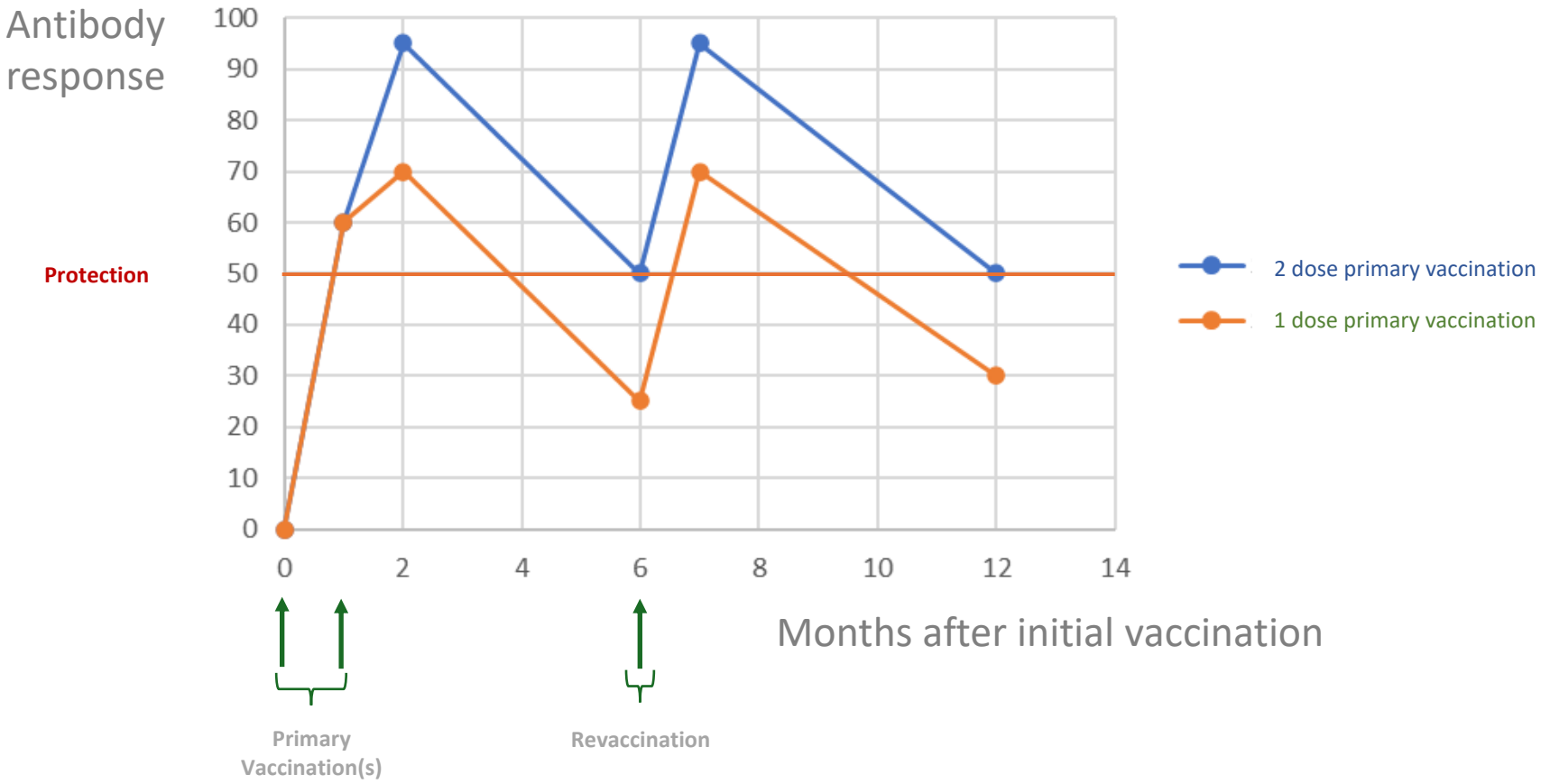
Same thresholds can be used in population immunity studies with certain caveats

Tests and correlations to protection imperfect and need to make assumptions that must be clearly stated

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# Population immunity waxes and wanes

Schematic Representation



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# Timing of population immunity studies

Two post-vaccination intervals:

Estimating the immune status at point of vaccination

(measures residual immunity);

Estimating the immune status shortly after vaccination

(measures peak immunity).

Can combine with a longitudinal study of smaller cohorts to understand dynamic rise and fall of antibodies with time after vaccination (duration of immunity (DoI) studies)

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# Population immunity surveys

- Aim to estimate the proportion of protected epidemiological units
  - usually measure peak immunity
- Also collect metadata on factors likely to influence vaccination effectiveness
  - animal demographics, herd management practices, vaccination history, vaccine batches, vaccinator teams, cold chain management and vaccination timing
- Two stage sampling design recommended with stratification by species, region and age
  - e.g. cattle aged 6–12, 13–18, and 19–24 months

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# Population immunity surveys

- Set thresholds for proportion of epi units expected to be protected (usually 80-90%) and proportion of protected animals that equate to a protected unit (may differ according to age)
- Select test and cut-off
- May be possible to combine sampling for PVM and NSP serosurveys
    - PVM requires fewer herds than NSP surveys, so can be a subset of NSP surveillance, but need to reconcile timing and age requirement differences

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# Choice of serological test and threshold

Is there any serotype-specific immunity ?

Is immunity consistent with expected response for the vaccine in question?

} Most SP ELISAs

Is immunity likely to protect against a homologous or heterologous challenge

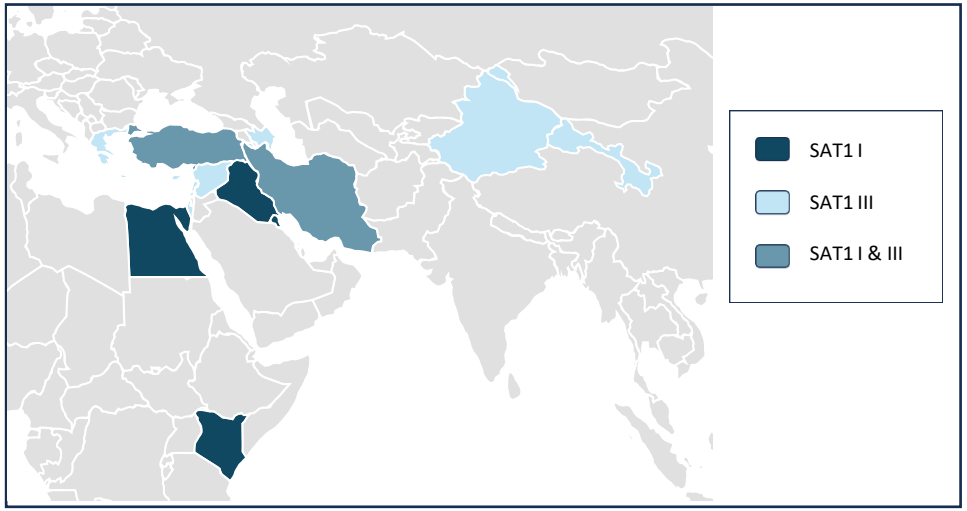
- Use threshold established in homologous challenge tests supplied by manufacturer
- Use cross-neutralization against heterologous field virus threats

} VNT (or LPBE)

**A pragmatic approach:** a simple test (SP ELISA) for bulk testing calibrated with “batch release sera”, and backed up by some more precise work (VNT) on a subset of samples

# Emergency preparedness

Threat from spread of exotic serotypes into Asia




Simulation exercises to test capacities and capabilities, e.g. outbreak investigation, tracing, emergency vaccination, etc



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# Acknowledgements

The WOAH Terrestrial Animal Health Code and Manual and the work of the WOAH FMD Ad Hoc Group

The Foot and mouth disease vaccination and post-vaccination Monitoring Guidelines: https://www.fao.org/3/i5975e/i5975e.pdf