The 12th Annual Meeting of the OIE/FAO FMD Reference Laboratories Network Hosted by: ARC-Onderstepoort Veterinary Institute, Pretoria, South Africa 29th – 30thNovember 2017



Day 1

Global Overview: Dr Don King, WRLFMD

Presentation previewed the significant epidemiological events that have occurred during 2017covering points that were discussed in more detail in the individual presentations from the delegates:

- Spread of O/ME-SA/Ind-2001d particularly in a number of East Asian countries
- The first field cases due to serotype Asia 1 in Southeast Asia (Myanmar) in ~ 10 years
- Emergence of a new genetic lineage of serotype O/ME-SA in Russia
- Evidence of FMD viruses of African origin (O/EA-3) and SAT 2 moving into the near East
- Further spread of the A/ASIA/G-VII lineage into northern Israel
- Outbreaks in North Africa (Algeria and Tunisia) due to A/AFRICA/G-IV most closely related to viruses from West Africa
- Clinical FMD cases in Colombia due to serotype O

Pool 1 Southeast Asia: Dr Wilai Linchonsubongkoch, RRLSEA

Samples (n=112) have been received recently from Thailand (representing O/SEA/Mya-98, O/ME-SA/Ind-2001d lineages), Lao PDR (O/SEA/Mya-98) and Myanmar (O/SEA/Mya-98, O/ME-SA/Ind-2001d, and Asia 1/G-VIII). Serum samples were also received from Thailand for NSP serology (n=16,832) and LP ELISA (n=3601). The most significant epidemiological event in 2017, was the Asia 1 outbreak in Myanmar, which was investigated by OIE SRR Bangkok. The outbreak started on 15thJanuary and was resolved by 6th of February - where 59 out of 1559 cattle demonstrated clinical signs in the affected villages. Laboratory analyses were hindered by the inability to recover live FMDV from clinical samples, but VP1 sequence data was obtained; characterising the virus as belonging to the G-VIII clade of serotype Asia 1 (most closely related to FMDVs of South Asia origin). Past outbreaks in Myanmar in 2005 were due to the Asia 1/G-IV lineage, so this is a new incursion into the SEA region.

Pool 1 East Asia and China: Dr Jijun He, LVRI

During 2017, clinical samples representing 19 serotype O and 8 serotype A samples were received to LVRI from 10 FMD outbreaks in China (8 serotype O and 2 serotype A). Sequence data for these cases, indicates that the O/ME-SA/Ind-2001d lineage has now entered China and has been found in the extreme west of the country. During this period, the A/ASIA/Sea-97 lineage has also been detected (in cattle and pigs), while sequence evidence indicates that two genetic groups within O/SEA/Mya-98 lineage affecting either cattle (2016-17) or pigs (2012-17) are present. At the same time, the Chinese national surveillance program has continued to monitor Northeast and the border region of Southeast China; where probang and lymph node samples (n=2475) were collected. Of these samples, 18 have yielded positive results (14 and 4 from the O/SEA/Mya-98 and O/CATHAY lineages, respectively). Vaccine matching and immunogenicity studies for O/MYA98/BY/2010 have been performed showing good match against all representative local strains including those from the O/ME-SA/Ind-2001d lineage.

Pool 1 Korea and East Asia: Dr Jong-hyeon Park, APQA

During February 2017, simultaneous FMD outbreaks due to serotypes O (O/ME-SA/Ind-2001d) and A (A/ASIA/Sea-97) occurred in South Korea. These cases represent at least two new incursions of FMDV into the country, although the precise source in East or Southeast Asia has not been identified. In addition to clinical cases, pro-active surveillance (using NSP serology [n=257,857] with support from RT-PCR [n=1604]) has been undertaken which has not revealed any evidence for undisclosed circulation of FMDV on any farms. SP (serotype O) serology (n=328,914) has also been widely used to assess population immunity in vaccinated animals where levels of 97.0%, 92.1% and 76.3% have been detected in cattle, breeding pigs and fattening pigs, respectively. National vaccination campaign now recommends either O1 Manisa+O-3039 or O-Campos or O-Primorsky for pigs and O1 Manisa+O-3039+A22 for cattle.

Pools 1 and 3: Russia: Dr Alexey Mischenko, FGBI-ARRIAH

Serotype O has been detected in both Russia and Mongolia in 2017. The cases in Russia (O/Bashkortostan/RUS/2017), do not belong to the O/ME-SA/PanAsia-2 lineage and are most closely related to FMD viruses detected in a central Asian country in 2016. The serotype O viruses from Mongolia have been characterised as belonging to the O/ME-SA/Ind-2001d and O/ME-SA/PanAsia lineages (closely related to viruses isolated in China in 2011). O/ME-SA/Ind-2001 appears to be covered by the Russian vaccines; and for A/ASIA/G-VII a new vaccine virus has been produced (A/ARRIAH/2016). Only local produced vaccine is being used in Russia.

<u>Discussion</u> – What is preventing certain countries from reporting FMDV? It appears that a reluctance to report is associated with a fear that countries will lose lucrative commercial markets. In response to these problems, ARRIAH has tried to initiate a program in 2014 which aimed to provide vaccine, training and funding to the countries that reported FMD; however, the project didn't proceed.

Pool 2 India: Dr Don King on behalf of colleagues at ICAR, PD-FMD

Serotype O (from the O/ME-SA/Ind-2001 lineage) has been the only detected FMDV serotype in 2016-2017 from the 523 samples submitted for laboratory investigation. Sequence data indicates that there is now a second cluster of viruses within the O/ME-SA/Ind-2001 lineage circulating in India (tentatively named O/ME-SA/Ind-2001e with a nucleotide divergence of 7.4% from the Ind-2001d lineage). No

dramatic spread of FMD was recorded during the past twelve months and most outbreaks are relatively mild in nature only involving a few animals. Vaccine-matching performed using the O/IND R2/1975 strain shows 91% antigenic homology (for 42 isolates).

Pool 3 Turkey and the West Eurasia Laboratory Network (WELNET FMD): Dr A. Naci Bulut, Şap Institute, Ankara, Turkey

Sequence data indicates that the FMDV lineages currently present in Turkey are O/ME-SA/PanAsia-2^{Qom-15}, A/ASIA/G-VII (including a sub-lineage called A/ASIA/G-VII^{SAM-16}), while serotype Asia 1 has not been recorded since 2015.Retrospective analyses (back to 2006) shows that successive waves of FMDV representing different serotypes affect the country in a cyclical manner. Samples (n=22,906) have also been tested for FMDV-specific antibodies to assess vaccine performance and disease-free status of certain regions in the country. Additional samples (n=5) from Iran (A/ASIA/Iran-05^{FAR-05} and FAR-09</sup> and serotype Asia 1) have also been characterised. The presentation also reviewed challenges for FMD control in the region and sustainability of WELNET FMD.

<u>Discussion:</u> The new A/ASIA/G-VII vaccine does not appear to protect against the A/ASIA/Iran-05 lineage, which is currently circulating in Iran; therefore A/Iran-05 vaccine strain will be included in the 2018 vaccination strategy. ARRIAH and Merial/BI recommends that both A/Iran-05 vaccine and A/ASIA/G-VII vaccine be included.

Pool 4 Kenya and East Africa: Dr Abraham Sangula, Embakasi

During 2017, there have been reports of FMD outbreaks due to serotype O (EA-2), A (AFRICA/G-1), SAT 1 (NWZ) and SAT 2 (IV) in Kenya. Most samples were serotype SAT 1 (n=17) and serotype O (n=25). A collaboration with Plum Island (USA) is sequencing FMDVs recovered from cases in both buffalo and cattle, and is also undertaking NSP serology in these two species. The quadravalent vaccine from KEVEVAPI is recommended for use in the country.

Pool 4 Ethiopia and East Africa: Dr Daniel Gizaw, NAHDIC

During 2017, NAHDIC has received 112 samples for virological testing purposes. The serotypes detected were O (n = 70), A (n = 10) and SAT 1 (n = 4). This is a change from previous years where most outbreaks were caused by serotype SAT 2. The Western and Central parts of the country appear to have different circulating strains for serotype O (EA-3 and EA-4. NSP serology indicates 11.6% of small ruminants and 31.7% of cattle have FMDV-specific antibodies. Testing has also been performed for export certification purposes (687 sera from small ruminants and 2163 sera from cattle were positive).

<u>Discussion:</u> relating to NSP test results in Ethiopia, if an animal is positive for NSP they cannot be exported out of the region.

Pool 5: Nigeria and West Africa: Dr Hussaini Ularamu, NVRI

Serotypes O (O/EA-3 and O/WA), A (A/AFRICA/G-IV), SAT 1 (X) and SAT 2 (VII) are circulating in Nigeria. The current strategy is to target clinical samples (n=70 from 2017) rather than serological samples since the country is endemic. Recent data generated with the antigen ELISA (from IZSLER), shows that SAT 1 viruses (topotype X) circulating in Nigeria could only be detected by the PanFMD component of the test, but not by the SAT 1 monoclonal specific part of the assay. Sequencing and additional support to NVRI has been provided as part of an OIE twinning project with CODA-CERVA.

Pool 5 Nigeria, FMDV Serology: Dr David Lefebvre, CODA-CERVA

Serological assays were carried out as part of surveillance activities in Nigeria. Samples were collected during 2009-2015 from sheep, goat and wildlife (waterbuck, wildebeest, and African eland). None of the samples reacted with serotype C, SAT 1 and SAT 3. It is unclear at this point as to why SAT 1 was not detected by serology, since it has been isolated in the area. For sheep and goats (n=300), approximately 20% of the samples were antibody positive. For wildlife less than 50% were positive by antibodies.

<u>Discussion:</u> An observation was that some samples were NSP negative and SP positive. This could have occurred because the NSP levels decrease faster than the SP antibodies or there is a sensitivity problem with the test.

Update from IZSLER: Dr Santina Grazioli, IZSLER

During 2017, IZSLER has received samples from Algeria and Tunisia which were characterised as belonging to the serotype A/AFRICA/G-IV lineage, most closely related to isolates in West Africa (Nigeria, 2015 - ~98% nucleotide identity). There were problems with shipping samples due to incorrect paperwork and labelling. There appears to be a need for training in REMESA countries. Elsewhere, serological testing of 1535 Kenya samples was performed; where antibodies to serotypes A, O and SAT 2 were identified. However, the general conclusion form this work was that the antibody ELISA was not serotype specific. A post vaccination study was also carried out, which highlighted a poor or null response to the first vaccine dose using local vaccine containing serotype O, A, SAT 1 and SAT 2. The number of ELISA kits supplied has increased every year; during 2017, 2135 kits have been supplied to 34 countries.

<u>Discussion</u> – The updated chapter on sample dispatch in the OIE manual may help to provide guidance on how to ship FMDV samples.

ACTION 1 – **WRLFMD** (with help from the partners) to compile a list of dangerous good couriers that could be used for shipments in the different FMDV pools.

Pool 4 New connections in Burundi: Dr Kris de Clercq, CODA-CERVA

The presentation highlighted a new partnership that has been established in Burundi. The particular focus of the work covered investigation of a possible FMDV epidemic in March 2016 in an area where no vaccination is reported. In total 924 virological samples and a 172 serum samples were collected. Due to cross-reactivity of the serological tests, the dominant serotype was used to assess the most likely (recent) serotype present; using this approach serotype O, A, and SAT 2 were identified. Serotype SAT 2 (IV) and A (AFRICA/G-I) were subsequently isolated and sequenced.

<u>Discussion:</u> Saliva was taken instead of probang samples, as there was no experience of taking probang samples. Also the interest was the acute-phase excretion of FMD virus not the carrier state. The solid phase competition ELISA (in-house and commercial) and VNT were used for this work. The VNT had better specificity however some cross-reactivity was still evident. Several studies have shown that cross-reactivity happens when animals are infected with multiple serotypes. Can use a negative control of a serotype that is not present; for example using Asia 1 tests in Africa to determine cross-reactivity.

West and Central Africa: Dr Labib Bakkali Kassimi, ANSES

Sample received from an FMD outbreak in Guinea-Bissau (in 2016) were characterised as serotype O (O/WA). Samples were also collected from Chad, where the SP ELISA suggested that serotype O, A, SAT 1 and SAT 2 are present; however, in young animals serotype SAT 2 was most dominant. One sample was sequenced (partial VP1) as serotype SAT 2 (topotype VII) which was most closely related to FMD viruses from Libya and Cameroon. A multiplex (gel-based) RT-PCR assay was also evaluated in collaboration with NVRI, Nigeria, which suggests that serotypes O, A, SAT 1 and SAT 2 circulate in 6 states in the country. Additional SAT 1 viruses will be sequenced with the view to redesigning the RT-PCR (if needed).

Pools 4-6 Sub Saharan Africa: Dr Francois Maree, ARC-OVI

Samples have been received from South Africa (serotypes SAT 1 and SAT 2), Mozambique (serotypes SAT 1, SAT 2and SAT 3) and Uganda (serotypes O, SAT 1 and SAT 2). Additional samples from UAE and Swaziland were negative. There is no overall change in epidemiological pattern since the samples from South Africa were in the FMD Protective Zone adjacent to the KNP so the outbreak did not impact the OIE status. This presentation also briefly summarised results from FMD transmission studies in an isolated buffalo herd in KNP, South Africa. Using LPBE, the predominant serotype detected in buffalo was serotype SAT 1, followed by a few cases of serotype SAT 2. Maternal antibodies declined between 2-6months and this appears to correlate with the susceptible time for infection of young buffalo.

Pool 4-6 Sub Saharan Africa: Dr Elliot Fana, BVI

During 2017, samples (n=78) have been received from Zimbabwe (SAT 1 and SAT 2), Zambia (SAT 1, SAT 2, and SAT 3), Uganda (O and SAT 2), Namibia (SAT 2), Malawi (negative) and Botswana (SAT 2). In addition, a small number of samples from Zimbabwe, Namibia, Uganda, Malawi, Botswana and Zambia have been tested for NSP antibodies. The recent Botswana outbreak occurred in the 'free with vaccination' zone; and upon investigation it was found that the vaccination schedule had lapsed.

<u>Discussion:</u> Recent experience from ANSES is that negative NSP samples turned positive after storage in the fridge (+5 °C \pm 3 °C) for two weeks. This observation is thought to be due to low contamination of bacteria (since the sample became negative after heat inactivation). WRLFMD has also recently observed this phenomenon for a small number of samples sent out as part of an inter-laboratory exercise (using multiple NSP ELISA test kit formats). Canada also observed that NSP negative samples can become positive on re-testing.

ACTION 2 – ANSES and WRLFMD to review data from samples that generated inconsistent NSP test results and report back to the Network with these findings

Pool 7 South America: Dr Rossana Allende, PANAFTOSA

FMD-free zones (with and without vaccination) cover large parts of the South American continent. Countries/regions without official OIE status are Venezuela, Surinam and the Amazon region of Brazil. In Colombia (Department of Arauca that neighbours Venezuela) a serotype O outbreak (O/EURO-SA) was identified in June 2017 and immediately after there were three more outbreaks identified in other parts of the country. In the affected herds, one to two years old animals were found that were partially or not vaccinated. The outbreak has been controlled and the vaccination campaign in Colombia has been strengthened. NSP testing is now complete to verify the area is free from active FMD infection. Elsewhere, Surinam is working with PANAFTOSA to apply for OIE recognition of FMD free status and

the implementation of a FMDV regional antigen bank has been approved (by PAHO and COSALFA countries).

Pool 7: South America: Dr Andrea Pedemonte, SENASA

SENASA has not received any clinical FMD samples for testing during 2017 and there is no change in Argentina's status. Tetravalent vaccine is used in the region and these have been sold to areas outside of S. America. There are active on-going collaborative projects in Vietnam, South Korea and Paraguay.

Update from Winnipeg: Dr Charles Nfon, NCFAD

Testing has continued to monitor cases of vesicular disease (37 submissions – 789 samples) in Canada due to Senecavirus A. This emerging virus has continued to be a problem for pig industries in Canada and the USA.

Update on Australia - Emergency (high potency) serotype A and O vaccines protect against heterologous viruses: Dr Wilna Vosloo, CSIRO

This presentation reviewed collaborative work undertaken by CSIRO, Wageningen Bioveterinary Research (Lelystad) and WRLFMD to assess the in vivo performance of FMD vaccines against emerging FMDV lineages. The first example covered the A/ASIA/G-VII lineage where *in-vitro* vaccine-matching has yielded poor results. An initial study using a multivalent vaccine (from Merial/BI) containing A-SAU-95 generated a PPG protective result of only 56%. Subsequent pilot studies were carried out using A/MAY/97 (5/7 cattle were protected) and A₂₂/IRQ (2/7 cattle were protected). A full potency test has recently been performed with the A/MAY/97vaccine that showed a PD50 of 6.47. Field viruses from the O/ME-SA/Ind-2001d lineage generally have poor *in-vitro* match to O₁ Manisa and intermediate to good values against the O-3039 vaccine. Studies to evaluate emergency high potency vaccine use have recently been carried out with O₁ Manisa/O-3039 (combination) and O-3039 only. One group was challenged 7 days post vaccination and the other at 21 post vaccination vaccine. At 21 days, both groups were 100% protected; at 7 days 60% were protected when using the monovalent vaccine and 80% were protected when using the bivalent vaccine (this is not statistically significant).

Review of regional FMDV strains and changes in epidemiological patterns - breakout session



Day 2

Breakout session: short summary from each endemic pool and discussion on gaps in surveillance (information to be collated for the Annual Report)

Discussion topic 1: Mapping FMD outbreaks and risk; new ideas to display real-time epi and lab data

Collecting information via EuFMD monthly reports (GMR): Dr Maria Teresa Scicluna, EuFMD

This presentation provided an overview of work undertaken by EuFMD to collate information from Reference Laboratories (as well as OIE and FAO sources) to define patterns of risk for FMD. These data can feed into the tables (within the PRAGMATIST tool) to define which are the most important FMDV serotypes/strains that are circulating in a particular region or country. It is imagined that the PRAGMATIST tool will assist vaccine antigen managers to make decisions about what FMD vaccines are purchased and maintained within antigen banks.

<u>Discussion</u> covered the approaches used to assign risk scores for the circulating FMDV strains – particularly in regions/countries where sampling and testing is very sparse. EuFMD propose to establish a group of regional experts (focal points) to review and analyse the data and help fill in these gaps. Some delegates were uncomfortable with inferences being applied from neighbouring countries where data was missing, since neighbouring countries often have different livestock, practices and trade patterns. With the current extent of lab/epidemiological data available, it is difficult to precisely define these parameters (at a country level) – perhaps starting at the regional level is more sensible (using the data that is generated from the Network breakout sessions). Additional discussion covered the nature of the Global Monthly Report (GMR) and whether these outputs could be integrated into a more dynamic "Network" website that highlighting important epidemiological events (and changes), as well as known trade patterns and livestock densities to help predict likely virus movements.

Update on plans for OIE WAHIS: Dr Min Kyung Park, OIE

OIE is working on improving the maps, which are currently of a low resolution. The High Throughput Sequencing, Bioinformatics and Computation Genomics Group (HTS-BCG) meets to discuss what platform should be used (it will include all genomic data). This group will also take into consideration the Nagoya Protocol. Some of the information is in the Terrestrial manual 1.1.7; however it is an ongoing process. It was decided that FMDV would not to be part of the pilot study to evaluate this platform; bluetongue virus and rabies virus will be included.

<u>Discussion</u>: How will it link to GenBank? The sequence data will not be directly linked. It will be interesting to understand whether endemic sequences will be added to this type of platform or whether it is just "exotic" outbreaks.

Action 3: **Min Kyung Park** will send the report of the last HTS-BCG meeting, which identifies what information will be included in the future.

Discussion Topic 2: FMDV vaccines for Africa

FMDV strains and vaccines: overview of the challenges

Introduction: Dr Anna Ludi, WRLFMD

There are many gaps in our knowledge regarding the performance of vaccines against the FMDV lineages that are present in Africa:

- *In vivo* potency tests are rarely done, particularly those that define cross-protective responses
- Batch serological testing data supplied from manufacturers in Africa is not often reported
- Immunogenicity studies for monovalent or multivalent vaccines are rarely reported
- Reference reagents (such as validated BVS) from vaccines suppliers are not readily available to the Reference laboratory community
- Field vaccine evaluation studies are lacking

Discussion: In addition to the countries highlighted in the presentation, Senegal also produce FMDV vaccine

In-vitro and *in-vivo* guidelines to select and assess vaccine performance: Dr David Lefebvre, CODA-CERVA

An overview of the OIE Terrestrial Manual of Diagnostic Tests and Vaccines was provided which highlighted the requirements for vaccines QA of the final product batch test and the requirements for making a vaccine. The manual states that the post-vaccination sera should come from the manufacturers or OIE Reference Laboratories. At the end of the chapter a method is given for testing fitness for purpose of a vaccine (*in-vivo*).

Data gaps and using data intelligently: Dr Francois Maree, ARC-OVI

For the SATs there is little data for proper vaccine matching using *in vivo* testing. This presentation overviewed serological cross-neutralisation data collected by OVI using a wide range of southern African field strains from SAT 1 and SAT 2 serotypes with representative vaccine sera as well as sera from infected cattle. Two approaches to model these data and estimate likely antigenic phenotype were presented: (i) antigenic cartography and (ii) sequence based antigenic prediction methods. Sequence data (together with serological data) has been used to highlight surface exposed amino acid residues on the FMDV capsid that confer antigenic properties.

Data gaps and using data intelligently: Dr Wilna Vosloo, CSIRO

This presentation reviewed different (yet complementary) approaches that can be used to demonstrate vaccine suitability. Points to consider are (i) do high potency vaccines for SATs protect against heterologous challenge even with poor *in vitro* match as for serotype O, A and Asia 1? – since this might reduce the number of potential vaccine strains required to cover the diversity of FMDVs found in Africa, (ii) are there alternative(i.e., less expensive) approaches that can be used to assess protective responses in target species?, and (iii) how do we determine accurate (i.e., serological) correlates of protection?

What can we learn from existing vaccine QC systems in S. America? Dr Rossana Allende, PANAFTOSA

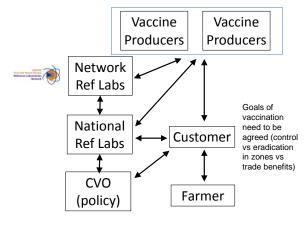
In South America there is a well-established system to monitor the QA of FMDV vaccines and their use. This presentation reviewed the key "actors" (National Veterinary Authority (NVA), vaccine producers, farmers, stores that sell vaccine, regional political bodies, Reference laboratories and OIE) and their roles and responsibilities in this process. The quality control pathway involves the national veterinary authorities and the vaccine manufacturer. The PANAFTOSA reference centre has the responsibility to collect epidemiological data, harmonise the methods used and coordinate activities with the continental FMD eradication plan (PHEFA). As routine tests performed in the final product of each vaccine batch are innocuity (freedom of infectious virus); sterility, stability of emulsion, purity

(no induction of NSP antibodies), security (no adverse reactions) and potency. A standardised EPP approach has been heavily validated as the method used to verify the potency on the final product of the vaccine batches. Additional tests of duration of immunity are required for licencing and also after licensed they are aleatory performed over time. All tests are done by the NVA. PVM studies are generally performed annually to monitor the efficiency of the vaccination programs.

FMD vaccination and post vaccination monitoring guidelines: Dr Samia Metwally, FAO

The PVM document (<u>http://www.fao.org/3/a-i5975e.pdf</u>) provides practical guidance on how to evaluate the effectiveness of vaccination campaigns that is tailored to the requirements of countries at different stages of the PCP. The plan is to have (a) vaccine quality centres, (b) ELISA kits for the most common commercially available vaccines and (c) training. It is anticipated that a pocket guide for field veterinarians will be produced shortly, together with training sessions (on [i] design of field studies and [ii] lab ELISA methods).

Using the Network to validate a pipeline? Future prospects: Dr Don King, WRLFMD



The "actors" and their interactions:

A table (see next page) was proposed by WRLFMD to highlight the responsibilities of each of these "actors" including the vaccine producers and role that could be undertaken by the OIE/FAO reference laboratories. It was noted that such a generic table has limitations since different regions/countries adopt different approaches with respect to vaccine potency and safety testing. This table has been circulated for comments from the Network Partners and may be subject to revisions.

Discussion to agree priorities for the Network: It is anticipated that the vaccine producer will undertake studies to define the homologous potency of the vaccine, as well as produce data to support the safety and batch agreement of these products (black boxes). Some countries use registration dossiers to validate the vaccine batch, while in others this work is undertaken by the Reference Laboratories. Key roles for Network laboratories (highlighted in green) include: (i) continued review of regional epidemiological risks via testing of field samples and exchange of data, (ii) generation of tailored and harmonised diagnostic tools (to cover post-vaccination responses of specific vaccines), (iii) generation, collation and exchange of reference sera for vaccines (including "validated" BVS), coordination and implementation of immunogenicity studies and (iv) contribution to efforts to define correlates of protection for the vaccines. Specific activities are indicated in the footnote of the table. The OIE has expressed an interest in developing improved capacity for FMDV vaccine Quality control in Africa – via PanVac (under the auspices of the African Union). Key priority activities are highlighted in the dark red and pale red boxes including the generation and testing of reagents (including BVS) and capacity to perform immunogenicity studies in targeted populations. In addition, inocuity testing to confirm that products are fully inactivated is important and may need to be addressed.

Activity	Vaccine Producer	National Ref labs	Customer	Farmer	OIE/FAO Network labs
Homologous potency testing	++	+/-	Performance defined by the NVA ⁷		
Safety testing Inc. innocuity	++	+/-			
Batch testing Potency, 146s assessment, stability oil emulsion, purity	++	+/-			+/-
Defining regional risks (and identifying gaps)	+	++	+	+	++1
Providing relevant diagnostic tools	+	+			++2
Generation and validation of BVS	++	+			++ ³
Immunogenicity studies (in target populations)	+	++		+	++4
Defining correlates of protection (in different species)	++	+			++5
PVM: population immunity ⁸ (extent and degree of immunity)	+	++	+	+	+ ⁶
PVM: Investigation of cases of vaccine breakdown	+	++	+	++	+
PVM: measuring the impact of vaccination campaigns (disease clinical cases and infection - NSP)		++	++	+	+

Footnotes defining priorities for Network (and associated Working Groups):

¹ Via exchange of field and laboratory data and presentation via Website (and PRAGMATIST)

- ²Work to assess vaccine matching approaches in different laboratories and future development of "tailored" ELISAs to measure post-vaccination serological responses
- ³ Network to prepare a list of available reagents and to highlight gaps that should be prioritised for the generation of new BVS (possibly seek funding from vaccine suppliers for this work?)
- ⁴Focus of Network Woking Group
- ⁵ Focus of Network Working Group
- ⁶ via contribution to training initiatives (led by FAO and EuFMD?)
- ⁷ NVA: National Veterinary Authority
- ⁸ PVM serology determined using homologous vaccine strains or representative field viruses

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