GFRA-EuFMD Regional meeting

FMDV in America

March 10th, 2020

REPORT

Regional meeting: FMDV in America/ GFRA + EuFMD

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1 Epidemiology and Risk Analysis Session

GENERAL DATA

Panelists: Andres Perez, Manuel Sanchez.
Moderators: Guido Konig, Melissa Mclaws, Pamela Hullinger.
Rapporteurs: Maria de la Puente-Arevalo, Laura Lozano Calderón
Registered Participant in the meeting: 413
Approximate number of participants in the room: 260.

1. Dr. Andres Perez began with the first presentation of the meeting called "An overview of surveillance approaches for FMD"

During the presentation, Dr. Andres Perez highlighted the importance of epidemiological surveillance systems for the early detection of diseases in a population. In addition to the guidelines proposed by the OIE, other strategies and approaches need to be taken into account like Definition of the intended purpose(s), Optimization, Standardization, Repeatability, Analytical sensitivity, Analytical specificity, Thresholds (cut-offs), Diagnostic sensitivity, Diagnostic specificity, Reproducibility, and Fitness for the intended purpose(s). It is also necessary to differentiate the purposes of the surveillance system and adapt them to the epidemiological context.

2. Dr. Manuel Sanchez presented his work called "Examples of targeted surveillance approaches for FMD in South America"

Dr. Sanchez began his presentation by highlighting that Risk-based surveillance (RBS) needs to be accommodated in the epidemiological context to optimize resources in populations where the risk of having FMD is low, as in FMD free areas with vaccination. His objective was to identify municipalities with greater likelihood of having FMD to be the target of non-structural protein (NSP) surveys designed to detect the presence of FMD virus (FMDV) transmission, combining indicators associated with the probability of introduction and transmission with indicators related to the vulnerability to represent the probability.

1.1 DISCUSSION

The moderators and rapporteurs grouped and simplified some of the most relevant questions and discussed them with the panelists. The main topics were:

Barriers and challenges to surveillance in the context of The Americas. For RBS it is important to understand well the population (location of the farms, data on the movements for all types of farms). Good data are essential. It is also critical to understand the risk factors, which are related to the context.

Hazard and Risk. In an event of moving animals, FMD would be the hazard, while risk analysis would estimate the probability and consequences of that hazard entering and spreading within a population. Risk analysis can be performed with different methodologies, with their pros and cons. In South America is commonly assumed that risks would be at the borders of the countries and therefore RBS can be used in border areas. Both introduction and spread following the introduction are equally relevant.

FMDV reservoirs in the Americas. Wild animals are not considered a key player in the continent.

The importance of RBS. It has been discussed that, during an outbreak, initially you would trace contacts from an infected farm and the neighboring farms. However, RBS approaches can be useful when you want to start looking beyond that at other farms that have a similar demographics/situation to those infected and therefore may be at higher risk to be infected. An RB approach can be also very useful when there are limited resources during an outbreak to better focus/target the surveillance efforts.

Comparison between surveillance systems in the Americas. It was argued that active surveillance systems would be easier to compare as the different parameters are well defined. Passive surveillance systems are more difficult to compare from country to country as it is more challenging to define indicators to compare.

Possibility of having a common goal, or at least setting up minimum requirements for RBS to be shared among countries in The Americas. A set of minimum requirements already exists. COSALFA contributes to the establishment of these minimum requirements on how surveillance should take place. There are also indications from the OIE but, and at the regional level, they are quite similar approaches.

1.2 CONCLUSIONS

There is a need to explore the use of targeted (risk-based) or enhanced passive surveillance approaches for the early detection of disease as the most efficient strategy to mitigate the impact of a hypothetical FMD incursion into a free country or region. Regardless of the approach, high quality data are critical to ensure effective surveillance in areas, countries, and regions.

2 Regional Vaccine Banks Session

GENERAL DATA

Panelists: Alejandro Rivera, Jamie Barnabei and Ana Taffarel.
Moderators: Mariano Pérez Filgueira and Kees Van Maanem.
Special guests for discussion: Hernando Duque, Rodolfo Bellinzoni, Danny Goovaerts and Dardo Chiesa.
Rapporteurs: Sebastián Di Giacomo and María Cruz Miraglia
Registered Participant in the meeting: 413

2.1 Summary of the meeting

The meeting focused on Vaccine Banks and Epidemiology, two highly relevant issues in the Americas. Our continent has different epidemiological situation although is mostly free of foot-and mouth (FMD) with or without vaccination, while outbreaks have been sporadic and controlled by vaccination. Many countries are pursuing the retrieval of vaccination and move to a vaccine-free status, supported by a vaccine bank to respond to an emergency. Countries that pursue continuing vaccination also rely on vaccine banks to respond to introductions of new strains.

In this scenario, more information of the available regional vaccine bank was needed, together with the novel tools and epidemiological data that can be applied to have a knowledge of the situation and organize an accurate contingency plan in the case of an emergency.

In this context, representatives from the different banks in the continent were gathered and as well as referents of the epidemiology in the region. Participants received and discussed over novel information provided by the experts and guided by the moderators.

This was the first time EuFMD and the GFRA worked together and promoted a bilingual meeting that enabled the involvement of Latin-American professionals including scientists, experts, veterinarians, and graduate students who are sometimes excluded from these discussions due to the language. We fulfilled our commitment of "giving a voice" all the FMD actors in our vast continent.

2.2 THE AMERICAN VACCINE BANKS: presentations

1. Dr. Alejandro M. Rivera began with the first presentation of the session called "Regional FMD Antigens and Vaccines Bank BANVACO."

   Dr. Rivera described the regional context where most of the national FMD contingency plans consider Emergency Vaccination as a priority measure to respond to FMD introduction, and yet the majority of COFALSA member countries are not associated with an antigen bank.

   Dr. Rivera pointed out the timeline since the creation of a working group to design the strategy for the creation of a regional antigen bank (BANVACO) in 2012, the resolution about the management of exogenous FMD virus (FMDV) strains in the region published by COFALSA in 2016, and the recommendation to create a regional commission for biological risk and biosafety management reviewed and approved by PANAFTOSA-PAHO/WHO in December 2018.

   Next, Dr. Rivera commented the main features of the BANVACO project, emphasizing that FMD is a challenge for all countries in the Americas, which can be addressed more efficiently and effectively through collective actions and regional cooperation.

He detailed the organizational structure with an executive committee, technical consultant committee, management, and laboratories. He also explained political rules to ensure the international, supranational, and neutral character of Banvaco, the financial management of both fixed and variable costs, and the criteria and procedures for the inclusion of FMD antigens of different FMDV strains.

2. Dr. Jamie Barnabei presented her talk called "USDA & Vaccine Banks: Strategic Risk mitigation for an FMD introduction."

   Dr. Barnabei began her presentation by giving a background on The Foreign Animal Disease Diagnostic Laboratory (FADDL) and its scientific mission, which is broader than a diagnostic laboratory on samples from animals across the United States who exhibit clinical signs consistent with foreign or transboundary animal diseases. As a specialized unit, FADDL serves as a reference laboratory to FAO, the OIE, and the National Animal Health Laboratory Network, andalso maintains two FMD vaccine banks.

   Dr. Barnabei introduced the North American FMD vaccine bank (NAFMDVB), and the National Animal Vaccine and Veterinary Countermeasures Bank (NAVVCB). Although both vaccine banks have the goal to ensure the availability and readiness of vaccines needed to control an outbreak of FMD in North América, the second one ensures additional availability of vaccines, specifically in the United States.

   Both vaccine banks have a technical team consisting of representative members from the field operation division, veterinarians, biologists, and epidemiologists that contribute with the surveillance and modeling data that are convened for discussion on what strain should they be looking for next.

   Dr. Barnabei also explained how the technical team works and mentioned that during the discussion, they consider diagnostic results, sequencing data, vaccine test data, and pharmacovigilance data. She also introduced the Pragmatist Tool, which considers the available information about source area score, circulating strain data, and quality of vaccine match to those circulating strain an get the overall risk and coverage levels based on the strain selection.

   Lastly, Dr. Barnabei explained how the vaccine bank testing evaluates the stability, potency and other testing to comply with the purity, safety, and quality standards required for any biological product permitted or licensed for use in United States.

3. Dr. Ana Taffarel presented the third talk called "Banco de Antígenos-Experiencia Argentina."

   Dr. Taffarel exposed the important role of the vaccine banks to guarantee the antigenic supply to control an outbreak. She reviewed the Argentinian experience during the outbreak of 2000/2001, highlighting the essential role the Argentinean vaccine bank had in the development of safe vaccines that granted protection against the circulating field strains, allowing strategical vaccination to rapidly control the disease.

   The success consisted in the coordinated activities and joint effort between different organisms in Argentina like SENASA, INTA, CEVAN, agricultural associations (farmers), and the vaccine bank held by Biogenesis-Bago. Altogether, these groups rapidly characterized the strain, performed the epidemiological studies and pursued the vaccine development.

Dr. Taffarel explained the legal framework that gave the acquisition of ultra-concentrated antigens to the laboratory Biogénesis Bagó where both ultra-concentrated antigens and ready to use vaccines are stockpiled. She also explained the role of SENASA as an auditor testing safety, antigenic payload, physical-chemical properties, stability, potency from *in vitro* and *in vivo* assays, and tolerance in animals. SENASA also analyzes the phenotype of the virus and performs genetic characterization assays. Finally, they also produce immune sera used to assess vaccine matching between vaccine and field strains.

2.3 DISCUSSION

The discussion was divided into two parts. During the first part, moderators and rapporteurs took the most relevant questions to be discussed with the panelists. The second part was focused on putting together the information about epidemiology, risk analysis, and vaccine banks to connect and trigger the general discussion. The discussion panel was expanded including Dr Rodolfo Bellinzoni (Biogenesis Bago) and Dr. Danny Goovaerts and Mr. Dardo Chiesa as representatives of the pharmaceutical industry and the Argentinean farmers, respectively. The four main topics were:

Manufacturing Capacity. The first question was focused on the logistics of manufacturing and development of ready-to-use vaccines and the lag time necessary. This question triggered the discussion about the information needed and the use of risk analysis to predict the operative capacity and antigenic demand needed from the industry to attend an emergency. Concern was raised on the commercial sustainability of the industry to maintain the operational systems facing an outbreak that goes out of hand. Some questions, regarding this main topic by the end of the first part, let us address the issue about the possibility to produce vaccines from exotic strains to export and the mechanisms of the sanitary organizations to evaluate the capacity of technical and professional resources, that are paramount for developing an emergency plan.

The end of vaccination programs. The second main topic was around the concern of the existence of epidemiological and a real risk analysis to sustain stop-vaccination programs, considering both the economic and social effect.

The coordination between vaccine banks around the globe. The debate was redirected about the need of official agreements to share information between vaccine banks, which is challenged by the possibility of using this information for agroterrorism purposes. FMDV is considered a biological weapon imposing defense protection that complicates the collaboration between North American, South American and the European vaccine banks.

Technical issues. *Some of the questions were orientated to discuss technical issues related to* the use of new technologies as an alternative to inactivated classical vaccines, technical issues to corroborate the integrity of concentrated antigens, and *the minimal potency needed for emergency vaccines.*

3 CONCLUSIONS

Many vaccine banks are functional in the region, although the actual collaboration between them is not as active as it would be needed, and this can be understood by defense issues, among others. However, the existence and interchange of a global community of scientists, regulatory agencies and field actors with open communication can work towards a common aim: fill the gaps in our knowledge of FMD-surveillance, vaccine matching, diagnostic tools, viral reservoirs, among other issues. FMD is recognized as a transboundary global disease that should be tacked through

strong regional collaboration to improve science, particularly that of the low-middle income countries. It is worth noting that sporadically endemic areas and those that still perform vaccination programs are in Center and South America and constitute most of the countries in this continent.