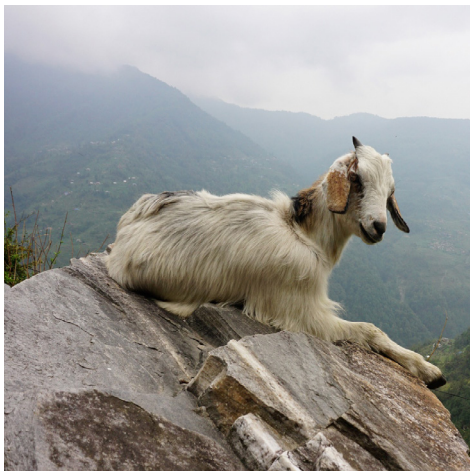
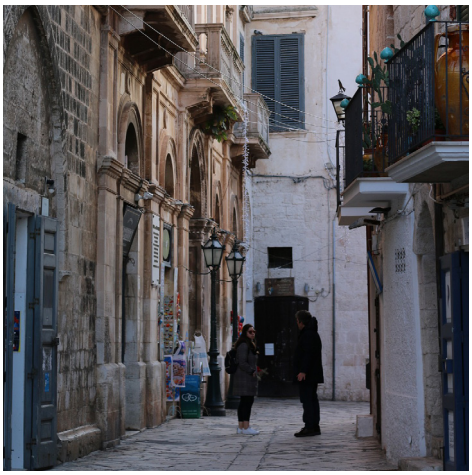
Food and Agriculture Organization of the United Nations

eufmd
european commission for the control of foot-and-mouth disease

BORGO EGNAZIA 29-31 OCTOBER 2018

Report

OPEN SESSION OF THE STANDING TECHNICAL COMMITTEE OF THE EUFMD

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
European Commission for the control of Foot-and-Mouth disease (EuFMD)
Rome, 2018

Contents

FOREWORD

Increasing global security in the supply of effective foot-and-mouth disease (FMD) vaccines: can we really manage the risks and achieve progressive control without it?

Behind almost all of our problems with FMD are four things: the frequency of emergence of new strains, the exceptional virus infectivity and speed of spread, the impact on producers and the lack of security that comes from the limited and uncertain access to suitable vaccines.

Behind almost all our FMD mitigation nightmares is one simple fact: we do not have vaccine security.

Instead, we live with the fear that vaccine will not be available when needed, or if available, will not be effective when used, or achieve the outcomes desired. In FMD free regions, the 'standard model' of vaccine banks is being challenged by the potential scale of need and the diversity of circulating FMD strains. In regions not free of FMD, the efforts being made for 'risk based vaccination' and optimizing control measures relate to the same problem of lack of vaccine security. The lack of available quality vaccines results in ineffective vaccines being used, with disappointing results for the animal producers as well as nationally.

Without vaccine security, we need elaborate and well drilled preparedness for an FMD emergency, to contain incursions before they outstrip vaccine supply. In endemic regions, millions of animals – and their owners – cannot access effective vaccines when they need them so lack of supply does matter for food security and livelihoods.

Global security of supply of FMD vaccines therefore affects all countries – so what can be done about it, and how do we manage the risks without it?

This is a big issue and needs all involved to have an overview of the scale of the problem, and the barriers and constraints to increased security. We must continue to cope with the risks posed by lack of vaccine, or to over-reliance on vaccination.

This issue is as relevant to FMD free countries as those endemically affected. If we are to progress we must do more than listen, we need also to talk, to meet together, and work out new and better ways to get big actions to address this global issue. We urge all those concerned to improve this situation to collaborate, from scientists interested in what limits new vaccines to be used, those work on epidemiology and surveillance to vaccine bank managers through to industry leaders and investors keen to form new alliances to increase supply of vaccines.

Vaccine security would mean the confidence that vaccines are affordable, available and effective and accessible by stakeholders.

Isn't that worth giving our attention, time and effort to?

Dr. Keith Sumption

EuFMD Executive Secretary
European Commission for the Control of Foot-and-Mouth Disease

SUMMARY OF THE OPEN SESSION 2018

The Open Session of the Standing Technical Committee of the European Commission for the Control of Foot-and-Mouth Disease (EuFMD) is held every two years and has become the largest technical and scientific meeting on FMD to be convened on a regular basis. The EuFMD has organized these meetings since the early 1970s, alternating a Closed Session with an Open Session for scientific exchange.

The Open Session 2018 (OS18) meeting was held in Borgo Egnazia, Italy, from 29–31 October. Under the theme of *Increasing Global Security in the supply of effective FMD vaccines*, a total of 23 technical sessions were held in plenary and parallel streams, along with panel discussions, poster sessions and post-meeting workshops. The meeting agenda is provided in **Appendix 1**.

The meeting was attended by 270 participants from around the world, including five members of the Standing Technical Committee and observers from both public and private sectors, scientific institutions, research laboratories and academia. The list of participants is provided in **Appendix 2**. The recording and uploading of presentations to the Open Session Online platform facilitated participation of a broad international audience. An additional 290 participants joined the Open Session Online, which was streamed live during the meeting and can be accessed at https://eufmdlearning.works/course/view.php?id=178.

All talks were mentioned using the Twitter handle #OS18 and a number of videos of the talks were shared live using social media. A dedicated mobile application enabled participants to keep track of events, plan their meeting timetables, vote for the posters and provide feedback on the meeting conclusions. Awards were handed out to best presentation for each day, overall, and best poster.

Following the conclusion of the OS18 programme, two post-meeting workshops were held at the same venue on (1) *Field evaluation of novel livestock vaccines,* with support from the International Veterinary Vaccinology Network; and (2) *Pragmatist vaccine antigen priorization,* in partnership with the Pirbright Institute.

Key messages were captured from meeting presentations, panel discussions and in consultation with participants though the mobile application. It was agreed that qquality vaccines are not enough, and that the barriers that prevent their availability must be addressed. The meeting concluded that improving vaccine availability needs urgent attention by both public and private sectors and a new form of partnership is needed to shift the vaccine stewardship paradigm to (1) create an enabling environment for investment in vaccine security; (2) continue to support research and development for innovative technologies and partnerships; and (3) ensure inclusion of all stakeholders in the value chain. The meeting conclusions and recommendations are given below.

CONCLUSIONS AND RECOMMENDATIONS FROM THE OPEN SESSION 2018

The conclusions and recommendations from OS18 combine key messages from the presentations, discussions and feedback directly from participants via the dedicated OS18 App and the section on the opinion of the particioants upon the topics below.

CONCLUSIONS

1. Improving vaccine availability needs urgent attention by both the public and private sectors to increase global security in the supply of effective vaccines.
2. Manufacturers are key partners in the network of stakeholders that contribute to FMD control, and engagement with them is valued and necessary to address the issues surrounding Global Vaccine Security.
3. Development of a new form of partnership through a public-private professional network is needed to achieve real change in vaccine supply through:
    a. creating an enabling environment for investment in vaccine security;
    b. continuing to support R&D for innovative technologies and partnerships; and
    c. ensuring inclusion of all stakeholders in the value chain.

4. Quality vaccines are not enough, the barriers that prevent their availability must be addressed. Further work is required to better understand the barriers to vaccine supply, including registration and regulation barriers; and solutions, such as mutual registration.
5. The five key challenges requiring consideration to support manufacturing FMD vaccines are:
    a. biosecure facilities require a significant capital investment;
    b. it is difficult and expensive to produce quality FMD vaccine;
    c. constant research and development into emerging strains is needed;
    d. the registration process is complex; and
    e. there is a lack of visibility in the demand and forecasts for FMD vaccine need.

6. Capacity to identify and prepare for future risks relies on the adequacy of viral information for the identification of vaccines for use in regional programmes. Outbreak investigation and sample submission remain core activities to support the continued monitoring of circulating viruses and provision of accurate vaccine matching advice.
7. In endemic settings, livestock keepers should have the right to access effective vaccines to protect their livestock and livelihoods, and inadequate access to effective vaccines in endemic regions is an animal welfare issue.

RECOMMENDS

8. Further work to better understand the drivers for adoption and factors influencing willingness to pay for vaccines, and to quantify the current 'unmet' demand and predicted future growth for vaccines.
9. Recognising that novel vaccine platforms provide opportunities for safe and high potency FMD vaccines and may offer a commercially viable alternative to conventional killed vaccines, further work is recommended to address the many remaining technical and registration challenges, such as addressing criteria for GMO licencing in Europe.
10. Recognising that the traditional vaccine bank model is poorly equipped to respond to trans-pool movements of viruses, Innovative approaches to vaccine resources are recommended including:
    a. exploration of alternatives and/or complementary approaches to traditional vaccine banks; and
    b. application of new modelling tools to examine the range of policy and operational issues related to vaccine resources
11. Further work is recommended to establish the potential benefits and risks associated with use of attenuated vaccines and the topic of attenuated live FMD vaccines should remain on the agenda for future discussion.
12. The regulatory environment is becoming increasingly demanding, and it is recommended that proposed novel vaccine products should demonstrate significant advantages over existing products to facilitate the licencing process.

OPENING CEREMONY

The OS18 was formally opened by Jean-Luc Angot, President of the EuFMD Executive Committee. Dr Angot reflected that securing adequate volumes of effective vaccines has presented a challenge since the 1950's, when European Commission of Foot and Mouth Disease was established in response to the devastating post-war epizootics of foot and mouth disease in Europe. Through collaborative efforts significant progress in the progressive control of FMD has been made, with almost all of Europe and South America now recognized as officially FMD-free. The role that quality vaccines have played in this progress is acknowledged, and the contributions of pioneers of vaccine technologies must not be forgotten; notably H.S. Frenkel (1891 - 1968) and J.G van Bekkum (1922 – 2018). However, the challenge remains to increase security in the supply of effective FMD vaccines. To move forward, we should embrace public private partnerships and recall the mentality of the 1950s, when progress was made possible through a strong political will.

Dr Silvio Borello, Chief Veterinary Officer for Italy, welcomed participants to Borgo Egnazia. He noted that good progress had been made in the progressive control of FMD since Italy last hosted an Open Session in 2008. However, FMD continues to present a risk to the European region, and Dr Borello congratulated EuFMD for organizing this important multidisciplinary congress, as well as for its continual activity in supporting and enhancing prevention in its 39 European member states, in close collaboration with the European

Commission. The three pillars of EuFMD remain central to reducing the risk posed by FMD. Dr Borello proposed a fourth pillar, solidarity, and offered support on behalf of Italy to address the issues surrounding global FMD vaccine security.

Dr Juan Lubroth, Chief FAO Animal Production and Health, spoke on behalf of FAO, noting the success of the Progressive Control Pathway and the framework it has provided for national capacity and policy development, not only for FMD but for a range of other applications. However, Dr Lubroth reiterated that the global burden of animal diseases remains enormous. FMD is among the most common diseases of ruminants and pigs in endemic regions, with estimates of 250 million cases annually. Considering many of the cases are treated with antibiotics, a holistic approach to address the collective issues of disease burdens is required. Dr Lubroth recognized that almost all resources in the fight against FMD are provided by countries themselves, and increasingly, from the affected livestock producer. To tackle the disease at its source, livestock producers must gain access to the means to protect their animals, through information, early warnings, biosecurity and vaccines. Access to quality vaccines is therefore required to support progressive control. Dr Lubroth recognized the key role of the private sector in developing and delivering vaccines, and identified the need to collaborate to stimulate investment and supply of vaccines. He highlighted FAO's support for creating a dialogue with the private sector to encourage new innovations to support Global Vaccine Security.

Welcoming comments were also provided by Dr Antonio Fasanella (Direttore Generale dell'Istituto Zooprofilattico sperimentale di Puglia e Basilicata), Dr Yu Qiu (Representative, World Organisation for Animal Health), Dr Ewa Camara (Representative, DG-SANTE). Eoin Ryan, Chair, EuFMD Standing Technical Committee, reiterated that OS18 not only facilitates information exchange, but also provides a forum for generation of innovative solutions amongst scientists, policy makers, industry and international non-government organisations. He confirmed that Global Vaccine Security is at the forefront of the Standing Technical Committee's agenda, and declared the OS18 officially open.

SESSION 1: GLOBAL OVERVIEW

A keynote paper presented by Dr Keith Sumption (EuFMD) introduced the concept of Global Vaccine Security and emphasised the importance of access to effective vaccines for the progressive control of FMD. Dr Sumption summarised progress made in the control of FMD over the past 10 years, but highlighted that the burden of FMD remains considerable, particularly in endemic regions of Africa, Asia and the Mid-East. In the ten years following Open Session 2008 in Erice, Italy, a number of key recommendations have been achieved, including implementation and enhancement of the Progressive Control Pathway for FMD (PCP-FMD). However, Dr Sumption reiterated statements made in 2008 that remain relevant today: that FMD control can only be achieved (1) by actions at the field level to break transmission cycles; (2) when vets and animal owners in the front-line are armed with sufficient information and suitable vaccines; and (3) when there is sufficient private and public support. Dr Sumption closed by highlighting that Global Vaccine Security is an issue that affects all countries. He noted that international organisations have a role in supporting the conditions that promote sustained national actions, and that the scale of change needed demands a new approach of global public private partnerships for vaccine security.

Dr Don King (The Pirbright Institute) presented a keynote paper [**Appendix 4**] on the global status report for FMD, with particular focus on tracking the emergence and spread of new viral lineages. Dr King's presentation illustrated the continuing dynamic nature of FMD virus circulation, and the role of the OIE/FAO FMD Laboratory Network in monitoring geographical distribution and spread of transboundary FMD virus lineages to highlight future risks. Capacity to identify and prepare for future risks relies on the adequacy of viral information for the identification of vaccines for use in regional programmes.

Presentation available HERE.

SESSION 2: THE SCALE OF THE PROBLEM

Six papers [**Appendix 5, 6, 7, 8, 9 and 10**] were presented to bring attention to recent and ongoing work being undertaken to estimate the scale of demand for: (1) emergency supplies of vaccine in FMD-free regions; (2) vaccine to meet the projected growth in livestock populations and demand for FMD control to meet PCP-programmes; and (3) vaccines for regional crises such as epidemic jumps between virus pools. The drivers for demand were explored, contrasting public financed campaigns with drivers operating at the owner level; for private uptake of vaccines for protection of livestock and to support emerging markets in endemic regions.

The session identified that an extensive population of at-risk livestock exists in endemic regions and demand for vaccines is projected to increase, so a new revolution in supply is needed. A willingness to pay for FMD vaccines appears to exist, but more is needed to quantify this willingness to pay, to understand the drivers for adoption and predict growth in demand.

SESSION 3A: VACCINE SUPPLY

Four papers were presented with the aim of increasing the understanding of the barriers affecting supply and availability of vaccines to private and public buyers, how these barriers may be overcome, and by whom. Aldo Dekker gave a presentation dedicated to the memory of H.S. Frenkel and J.G van Bekkum. He reflected on the 50 years since the death of Frenkel and the passing in 2018 of Professor van Bekkum, both being pioneers in FMD vaccine security in Europe and important contributors to EuFMD. His presentation demonstrated how European vaccine supply issues in the past were met by international partnerships. Ron Bergevoet [**Appendix 11**] explored the policy issues behind emergency banks as a means to address immediate emergency demands. Pascal Hudelet [**Appendix 12**] provided valuable insight into the issues for investors in building capacity to upscale supply. Finally, Noel Ainepaln [**Appendix 13**] introduced how mutual registration processes in East Africa may offer a potential solution to remove barriers of entry to markets and increase access to vaccines.

A panel discussion, chaired by Keith Sumption, followed the session with industry representation from Pascal Hudelet (Boehringer Ingelheim), John Atkinson (MSD Animal Health) and Sacha Seneque (Ceva Global). The panel invited investors to identify priority barriers to address in order to increase supply, and how these might be overcome. Five key challenges were identified by the panel when considering a change to the supply of FMD vaccines:

(1) biosecure facilities require a significant capital investment;
(2) it is difficult and expensive to produce quality FMD vaccine;
(3) constant research and development into emerging strains is needed;
(4) the registration process is complex; and
(5) there is a lack of visibility in the demand and forecasts for FMD vaccine need.

The discussion highlighted that reducing unpredictability in demand through enhancing our understanding of future needs would support investment in manufacturing. It was suggested that global capacity is theoretically capable of meeting current demand, but this is not able to be harnessed due to registration complexities and regulations against working with foreign viruses. The panel agreed that mutual registration of vaccines, as is being pioneered in East Africa, would help to address some of the barriers faced. In addition, acceptance of multistrain dosage would support investment, but it is currently not widely accepted outside the EU. A need to increase transparency in the tendering process was also cited. It was concluded that manufacturers are a key partner in the network of stakeholders that contribute to FMD control, and engagement with them is valued and necessary to address the issues surrounding Global Vaccine Security.

SESSION 3B: VIROLOGY

During this session, five papers [**Appendix 14, 15, 16, 17 and 18**] were presented to showcase cutting edge research investigating the mechanisms of virus pathogenicity, ecology, evolutionary dynamics and phylogenetics. Findings from studies presented in this session support improved strategies for vaccine strain selection, vaccine implementation and post-vaccination surveillance.

SESSION 4A: BREAKING BARRIERS

Presentations in this session [**Appendix 19 and 20**] investigated the barriers that prevent end-users from accessing quality vaccines, including the public policy environments affecting who can import, distribute, purchase and deliver FMD vaccines to animals. The private and public sector rights and responsibilities in FMD prevention and control were considered, and discussions explored the historic implications of vaccine safety concerns on vaccine stewardship and the notion of FMD control as a public good and responsibility. Research

gaps were reviewed and the potential of developments in vaccine technologies to reduce biocontainment barriers were explored.

SESSION 4B: IMMUNOPATHOLOGY

During this session, three papers [**Appendix 21, 22 and 23**] were presented on the gene signatures associated with FMD virus infection and persistence, and on transmission from carrier animals via oropharyngeal fluid. The session concluded more work is required to improve our understanding of FMD virus persistence mechanisms, as well as the epidemiological importance of carriers in the transmission of FMD.

SESSION 5A: VACCINE SELECTION

Seven papers [**Appendix 24, 25, 26, 27, 28, 29 and 30**] examined the issues related to vaccine selection. It was suggested that consumer confidence in vaccines is affected by the limited data available on circulating viruses in endemic settings. New surveillance tools, such as environmental and bulk milk testing, may reduce reliance on outbreaks for sample collection data. Discussion highlighted that both public and private consumers have an interest in increasing confidence in vaccine selection, and a role may exist for the public sector to disseminate information to support appropriate vaccine selection.

SESSION 5B: MODELLING FREE AND NON-FREE AREAS

In this session, six papers [**Appendix 31, 32, 33, 34, 35 and 36**] shared approaches and results from recent modelling studies in both FMD and non-free settings. A range of modelling approaches were presented, investigating (1) the application of reinforcement learning and adaptive management approaches for outbreak control; (2) FMD virus transmission dynamics and spread pathways; (3) implications of control strategies; and (4) livestock mobility network analysis. Discussion highlighted the role that modern modelling capabilities might play in advising on policy for (1) progressive control of FMD in non-free areas; and (2) surveillance, preparedness and response in free areas.

SESSION 6A: CONVENTIONAL VACCINES

In this session, papers discussed the existing potential of conventional vaccines, what limits them and how much room for improvement remains with regards to stability, optimization for species and quality of immune response [**Appendix 37**].

In his keynote presentation, Tim Doel highlighted the important role of trivalent vaccination campaigns in supporting FMD control and eradication programmes in Europe and South America. He noted that, in cattle, good quality conventional vaccines confer high levels of protection and some cross-protectivity has been demonstrated between serologically diverse strains of the A serotype. While the instability of conventional FMD vaccines is recognised, Dr Dole clarified that good quality GMP products and proper cold chain maintenance minimises the issues associated with virus and vaccine instability. However, the limitations for good quality conventional vaccines are associated with their use in the field, where suboptimal conditions for storage and use often exist, in addition to complications such as maternal antibodies. A number of challenges associated with bringing a novel vaccine to market were noted, associated with: (1) product development and licencing; (2) manufacturing costs; (3) quality control; (4) quality assurance; and (5) the cost of facilities. In summary, conventional vaccines have a large body of safety and efficacy data to support their continued acceptance by regulators and practitioners. The regulatory environment is becoming increasingly demanding, and proposed novel vaccine products should demonstrate significant advantages over existing products to facilitate the licencing process.

SESSION 6B: MODELLING BUSINESS SECURITY DURING OUTBREAKS

The session showcased recent modelling work and provided a forum to consider the ways in which models can assist with questions of risk, costs and benefits associated with maintaining business continuity during outbreaks in FMD-free settings. Discussions identified the need for well-planned responses that balance the needs for disease control and business continuity in the livestock industries [**Appendix 38**]. As movement restrictions have a dramatic impact on the cost of livestock diseases such as FMD, it was suggested that

movement controls need to be carefully matched to the epidemiological and economic consequences of the disease, as optimal bans can have substantial financial benefits [**Appendix 39**].

Enhancements to the Australian Animal Disease Spread Model (AADIS) were also presented [**Appendix 40**], which allow comparisons of post-outbreak management strategies for securing proof-of-freedom from FMD and return to trade. The new modelling capability will support the development and refinement of post-outbreak management policies that facilitate the earliest possible recovery of FMD-free status and return to trade.

SESSION 7: CHAMPIONING NEW VACCINES

Three papers considered the potential for novel vaccine technologies. Vaccine production is currently carried out in high containment manufacturing facilities, resulting in significant production costs and limitations for production capacity. Issues associated with stability and production times for conventional vaccines were also cited. The session discussed progress and limitations faced when seeking to improve vaccine potency, vector stability and route of delivery, while minimising time until protection, number of vaccine doses, cost and side effects. Promising innovations discussed in this session included:

(1) virus like particles (VLPs) expressed in insect cells using the baculovirus expression system and used to formulate vaccines with an appropriate adjuvant [**Appendix 41**];
(2) a recombinant-replication-defective human adenovirus type 5 coding for FMDV capsid proteins and also the 3Cpro that allows for the in vivo assembly of VLPs (Ad5-FMD) [**Appendix 42**]; and
(3) a novel, marked FMD-LL3B3D vaccine platform consisting of attenuated virus containing negative markers in the NSPs 3B and 3Dpol [**Appendix 43**].

It was suggested that novel vaccine platforms provide opportunities for safe and high potency FMD vaccines and may offer a commercially viable alternative to conventional killed vaccines. However, further work is required to address the many remaining technical and registration challenges, such as addressing criteria for GMO licencing in Europe.

SESSION 8A: THE FUTURE OF FMD VACCINES

The two papers in this session considered the future of FMD vaccines, and the potential acceptability of novel technologies for future commercial use. The application of structural design and reverse genetics to enhance FMD vaccines in Africa was discussed [**Appendix 44**]. It was concluded that applied research into the development of novel FMD vaccines and disease control strategies need to enable a fit-for-purpose approach to FMD control in the geographical context of interest.

Rational design of attenuated FMD vaccines using the Synthetic Attenuated Virus Engineering (SAVE) method was also described [**Appendix 45**]. It was discussed that these live, attenuated FMD virus strains may: (1) offer potential application for use directly as vaccines; (2) decrease biosecurity risks and costs related to vaccine production; (3) facilitate rapid production of vaccines in response to new strains; (4) be applicable to all serotypes; and (5) enable targeted vaccination of wildlife reservoirs.

During discussion time, it was noted that successful global disease eradication campaigns have all used live attenuated vaccines. The potential benefits and risks associated with use of attenuated vaccines were discussed, and concerns were raised regarding the possibility for recombination and reversion to virulence. Further work is needed, including to understand the mechanism for attenuation, before these methods can be applied in animal trails. There was a general consensus that the topic of attenuated live FMD vaccines should remain on the agenda for future discussion.

SESSION 8B: VACCINE EFFICACY AND EFFECTIVENESS

An introduction to this session was provided by David Paton and Giancarlo Ferrari, who gave an overview of the importance of improved field studies to support vaccine efficacy and effectiveness. A key message was that, regardless of whether a country intends to progress beyond Stage 2 of the PCP-FMD, verification of the effectiveness of a vaccination program is necessary, as is monitoring maintenance of vaccine efficacy between

campaigns. Field observational studies were noted as a very practical approach to monitor this in the endemic setting. Two papers were presented to consider: (1) the application of field trials to estimate the effectiveness of vaccination programmes in the Maghreb region [**Appendix 46**]; and (2) preliminary results from work to model the impact of farming practices on vaccine effectiveness in endemic settings [**Appendix 47**].

SESSION 9A: AFRICA EPI-NET

Ten papers [**appendices 48 - 57**] were presented as part of a discussion to foster greater understanding of viral circulation and FMD epidemiology in Africa, with the objective to promote networking and facilitate ongoing collaboration in surveillance between regional laboratories and academic partners.

SESSION 9B: IMPROVING CONVENTIONAL VACCINES

Six papers [**Appendix 58, 59, 60, 61, 62 and 63**] shared recent research related to improving conventional vaccines, including through development of higher yields, lower doses, duration of immunity and wider coverage. Presentations indicated that classical vaccine production systems remain important for delivery of global vaccine needs. While development of new vaccines is time consuming, it was also shown that established vaccine strains can cover more variants if they are produced to a sufficient quality. Furthermore, addition of immune stimulants to existing vaccines can improve the response and reduce the amount of antigen needed. However, quality control of vaccines is essential and new tools to test antigen integrity are required. The time taken to get new vaccines to market can be reduced if molecular biotechnology is used to improve adaptation to cell culture. New adjuvants as well as new routes of application can improve the quality and thereby the duration of immunity. But for all vaccines it remains important that quality is monitored and validated, not only by producers but also by customers.

SESSION 9C: BREAKOUT SESSIONS

A side workshop focused on managing the risk and achieving progressive control of FMD in North Africa took place on the 29th October 2018 with participants from Algeria, Morocco, and Tunisia. During the event, participants and EuFMD experts presented and discussed: (1) the current FMD situation; (2) the surveillance and control measures implemented and possible improvements; and (3) the vaccine quality, availability and vaccination strategies applied.
A side meeting was organized on the 30th October between participants from Turkey and EuFMD experts to discuss: (1) the status of the West-Eurasia laboratory network; (2) the implementation of immunogenicity studies in the Trans Caucasus with the possible support of the SAP institute of Turkey; and (3) the animal mobility programme.

SESSION 10A: DIAGNOSES AND DIAGNOSTIC TOOLS

Through four papers [**Appendix 64, 65, 66 and 67**], this session provided information on the recent assay validation work for improved diagnosis, and addressed the issue of emergency supply of diagnostic kits. Different options for serological diagnostic banks with their advantages and limitations were presented by a representative of a commercial company, which motivated a short debate and common agreement on the importance for a collaborative, multinational approach to this issue.

SESSION 10B: VACCINE QUALITY ASSURANCE

Three papers considered the interdependence of FMD virus pathogenicity, challenge system and outcome of vaccine studies [**Appendix 68**]; correlation between vaccine match in potency tests and r1-value [**Appendix 69**]; and potency assessment using standardised serological assays [**Appendix 70**]. Key messages from the session included:

(1) Although tongue inoculation is useful as a standardized approach to FMDV vaccine testing, it is important that intrinsic aspects of FMDV pathogenesis are considered in the interpretation of experimental outcomes.
(2) The choice of vaccine is often based on r1-value, however the optimal measure for vaccine match would be the heterologous potency of a vaccine divided by the homologous potency of a vaccine. Existing studies suggest a significant correlation between potency ratio and r1-value, but further work is needed as studies are limited and publication bias likely exists.

(3) When considering correlation between antibody titres and protection, inclusion of a standard serum is a good way to make results between laboratories more comparable.

SESSION 10C: EUFMDIS DEMONSTRATION

The EuFMD outbreak simulation model (EuFMDis) was presented during several talks earlier in the week, as well as demonstrated during coffee breaks. This session provided a formal demonstration of the model capabilities, along with facilitated discussion. Participants demonstrated a strong interest in the model, with around thirty attendees and a lively discussion about opportunities and challenges for disease simulation modelling. The value of a pan-European FMD simulation model was supported.

SESSION 11A: MIDDLE EAST AND ASIA EPI-NET

Six papers [**Appendix 71, 72, 73, 74, 75 and 76**] were presented on the FMD situation in pools 1, 2 and 3 to facilitate networking and encourage a collaborative approach to surveillance and research within and between the regions.

SESSION 11B: VACCINE PERFORMANCE

This session reiterated the importance of post vaccination monitoring and field studies to validate vaccine performance. Three papers [**Appendix 77, 78 and 79**] presented findings of recent studies. A need was highlighted for regional collaboration and improved surveillance to support appropriate vaccine selection. Establishment of a vaccine banks was advocated in endemic areas, such as the Maghreb region, to improve timely access to appropriate vaccines.

CLOSING CEREMONY

At the closing ceremony, Corissa Miller presented a summary of the feedback collected through the mobile application, which is outlined in full in **Appendix 80**. Awards were handed out for the following:

- Best presentation of day 1: Jonahton Arzt - Transmission of FMD from persistently infected carrier cattle to naïve cattle via transfer of oropharyngeal fluid; Pascal Hudelet - The Challenges of FMD Vaccine Production
- Best presentation of day 2: Aurore Romey - Rapid On Site Diagnosis of FMD and Safe and Cost-Effective Shipment of Samples Using Lateral Flow Devices for Laboratory Diagnostics; Emiliana Brocchi - Field Trial to Estimate the Effectiveness of the vaccination program implemented in the Maghreb region
- Best presentation of day 3: Michael Eschboumer - Multiplex Real Time RT-PCR for Detection of FMDV Rift Valley Fever Virus and Bovine Viral Diarrhea Virus in Bulk Tank Milk; Carolina Stenfeldt - The Interdependence of FMDV Pathogenesis Challenge System and Outcome of Vaccine Studies
- Best presentation overall: Martin Ryan - Rational Design of Attenuated FMDV vaccines by elevation of CPG and UPA Dinucleotide Frequencies
- Best poster: Emma Brown-Evaluation of Environmental Sampling as a Low Technology Method for Surveillance of FMD Virus in an Endemic Area
- Lifetime achievement award: Tim Dole, for 38 years of service to improving FMD vaccines.

The meeting was formally closed by Keith Sumption, who thanked the hosts, presenters, participants and staff of EuFMD for their contributions and support to make the OS18 a success.

WORKSHOP 1: PRAGMATIST VACCINE ANTIGEN PRIORITISATION

A workshop was held the day after the Open Session to introduce participants to the *Prioritisation of Antigen Management with International Surveillance Tool* (PRAGMATIST). The tool was developed collaboratively by EuFMD and the World Reference Laboratory to assist risk managers to select which strains are most important to maintain in their FMD vaccine banks. The workshop demonstrated how to apply the transparent, evidence-based framework to evaluate available vaccine antigens and participants practiced adapting the tool to their region-specific risk profiles.

WORKSHOP 2: FIELD EVALUATION OF NOVEL LIVESTOCK VACCINES

A workshop funded by the International Veterinary Vaccine Network (IVVN) on performing vaccine field efficacy trials was conducted the day after the Open Session. It was attended by 30 people, with fully funded scholarships given to attendees from Nigeria, Mongolia and Tunisia. Bursaries were also given for other attendees from countries including Europe, South Africa and Zambia. There were additional attendees from Turkey and the USA. The workshop was an excellent forum for discussion on performing vaccine field trials.

www.fao.org/eufmd.html