

# AN OVERVIEW OF ACTIVE, PASSIVE, AND TARGETED SURVEILLANCE APPROACHES APPLIED TO EARLY DETECTION AND SUBSTANTIATING FREEDOM FROM DISEASE

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## Introduction

Surveillance has been defined as *an active, ongoing, formal, and systematic process aimed at early detection of a specific disease or agent in a population or early prediction of elevated risk of a population acquiring an infectious disease, with a prespecified action that would follow the detection of disease*. The World Organization for Animal Health (OIE) Terrestrial Code chapter on foot-and-mouth disease (FMD) provides some general guidelines to the design of surveillance systems applicable to FMD detection. There are, however, multiple strategies and approaches that could be used for implementing a surveillance system, which may result in benefits and drawbacks for countries and partners. Here, we offer an overview of alternative approaches intended to inform the design of an FMD surveillance system.

## Materials and methods

Approaches used for the design of surveillance systems may be classified as passive, active, enhanced, or target (risk-based). Important considerations for the design are the epidemiological context, the features of the disease, and the attributes of the surveillance plan, which includes aspects related with i) Definition of the intended purpose(s), ii) Optimization, iii) Standardization, iv) Repeatability, v) Analytical sensitivity, vi) Analytical specificity, vii) Thresholds (cut-offs), viii) Diagnostic sensitivity, ix) Diagnostic specificity, x) Reproducibility, and xi) Fitness for intended purpose(s)

## Results and Discussion

As there is a need for differentiating between purposes of a surveillance system intended to demonstrate freedom from FMD from those intended to early detect an epidemic incursion, there is a need for adapting the design and metrics of evaluation of those systems to the epidemiological context. We will argue that there is a need for exploring the use of target (risk-based) or enhanced passive surveillance approaches for the early detection of the disease as the most efficient strategy to mitigate the impact of a hypothetical FMD incursion into a free country or region.

## EXAMPLES OF TARGETED SURVEILLANCE APPROACHES FOR FMD IN SOUTH AMERICA

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### Introduction

Risk-based surveillance needs to be accommodated to the epidemiological context. This approach is particularly useful for optimizing resources in populations where the risk of having undetected FMD is very low, as in FMD free areas with vaccination. This study is focused on zones under continuous comprehensive surveillance and where FMD has been not been detected for more over a decade. These zones were already OIE recognized as FMD free with vaccination and are in transition to obtain the FMD free without vaccination status. The objective of this study is to identify areas (municipalities) with greater risks of having FMD, to be the target of NSP surveys designed to detect the presence of FMDv transmission – so that its non-detection contributes to demonstrate absence.

### Materials and methods

It is assumed that for these areas any potential presence of FMDv would be relatively recent, rather than due to a long-term undetected residual. Thus, to depict the risk, indicators associated with the probability of introduction and transmission were combined with indicators related to the vulnerability. Databases available, such as farm property registry, bovine movement records, and recent vaccination coverage, were sourced to inform the analyses with quantitative variables. A Hierarchical Clustering on Principal Components was computed on the chosen variables. In that way, mathematical clusters of municipalities were identified based on their similarities /discrepancies regarding the FMD risk indicators and its association was estimated through v-testing.

### Results

A discrimination for two different groups of municipalities was obtained, i.e. lower and higher risk. The former aggregates the clusters showing a negative association with the indicators of FMD risk transmission and introduction, and a positive association with the vaccination coverage (indicating less vulnerability). While the rest of municipalities were considered at relatively higher risk and were therefore proposed as the target of the survey.

## **VACCINE BANKS ARGENTINEAN EXPERIENCE AND ONGOING ACTIVITIES**

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Vaccination is a fundamental tool in a strategy to control and eradicate major emerging diseases. Vaccine and diagnostic banks improve the feasibility of emergency vaccination by guaranteeing supplies if there is no immediate alternative.

In this sense, and after the experience of the use of the vaccine bank in a previous opportunity during the outbreaks of 2001, Argentina has maintained an antigen bank under controlled conditions since more than 20 years. These activities must be included in a legal framework that should be actualized according to the requirements that the epidemiologic situation demands.

Research on characterization of new circulating strains is of utmost importance: a battery of studies must be included before making a decision on whether to include or not new field strains in an antigen or vaccine bank. Future goals require improving and focusing on the study in risk analysis, genetic and antigenic characterization of new lineages and strains and research on animal and product movements as well as people globalization activities.

## REGIONAL FMDV – ANTIGEN AND VACCINE BANK – BANVACO

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### **Introduction**

All FMD-free countries, whether with or without vaccination, face a similar threat. The appearance of an outbreak of foot-and-mouth disease. Emergency vaccination is today a universally accepted measure in the control of outbreaks of foot-and-mouth disease. At the 12th COHEFA Meeting in 2012, a request to review the restrictions imposed on the management of strains of the foot-and-mouth disease virus exogenous to the region was made and that PANAFTOSA prepares a project for the creation of a regional antigen/vaccine bank that meets the strategic needs of the region. The BANVACO project (Vaccine Bank of COSALFA's countries) aims to develop and maintain a bank of antigens, which ensures the effective availability of vaccines for the primary containment of FMD emergencies.

### **Materials and methods**

The project was prepared with the assistance of specialists from the region and approved by the COSALFA countries. Its components are a Constitutive Agreement, a Technical Project and an estimated budget. The management of BANVACO was delegated to PAHO to ensure its status as a supranational entity and technical neutrality. BANVACO does not mean the creation of a new physical facility, but rather, its management will be at the headquarters of PANAFTOSA-PAHO/WHO, and the stock of antigens/vaccines acquired by member countries will be kept at the facilities of vaccine providers in the region through specific contracts and under the supervision of the Biological Risk Management and Biosecurity Commission of COSALFA.

### **Results**

BANVACO is understood as the union of its members who have decided to join forces around the central objective of the project and is awaiting the adhesion to the constitutive agreement of at least three member countries to start its activities.

## **USDA AND VACCINE BANKS**

### **Strategic Risk Mitigation for an FMD Introduction**

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Foot and mouth disease (FMD) is a transboundary viral disease of cloven-hooved livestock known to cause serious production deficits with the potential to incur extreme acute and prolonged economic losses, particularly in countries and territories free of disease without the use of vaccination. A vital component of its FMD preparedness and risk mitigation, the United States Department of Agriculture (USDA) actively manages two strategic reserves of FMD vaccine antigen concentrate (VAC). The North American Foot and Mouth Disease Vaccine Bank (NAFMDVB), established in 1982, is a long-standing partnership between the United States (U.S.) and Canada. The National Animal Vaccine and Veterinary Countermeasures Bank (NAVVCB) is a new USDA initiative established through the 2018 Farm Bill; the NAVVCB is a U.S.-specific bank which will, in addition to FMD VAC, stockpile diagnostics and other countermeasures for a variety of high-consequence transboundary diseases. The banks, although independent entities, work collaboratively to acquire antigen via the tactical selection of strains, as recommended by their respective technical committees. Committee members are responsible for analyzing available data on the global FMD epidemiologic situation, peer-reviewed scientific literature, modeling and risk assessments, existing data from historical bank testing, while considering regional geopolitical status. In addition to vaccine requirements detailed in the OIE Terrestrial Manual, the U.S. adheres to stringent internal standards for quality, purity, safety, and potency of biologics, as specified by the USDA's Center for Veterinary Biologics (CVB). Such standards demand testing to admit and safeguard product inventory; simultaneously, they limit the pool of eligible FMD vaccine manufacturers, potentially reducing the number of strains and products available for stockpiling, while also lessening the bargaining power of these entities. The need for scientific collaboration is more critical than ever, and the NAFMDVB and the NAVVCB look to actively engage with the global FMD community.

## **BANCO REGIONAL DE ANTIGENOS Y VACUNAS – BANVACO**

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### **Introducción**

Todos los países libres de fiebre aftosa, sea con o sin vacunación, enfrentan una similar amenaza. La reaparición de un brote de fiebre aftosa. La vacunación de emergencia es hoy una medida universalmente aceptada en el control de brotes de fiebre aftosa. En la 12 Reunión de la COHEFA del 2012 se solicitó revisar las restricciones impuestas al manejo de cepas del virus de fiebre aftosa exógenas a la región y que PANAFTOSA elaborara un proyecto para la creación de un banco regional de antígenos/vacunas que atienda las necesidades estratégicas de la región. El proyecto BANVACO, (Banco de Vacunas de los países de la COSALFA) tiene como objetivo desarrollar y mantener un banco de antígenos, que permita asegurar la disponibilidad efectiva de dichos insumos para la contención primaria de situaciones de emergencia ante brotes de fiebre aftosa.

### **Material y métodos**

El proyecto fue elaborado con el concurso de especialistas de la región y está conformado por: un Convenio Constitutivo, un Proyecto Técnico y un presupuesto estimado, el que fue aprobado por los países de la COSALFA. La gerencia del BANVACO fue delegada a la OPS para asegurar su condición de entidad supranacional y neutralidad técnica. El BANVACO no significa la creación de una nueva instalación física, sino que, su gerencia estará en la sede de PANAFTOSA-OPS/OMS y el stock de antígenos y vacunas adquiridos por los países miembros, se mantendrá en las instalaciones de proveedores de vacunas de la región mediante contratos específicos y bajo la supervisión de la Comisión de Gestión de Riesgo Biológico y Bioseguridad de la COSALFA.

### **Resultados**

El BANVACO se entiende como la unión de sus miembros quienes han decidido unir esfuerzos en torno al objetivo central del proyecto y está aguardando la adhesión al convenio constitutivo de al menos, tres países miembros para iniciar sus actividades.