

Manual 3

Foot and Mouth Disease vaccination and post-vaccination monitoring





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Background

The SEACFMD campaign includes countries at varying stages in the control of FMD, ranging from countries which are recognized by the OIE as free from FMD without vaccination, to countries where FMD remains endemic. In addition, there are also zones within countries which are at a different stage in the FAO/OIE FMD Progressive Control Pathway compared to other areas within the same country. Therefore, vaccination has a varying role to play in these different countries and zones, including: emergency vaccination where an FMD outbreak occurs in an area previously free from FMD; preventative vaccination to protect populations where there is low prevalence or freedom from FMD, but where the risk of infection is significant; vaccination of animals prior to movement; and to reduce the impact of FMD and progressively control and eradicate the disease from endemic areas.

Vaccination currently forms a key component of the SEACFMD strategy and will continue to do so throughout Phase 5 of the SEACFMD campaign from 2016-2020. It should also be recognised that vaccination may be just one of a number of activities in a comprehensive FMD control program, which should also consider animal movement controls and biosecurity to enhance program effectiveness.

This manual provides technical information about FMD vaccines, details of the OIE vaccine bank and how this can be utilized by SEACFMD Member Countries, together with information on different vaccination strategies relevant to the SEACFMD Member Countries and factors to consider when planning a vaccination campaign.

A key publication, which should be used alongside this manual, recently published by FAO and OIE, is a set of guidelines on FMD vaccination and post-vaccination monitoring (PVM) (FAO-OIE, 2016). This will be referred to as the FAO-OIE guidelines throughout this manual. The reader is urged to use these guidelines to access additional detail on the information presented in this manual, particularly on planning of vaccination campaigns and post-vaccination monitoring. This manual will focus on details specific to the SEACFMD campaign and vaccination strategies applicable to this. Other references relevant to FMD vaccination are included at the end of the document. Most of these references are available as open-access documents on the world-wide-web.

Principles of vaccination against FMD

FMD is a highly contagious disease which is readily transmitted by direct and indirect contact between infected and susceptible species. Successful vaccination of an animal against FMD will ensure that the animal develops immunity against FMD sufficient to prevent clinical signs and reduce viral shedding. Vaccination against FMD does not, however, prevent infection of an animal with the virus.

The FMD Vaccine

FMD exists as seven immunologically distinct serotypes (O, A, Asia1, C, SAT-1, SAT-2 and SAT-3), whereby infection or vaccination with one serotype does not confer immunity against other serotypes. Cross-protection between the various subtypes, or strains, within the seven serotypes is also incomplete. The antigenic diversity that exists between different strains of FMDV complicates vaccination in that it is necessary to ensure that vaccines being used in a particular population include the serotypes and sub-types to which a population is likely to be exposed. Further information will be provided on vaccine matching below, but for detailed information refer to the FAO-OIE guidelines, and to the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. This will be referred to as the OIE Manual throughout the remainder of this manual.

The current FMD vaccine widely used in South-East Asia, including from the OIE vaccine bank, is an inactivated vaccine in a mineral oil adjuvant. As a general guide, this vaccine should confer immunity for approximately six months following the initial vaccination course which consists of two doses given one month apart. In areas where FMD is endemic or where vaccination has been previously conducted, female cattle may confer passive immunity to their calves through colostrum. These maternally derived antibodies can interfere with vaccination, making it less effective. It is understood that by approximately four months of age these antibodies will have waned in most calves. For more information on vaccine efficacy in different age groups and species, refer to the FAO-OIE guidelines.

When vaccinating a population in order to prevent outbreaks of FMD, it is important to achieve a certain minimum level of immunity within the population such that an outbreak of FMD cannot be sustained. This is known as 'herd immunity.' The proportion of a population which needs to be protected in order to achieve herd immunity depends upon a number of factors, including: the density and contact network of the population (where areas are densely populated or there is a lot of mixing, higher levels of vaccination will be needed), previous exposure to FMDV, previous vaccination, or existence of maternal antibodies in young stock. For detailed information on vaccination coverage refer to the FAO-OIE guidelines. However, as a general rule, achieving adequate levels of immunity in at least 80% of the target population should be sufficient in most cases to prevent outbreaks from spreading through that population. Due to the fact that not all vaccinated animals will respond to the vaccine sufficiently or there may be occasional problems with delivering vaccine to an individual animal, the vaccination strategy may aim to vaccinate at least 90% of the target population on the understanding that this should result in at least 80% of the total population achieving protective levels of antibody. This should be assessed by post-vaccination monitoring, and the vaccination strategy adjusted if the level of protection is found to be significantly below 80% in the target population.

Vaccination strategies applied under the SEACFMD campaign

Vaccination represents a key component of FMD control and eradication strategies in countries where FMD is endemic, and as an emergency measure where free countries or zones suffer an incursion of FMD.

A number of different vaccination strategies have been employed in South-East Asia but, in general, these have been based on emergency vaccination during an outbreak or targeted vaccination in identified FMD 'hotspot' and high risk areas within northern Lao PDR and central Myanmar (Bruckner, 2010).

While mass vaccination campaigns for FMD have been implemented in some SEACFMD Member Countries, this strategy is unlikely to be feasible in all SEACFMD Member Countries in the foreseeable future, due to limited resources for large scale vaccination campaigns. Therefore, alternative strategies should be considered whereby critical points or 'hotspots' are identified using risk-analysis techniques (see Manuals 1 and 3) where a high level of vaccination coverage can be achieved in a specific population or geographical area. The objective of targeted approaches to vaccination is to reduce prevalence of disease in strategic areas or a specific target population (e.g. animals moving across provincial or international borders), thus reducing the risk of further disease spread. Where countries currently implement mass vaccination, but the results of PVM suggest inadequate vaccine coverage, alternative, targeted strategies may be considered in preference to existing mass vaccination campaigns.

If correctly targeted, this type of approach can have significant impacts on FMD control at a fraction of the cost of a mass vaccination campaign. In any country or region where resources are limited, the strategy should ensure that optimum benefit can be achieved from a finite number of vaccines. Therefore, risk-based decision making should be employed to identify appropriate strategies, whereby controlling FMD or protecting a specific population will have the greatest impact for overall control of FMD. Due to the transboundary nature of FMD infection, it is critical to the success of control and eradication activities that a coordinated, regional approach is adopted where possible, in order to maximize the effectiveness of these activities on a regional basis.

This section of the manual focuses on targeted vaccination strategies, with some detail provided on four different strategies. These may be applied singly or in combination in different countries, depending upon, *inter alia*: the resources and funding available; FMD status; epidemiology; and trade patterns in a particular country or zone:

Controlling disease at its source: Using vaccination to control FMD in areas that serve as major sources for livestock movement throughout the region is key to the SEACFMD campaign and has already been implemented through a vaccination campaign in central Myanmar. By using information on livestock populations and trade pathways in the region (Smith et al., 2015), locations can be identified which represent sources of livestock destined for trade-related movement to other areas in the region. Given that movement of FMD susceptible livestock is a major cause of FMD spread in the region, using vaccination to reduce the prevalence of disease in source areas will help to reduce the risk that livestock leaving those areas are infected with FMD. Consequently, this would reduce the risk of FMD spreading to transit or destination areas in the region.

When a specific area has been identified as a source of livestock, and a potential target area for vaccination, the target population of livestock should be defined (for example, all cattle and buffalo in three adjacent villages) and the area assessed to determine whether a targeted vaccination strategy is feasible in this area. As described above, the strategy might aim to vaccinate at least 90% of the target population in the identified area. If there is insufficient vaccine/resources to achieve this level of vaccination, the target area should be reviewed so that a smaller population is targeted (for example, all cattle and buffalo in two adjacent villages) where it is possible to vaccinate at least 90% of the target population. Intensive vaccination coverage in key areas or populations is much more effective than low levels of vaccination coverage over a larger population. The latter approach will have little impact on disease transmission and may result in loss of confidence in vaccination amongst stakeholders.

- Protecting livestock prior to movement (for trade): As described above, there is an active trade in livestock throughout much of South-East Asia and China and this movement plays a key role in the spread of FMD, particularly throughout mainland South-East Asia and China. At the current time, it is not feasible to prevent movement of livestock given the existence of strong market forces driving the trade movement and the apparent freedom for traders to follow unofficial pathways. Therefore, the objective of vaccinating livestock intended for trade-related movement is to make this trade safer by reducing the risk of traded animals transmitting FMD to local livestock populations and seeding new outbreaks of FMD. In this case, implementation of measures which help to facilitate movement of vaccinated animals compared to unvaccinated animals should be considered, such that traders are required to have animals verifiably vaccinated (see Manual 5).
- Reducing prevalence of FMD in high risk areas: In addition to key source areas, critical points may also be identified where there is a high risk of FMD transmission or where FMD outbreaks are frequently reported (see Manual 3). These may be areas where there is a high volume of livestock trade and/or where there is a high density of livestock. Using a similar rationale to reducing disease at source, the use of targeted vaccination in these specific areas, if successful, will reduce the prevalence of FMD and thus reduce the risk of further transmission from these areas. This strategy has been implemented in northern Lao PDR in and around areas identified as livestock transport routes. The local, resident cattle are vaccinated in order to protect them from infection introduced by animals being moved for trade purposes.
- Protection of populations of higher health status: Vaccination can also be used to protect populations of higher health status from becoming infected (in areas of low prevalence or areas which are FMD-free with vaccination). Even if infected livestock contact this population, the virus will not be able to propagate through the immune population and will not become established. Monitoring these populations for evidence of FMD viral circulation is an important part of surveillance in areas which are considered FMD free with vaccination (refer to the OIE *Terrestrial Animal Health Code*, FAO-OIE guidelines and Manual 6).

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The targeted vaccination strategies outlined above rely heavily on knowledge of FMD outbreaks in the region, livestock population and husbandry systems as well as prevailing trade patterns. Therefore, it is important that outbreaks are investigated and reported soon after detection (see Manuals 7 and 8), that samples are collected and submitted for sequencing (see Manual 9) and that knowledge of livestock trade patterns is regularly updated (see Manual 5).

These same principles also apply to emergency vaccination in the face of an outbreak, in previously free zones or countries. Manual 11, Emergency Preparedness and Response Planning, covers the general principles that apply in such a scenario in more detail.

Once the specific vaccination strategy has been decided, it is important to ensure that it is feasible to conduct vaccination of a particular livestock population and that there is sufficient vaccine supply, technical capacity and resources, as well as regulatory and administrative support, to conduct the vaccination campaign successfully. The following section will address the factors which should be taken into account when planning a vaccination campaign.

Vaccination strategy: factors needed for a successful vaccination campaign

While a vaccine of suitable quality (see OIE Manual) and containing viral strains appropriately matched to the likely circulating field strain is an essential component of a vaccination campaign, there are many other factors which need to be considered in the planning of a campaign to ensure its success. These factors are outlined in Figure 1, the content of which is based on information from Brückner (2010) and the FAO-OIE guidelines. Any vaccination campaign should address these factors and ensure that they can be satisfactorily met before proceeding with the campaign. Even a relatively small-scale vaccination campaign will require considerable planning and significant funding. In addition, any deficiency in a vaccination campaign will not only fail to achieve its objective and waste significant resources but will also impact on future vaccination campaigns through a loss of stakeholder confidence in vaccination. Each of the factors outlined in Figure 1 are addressed individually in the following section.



Figure 1. A schematic outlining some of the necessary factors for a successful vaccination campaign (based on information from Brückner (2010) and FAO-OIE guidelines).

Vaccine

High quality vaccine produced to international standards (including information on the OIE FMD vaccine bank)

The vaccines used for the control of FMD in SEACFMD member countries should be produced to international standards as set out by the OIE Manual. Where vaccine is sourced from the OIE vaccine bank (see below for more detail) the vaccine will be of suitable quality. Where countries are producing or sourcing vaccine independently they should ensure that the vaccine meets international standards as set out by the OIE Manual.

The OIE FMD vaccine bank represents a key source of vaccine for use by SEACFMD member countries in emergency situations and for some agreed control and preventative vaccination campaigns in endemic settings. At the time of writing, vaccine from the OIE vaccine bank has been used for targeted vaccination in central Myanmar, in northern and southern Lao PDR and in Cambodia.

Details of the OIE FMD vaccine bank can be found at (http:// www.rr-asia.oie.int/activities/sub-regional-programme/ hped/vaccine-bank-fmd-rabies/vaccine-bank-for-footand-mouth-disease-fmd/). The reader should refer to this information for details on applying for vaccines from the bank.

Priority is given to providing emergency vaccines to developing countries within the region that have no immediate access to vaccines. When accessing the vaccine bank, countries must provide justification for the need of FMD vaccines, as well as information on logistics, financial and administrative framework of the planned vaccination campaign. This stipulation recognizes the importance of having all aspects of a vaccination campaign in place (such as cold chain, detailed plan for vaccination campaign, trained vaccination teams, etc.). It is noted that these should be in place BEFORE vaccine is ordered. In countries or zones free from FMD, planning for emergency vaccination should be included in emergency preparedness and response plans (see Manual 11), in countries where vaccine is being used as part of a preventative campaign or for specific control purposes, a detailed plan should be in place and be implementable before the vaccine is ordered.

Details of the responsibility of countries ordering vaccine and specific requirements are provided at (http://www. rr-asia.oie.int/activities/sub-regional-programme/hped/ vaccine-bank-fmd-rabies/vaccine-bank-for-foot-andmouth-disease-fmd/).

One of the key functions of a vaccine bank is to provide suitable vaccines (in terms of antigen content and quality) rapidly for use in emergency situations. From the OIE vaccine bank, there are a number of delivery options depending upon the urgency of the vaccination campaign. The following list provides a guide to the time needed for different delivery options:

- Urgent and immediate: within 5 working days
- Urgent but not immediate: more than 5 days but less than 15 working days
- Rapid: 15 days to 2 months
- Planned: more than 2 months

The FAO-OIE guidelines and the OIE Manual provide useful information on vaccine quality and efficacy testing. These should be referred to when planning to purchase vaccines.

Sufficient supply of suitable vaccine

An important part of planning a vaccination campaign is identifying the target population and ensuring that there is sufficient funding and capacity to purchase vaccines and deliver those vaccines successfully to an adequate proportion of the animals in the target population. The FAO-OIE guidelines provide detailed information regarding planning the number of animals in a population which should be vaccinated and about vaccination coverage in a particular population.

Once the number of vaccine doses needed to achieve an adequate level of herd immunity has been established, the feasibility of purchasing this number of vaccines and implementing a campaign of that size must be determined. This analysis should consider that an ongoing vaccination campaign will require that all previously unvaccinated animals have an initial vaccination, followed one month later by a booster vaccine, with re-vaccination six months after the initial vaccination course. The timing of subsequent vaccinations should be based on post vaccination monitoring. If there is not sufficient vaccine available to achieve herd immunity, then the target population should be revised and reduced to a size where adequate immunity can be achieved.

Vaccine strains well matched to viral strains which threaten the target population

FMD vaccination is complicated by the fact that FMD has seven immunologically distinct serotypes and, within those serotypes, viral sub-types between which there is incomplete cross-protection. Therefore, it is important that the viral strains contained within the vaccine are suitable to protect livestock against viral strains from which they are at most risk. The process of selecting viral strains for inclusion in a vaccine will be based upon knowledge of viruses circulating in the region, livestock trade pathways which could transmit new viral strains and collection of samples from outbreaks for viral sequencing and vaccine matching tests. Further information on vaccine matching is provided in the FAO-OIE guidelines and the OIE Manual and will not be covered further here. However, the importance of understanding the viruses which threaten certain livestock populations and collecting regular samples for vaccine matching should be stressed. FMD strains can change antigenically over time and so vaccine matching should be repeated on a regular basis, including before the selection of strains for each campaign, to ensure that vaccine strains continue to provide sufficient protection against prevailing field strains.

The OIE FMD vaccine bank currently holds a preformulated vaccine based on the major viruses circulating in South-East Asia which contains the following antigens: O-1 Manisa, O-3039, A Malaysia '97 and Asia 1 Shamir. As this is pre-formulated it could be dispatched rapidly in emergency situations. The bank also contains the following core strains (O1 Manisa, O-3039, A Malaysia '97, A Iran '05 and Asia 1 Shamir) and optional strains (A22 Iraq, SAT2 Eritrea, SAT 1, O-4625, A Saudi '95 and SAT 3). Selection of strains for inclusion in a vaccine will depend upon which viruses threaten the target population. It should be noted that the vaccine strains held at the vaccine bank may change over time based on changing field situation and, therefore, the OIE SRR-SEA should be contacted for up to date information on vaccine strains available if needed.

Planning and Logistics

Well formulated vaccination plan (clear objectives and target population)

This section emphasizes the importance of having a clear plan in place before commencing a vaccination campaign, including detailed objectives and a clearly defined target population. As described above, this plan should take into account the number of vaccines available, the funding available and the capacity of the veterinary services of a country to conduct a campaign of the scale included in the plan.

Much of this plan will be covered in the following section, but it is important to know about the target population before embarking on the campaign, such as its location, estimates of number of animals in the target population and distribution/husbandry system at the time of the planned vaccination campaign (are they housed or out in grazing areas, accessibility, etc.). Any necessary permission from local authorities or coordination with different organisations or government departments should be established as part of this planning process.

This component will incorporate all aspects of the vaccination campaign from vaccine selection and supply (outlined above) to vaccine storage, vaccine delivery and administration, post vaccination monitoring and communication, which will be covered in the following sections.

Ensure maintenance of the cold-chain from the point of vaccine supply to the point of administration

The FMD vaccine is sensitive to fluctuations in temperature and should be maintained between 2 and 8 degrees centigrade at all times during storage, transportation and right up to the point of administration. It is also important that the vaccine is protected from the sunlight as it can be inactivated over time when exposed to sunlight.

As part of a planned vaccination campaign (for preventative vaccination) and as part of an emergency response plan (for emergency vaccination) there should be detailed plans for how the cold chain will be maintained from the point of delivery of vaccines from the vaccine bank or manufacturer until the point of administration. It is also important to appoint responsibility to specific people along the supply chain and to ensure that monitoring is in place (particularly use of temperature strips/max-min thermometers) in order to monitor and verify that the cold chain has been maintained.

The cold-chain refers to maintaining the vaccine within a specific temperature range from point of delivery to point of

administration. The following should be taken into account during planning:

- Ensure that there are responsible person(s) designated for each stage in vaccine transportation, storage and delivery, and that there is a defined hand-over of responsibility at each stage (for example, to prevent batches of vaccine being left outside in unsuitable conditions if a vaccination storage area is not manned at the time of delivery)
- Ensure that each area where the vaccine is to be stored has refrigeration facilities which can maintain the vaccine between 2 and 8 degrees centigrade. This should include thermometers to record maximum and minimum temperature, alarms if temperatures approach the outer limits of this range and back-up power supplies in case of power outages (Animal Health Australia, 2011a)
- Ensure that during transportation, temperature controlled vehicles are used for large batches delivering vaccine to storage facilities and, when taking vaccine to individual properties/villages for administration, that cool boxes and ice packs are used to maintain the temperature between 2 and 8 degrees centigrade, without freezing. Temperature monitoring equipment, or strips should be used to monitor temperature at all times (Animal Health Australia 2011b provides a useful reference for transport of FMD vaccine to the field)

Vaccine should not be ordered until there is a clear plan for maintaining cold chain and all the necessary equipment is in place. For countries which may use emergency vaccination, maintenance of cold chain should form part of the emergency preparedness response plan. The following reference contains some useful information on cold-chain management which may be extrapolated to use for FMD vaccines (Ministry of Health New Zealand, 2012).

Sufficient and sustainable funding to cover all components of a vaccination campaign

Before embarking on a vaccination campaign, it is essential that there is sufficient funding available to complete all parts of the vaccination campaign during the time required to achieve the objectives of the campaign. Budgeting and outlining the source of funds should make up part of the overall plan described above.

Detailed communication plan

Communication and public awareness is an essential part of any vaccination campaign. If stakeholders perceive negative outcomes resulting from vaccinating their animals or do not appreciate the benefit, there can be a loss of support and even active resistance to a vaccination campaign. Without the support of livestock keepers and other stakeholders, a vaccination campaign will not be successful.

A communication plan should be formulated as part of the vaccination campaign. While more general information on communication strategies is included in Manual 12, some specific factors to include in public awareness and communication alongside a vaccination campaign are outlined below:

- Visits should be made to the target area prior to the vaccination campaign to discuss with local livestock keepers, para-vets, veterinarians, and other stakeholders about the vaccination campaign, including: why their area has been selected, what the campaign will involve and how this will affect them and their animals. This should also cover any other relevant information such as the need for permanent identification of animals (through application of ear tags), other control measures (animal movement control, etc.) and details of any follow up surveillance
- Livestock keepers and other stakeholders should also be made aware of certain features of the FMD vaccine, such as the time of onset to immunity (vaccinated animals are not immediately protected) and that if animals are already infected and incubating the virus at the time of vaccination, the disease will still become apparent soon after vaccination. It is important that these limitations are understood before vaccination is conducted so that this is not perceived as a failure of vaccination
- Establish a communication strategy and reporting pathway within the vaccination teams, so that there is a clear chain of command and clearly defined responsibilities. Communication should be built into the training of vaccinators
- If an outbreak occurs in a vaccinated population, there is a need to investigate the reason for the outbreak (details of possible reasons for this occurring are provided in the FAO-OIE guidelines). In the event of such an outbreak, good communication will be essential in order to ensure that stakeholders are aware of how the outbreak has occurred and what will be done in response to the outbreak. The results of any investigation should be communicated to all affected stakeholders in a timely and transparent manner

Detailed plan and funding for post-vaccination monitoring

Post-vaccination monitoring is an important part of any vaccination campaign, and is conducted to assess the

effectiveness of vaccination by measuring the immune response in vaccinated animals and the proportion of animals in a target population which have immunity to FMD. PVM can also inform amendments to a campaign, by helping to identify where vaccination has failed to achieve adequate levels of vaccination coverage or protection, and may form part of the investigation into apparent vaccination failures.

Post-vaccination monitoring may also involve testing vaccinated livestock for antibodies against non-structural proteins (NSP). The presence of NSP antibodies indicates that an animal has been exposed to infection with FMDV. The presence of NSP antibodies in a vaccinated population indicates that there is previous or ongoing infection in that population, even if there is no evidence of clinical disease. Where vaccines have not been adequately purified in accordance with international standards, or with repeated vaccination, there may be a detectable NSP antibody response. More information on NSP-antibody detection can be found in the FAO-OIE guidelines, the OIE *Terrestrial Animal Health Code* and the OIE Manual, and in Manual 6.

Post-vaccination monitoring is a very important component of the vaccination campaign but is only covered in brief here as the FAO-OIE guidelines provides comprehensive information on PVM.

Well trained vaccination teams

Before commencing a vaccination campaign, or as part of emergency response planning, teams of vaccinators should be trained in tasks relevant to carrying out their role in the field. The vaccinators should be well trained in vaccination technique (described later in this manual) and should also be aware of the clinical signs of FMD and other infectious diseases which they may encounter during a vaccination campaign, as well as what they should do in the event of a suspected case. It is also important that the vaccinators are trained in biosecurity measures and are aware of the importance of thoroughly decontaminating all personnel and equipment before leaving an area, even where there are no known FMD cases. Training should include the following, though this list is not exhaustive:

- Responsibilities of the vaccinator
- Vaccine transport, storage and handling requirements with particular emphasis on maintenance of cold-chain right up to administration of the vaccine
- Monitoring and recording of cold chain data
- Disease recognition (FMD and other relevant infectious diseases)
- Target population (age and species of animals to be vaccinated)

- Good biosecurity practice and use of personal protective equipment (PPE)
- Animal handling
- Animal identification and recording
- Vaccination technique (vaccine handling, loading syringes, administering injection)

Knowledge of FMD epidemiology and circulating serotypes and strains

When planning a vaccination campaign, it is important to understand the epidemiology of FMD in the area to be targeted. This will include information on livestock population (population number, population density, species (including wildlife)), livestock husbandry systems, livestock trade patterns, and circulating FMD strains, FMD prevalence, the number of FMD outbreaks usually occurring in that area and any seasonal patterns in FMD outbreaks.

Understanding the occurrence of FMD outbreaks and seasonal patterns will help when designing a vaccination schedule which corresponds with high risk periods and will also assist with monitoring the success of a vaccination campaign in terms of assessing whether there is a reduction in the number of outbreaks experienced before and after vaccination.

Understanding more about the viral strains in the region will assist with vaccine strain selection and vaccine matching, for both control programs and emergency preparedness. Similarly, general intelligence gathering, including understanding the trade patterns relevant to the area, will help to identify the risk of viruses being introduced from other areas through trade pathways for livestock and animal products. This will guide decisions regarding the inclusion of other strains in the vaccine which may threaten the target population.

Finally, it is important to understand the role of different species and different husbandry systems in the epidemiology of FMD in order to prioritise target species for vaccination. In South-East Asia and China, cattle and buffalo appear to be the main reservoirs of FMD and there is a relatively small population of sheep and goats. Barteling, *et al.* (2004) describe under which conditions different species might be included in a vaccination campaign.

Gathering information about epidemiology of FMD will most likely come from outbreak reports made through national, regional or global reporting systems (see Manual 7), from the result of outbreak investigations or from active surveillance studies (see Manuals 6 and 8). These will be addressed in each of the respective manuals.

Supporting mechanisms

Supporting legislation

It is important to have legislation in place to support vaccination campaigns, particularly any measures which may be necessary but deemed unfavourable by stakeholders such as animal movement controls. Animal health legislation is vital to any disease control program and will be outlined in more detail in Manual 2.

Other supporting control measures (i.e. animal movement controls)

While vaccination is a key and necessary component of many FMD control and eradication programs, it will not be successful in eradicating FMD without other, additional control measures in place to reduce the risk of FMD transmission. There may also be a need to restrict animal movements while vaccination is being conducted in a particular area. These control measures will be covered elsewhere in the manual and so will not be detailed further here.

Individual animal identification

Although individual animal identification, particularly in cattle, is being implemented increasingly in South-East Asia and China, there are still areas where this is not used and animals are not identifiable. As part of a vaccination campaign, animals should be permanently and, ideally, uniquely identified at the time of the first vaccination, and all vaccination details accurately recorded (via vaccination certificate and Department records). This is important to ensure that animals receive the two doses required as the primary course of vaccination as well as boosters at an appropriate interval, and for PVM or for investigating outbreaks of FMD in a vaccinated population. It can also be used to verify vaccination for movement purposes. Figure 2 shows ear-tags being applied as part of ongoing vaccination campaigns in Central Myanmar and Northern Lao PDR and figure 3 shows the ear-tag in place.

For further information on individual animal identification, refer to the OIE *Terrestrial Animal Health Code* (Chapters 4.1and 4.2).

Disease surveillance systems to monitor effectiveness of vaccination and identify infection

An effective disease surveillance system is a necessary part of a vaccination campaign and will be needed to conduct post-vaccination monitoring (as described above and in the FAO-OIE guidelines) and also to identify circulation of

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Figure 2. Application of eartags to a young buffalo as part of ongoing vaccination campaigns in Northern Lao PDR



Figure 3. Photograph showing ear tags used during the ongoing vaccination campaign in Central Myanmar and Northern Lao PDR

virus (through detection of NSP antibodies), or remaining pockets of infection. A surveillance system will need to be in place for at least two years in order to demonstrate freedom from disease as part of an application for OIE recognition of zone or country disease freedom with or without vaccination. Surveillance will also help to identify new strains of FMDV for sequencing and vaccine matching.

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Surveillance will not be described in detail here, but readers should refer to Manual 6 for further information.

Vaccine delivery

Timing

The timing of vaccination will be decided during the planning stage of the vaccination campaign (where planned preventative vaccination is being used) based on local conditions and epidemiology of the disease. It is important to have an understanding of the high-risk times for FMD transmission in given areas. For example, it is common to see more outbreaks reported in Cambodia, Lao PDR and Myanmar during June to September, which corresponds with the rainy season, whereas in southern Thailand and Malaysia, there are seasonal peaks corresponding with religious festivals in October to January (Bruckner, 2010) and in Vietnam and China there are peaks associated with Tet and Chinese New Year celebrations, respectively. Where such seasonal trends are apparent, vaccination should be timed so as to ensure the animals are maximally protected during these high-risk periods. In areas where there is an identified seasonal peak, animals should be vaccinated approximately three months prior to the high-risk period (providing this falls at a time where animals are accessible for vaccination), such that they should have peak immunity at this time. If vaccination is being given prior to movement, at least ten days should be allowed after a first vaccination or at least five days after a booster vaccine before movement is permitted (see FAO-OIE guidelines).

The reader should refer to the OIE *Terrestrial Animal Health Code*, OIE Manual and FAO-OIE guidelines for more detailed information on planning a vaccination schedule.

Species to be vaccinated

Based on the livestock production systems, populations and viral strains of FMD circulating in South-East Asia and China, cattle and buffalo are the major target species for vaccination against FMD in most countries, with some vaccination of pigs in large, commercial holdings. At present, small ruminants have not been included in most countries' vaccination campaigns, although they should not be overlooked as a potential source of losses as well as for disease dissemination in the region. The decision as to which species to include in each vaccination campaign should be based on the epidemiology of the disease and livestock populations in that area, rather than applying a single approach to all campaigns. This underlines the importance of surveillance across all sectors of the livestock industry, for evaluating the impact of the disease on all species and across various production systems, and to understand their role in disease dissemination.

Barteling, *et al.*, (2004) provides useful information on when to include different species in a vaccination campaign.

Vaccine administration

The oil adjuvant vaccine should be given by deep intramuscular injection, preferably in the lower value muscle groups of the neck rather than the rump. The vaccination should be given within a triangular area between the shoulder, the spinal cord and the jugular groove (as indicated in Figure 4).



Figure 4. Site of intramuscular injection in cattle: below the spinal column, above the jugular furrow/groove and in front of the shoulder).

There are a number of useful references available to describe administration of the FMD vaccine (Animal Heath Australia, 2011b), and the vaccine manufacturer will also supply information on vaccine delivery. The equipment needed to deliver FMD vaccines includes the following (taken from Animal Health Australia, 2011b):

- Syringes or a repeater injector gun
- 18 Gauge x 1-inch Luer needles for large ruminants and pigs
- 19-21 Gauge x ½-inch Luer needles for small ruminants and piglets (< 4 weeks)
- 18 Gauge x ½-inch Luer needles for withdrawing vaccine from bottles

23 Gauge x 2-inch Luer needles for allowing air to enter vaccine bottles

It should be noted that anaphylactic shock occurred in a small number of pigs vaccinated in the Philippines, thus epinephrine should be accessible to the vaccination teams in case of severe adverse reactions.

Restraint

Cattle, buffalo and pigs will need to be adequately restrained in order to ensure that the vaccine can be delivered effectively, identification applied and to minimize the risk of injury to people and animals. In larger, commercial farms or where there is a need for repeated visits to one area, animal handling facilities such as a permanent or make-shift crush and/or race may be available for restraint (Figure 5 shows an example). If there are sufficient cattle within a village to warrant construction of a more permanent handling facility, this may be considered at the start of a vaccination campaign given that there will be a need to return to the village and re-vaccinate animals on a relatively regular basis. However, this will not always be feasible or possible at the village level and, in such instances, each animal will need to be restrained individually for vaccination.



Figure 5. A temporary cattle race set up for a vaccination campaign in Cambodia

Where animals are used for draft purposes or are permanently haltered, these may be handled relatively easily using the halter with the attached rope wrapped around a substantial tree and held (not tied) by an operator (as shown in figure 6). This will generally provide sufficient

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restraint for vaccination but operators should be aware that the animals can still swing their body around (see Cameron, 1999).



Figure 6. A buffalo being restrained using a permanent halter for blood sampling in Myanmar.

For cattle which are not haltered but easily handled, a halter can be made from strong rope and used as above (refer to Cameron, 1999 for details on how to make a halter). If an animal requires more restraint, a technique known as the 'bleeding pole' can be used (shown in figure 7). Details of how to construct a bleeding pole and how to restrain an animal using this technique can be found in Cameron (1999).



Figure 7. A bleeding pole being used to restrain a buffalo during a vaccination campaign in Northern Lao PDR

Methods of restraint for pigs and small ruminants can also be found in the reference by Cameron, 1999.

CASE EXAMPLE: FMD VACCINATION (Cambodia)

Vaccination campaign in FMD hotspot border areas: Takeo, Kampot, Kampong Speu and Kandal provinces in Cambodia

Vaccination planning

The General Directorate of Animal Health and Production (GDAHP) and Provincial Offices of Animal Health and Production (OAHP) in Cambodia have a commitment to conduct FMD vaccination campaign to cover 100,000 animals and collection of 405 triple blood samples in Takeo, Kampot, Kandal and Kampong Speu provinces in Cambodia. These are triangle border areas surrounding the STANDZ identified hotspot, Tramkak district in Takeo province where FMD vaccination was completed in 2015.

Refresher training

In preparation for the FMD vaccination, a training was conducted for provincial, district and national veterinary staff to refresh them about important principles and proper application of animal identification, animal handling and vaccination. A meeting and extension program on FMD was conducted with the farmers in the said provinces with the addition of Pursat province.

Vaccination, animal identification and serum collection

FMD vaccination campaign was implemented in Takeo, Kampot, Kampong Speu and Kandal provinces. Animals were identified with numbered plastic ear tags and vaccinated twice with a one month period interval. A total of 90,256 cattle and buffalo were vaccinated twice while 30,000 animals across 354 villages in 42 communes were applied ear tags. Vaccination was extended in FMD outbreak area of Pursat province using the remaining vaccines under STANDZ programme. A recording system was set up where all data on FMD vaccination is kept.

CASE EXAMPLE: FMD VACCINATION (Cambodia) - Contd.

Vaccination campaign in FMD hotspot border areas: Takeo, Kampot, Kampong Speu and Kandal provinces in Cambodia

Serological Analysis

400 blood samples were randomly collected twice - first during the booster vaccination and second during the re-vaccination. The serum sample was used for detection of antibody using ELISA test and percentage protection in terms of HAHI. Around 90 samples were sent to Pakchong for analysis.

Monitoring and evaluation

Regular monitoring and evaluation are conducted by key staff of DAHP following the guideline for proper reporting. M&E data are used to inform key officials for policy development.

Public awareness

Public awareness campaigns at field level were done before and during the vaccination programme. Some of the mass media materials produced include FMD leaflets, signboards, pamphlets, booklets, banners and posters including TV promotion. IEC materials printed will be used during the annual free vaccination (demonstration) campaigns. Messages and lesson learned from the KAP survey on FMD under recently completed ADB/FAO project will be incorporated.

Results and Lessons Learnt

To monitor and coordinate the progress of the FMD vaccination, meetings are conducted at the provincial and central levels. Farmers strongly participated and were very satisfied by the programme. Reports indicated that no FMD cases occurred in the vaccinated areas. Cambodia will use the lessons learned from this FMD vaccination campaign to advocate for further support to sustain the programme and implement FMD progressive control in southern Cambodia in 2017 in compliance with the National Plan for FMD Control which has been updated and aligned with the SEACFMD 2020 Roadmap and the Global FMD Control Strategy.

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Foot and Mouth Disease vaccination and post-vaccination monitoring



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