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Practical surveillance guidelines for the progressive control of Foot-and-Mouth Disease and other transboundary animal diseases

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Practical surveillance guidelines for the progressive control of foot-and-mouth disease and other transboundary animal diseases

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Foreword

Disease control efforts are implemented to reduce food insecurity, promote safe trade and improve the livelihoods of people associated with animal and meat production. But control efforts are complex and expensive for both government and private sectors.

The progressive control pathway (PCP) was introduced to help guide these control efforts. Prior to the development of PCP for foot-and-mouth disease (PCP-FMD), countries were classified as either endemic or free. This categorization made it difficult to demonstrate progress nationally, regionally or in specific animal production types. The PCP framework allows for countries to progressively improve their disease control status by implementing and documenting increasingly stringent disease interventions. For programmes that are often measured in years rather than months, this approach gives countries interim milestones to achieve and, by demonstrating success, opportunities to increase sustainability.

Demonstrating success not only depends on identifying measurable outcomes but also on producing information that allows for progress evaluation, assessment of intervention efforts, and documentation of success to the world. The primary source of information will be the country's surveillance system. These guidelines are intended to assist in aligning measurable outcomes with surveillance programmes.

A wealth of information exists on surveillance, including strategic and operational planning, design, implementation and evaluation. This material can be found in government publications, peer-reviewed journals, and academic and government-sponsored training programmes. These guidelines draw on some of this information, with the aim of demonstrating practical surveillance approaches that progress from measuring broad disease epidemiology and risk factors to specific evaluation of intervention options and documentation of low disease prevalence. We hope these guidelines will be useful for countries as they implement PCP-FMD or other similar progressive programmes to control transboundary animal diseases.

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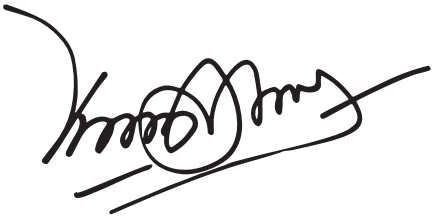

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Section 1
Overview

1.1 INTRODUCTION

The Progressive Control Pathway for Foot-and-Mouth Disease (PCP-FMD) was developed by the Food and Agriculture Organization of the United Nations (FAO) and the European Commission for the Control of Foot-and-Mouth Disease (EuFMD) and endorsed by the World Organisation for Animal Health (WOAH) (FAO and EUFMD, 2011). The PCP-FMD is a risk- and evidence-based framework to guide endemic countries to progressively improve the management of foot-and-mouth disease (FMD) risks and reduce disease impacts and viral circulation. Although similar progressive control pathways (PCPs) have been developed for other diseases such as peste des petits ruminants (PPR) (FAO and OIE, 2015), the PCP-FMD serves as an established example for progressive control processes. The original reason for framing efforts to prevent and control diseases such as FMD and PPR into a progressive pathway was to provide intermediate objectives towards achieving WOAH freedom status that could be measured against established indicators, especially for countries where such diseases may be endemic.

The PCP-FMD consists of two distinct domains: (1) a Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) pathway, including stages 0 to 3; and (2) a WOAH pathway beyond stage 3. The PCP-FMD is not intended to be compulsory or prescriptive; rather, it is a process to achieve effective outcomes that can be adapted to different countries and regions. The core component of the guidelines for PCP-FMD and other transboundary animal diseases (TADs) is the collection of reliable data for use in the decision-making process. Collection, analysis and reporting of animal health data for effective control or eradication depend on a reliable, integrated surveillance system. In all stages of the PCP, surveillance planning and implementation should be linked with progressive prevention and control activities for TADs.

The focus of this document is to provide guidance for animal health officials in endemic countries on surveillance approaches to achieve the first three PCP stages using the PCP-FMD as the primary example.

The surveillance system described for the PCP-FMD applies to other TADs that may not have fully developed PCPs. Surveillance methods for specific diseases should be adjusted according to the biological, financial, local and national culture and political factors, but they should also maintain the scientific integrity of the surveillance system.

1.2 PURPOSE OF THESE GUIDELINES

The PCP-FMD describes outcomes to be achieved in each stage and provides a general outline of the important surveillance component. Aligning a surveillance system with the PCP-FMD can be a daunting task. Planning, design, implementation and analysis of such a system are complex activities and, often, very intensive in terms of human and financial resources. Many resources describe both the technical and practical aspects of animal health surveillance and can be useful to surveillance teams. These guidelines are intended to offer more detailed insight into practical approaches to a comprehensive surveillance system that specifically address PCP-FMD outcomes. This document, further, can be used as a basic application for other PCP-like approaches to TADs with modifications according to the disease of concern.

1.3 IMPORTANCE OF A SURVEILLANCE SYSTEM IN PROGRESSIVE CONTROL PATHWAYS

The linkage of disease control strategic and operational goals with surveillance planning and implementation is extremely important. A surveillance system must accomplish three primary objectives in the context of the PCP. First, information generated from surveillance activities should allow countries to design and critically evaluate current prevention and control efforts by providing both baseline and updated information to measure progress over time and to identify and assess disease risks. Second, as control progresses, the surveillance system must be able to provide consolidated data and information to both internal and external groups to substantiate movement along the pathway. Third, the system must be flexible to accommodate progress and changes in disease status. Surveillance systems require several components to be implemented with flexibility to customize the needs within targeted populations, the ecology of diseases under consideration and geopolitical considerations.

Since circumstances driving surveillance design vary greatly, depending on the situation in the country, it is difficult to be prescriptive and detailed in this guide. The need for a practical approach suggests an evolving purpose of surveillance, starting with the goal of identifying information gaps and developing hypotheses on disease maintenance in the initial stages, to assessing the disease control interventions in later stages. In the initial PCP stages, the added value of collected information, even with

limited precision, should be considered. As PCP advances in its stages, the level of accuracy and precision in assessing prevention and control measures may require additional surveillance resources. Regardless of the PCP stage, data collection for the surveillance system must consider reliable representation of the population under the system. Often animal populations are not well enumerated, but innovative sampling approaches can be explored for this purpose (see Annex 1).

1.4 DESCRIPTION OF THESE GUIDELINES

These guidelines provide surveillance system background, concepts and general requirements in PCP-FMD stages 1 to 3 (Table 1.1, adapted from FAO & WOAH. 2018). We do not address stages 4 and beyond, since protocols in those stages follow WOAH requirements. Section 2 outlines a comprehensive surveillance system, including definitions, organization, strategy, objectives, planning and evaluation. Sections 3 to 5 link required surveillance activities with respective outcomes of stages 1 to 3.

Each section describes surveillance goals and activities that can be managed to provide scientific support for PCP outcomes. There are important concepts to keep in mind. First, most surveillance components are used in all stages (see definition in Section 2.1.1). Second, some components' attributes may change as control programmes progress and PCP outcomes change or require increasing accuracy and precision.

1.5 WHO NEEDS TO BE INVOLVED IN SURVEILLANCE?

Surveillance can be conducted in many different locations where animals and their products are kept, including villages, farms, markets and abattoirs. Further, many integrated activities such as surveillance design, data collection, diagnostic testing, data management and analysis must be accomplished to achieve useful information for decision makers at local, regional, national and international levels. Successful implementation of these activities in different places requires participation by individuals representing a broad set of roles and expertise.

Surveillance is conducted to support strategic and operational goals for disease prevention and control. Often these goals are intended for the long term and require political and financial capability, capacity and commitment. Consequently, it is essential for decision makers who can impact the political and financial situation to become involved early.

Perhaps most important in the design and implementation of surveillance is the representation of specific entities related to livestock keeping, including both animal management and cultural aspects. Local farmers and community leaders, industry representatives, and animal health workers are among those who can help ensure that surveillance planning is well understood, that it offers a realistic and practical approach, and that the specific required outcome is achievable.

The design and implementation of surveillance will require a team of veterinarians, diagnosticians, epidemiologists, statisticians and data management specialists. This shared expertise enables the team to comprehensively plan and implement a surveillance system.

TABLE 1.1
Surveillance requirements at each stage of a progressive control programme for TAD (adapted from FAO, 2018)

Stage	Focus	Requirements for surveillance
1	Gain understanding of the ecology/epidemiology of the disease in the country and develop a risk-based approach to reduce disease impact	Activities to understand disease behaviour and its specific risk so that a risk-based strategic plan can be developed
2	Implement risk-based control measures to reduce impact of disease in one or more livestock sectors	As per stage 1 + monitor the effectiveness of risk-based control measures
3	Progressive reduction in both outbreak incidence and virus circulation in at least one zone of the country	As per stages 1 and 2 + rapid detection and response to most disease outbreaks
4	Continue to implement endorsed national official control programme and achieve WOAH recognition of freedom with vaccination	• As per stages 1–3 + monitoring intervention/ vaccine effectiveness • Early warning and detection of incursion of new outbreak/introduction of new strain. Contingency planning.
Beyond stage 4	• Maintain FMD freedom without vaccination • Control transboundary disease introduction and remain vigilant	As per stages 1–4 + monitor risk-based control measures

Section 2

Characterization of a comprehensive surveillance system

2.1 OVERVIEW

This section is divided into three parts. The first part defines surveillance in the context of PCP, discusses how it should be organized, and introduces surveillance objectives and strategic purposes that align with disease control strategy. The second part explains how to develop a surveillance action plan in the context of PCP. The last part introduces a stepwise evaluation of a surveillance system, which should be done periodically to determine if a surveillance system is achieving its objectives.

2.2 WHAT IS SURVEILLANCE?

Effective control of TADs requires reliable, relevant data and adequate resources. Information about the presence and the spatial and temporal trends of a disease in an animal population can help us assess the need for and effectiveness of disease risk mitigation interventions. The information can also help ensure that interventions are suitable and effective.

Animal health surveillance can be defined as the systematic, continuous or repeated measurement, collection, collation, analysis, interpretation and timely dissemination of animal health-related data from defined populations, for the purposes of taking action to control disease (definition adapted from Hoinville *et al.*, 2013). Surveillance includes these key concepts:

Systematic. The way in which data are generated should follow a methodical plan that has been thoroughly designed and implemented. This plan should allow for the meaningful interpretation of the data, including extrapolation of outputs to the target population and assessment of risk factors.

Continuous or repeated. This characteristic allows the detection of temporal and spatial variations in disease patterns and risk factors, and therefore the possible adaptation and evaluation of risk mitigation interventions. This feature differentiates surveillance activities from one-off, cross-sectional surveys. When data generation is not continuous, but rather repeated through multiple surveys, the survey frequency will have a major impact on the timeliness of the information-based decisions.

Animal health-related data. In the context of the PCP, animal health-related data usually refer to the occurrence of, or examination for, infectious pathogens. Surveillance may be conducted to look for infection or disease; although these terms are often used interchangeably, their meanings are distinct. Infection refers to the entry and establishment mainly through multiplication of a pathogenic agent in the body of humans or animals, whereas disease (in the context of this guideline) refers to illness with detectable clinical signs due to the adverse health effects of a pathogen infection on the body. Detection of cases can be difficult when infection occurs without disease. The reason for using the term animal health-related, rather than simply animal health, is that surveillance often extends beyond cases of the infectious pathogen. For example, in risk-based surveillance, other parts of the system may also be under surveillance, such as trade nodes, vectors or environmental factors.

Defined populations. Ideally, the animal populations targeted by surveillance activities should be explicitly and unambiguously defined, to measure and calculate the frequency of occurrence and interpret the data generated. Defining host populations is not just about specifying the host species, breeds and geographical locations, but also the types of nodes (e.g. farming systems, markets and slaughterhouses) along the value chains in which these populations are embedded. This explicit population definition requirement can be a major challenge in settings where up-to-date data are lacking on the structure of animal populations.

Timely dissemination. The acceptable length of time for dissemination of surveillance data depends on the surveillance objectives and purpose (see below). Realistic timelines and consistent dissemination are key to the value and sustainability of a surveillance system.

Taking action. Information generated through surveillance activities is used to enable decisions regarding actions to control disease or modify the surveillance system. Usually, actions are related to a pre-specified disease threshold that should be defined as part of the surveillance system planning. Disease surveillance and control actions are thus tightly linked.

2.2.1 Organization of surveillance

The design of surveillance activities depends on the underlying objective(s) and the characteristics of the targeted host–pathogen system(s). Depending on the surveillance objectives, the surveillance design can range

from a single activity focused on one pathogen to a set of complex and continuous activities to address multiple pathogens. Thus, there is not a one-size-fits-all approach in surveillance design. Two levels of surveillance are useful to consider.

Surveillance component: the specific activity used to investigate one or more pathogens in a target population. Components are sometimes referred to as surveillance tools (Cameron, 2012) or activities; the tools include passive surveillance, representative surveys or outbreak investigations. An example of a passive surveillance component is the testing for PPR virus infection in small ruminant flocks with PPR-suggestive signs reported by farmers to veterinary officers. Another example of a surveillance component is a cross-sectional study, repeated annually, assessing the seroprevalence status of cattle against FMD virus in pastoralist herds transiting through a given province. Some of the surveillance components and how they relate to each stage of the PCP are shown in Table 2.1. Later sections of this document include a more thorough exploration of PCP stage-specific components.

Surveillance system: a range of surveillance components and the associated organizational structures used to investigate a single pathogen, such as FMD virus; a group of diseases with similar manifestations, such as vesicular diseases; or a threat, such as the detection of an emerging disease in a specified population. For example, a surveillance system may aim to detect the incursion of a new avian influenza variant in a country through two components: (1) the systematic sampling and testing of all poultry flocks reported to veterinary officers because of a sudden increase in mortality within the flocks; and (2) the monthly collection and testing of environmental samples from a set of live bird markets across the country.

TABLE 2.1
Relevance of each surveillance objective to each stage of the PCP process for TADs/FMD

Surveillance objective	Examples of surveillance components that may be used to achieve the surveillance objective	Likely relevance to PCP stages				Comments
		PCP Stage 1	PCP Stage 2	PCP Stage 3	PCP Stage 4	
Measure disease frequency	• Passive disease reporting • Testing of laboratory submissions • Clinical inspections at livestock markets and abattoirs • Abattoir meat inspection records • Representative surveys (e.g. serosurvey, bulk tank milk testing or environmental sampling)	x	x	x	x	Early in the PCP, the focus is on temporal and spatial disease distribution. In later PCP stages, surveillance will help assess the impact of control measures.
Detect cases of the disease to facilitate control	• Passive disease reporting • Testing laboratory submissions (national and international reference laboratories) • Outbreak investigations • Active surveillance (e.g. pre- and post-mortem examinations, market inspections, surveys)	x	x	x	x	Detecting cases may also allow circulating strains of virus to be identified and characterized. Rapid detection of new cases becomes more important as a country progresses along the PCP.
Demonstrate freedom from disease	• Repeated (sero)surveys to build confidence in freedom from disease or pathogen; may be risk-based			x	x	Disease freedom may be in a subpopulation initially (e.g. vaccinated, region/zone) and then progress to the full population.
Early detection of emerging pathogen/ disease	• Disease reporting • Outbreak investigations • Risk-based surveillance, including active surveillance testing programmes				x	Ongoing surveillance is important to rapidly detect re emergence of disease.

2.2.2 Conventional versus risk-based surveillance

Disease risk is unlikely to be uniformly distributed among the units forming a population (e.g. animals, herds/flocks, groups of herds/flocks). The likelihood of infection and spread, as well as the health and economic consequences of infection, may differ across the population. The purpose of a risk-based surveillance approach is to target high-risk populations. This targeting allows more efficient allocation of resources by focusing surveillance activities on unit selection based on disease risk factors such as environmental, animal management, and pathogen characteristics. In other words, the effectiveness of surveillance activities can be increased, while fewer units are selected and costs reduced, compared to a conventional approach which would rely on the random selection of units from the whole population. However, targeting surveillance requires prior knowledge about risk factors and the population at risk, and its design is biased towards a subset of units in the population. Therefore, different from a random survey, inferring the frequency with which a pathogen occurs in the target population can be complex, if achievable at all.

While adopting a risk-based approach can be tempting, given the promise of achieving a highly effective surveillance system at a lower cost, this approach has limitations. If access to information about a unit's disease risk is difficult and resource-intensive (e.g. time-consuming or demanding in terms of data analytics), risk-based surveillance may not be the most appropriate approach, and it may be advisable to revert to conventional surveillance based on the randomized selection of units. Likewise, if the estimated association between risk factors and disease, and the estimated distribution of these risk factors among units is unreliable and potentially biased, risk-based surveillance may perform poorly and its outputs be greatly misleading, jeopardizing efforts to mitigate disease risk. Risk-based surveillance should then be avoided. Therefore, the choice of a surveillance approach needs to be carefully considered, depending on its purpose and objective and the availability of reliable data. More information on risk-based surveillance can be found in Annex 1, Section 3.2.1.

2.2.3 Disease control strategic purpose

The disease control strategic purpose describes the broad reasons and policy goals that ultimately define surveillance: why it is needed, and how surveillance outputs will contribute to achieving policy goals. These purposes, which should be well described before designing surveillance, may include protecting animal health, welfare and public health; improving animal productivity and product quality; enabling trade; ensuring food security; and protecting the agricultural sector and the wider economy. Surveillance purpose should detail how, when combined with risk mitigation interventions, surveillance outputs will reduce the negative impacts of targeted disease(s) on animal health, economic activities and public health. Some specific ways in which surveillance information can assist policy-makers in their decisions follow.

Prioritization: to identify the pathogens to be targeted for further surveillance and disease risk mitigation interventions. Surveillance provides data on pathogen occurrence, which, combined with the estimated impact on animal health and welfare, public health, trade and other economic activities, can inform a ranking of pathogens based on their relative importance.

Trade considerations: to facilitate access to markets by assessing whether to permit the importation or exportation of animals or animal products. This decision should be based on risk assessment, applying evidence about the prevalence of pathogens in exporting areas and the likelihood of traded commodities spreading the pathogens in host populations in the importing areas.

Response to disease emergence: to facilitate rapid response to the emergence of a pathogen in a population by assessing whether additional risk mitigation interventions are required to limit its spread. As progress is made along the PCP, this aim is relevant to plan for the possible re-emergence of pathogens which may have been eliminated from a country or an area within a country.

Evaluating risk mitigation interventions: to assess whether existing interventions such as vaccination or movement controls should be stopped, maintained or changed to improve the efficiency of disease risk mitigation. This includes the confirmation that given pathogens are absent and that additional interventions to mitigate risks associated with these pathogens are not needed. Additionally, to provide data for the construction, parameterization and validation of disease transmission models to address specific questions related to intervention strategies.

2.2.4 Surveillance objectives

There are four main categories of surveillance objectives, which fall into two combinations, depending on whether the pathogen is present in or absent from the population of interest.

***If the pathogen is* present**

Measure disease frequency. This objective will provide information on the frequency of a specific pathogen's occurrence in defined populations and how this may vary temporally and spatially. This assessment can consider changes in the population structure, contact patterns, and the distribution of risk factors and herd immunity status. These changes may impact the distribution of pathogens and consequently affect the health status of underlying animal populations. This surveillance objective is particularly

likely to be associated with PCP stages 1 and 2 but may also be important in later stages.

Detect cases of infection/disease to facilitate control. This could apply to either an endemic disease or an investigation of a newly introduced pathogen. The interest is in finding infected units (e.g. animals, herds/flocks, groups of herds/flocks) to guide the implementation of disease risk mitigation interventions, such as vaccination, movement restrictions or culling. This second surveillance objective is particularly likely to be associated with PCP stages 2 and 3.

***If the pathogen is* absent**

Demonstrate freedom from disease. It is important for international trade purposes to provide evidence that a given pathogen is not circulating in a population. Note that evidence of absence (demonstrating that a pathogen is not circulating) is different from the absence of evidence (a lack of reports of a pathogen due to poor observation or detection). Effective surveillance ensures that confidence in the sanitary status and herd immunity status of exported animals and animal products is maintained, and that trade barriers are justified. This third surveillance objective is particularly likely to be associated with moving from PCP stage 3 to WOAH-recognized freedom.

Early detection of an incursion or emerging disease. This objective is to ensure that a pathogen's emergence in a population is detected quickly enough to enable its rapid containment before spread becomes difficult or impossible to control. Defining an acceptable length of time between emergence and detection depends on the pathogen, its potential to spread in and affect the health of the population of interest, available disease control tools (such as movement control, quarantine, vaccines and stamping out), and the capacity of the veterinary services to contain such spread. This objective depends on the country's contingency plan to handle early detection of the infection or the disease. This is particularly likely to be associated with PCP stage 4 and beyond.

These four objectives can help guide the choice and application of surveillance components in each PCP stage (Table 2.1). Components should be tailored to the progression of the control and prevention programme and its outcomes. For example, if the objective is to measure disease frequency, then a serological survey could be used to understand the spatial and temporal distribution in PCP stage 1, while a serological survey in PCP stage 3 could help understand vaccine effectiveness to assess herd immunity. More information on the components used to address PCP outcomes in each stage is provided later in these guidelines. Additional detailed background on components can be found in Annex 1.

2.3 PLANNING SURVEILLANCE

2.3.1 Strategic and operational surveillance planning

A surveillance system needs careful planning to meet the objectives of the disease control strategic planning and to be sustainable. An important aspect of planning is defining the disease cases (case definition), as well as the actions in response to surveillance results. Additionally, planning should be a dynamic process with regular assessment and revision as appropriate. Annex 1 describes several tools available to help guide the planning process.

There are two levels of surveillance planning: strategic and operational.

Strategic planning: A strategic plan is a high-level, integrated and cohesive plan that defines the vision, sets the directions, and outlines the fundamental surveillance objectives to be achieved in the long term (WHO, 2006). In the context of surveillance as part of the PCP, this strategy would apply to a period of 5 to 10 years. Surveillance strategic planning should relate to the specific aims of each PCP stage, considering the required threshold for a specific strategy. Key factors in setting surveillance strategic goals include:

- Ensure alignment with disease control goals for the PCP stage, including outcome indicators for measuring progress.
- As per the objectives, define the livestock and geographical areas of concern for surveillance activities (see "Defined populations" above).
- Identify the technical and administrative human resources and institutions responsible for designing, coordinating, and implementing each surveillance component.
- Identify legal and administrative authorities and state their roles and responsibilities.
- Reality check: assess capabilities and resources, including human and financial resources, and ensure that resources are available and aligned with the goals.

Operational planning: Operational planning involves translating the strategic plan into specific and measurable tactical tasks required to achieve the strategic goals, setting realistic targets over reasonable time frames, quantifying the costs of implementing the planned activities, and allocating/distributing responsibilities. Operational planning usually covers a relatively short period, such as 12 months, after which it is reviewed and revised. In the context of the PCP, operational planning refers to the components conducted within each PCP stage to achieve that stage's aim and can include development of information to move to the next stage.

2.3.2 Developing a surveillance action plan in the context of the PCP

Developing the surveillance action plan and the strategic and operational planning requires specifying strategic goals and short-term tasks and ensuring they are aligned. In the context of the PCP, important elements to be clearly defined for the action plan are:

- strategy purpose – align with PCP stage (outcomes) (see above);
- surveillance objective – align with PCP stage (outcomes) (see above);
- case definition – an essential part of basic surveillance;
- data sources and sampling methods (data collection methods and sampling frame: representativeness, inference);
- availability of diagnostic tests and other measurements of the pathogen(s) under consideration – likely to be disease-specific;
- activities to achieve these objectives (WHO, 2006);
- measurable and realistic targets (WHO, 2006);
- technical/human resources, including persons responsible for implementation of activities (WHO, 2006);
- financial requirements and sources; and
- time frame for implementation and milestones for measuring outputs and outcomes.

Several tools are available to help guide surveillance planning at both the strategic and operational levels (Annex 1).

2.4 EVALUATION OF SURVEILLANCE

Evaluation is a process of critically investigating a system to determine what is working well and what can be improved to better inform animal health programming decisions (FAO, WOAH and WHO, 2019). The aim of the evaluation is to: (1) inform the strategic and operational (planning/design) processes; (2) assess the progress made when surveillance is implemented and add corrective measures if needed; and (3) document the success of the surveillance activities and demonstrate the value of the investment.

In a PCP, a clear sequential series of steps takes a population from a disease situation of concern to a low- or no-disease situation. At each step, the surveillance activities have a distinct purpose with a clearly defined information objective.

The activities need to ensure that the surveillance system is fit for purpose, working effectively, and delivering value for money. Thus, the surveillance must undergo regular systematic and objective assessments of its relevance, adequacy, progress, efficiency, effectiveness and impact, relating to the objectives and considering the resources and facilities used.

An evaluation considers which PCP stage a programme is at and the corresponding surveillance objective, the context of the surveillance, and the indicators that determine whether the surveillance system is operating as desired. Available resources must also be factored in. All these criteria require the design of comprehensive, practical and affordable evaluation plans to assess selected attributes and the wider factors that influence the performance and value of the system. The degree of complexity and resources needed will increase with the scale and depth of evaluation.

Several free tools, guidelines and frameworks can assist with surveillance evaluation; many can be tailored to fit the context of the evaluation. The Surveillance and Information Sharing Operational Tool of the Tripartite Zoonoses Guide provides links (see Table A1.3 in Annex 1).

2.5 SUMMARY

This section has defined animal health surveillance, emphasized the need for careful planning and objective setting, and indicated why periodic evaluation of surveillance is important. In the next sections, we will examine each stage of the PCP and apply the concepts from this section using FMD surveillance and control as an example.

Surveillance monitoring and evaluation

Monitoring and evaluation are processes that work together to help measure system performance. While evaluation seeks to assess the effectiveness of surveillance activities, monitoring can similarly be employed to guide surveillance activities by tracking their progress towards the intended objective. Monitoring information is generally measured regularly by those within the system to check that activities are proceeding as planned. While the primary focus of material in this section relates to evaluation, the majority also applies to monitoring.

Source: UNDP, 2009

Section 3

Surveillance in PCP stage 1

3.1 OVERVIEW

This section includes three parts:

- an introduction on the purpose of PCP stage 1, including background information used to initiate a situation analysis;
- an overview of the outcomes of PCP stage 1 and surveillance objectives and components linked to PCP outcomes; and
- a description of the specific activities (farmer reporting, representative surveys and participatory surveillance) for use in PCP stage 1.

3.2 INTRODUCTION

The purpose of stage 1 is to understand the disease ecology and epidemiology to develop an approach to reduce the disease impact. During stage 1, activities are implemented to systematically collect and analyse all relevant baseline information; this is also called a situation analysis. The situation analysis considers all components of the epidemiological triad (host, agent and environment) that interact in a variety of complex ways to produce disease. The information is analysed to identify and describe the risks contributing to the introduction and spread of disease and applied to develop a strategy to mitigate those risks and improve disease control.

Surveillance components (activities) are essential to provide information, including:

- spatial and temporal distribution of the disease (number of cases per month per district);
- prevalence of disease in the different subpopulations (per susceptible species or livestock sector);
- potential associated risk factors; and
- circulating serotypes and strains.

Review of existing surveillance components or research studies is important at this early phase to assess available data and relevant information. It is also important in identify key knowledge gaps. During this stage, the country should take stock of current surveillance efforts, define surveillance needs, identify sustainable and feasible surveillance components, and continually update this information.

3.3 THE RELATIONSHIP OF PCP-FMD STAGE 1 OUTCOMES WITH SURVEILLANCE

Surveillance in stage 1 should generate information to understand the epidemiology of the disease and support the defined PCP-FMD outcomes. Nine outcomes are defined in stage 1 to guide countries. Good alignment of the surveillance system with desired outcomes is critically important. For example, PCP-FMD outcome 1 is a value chain analysis. Data compiled to meet the outcome can be used to plan surveillance; they include susceptible species demographics, trade patterns and animal movements. There will also be an opportunity to verify data during surveillance activities (Table 3.1). Outcome 2, understanding the distribution of FMD in the country, will depend on information obtained from implemented surveillance components, including outbreak patterns, serosurveys and participatory surveillance (highlighted in the second column of Table 3.1).

Information resulting from surveillance is critical to the achievement of stage 1 outcomes 2, 4 and 7 (highlighted cells in the right-most column of Table 3.1). These components will be discussed in the following sections.

3.4 SURVEILLANCE COMPONENTS TO MEET INFORMATION NEEDS FOR PCP STAGE 1 OUTCOME 2

Outcome 2. The distribution of FMD in the country is well described and understood

3.4.1 Compile existing information

PCP stage 1 should begin with compiling and summarizing all available (historical) surveillance information, focusing on the previous 5 years. The following information may be available:

- number of outbreaks per month/year (may be summarized with a bar chart);
- number of outbreaks (or FMD incidence rate) by province/district (visualize on a map);
- number of outbreaks (or FMD incidence rate) by species and/or production sector;
- proportion of outbreaks and cases confirmed clinically versus laboratory confirmed; and
- identification of the circulating serotypes and most important viral strains.

Gaps in information should be identified and surveillance planned to fill these gaps.

TABLE 3.1
The relationship of PCP-FMD stage 1 outcomes with surveillance (highlighted cells include surveillance components used to address stage 1 outcomes)

PCP-FMD stage 1 outcome		Surveillance relationship with PCP outcome
1	All husbandry systems, the livestock marketing network and associated socioeconomic drivers are well described and understood for FMD-susceptible species (value chain analysis)	• Data on FMD-susceptible species, importation of animals and animal products, and animal movement used to guide stratification of surveillance data • Data collected during surveillance implementation can be used to validate or enhance understanding of the value chain
2	The distribution of FMD in the country is well described and understood	• Collation of FMD outbreak reporting from all regions/areas in the country through farmer disease reporting/passive surveillance • Representative surveys (serological survey to assess seroprevalence of FMD virus in different husbandry and/or production systems – non-structural protein [NSP] survey) • Participatory epidemiology studies
3	Socioeconomic impact of FMD on different stakeholders/livestock production systems have been estimated	• Surveillance data may be used to describe and determine the impact of direct losses in husbandry production system due to FMD • Understanding the socioeconomic impact can guide programme interventions and surveillance system requirements
4	The most common circulating strains of FMD virus (FMDV) have been identified	• Outbreak investigation and sample collection from different production sectors for diagnostic analysis • Samples shipped regularly to a WOAH/FAO reference centre for virus characterization
5	There has been progress towards developing an enabling environment for control activities	• Successful implementation of surveillance components is supporting evidence of an enabling environment • FMD should be a notifiable disease to enable passive surveillance. A competent veterinary service and stakeholder coordination and cooperation are essential to identify and diagnose cases within an outbreak
6	The country demonstrates transparency and commitment to participating in regional FMD control initiatives	• Surveillance results from stage 1 can be used to develop control initiatives • Surveillance information should be shared with national and international stakeholders to reduce disease spread and allow more effective risk-based control (e.g. by ensuring vaccines used are matched to circulating strains)
7	Important risk hotspots for FMD transmission and FMD impact are identified, and a "working hypothesis" of how FMDV circulates in the country has been developed	• Representative surveys • Outbreak investigations • Participatory surveillance
8	Identification of potential synergies with other TAD control initiatives	• Surveillance activities, as well as investments to improve surveillance capacity, can often be combined with those for other livestock diseases such as PPR, Sheep and Goat pox or brucellosis • Overview of the national or regional surveillance to assess the incorporation of FMD surveillance in existing relevant activities
9	A written Risk-Based Strategic Plan to reduce the impact of FMD in at least one zone or husbandry sector is developed	• Use surveillance information to develop the strategic plan and advance to PCP stage 2 • Risk-based information can guide approaches to surveillance in later PCP stages

3.4.2 Passive disease surveillance

Passive disease surveillance (farmer reporting) is likely to be the most important surveillance component in stage 1. As such, it should be assessed and strengthened during this stage. As a pre-condition, FMD should be a notifiable disease. Passive surveillance has several advantages:

- lower cost than active surveillance options, and it provides continuous, complete coverage of the population;
- farmers are well placed to detect disease in their animals because they observe them more frequently than animal health professionals such as veterinarians or paravets/community animal health workers; and
- it is most effective when clinical signs are obvious.

The main disadvantage of passive surveillance is that it may lead to an inaccurate picture of the disease distribution. This inaccuracy could be due to under- or over-reporting, which may be uneven across the country and in different livestock sectors, leading to a biased result. Under-reporting can occur for many reasons, including lack of awareness and incentives, or barriers such as inconvenience, stigma and punitive control measures. Over-reporting can occur when other endemic diseases with similar clinical signs are present. During PCP-FMD stage 1, these issues should be identified, and efforts made to mitigate them. Reporting of suspected cases should be encouraged through awareness-raising activities, streamlining communication and removing barriers.

Case definitions must be developed to accurately describe the disease distribution across time, space and production systems (Table 3.2). While laboratory confirmation of cases is preferred, it may not be feasible to conduct laboratory testing of all suspected cases. If laboratory capacity is limited, prioritize clinical cases without a known epidemiological link to another outbreak and cases with unusual clinical signs. An effort should be made to ensure that all geographical regions of the country are represented over the course of a year.

To optimize the value of passive surveillance and ensure it will be suitable to compare across the country, information should be recorded on a standard form, preferably in digital (electronic) format.

Suggested data elements that could serve as the foundation for a questionnaire include the following.

Data elements for passive surveillance

- Name and position of person(s) who received and responded to the report
- Date and location (x, y coordinates) of suspected cases
- Information about the owner (name, address, phone number, etc.
- Information about the animals (total number of susceptible animals present, broken down by species and age)
- History, including number of animals with clinical signs, their demographic data (age, breed, etc.) and a brief description of clinical signs
- Action taken by the responder (premises visited, investigation performed, samples taken, etc.)
- Outcome (diagnosis, measures implemented)

If disease reports are received and managed at subnational level (e.g. at district or provincial offices), clear procedures must be developed to ensure that the reports from across the country are centrally compiled regularly – for example, monthly.

TABLE 3.2
Example of a case definition for FMD

Unit of analysis		Example of case definitions for FMD
Animal level	Suspect case	In ruminants and/or pigs, lameness and/or salivation together with decrease of appetite, lethargy
	Clinical case (bovine)	Animal health professional (veterinarian or para-veterinarian) confirms increased salivation and any of the following additional clinical signs: mouth lesions (vesicles or ulcers), feet lesions, teat lesions, fever, reduced feed intake and lameness (Armson *et al*., 2020)
	Confirmed case	FMDV isolated OR positive polymerase chain reaction (PCR) result OR positive antigen enzyme-linked immunosorbent assay (ELISA) result
Epidemiological unit level (i.e. herd, village, crush)	Outbreak	• The occurrence of FMD in one or more animals in an epidemiological unit • All cases detected within 2 weeks from the most recent case on the epidemiological unit are considered part of the same outbreak (Qiu, 2017)

Monthly situation reports should present the data in a way that enables comparison to detect changes in level of disease over time, geographically or related to other risk factors. The report should include the same information as in the historical data report.

Examples of information for monthly disease reporting

- Number of outbreaks detected each month (bar chart)
- Number of outbreaks by province/district (table and map)
- Number of outbreaks by species and/or production sector (table or pie/bar chart)
- Proportion of outbreaks and cases confirmed clinically versus laboratory confirmed
- Identification of the circulating serotypes and viral strains

3.4.3 Representative serological survey

If resources are available for a representative survey component, a national serosurvey is useful to establish an indication of virus distribution that can act as a baseline for future monitoring. Serosurveys can assess the prevalence of animals with antibodies for foot-and-mouth disease virus (FMDV). Antibodies are an indicator of past infection or vaccination. Serosurveys can provide a more accurate picture of FMD distribution than passive surveillance because they do not rely on noticing and reporting clinical signs of disease. Therefore, previous infection (either subclinical or mild infection) can be detected in animals. During PCP-FMD stage 1, there are unlikely to be substantial changes to disease control interventions and no reason to expect substantial changes in infection prevalence. Consequently, there may be no need for more than one national survey in this stage. In PCP-FMD stage 2, an additional representative survey may be needed (see Section 4). Surveys can be difficult to implement to ensure that they are meaningful and unbiased, so we recommend that an epidemiologist be involved in the survey design and analysis.

Antibodies can persist for years, so a positive result could mean the animal was infected last week, last month or last year. It is critical to record the animal's age to properly analyse the serosurvey. If the objective of the survey is to estimate the prevalence of recent infection, then only young animals should be sampled (less than 12–18 months). The serum collected can also be tested for other diseases of interest such as PPR.

For FMD specifically, purified vaccine will not induce non-structural protein (NSP) antibodies, so animals with NSP antibodies are considered to have been infected, even if vaccinated with a purified vaccine. However, use of non-purified vaccines prior to or during PCP stage 1 may induce NSP antibodies, so serosurvey results should be interpreted with caution.

The survey should also collect information on risk factors. Common risk factors include vaccination status, age, exposure to common grazing, movement, and markets (see PCP outcome 7 below).

3.4.4 Participatory surveillance

Participatory surveillance is an active surveillance component in which specifically trained veterinary staff search for a disease syndrome to explore local knowledge about a disease. This will improve the understanding of the disease situation and/or detect outbreaks.

Participatory surveillance involves conducting group interviews with livestock keepers at the village or community level, together with observation of flocks/herds, examination of clinical cases, and investigation of any suspected cases of the disease of interest. It can also be carried out at livestock markets or other places where livestock keepers come together.

This surveillance approach is a very powerful tool for investigating the spread of diseases in a population and can also be used to detect active outbreaks.

Additional sources of information on participatory surveillance

- Manual 5 Surveillance and epidemiology (OIE, 2018)
- FAO Animal Health Manual 10 – Manual on participatory epidemiology – method for the collection of action-oriented epidemiological intelligence (FAO, 2000)
- Participatory Epidemiology Network for Animal and Public Health (PENAPH, 2022)
- Outcome (diagnosis, measures implemented)

3.5 SURVEILLANCE COMPONENT TO MEET INFORMATION NEEDS FOR PCP STAGE 1 OUTCOME 4

Outcome 4. The most common circulating strains of FMDV have been identified

As there is no cross-protection between serotypes (and even some strains within serotypes), it is crucial to know which serotypes and strains are circulating to inform vaccine selection.

3.5.1 Outbreak investigations

Suspect cases identified during passive or active surveillance should be examined under the outbreak investigation component. Unless FMD can be ruled out based on the history and clinical signs, samples should be taken for laboratory testing if possible. Some laboratory tests, but not all, are able to identify the causative serotype. For more information about sample collection, submission and testing, consult the laboratory's operating instructions (Annex 1).

For many countries in PCP-FMD stage 1, it will not be feasible to submit samples from every outbreak to a laboratory. In this situation, it should be a priority to collect samples from outbreaks where it is more difficult to infer the likely serotype or if you suspect a novel serotype or strain, specifically:

- outbreaks that are not linked to spread from an outbreak from which samples have already been taken – usually this means collecting samples from outbreaks at a large distance from other outbreaks, or areas where an outbreak has not been reported for a month or more; or
- outbreaks with a history of vaccine failure (i.e. animals that have been recently vaccinated are exhibiting clinical signs) or an unusual clinical presentation.

Outbreak investigation can provide much more information than confirming the diagnosis, including identifying source, spread tracing, identifying risk factors, measuring the impact of FMD, and assessing control measures. The use of the outbreak investigation in PCP-FMD stage 2 focuses on this broader use of the outbreak investigation component (see section 4.7.1). For further information on outbreak investigations, see Annex 1.

Countries should ship samples regularly to a WOAH/FAO reference laboratory for further characterization (sequencing) to identify the topotype and lineage. The samples should be selected to represent all regions of the country where FMD is circulating and include all serotypes if more than one serotype is circulating.

3.6 SURVEILLANCE COMPONENT TO MEET INFORMATION NEEDS FOR PCP STAGE 1 OUTCOME 7

Outcome 7. Important risk hotspots for FMD transmission and FMD impact are identified, and a "working hypothesis" has been developed for how FMDV circulates in the country

Risk hotspots are points in animal production with a high risk of FMD entry or spread. These hotspots can be geographical areas or a farmer's behaviour or management practice. Successful completion of outcome 7 relies on information from surveillance activities that support other stage 1 PCP outcomes (i.e. representative surveys, outbreak investigations and participatory surveillance). The geographical distribution of seropositive epidemiological units from a serologic survey, as well as positive epidemiological units from passive surveillance and outbreak investigations, directly contribute to identifying important geographic risk hotspots using spatial analysis techniques (Munsey *et al.*, 2019).

A representative survey based on clinical signs can also be used to identify hotspots and contribute to the understanding of animal or other associated movements linked with virus circulation. A representative survey also can provide information that helps identify behaviour or husbandry risk factors and how they are distributed in the population. Surveillance information, including variables such as age of animal, vaccination status, presence of clinical signs, animal trading patterns, and husbandry system information, can be statistically compared to assess risk characteristics (Emami *et al.*, 2015).

Information on risk hotspots is essential to develop a control strategy to mitigate these risks. Moving into PCP-FMD stage 2 (PCP stage 1 outcome 9) requires creating a risk-based strategic plan (FAO and EuFMD, 2020).

The design of surveillance should also support risk-based control efforts. Sections 4 and 5 provide more detail on incorporating risk into surveillance.

3.7 SURVEILLANCE COMPONENT TO MEET INFORMATION NEEDS FOR PCP STAGE 1 OUTCOME 8

Outcome 8. Identification of potential synergies with other TAD control initiatives

To best use the limited resources available for disease surveillance, it is important to find synergies with other disease prevention and control initiatives. During stage 1, strengthening passive surveillance should also benefit surveillance for other notifiable diseases. Education on clinical signs of these additional diseases could be combined with education on the primary disease of interest. Active surveillance components can also provide information for multiple diseases. For example, serum samples collected in a seroprevalence study for one disease also may also be tested for other diseases. If properly stored, samples can even be tested retrospectively. Similarly, risk-factor data on animal populations, movements and husbandry practices collected from representative surveys or outbreak investigations are likely to be relevant for several diseases. An important caveat is to carefully consider whether the survey design is appropriate for the FMD objective. As diseases differ in epidemiological characteristics (e.g. susceptible species, expected prevalence), the survey design may not always be transferable.

3.8 SUMMARY

Surveillance in PCP stage 1 is intended to provide information on the epidemiology, including the spatial and temporal distribution and risk factors for disease introduction or spread. Available animal health information should be the starting point for a situation analysis. Passive disease surveillance (reporting by farmers) is the initial component recommended to help address surveillance objectives. Additionally, representative surveys can be used to provide a broad, unbiased examination of disease distribution and risk factors. Participatory surveillance can be useful for investigating disease spread.

Section 4

Surveillance in PCP stage 2

4.1 OVERVIEW

This section includes three parts:

- an introduction to the purpose of PCP stage 2, including background on the scope of surveillance based on the impact of disease interventions;
- an overview of the outcomes of PCP-FMD stage 2 and the surveillance objectives linked to the PCP outcomes; and
- a description of specific activities for PCP-FMD stage 2, including background on the scope of surveillance based on the impact of disease interventions.

4.2 INTRODUCTION

The framework for a surveillance system and its components in stage 2 is based on surveillance components initiated in stage 1. As in stage 1, surveillance must be designed to meet the information needs to support PCP stage 2 outcomes. Additionally, the surveillance system designed for stage 2 applies to other TADs that may not have fully developed PCPs.

While the broad goal of PCP stage 1 is to understand the epidemiology of the disease in the country, the goal of surveillance in stage 2 is to assess a set of disease control activities the country is implementing. The endpoint for control measures in this stage is to reduce the impact of disease and not necessarily to achieve disease freedom status. Assessment of disease control efforts is important, especially for diseases such as FMD where eradication is a challenging objective, to realistically allow individual countries to balance investments made with results achieved. The surveillance system in PCP stage 2 can provide information to enable moving to PCP stage 3.

4.3 RELATIONSHIP OF PCP-FMD STAGE 2 OUTCOMES WITH SURVEILLANCE COMPONENTS

The key PCP-FMD stage 2 outcomes are directly based on findings from the situation analysis, surveillance results and risk assessment from stage 1 that lead to the categorization of different farming systems according to the assessed or perceived risks (Table 4.1). All seven of the PCP outcomes in stage 2 require ongoing surveillance information, except outcome 3. Outcome 3 is an intervention based on information from PCP-FMD stage 1. Surveillance components that support stage 2 outcomes 1 and 2 were developed in stage 1 (see Section 3) and can continue into stage 2 with some modification.

However, stage 2 outcome 4 requires substantial change or enhancement to the sampling approach and the required disease information, including disease investigations/outbreak investigations. Changes in the representative sample of the population would also provide additional information for stage 2 outcome 2. Stage 2 outcomes 5, 6 and 7 depend on compilation of the surveillance components implemented for the stage 1 outcomes. The next sections cover the surveillance components for PCP-FMD outcomes 1, 2 and 4 (highlighted in Table 4.1).

4.4 DETERMINING THE POPULATION OF INTEREST

Prevention and disease control activities may not be uniformly applied to animal populations. Different strategies can be applied, when appropriate, to specific subpopulations. The selection of a subpopulation for a prevention and control programme could be viewed from two different perspectives: (1) acquiring a comprehensive understanding of the epidemiological dynamics of a specific disease, which allows identification of a subpopulation most likely to play a major role in the maintenance and spread of the agent across other subpopulations; or (2) focusing solely on the subpopulation exhibiting the severest disease impact. The prevention and control programme objective must be clearly stated because it will define surveillance requirements.

With the first perspective, the prevention and control programme may expect to benefit not only the target subpopulation but also the rest of the animal population. However, with the second subpopulation option, this secondary disease control effect may not be expected outside of the target subpopulation. A surveillance programme would need to be broader if measuring potential secondary effects, as with the first perspective, compared to a more focused surveillance when secondary control effects are not expected.

There are examples of both approaches to selecting a subpopulation and the breadth of expected prevention and control programme impacts on levels of disease. In one example, based on a preliminary risk assessment, the nomadic farming system was assumed to play a major role in maintaining and spreading PPR, such that vaccination was expected to create a secondary beneficial effect in sedentary farming systems not specifically included in the vaccination programme. Consequently, the vaccinated subpopulation and the sedentary farming system would need

TABLE 4.1
The relationships of PCP-FMD stage 2 outcomes with required surveillance components

PCP-FMD stage 2 outcomes		Surveillance supporting PCP outcome
1	Ongoing monitoring of FMD risk in different husbandry systems	• Collation of FMD outbreak reporting from all regions/ areas in the country (farmer disease reporting/passive surveillance) • Active surveillance; actively recruit FMD cases through disease investigation • Representative surveys (serological survey to assess seroprevalence to FMD virus in different production husbandry systems; NSP survey) • Participatory epidemiology studies; building an active recruitment of FMD cases directly from producers
2	Ongoing monitoring of circulating strains	• Disease investigation and sample collection from different production sectors for diagnostic analysis • Samples shipped regularly to a WOAH/FAO reference centre for virus characterization
3	Risk-based control measures are implemented for a selected sector or zone targeted, based on a risk-based strategic plan developed in stage 1	• Surveillance data evaluating risk-based measures used to document implementation (see outcome 1 surveillance components) • Proposed intervention strategies based on identified critical control points as part of the surveillance planning
4	It is clearly established that the impact of FMD is being reduced by control measures in at least some livestock sectors	• Enhanced disease investigation process • Representative sampling approaches for the required surveys • Monitoring post-vaccination, including serological surveys to assess immunity and coverage within the target population(s)
5	There is further development of an enabling environment for control activities	• Information from surveillance implementation, outcomes, and reporting used to provide evidence of an enabling environment • Crude analysis of surveillance findings focused on potential factors to facilitate further implementation of surveillance
6	Selected FMD control activities are combined with other TAD control activities	• Overview of national or regional surveillance to assess incorporation of FMD surveillance in existing relevant activities • Surveillance information to support integration of prevention and control programmes, including use of surveillance components to meet multiple objectives
7	A written official control programme is developed, aimed at eliminating virus circulation in a susceptible domestic animal population in at least one zone in the country	• Use surveillance information from other PCP-FMD outcomes to guide selection of intervention options • Review existing reporting formats for surveillance system with aim to apply the most suitable approaches

to be included in the surveillance programme to assess the impact of vaccination.

In Afghanistan, the dairy sector was identified as the main target for FMD control through vaccination. The programme was intended to control the disease in the dairy population because the disease was substantially impacting dairies. There were no expectations that this programme would have resulted in a decreased disease load in the general population. Other examples of interventions in a subpopulation with substantial disease impacts in the unvaccinated general population come from countries such as the Philippines and Uruguay. In these two countries, vaccination targeted specific species (pigs in the Philippines and large ruminants in Uruguay) as part of a prevention and control programme that ultimately resulted in disease eradication in the countries.

Implementing risk-based disease control measures (PCP stage 2 outcome 3) in selected sectors or zones influences the overall design of the surveillance activities. Surveillance should be designed to account for the nonhomogeneous application of prevention and control measures that might target only specific subsectors of the population at risk. At this stage it is essential to clarify the criteria adopted to enrol a specific farming system in the prevention and control system. For example, if vaccination is one of the major tools to control a specific disease, as it often is, then the criteria for being part of the population vaccinated should be explicitly stated. These criteria will create a distinction

between farming systems that are enrolled in the prevention/control system and those that are not, and surveillance should be the main tool to inform the extent to which the expectation of decreased disease/infection is achieved (PCP stage 2 outcome 4).

4.5 SURVEILLANCE COMPONENTS TO MEET INFORMATION NEEDS FOR STAGE 2 OUTCOME 1

Outcome 1. Ongoing monitoring of FMD risk in different husbandry systems

Surveillance components associated with PCP-FMD stage 2 outcome 1 are like those developed to address PCP-FMD stage 1 outcomes. The primary change would be to include collection of information associated with control measures that may have been implemented in animal populations. A notable change would be in the approach to representative surveys, a component that can be used to support PCP-FMD stage 2 outcome 4. The design of representative surveys for stage 2 is discussed in the outcome 4 section below.

4.6 SURVEILLANCE COMPONENTS TO MEET INFORMATION NEEDS FOR STAGE 2 OUTCOME 2

Outcome 2. Ongoing monitoring of circulating strains

The two surveillance activities supporting PCP stage 2 outcome 2 are: (1) disease investigations including samples collected from different production sectors for diagnostic analysis; and (2) regular shipping of samples to a WOAH/FAO reference centre for virus characterization. These activities parallel those established in PCP-FMD stage 1 and should continue in stage 2. Disease investigations supporting stage 2 outcomes are intended to address stage 2 outcome 4 (see below), but the activity will still provide information on circulating strains. However, interpretation of trends may need to be carefully assessed due to changes in collection methods and implemented control measures. Activities listed under outcomes 1 and 2 will most likely rely on passive surveillance, so raising awareness among farmers to encourage reporting is an essential activity to be carried on from stage 1.

4.7 SURVEILLANCE COMPONENTS TO MEET INFORMATION NEEDS FOR STAGE 2 OUTCOME 4

Outcome 4. It is established that the impact of FMD is being reduced by the control measures in at least some livestock sectors

4.7.1 Disease investigations

Disease investigation was a component previously used to accomplish PCP-FMD stage 1 outcomes 1 and 2 by generating information about disease frequency and distribution, and characterization of circulating strains. This utility highlights the dual purpose of outbreak investigation: (1) diagnostic, and (2) epidemiologic.

For diagnostic purposes, the activities are no different from those in stage 1, and investigators will look for animals with evident clinical signs or even dead animals from which to collect good-quality biological samples for laboratory testing.

For epidemiology, the utility of outbreak investigations is further expanded to better understand the dynamics of outbreaks and possibly inform the effectiveness of intervention measures (stage 2 outcome 4). The basic questions to be answered are: To what extent are clinical outbreaks occurring in the subpopulation covered by the prevention and control system? Is the impact on those subpopulations covered by the prevention and control system different from the impact on those not covered?

An additional important objective to enhance the methodological approach to outbreak investigations is to gather information, at any point, about the frequency of outbreak occurrences and the number of outbreaks considered active. Determining herd status might be challenging, because in addition to adopting criteria through which an outbreak is considered opened, criteria also need to be formulated to declare an outbreak closed.

Under a scenario where a stamping-out policy applies, the outbreaks can be considered controlled once all animals have been slaughtered and cleaning and disinfection of infected premises has concluded. However, if the disease control programme has not progressed to the point of stamping out or if policy cannot be applied (as in many low-income countries), deciding when an outbreak is considered closed (controlled) may not be straightforward. If observations are mainly based on clinical detection, an outbreak might be considered closed after detection of the last case, providing that no additional cases are detected after two or three maximum incubation periods are passed following the date of onset of the last case. The major drawback in closing cases in this manner is that silent cases can occur, which may require case enrolment approaches or surveillance testing for identification.

All the above information introduces additional complexity regarding the need for follow-up action once an outbreak is identified and confirmed. The minimum data required for this action are as follows: (1) estimated date and plausible source(s) of introduction; (2) date of onset; (3) date of notification; (4) evolution of the outbreak (follow-up to count new individual cases and deaths attributable to the disease); and (5) date of closure (Table 4.2).

Examples of training activities conducted by the EuFMD are available online. Although the training is specific to FMD, the methodological approach also can also be used for other diseases.

The dataset proposed for collection is aimed at building the timeline of events. If the individual epidemiological unit where the outbreak occurs is enrolled in a vaccination programme against the disease of concern, the date of vaccination is an important data point to be collected and evaluated against the possibility of vaccine failure (vaccine ineffective), as well as the decreased ability to detect the disease via passive surveillance. Specific forms should be designed to collect such data to include the indicators in Table 4.2. Examples of forms are provided in Annex 3.

Building such indicators can assist in defining possible targets, making comparisons, generating useful insights on the duration of infectivity of an outbreak, and measuring its impact.

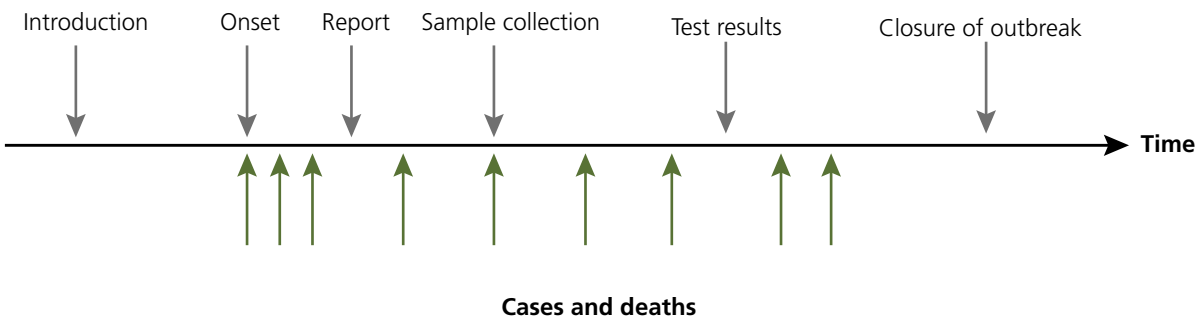
The sequence of events is summarized in Figure 4.1.

In this sequence, vaccination (if adopted as a preventive measure) can be inserted. This approach can provide useful information on whether vaccination delivery was carried out

TABLE 4.2
Suggested data elements for collection in disease/outbreak investigations

Data	Significance	Indicators	Interpretation
Date of introduction of the agent (or window period of introduction)	Indicates date (or window period) when agent has been introduced	This is the starting point for a thorough description of the outbreak's evolution	Can assist in identifying the event(s) associated with introduction of the agent
Date of onset	This date should correspond to the date when the very first cases were observed and the date of introduction	[Date of onset – Date of introduction = number of days from introduction to onset] This indicator may be a range of time, since the date of introduction may represent a window period	If the number of days clearly exceeds one maximum incubation period of the disease, it may mean that initial cases have been missed (early detection needs to be improved)
Date of notification	This is the date of disease notification to authorities	[Date of notification – Date of onset = number of days from notification to onset]	If the number of days is above a threshold (e.g. 2–3 days), it means there are delays in notifying cases (early notification needs to be improved)
Date of investigation/sample collection	Date of investigation and/ or when samples have been collected to confirm or rule out disease presence	[Date of investigation / sample collection – Date of notification = number of days passed before investigation/ sampling]	If number of days is too high compared to established targets or if no samples are collected, it indicates a delay in response (early response to be improved)
Date of availability of test results	Date when results have been made available by the laboratory	[Date results – Date of sampling = number of days before results available]	If the number of days required for results exceeds a pre-established target for the expected laboratory performance, then there is a delay in confirmation (early confirmation to be improved)
Counts of clinical cases and deaths from the onset to the date of closure	Such data are relevant to gain an understanding of the overall impact of the disease on morbidity and lethality	Morbidity rate (total number of clinical cases divided by the total number of animals at risk at the onset of the outbreak) Case fatality rate (total number of deaths divided by the total number of clinical cases) [under the assumption that deaths were related to the disease of concern]	The indicators proposed can inform about the severity of the disease and could be made more informative if morbidity and lethality are grouped by age
Date of closure of the outbreak	This date is intended to indicate the closure of an outbreak (no longer infectious)	[Date of closure – Date of introduction = number of days during which the outbreak has been active]	This number may vary according to the size of the epidemiological unit and can provide a useful indication of how long it takes to manage disease outbreaks

FIGURE 4.1
Hypothetical timeline for outbreak testing and closure



Source: Authors' own elaboration.

when the disease was already present. The vaccination process may take more than a single day, so you may need to insert a start date and an end date.

A challenging part of outbreak investigation is determining the window of exposure (i.e. the period during which the agent may have been introduced), which relates to identification of the index case(s). Importantly, the index case(s) may not necessarily be the case(s) that led to reporting the disease, but rather antecedent cases occurring prior to those that led to reporting. Refer to the available EuFMD training material regarding establishment of event timelines.

Evaluation of the disease impact in terms of morbidity and lethality requires the counting and timing of cases and deaths until the outbreak may be considered closed. This tracking may be a challenging task. Ideally, if the workforce is available, a veterinarian should be assigned to this task. The veterinarian would establish a process to periodically contact the farmer and obtain updates about new cases and deaths (e.g. mobile phones are widely used). Simple forms can be created for this purpose.

If silent cases occur, it may be challenging to establish when an outbreak can be considered closed. Under such circumstances, outbreak closure based only on clinical detection may fail. Serology could assist in establishing closure as described here. Assume, as an example, that two incubation periods have passed since the last clinical case was detected. Serum samples can be collected from animals that have not shown clinical signs during the outbreak. If animals without clinical signs are not available, then it is suggested to sample at least 30 animals. These animals should be re sampled after at least 21 days. Ideally there may be a few seronegative animals; if those detected during the first round remain negative for NSP upon retest, the outbreak may be considered closed (no more incident cases detected). The serological results of the animals sampled 21 days apart can be used to assess the presence of new silent cases.

4.7.2 Representative surveys in targeted subpopulations

The representative survey components can build on information gathered in PCP-FMD stage 1 and can complement information generated through the enhanced outbreak investigations described above. The purpose is to better understand the health status of the farming system(s) or geographical area covered by the prevention and control programme. Results of the survey could be used to assess whether disease/infection prevalence is declining in the epidemiological units enrolled by the prevention and control programme. Since these surveys are intended to broadly assess the programme's impact, they should only be implemented after an appropriate period has passed since the introduction of vaccination or any other risk mitigation measure. For example, a country may decide to implement such surveys 6 months or 1 year after implementation of a vaccination programme or vaccination campaign. The survey should assess subsequent changes after the intervention(s). It may be important to focus on the animals born after the introduction of such a mitigation measure. While it is expected that the passive surveillance system will capture the occurrence of clinical cases, such a system may not be sensitive enough to capture milder cases of disease, especially if animals have been vaccinated.
Serology might be the appropriate diagnostic tool, and the animals sampled for testing could be the generation born after the last vaccination campaign (see post-vaccination monitoring below).

Such surveys are much more informative if they allow for a comparison, and this might be accomplished in two ways: (1) use as a baseline the seroprevalence level of disease/infection at the start of the preventive programme and observe whether a progressive reduction results; or (2) use a case-control approach where, in addition to enrolling farms/epidemiological units where vaccination has been

carried out (case), also collect data from those where vaccination was not applied (control).

Since vaccination has been implemented by this time as part of control efforts, it is important to consider the potential serological results (see Annex 2, "Guidelines for conducting a serological survey to assess the distribution of FMDV in a population"). In both approaches, recording the age of the animal sampled remains of extreme importance. In PCP stage 2, since the removal of clinical cases can be considered a major outcome, the absence of animals with clinical signs should be recorded.

An appropriate design for a seroprevalence survey would include two-stage sampling as earlier addressed for stage 3. The most important difference (and implication) is that the design and sample size should be powerful enough to detect differences considered important. Many resources provide information on design (Cameron, 2012; Cameron *et. al.*, 2003).

Minimum information to collect during representative survey

- Owner's personal contact information (address, phone number)
- Date of enrolment in prevention and control programme (if vaccination is used, this date would be the date of last vaccination)
- Total number of susceptible animals present (divided by species and age groups, if disease of concern can affect different species)
- Retrospective assessment if clinical signs were observed since the risk mitigation measure was introduced (if vaccination was carried out, this would be the date of last vaccination)
- Total number of existing animals born after introduction of risk mitigation measure (if vaccination was used, depending on time of survey, some animals may still be unvaccinated and thus a good target)
- Date of sampling
- List of individual animals sampled (if individual identification is available, indicate this), along with the specific age of all individuals sampled
- Vaccination status (if applicable)

4.7.3 Surveillance system checklist for surveillance components related to outcome 4

Component: Disease/outbreak investigations checklist to follow up on detected outbreaks

Below is a practical checklist that may be helpful as you develop investigations.

- ☐ Has a case definition been developed? (This may differ depending on whether epidemiological units are enrolled in the prevention and control programme.)
- ☐ Has a specific notification form been designed?
- ☐ Has the flow of the notification form been clearly defined?
- ☐ Does the notification form clearly distinguish outbreaks by whether the epidemiological unit of concern is covered by the prevention/control system?
- ☐ Has a system been designed to archive the reporting forms?
- ☐ Does the reporting form have a clear link with the diagnostic system (especially if a confirmed outbreak is based on laboratory confirmation)?
- ☐ Has the frequency of outputs to be produced been defined?
- ☐ Has a definition of a confirmed outbreak been written?
- ☐ Has a follow-up form been developed to collect data in the confirmed outbreaks?
- ☐ Does the follow-up form have a clear link with the notification system?
- ☐ Have criteria been defined for when an outbreak can be considered opened/closed? Is there a need to use serology to formally close an outbreak?
- ☐ Has the flow of data been defined?
- ☐ Has an archive of the follow-up forms been developed?
- ☐ Have the outputs of the follow-up forms been defined and dissemination determined?

Annex 1 provides details on disease/outbreak investigations, and Annex 3 includes an example of an outbreak investigation form.

Component: Implementing surveys to check health status on epidemiological units enrolled in the prevention and control programme

- ☐ Has a list of all epidemiological units enrolled in the prevention and control system been prepared with complete address and contact numbers of all livestock keepers?
- ☐ Has a case definition been developed?
- ☐ Has a form to collect information been developed?

- ☐ Have criteria been developed to determine which specific animals will be tested?
- ☐ Has a decision been made on production frequency of outputs of this activity and on dissemination?
- ☐ Have leaflets and brochures been developed for livestock keepers to facilitate reporting of events associated with the disease of concern?

4.7.4 Post-vaccination monitoring

Post-vaccination monitoring can occur at multiple levels and can look at vaccine quality, programme objectives, immune response and the impact of the vaccination programme.

In the context of PCP stage 2 outcome 4 and surveillance, the post-vaccination monitoring could be integrated into multiple activities, including representative surveys and outbreak investigations. For details on designing surveillance, see Ferrari *et al*. (2016).

4.8 SUMMARY

Surveillance in PCP stage 2 is intended to provide information on the impact of the prevention and control system introduced at this stage. Such a system was assumed not to be present during stage 1. The available resources may dictate that only a subpopulation of the susceptible animals will be enrolled in the prevention and control system (usually vaccination is the choice). Consequently, the surveillance system should inform a comparison of the level of disease/infection observed among those enrolled with those that are not enrolled. This objective can be achieved by combining various components of the surveillance system and can be added to components implemented in stage 1.

Section 5

Surveillance in PCP stage 3

5.1 OVERVIEW

This section:

- introduces the purpose of PCP stage 3, outlines the outcomes of this stage linked to surveillance objectives and components, and describes the progression of surveillance components over time;
- describes the structure of specific surveillance activities: clinical inspections, environmental surveillance, serological surveys (random and risk-based) and the corresponding follow-up investigations; and
- describes additional sources of evidence to monitor the control programme and disease presence/absence such as assessing vaccination coverage, herd immunity and wildlife surveillance; it also considers the application of the discussed surveillance activities for multiple TADs.

5.2 INTRODUCTION

The focus of PCP stage 3 is progressive reduction in both the number of outbreaks and virus circulation in at least one zone of the country that may lead to disease freedom.

Moving to this stage indicates a strong commitment to progress towards elimination of disease and subsequently infection. A country at this stage implements an official control programme aiming to eliminate virus circulation either in the country or in a specified zone. Therefore, surveillance activities in stage 3 should focus on monitoring and evaluating the effectiveness of this control programme and ensure rapid detection of and response to all outbreaks.

A prevention and control programme would implement measures/activities to mitigate the risk of virus transmission, reducing the virus reproduction ratio. A well-structured veterinary service with adequate resources to ensure high geographical and farm/animal population coverage is a solid basis for the implementation of surveillance and control measures in the country or zone under the programme.

The main control activities implemented in such a programme are:

- prophylactic vaccination if applicable;
- reliable biosecurity measures to prevent transmission between herds – these measures could include quarantine of infected herds when incidence of infection is still high;
- appropriate traceability of animal movements; and
- effective detection of infection and rapid response.

This activity, which occurs under low prevalence conditions, requires implementation of a surveillance system with high overall sensitivity, including increased herd-level sensitivity (capacity to reduce the delay in finding herds in early stage of infection). At this level, response measures to control detected outbreaks could include slaughtering infected animals or entire herds if feasible.

5.3 THE RELATIONSHIP OF PCP-FMD STAGE 3 OUTCOMES WITH SURVEILLANCE COMPONENTS

The objective of PCP stage 3 – reduction in both the number of outbreaks and virus circulation – directly influences stage 3 outcomes (Table 5.1). The supporting surveillance components must address both the change in disease status and the need to achieve PCP-FMD stage 3 outcomes. Many surveillance activities will continue from stages 1 and 2 but will progressively change to address the need for rapid detection and response in a reduced disease prevalence environment. Surveillance components for PCP-FMD outcomes 1, 2, 3, 5 and 7 are discussed in later parts of this section (highlighted in Table 5.1).

5.4 SURVEILLANCE COMPONENTS TO MEET INFORMATION NEEDS FOR STAGE 3 OUTCOME 1

Outcome 1. Ongoing monitoring of FMD risk in different husbandry systems

Surveillance components associated with PCP-FMD stage 3 outcomes resemble those developed to address stages 1 and 2 outcomes, but they must be modified to address lower disease prevalence that occurs in stage 3. The primary changes are in the use of representative surveys (see outcome 3, section 5.6), outbreak investigations (see outcome 2, section 5.5) and sampling at aggregation points. Farmer-based reporting described in Section 3 is an important component in a surveillance system, but the sensitivity of this activity decreases because of very low herd-level prevalence of infection and disease. Few animals show clinical signs, and farmers do not readily notice, particularly in large herds, and infection may start circulating subclinically in vaccinated populations. In this scenario, there is a risk that farmers will become less familiar with and then less aware of the disease, so there is less reporting. Therefore, a successful reporting component that supports ongoing monitoring of FMD risk requires disease awareness among farmers and other personnel handling livestock. Active clinical inspections on farms and at aggregation points (see outcome 2, section 5.5) may provide information in situations with low disease prevalence.

TABLE 5.1
The relationships of PCP-FMD stage 3 outcomes with surveillance PCP stage 3

PCP-FMD stage 3 outcome		Surveillance relationship with PCP outcome
1	Ongoing monitoring of risk in different husbandry systems	• Disease reporting by farmers (passive surveillance) • Representative surveys • Outbreak investigation • Participatory disease surveillance • Clinical inspections • Environmental sampling at aggregation points, bulk tank surveillance
2	The official control programme developed to conclude stage 2 and enter stage 3 is implemented, resulting in rapid detection of, and response to, all FMD outbreaks in at least one zone in the country	• Enhanced outbreak investigations • Clinical inspections and environmental sampling at aggregation points
3	The disease prevalence is progressively reduced in domestic animals in at least one zone in the country	• Disease reporting by farmers (passive surveillance), representative and risk-based surveys • Enhanced outbreak investigations • Participatory disease surveillance • Aggregation points, bulk tank surveillance
4	There is further development of an enabling environment for control activities	• Information from surveillance implementation, outcomes and reporting provides evidence of an enabling environment • Legislation, notification, regulatory frameworks, compensation • Monitoring policy studies using data from the surveillance system
5	There is a body of evidence that FMD virus elimination is progressively being achieved in domestic animals within the country or zone	• Evaluation of vaccination programme • Integration of all surveillance activities • Wildlife surveillance
6	Contingency (emergency preparedness) plans are available and ready for full implementation	• Outbreak surveillance approaches should be an important component of the emergency preparedness plan • Response when outbreaks are confirmed; planned mitigation measures to stop transmission from infected herds are defined • A written document of national preparedness and emergency plans for selected TADs
7	Some FMD control activities are combined with other TAD control activities	• Broad integration of surveillance programmes across multiple diseases
8	The country has received endorsement of its official control programme from the WOAH	• Surveillance information used to document the official control programme • Low risk of virus circulation; all information generated from the surveillance system used to provide evidence of low risk of virus circulation • An official letter from WOAH to the country details accepted control interventions to be assessed through surveillance

5.5 SURVEILLANCE COMPONENTS TO MEET INFORMATION NEEDS FOR STAGE 3 OUTCOME 2

Outcome 2. The official prevention and control programme developed to conclude stage 2 and enter stage 3 is implemented, resulting in rapid detection of and response to all FMD outbreaks in at least one zone in the country

The two surveillance components supporting PCP-FMD stage 3 outcome 2 are enhanced outbreak investigations and clinical inspections and environmental sampling at aggregation points. In PCP-FMD stage 3, disease cases that result in outbreak investigations can be detected in many ways, but serologic surveys become an increasingly important detection mechanism. The application of serological surveys for disease detection is discussed in PCP-FMD outcome 3 (section 5.6).

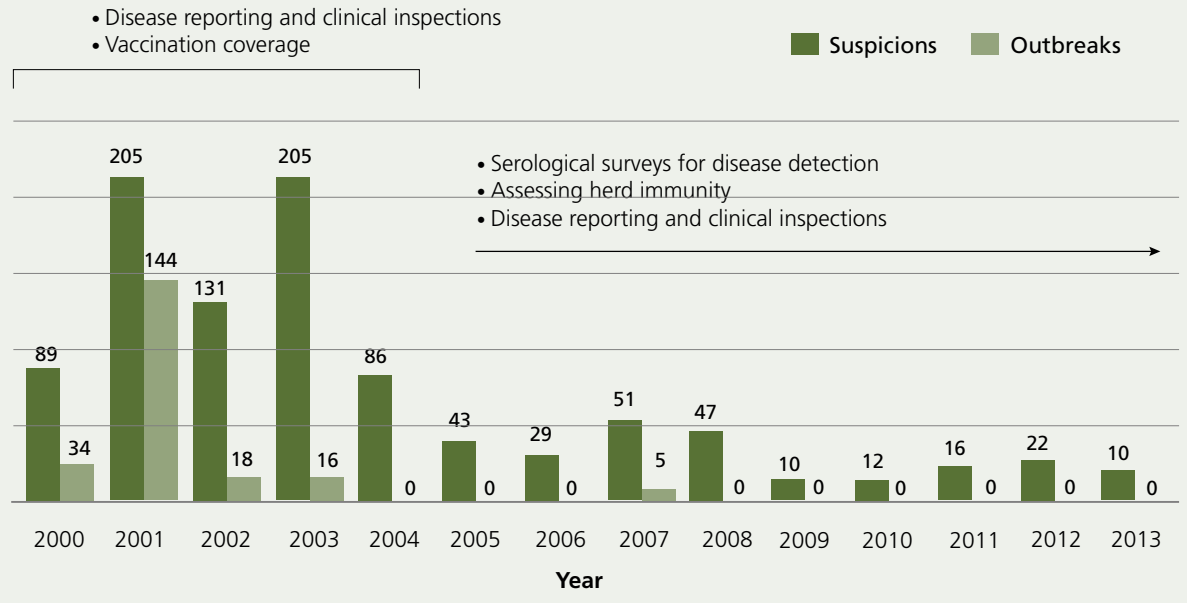
The prevention and control programme and epidemiologic context in PCP stage 3: Bolivian example

Bolivia, a country in South America, implemented an official prevention and control programme for FMD in 2000, with a strong commitment to eliminate infection. The country based its programme on the main control activities listed in section 5.2, vaccinating the cattle population twice per year in identified high-risk areas and once a year in areas considered lower risk (Bolivia, 2000; SENASAG, 2001). Characterization of risk was based on indirect indicators developed for South American cattle production systems (Astudillo, Dora and Silva, 1986; Astudillo *et al*., 1985; UNDP, 2009) and characteristics of cattle movements and commercialization in Bolivia (Daza, 2008). In addition to risk, logistics around implementation of vaccination played a role in the implementation of one or two vaccinations per year.

The distribution of outbreaks and suspicious cases since the implementation of the prevention and control programme highlights the need for surveillance information in PCP stage 3 to understand the epidemiologic situation (Figure 5.1). The programme resulted in lower prevalence of disease outbreaks, and the zones where vaccination was applied were certified as infection-free in 2003, 2005 and 2012. In 2014, the whole country was recognized as free with vaccination.

This example shows the role of different surveillance components in the progression of a control programme, with passive disease reporting and clinical surveillance components (including active clinical inspections) initially aimed at detecting disease, and serological surveys to assess virus circulation becoming important when prevalence is close to zero and no clinically ill animals are detected (from 2004 to 2006 and from 2008 onwards). In these latter periods no outbreaks are detected, particularly via disease reporting and clinical surveillance, because low prevalence of infection and levels of immunity due to vaccination mask expression of clinical signs in the population. Similarly, the strategies to assess the efficacy of vaccination will change along with the programme progression.

FIGURE 5.1
Progress in the epidemiological situation of FMD in Bolivia following the first 13 years of a control programme to eliminate virus circulation in the country



Source: Author's own elaboration.

Active herd-level clinical inspections supplement passive collection of data through farmers' disease reporting.

Veterinary officers could plan periodic (e.g. monthly) visits to farms/villages in specified zones/districts to interview farmers and perform clinical inspections on a defined number of animals (e.g. 10, or based on a calculated sample size) selected according to risk (animals that appeared to be sick recently) or randomly. For example, during FMD active clinical inspections of a vaccinated herd, unvaccinated cattle (usually animals younger than 12 months) and cattle 12–24 months old could be selected. The latter group should have received a lower number of vaccinations and appear to have higher risk of clinical disease than older animals in partially immune herds – the odds are 2–3 times higher (Gonzales *et al.*, 2014).

The number of farms to be visited monthly could be defined based on risk, budget, personnel and operationalization criteria. Risk characteristics considered when selecting zones and farms for clinical inspections, could be herds or regions with low vaccination coverage or herd immunity (see section 5.6.3 and table 5.2).

Similarly, clinical inspections at aggregation points, such as livestock markets and abattoirs, can be implemented. All animals presented for slaughter at abattoirs can be routinely inspected, and reports submitted to the veterinary authorities. At markets, veterinary officers could select a random number of animals for clinical inspection. The number of animals to be investigated can be calculated following the approach explained in section 5.6.2 and Annex 1. A key factor to consider for this estimation is the diagnostic sensitivity of clinical inspection. For FMD in partially immune cattle, this Se has been estimated to be around 0.3, or 30 percent (Gonzales *et al.*, 2014).

When assessing disease reporting and clinical components of the surveillance, the probability of detection (sensitivity) via disease reporting is conditional on the probability that:

- infected animals show clinical signs;
- the farmer detects/observes diseased animals;
- the farmer reports this to the veterinary officer;
- the veterinary officer visits, inspects the animals and confirms suspicion;
- the veterinary officer submits samples for laboratory confirmation; and
- laboratory results are positive.

The probability of detection via active clinical inspections is determined by the number of animals clinically inspected and the sensitivity of clinical inspection. See Hernández-Jover (2011) for an example using scenario tree models to evaluate the efficacy of disease reporting and the clinical component of surveillance.

Environmental surveillance involves sampling of contaminated surfaces in specific epidemiological units. This type of surveillance in animal health has been commonly used for monitoring and detection of salmonellosis in poultry farms. With the improved sensitivity provided by molecular methods, the approach is being explored for diseases such as PPR and FMD (Colenutt *et al.*, 2021). By sampling aggregation places, environmental sampling offers opportunities to monitor the geographical distribution of multiple diseases using the same samples (PCP stages 1 and 2) and to contribute to confirmation of virus circulation when approaching eradication (PCP stage 3). The sampling approach is based on the use of electrostatic dust cloths to swab (wipe) surfaces selected for sampling.

Considerations when implementing this type of surveillance in aggregation points such as livestock markets and abattoirs are:

- What to sample: The surfaces selected for sampling could be those most likely to have contact with excretions and secretions from the animals. These surfaces could include fences, feed troughs, walls or other appropriate surfaces.
- The number of samples to take: This number will depend on the size of the aggregation place, which could have multiple pens, troughs within each pen, etc. One approach is to sample all feed troughs and several randomly selected surfaces from the pen's fences/walls. This sampling could be done by creating a map of the pens' perimeter and dividing each side of the pens in numbered (identified) areas (e.g. 1 or 2 m long). These numbered areas become our sampling units, and the map our sampling frame for random selection of units. The sample size can be calculated following the procedure explained in section 5.6.2. From each selected unit approximately 1 m^2 of surface could be swabbed.

Environmental sampling of surfaces in aggregation locations could be cost-effective. Considering that the required efforts are much simpler than with serological surveys, these places could be sampled with higher frequency, increasing the sensitivity of this surveillance component. Furthermore, conclusions on virus circulation or freedom can be complex when based on serological surveys alone. Including environmental surveillance that detects the virus genome can facilitate interpretation of virus circulation.

5.6 SURVEILLANCE COMPONENTS TO MEET INFORMATION NEEDS FOR STAGE 3 OUTCOME 3

Outcome 3. The disease prevalence is progressively reduced in domestic animals in at least one zone in the country

In the absence of detection of diseased animals, particularly when much of the population is vaccinated, the use of surveys targeting detection of subclinical infection becomes important. Detection of infection is mostly done through serological surveys using DIVA (differentiating infected from vaccinated animals) tests, such as detection of antibodies against FMD NSP. Such surveys contribute to: (1) detecting infection; (2) identifying zones, compartments, etc. with higher risk of infection; and (3) building evidence, when repeated surveys appear to indicate freedom, to prove disease freedom (in combination with evidence provided by other surveillance system components). A strategic time for these surveys in PCP stage 3 could be 2 years after the last case of infection has been detected. This timing would also align/overlap with the WOAH requirements to prove disease freedom with vaccination (WOAH, 2021).

In this section we suggest approaches for conventional (random) and risk-based (targeted) serological surveys to assess virus circulation. We will use FMD as an example to describe the different survey approaches, but the approaches can be tailored to PPR and other TADs.

5.6.1 Serological surveys

When designing surveys, the study population needs to be clearly identified. The study population is the group of animals that will be subject to sampling. Often this is a risk-based subset of the population targeted in the surveillance system. For example, surveillance systems for FMD in South America include all susceptible animals in a country or zone; however, based on their value chain and assessed risk of infection and transmission, these countries only vaccinate cattle. In this scenario, a survey can assess virus circulation in cattle. Other susceptible species (e.g. sheep) could be included in a second phase with follow-up investigations based on the results of the first survey.

5.6.2 Randomized surveys

Livestock production, animal movements and the dynamics of infectious diseases often lead to clusters of infection. This clustering means that, in general, an infectious hazard such as FMD is not homogeneously distributed in the animal population. Furthermore, animals are clustered within farms or village herds, and infectious diseases also tend to cluster at this level. This means that the prevalence of infected animals in affected farms (villages) could be high, but the prevalence of affected farms is low.

Survey design. Because of clustering and implementation of interventions at farm/village level when infections are detected, we recommend a two-stage sampling approach to design a survey (see Annex 2). In this approach, the first stage is the random selection of farms/villages from a sampling frame and the second stage involves the random selection of animals within the selected farms. The study unit for analysis and interpretation of the results is the farm/village (referred to as the epidemiological units).

The objective when designing this survey and calculating sample size is detection of at least one infected unit if the prevalence of infection is higher than an expected (hypothetical) prevalence (also known as design prevalence or minimum detectable prevalence). In a two-stage sampling approach this question applies to both stages (epidemiological units and animals within a unit). Note that for an infectious disease, as previously mentioned, one would expect the prevalence at cluster level to be much lower than at the animal level within the cluster.

A key step in the design process is calculating the sample size for each stage (details in Annex 2). For this, the following factors are needed:

- the confidence level (or desired surveillance sensitivity);
- the minimum detectable prevalence (or design prevalence);
- the population size; and
- diagnostic test accuracy parameters sensitivity (Se) and specificity (Sp).

The first two parameters are necessary and the other two parameters can be optional and included to correct sample sizes in finite (small) populations and when the investigator wishes to account for imperfect tests. Formulae for the calculation of sample size using the above-mentioned parameters can be found in epidemiology textbooks or in published manuscripts (Cameron and Baldock, 1998). This calculation can be performed online by accessing applications such as FreeCalc (https://epitools.ausvet.com.au/freecalctwo) or using the package epiR (Stevenson and Sergeant, 2022) for the free software R, and openepi.com (see Annex 1).

In a hypothetical example of two-stage sampling in PCP stage 3, consider a country or zone(s) within a country where, because of a control programme against FMD, the prevalence dropped to levels close to zero and no outbreaks have been detected for the last 2 years (e.g. years 2004 and 2005 in Figure 5.1). This country planned a survey to assess virus circulation (detection of infection) based on detection of antibodies against NSP of FMD in cattle. For this survey, four zones, A, B, C and D, were targeted (Table 5.2). The country used different sampling approaches for each region (stratification). For zones A, B and C, a sample size for disease detection was estimated for each subregion, while a risk-based approach was used for zone D.

- Study population: Cattle farms/village herds (epidemiological units). Within each epidemiological unit, cattle between 6 and 24 months of age were sampled. These animals had received fewer vaccines than adults, hence they are expected to be more susceptible than older animals (increased probability of detection if infection is present at higher prevalence; see "Conventional versus risk-based surveillance", section 2.2.2). Sampling young animals can increase the specificity of the sampling approach where vaccine-induced NSP antibody responses are likely to be less. Since the goal is to detect disease in epidemiological units in a population with low prevalence, the prevalence to be detected is set to be low (1 percent). However, if the disease is present within a susceptible set of animals (young animals within an epidemiological unit), the prevalence of the disease to be detected can be set higher (10 percent).
- First stage (epidemiological units):
  - o Confidence level = 0.95 (95 percent); this is the desired surveillance sensitivity.
  - o Minimum detectable prevalence = 0.01 (1 percent).
  - o Population size (see Table 5.2).
- Second stage (animals within an epidemiological unit)
  - o Confidence level = 0.95 (95 percent); this is the desired herd sensitivity.
  - o Minimum detectable prevalence = 0.1 (10 percent).
  - o Diagnostic (NSP) test sensitivity = 0.9 (90 percent).
  - o Diagnostic specificity = 1 (100 percent). This specificity was assumed to be 100 percent because all epidemiological units with seropositive animals would be followed up in investigations until confirmation of infection. Further studies for following seropositive animals are recommended by WOAH (https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_fmd.htm) and are summarized in section 5.6.4 of this chapter.
  - o At this stage, the population of animals within an epidemiological unit varied from small units with fewer than 20 animals of all ages to units with more than 1 000 animals. Sample sizes were estimated accordingly, resulting in a sampling protocol of 18 animals from epidemiological units with up to 20 cattle, 24 from epidemiological units with 20–40 cattle, 29 for units with 40–100, 32 for units with 100–250, and 34 for units with more than 250 cattle. The small epidemiological units require special attention, since the number of animals required to be sampled (6–24 months old) may not be present. In such a situation, adjacent small epidemiological units were also sampled until the required number was reached.
  - o All animals sampled also need to be clinically assessed and this information recorded. Because a perfect specificity was assumed and follow-up investigations on sero-reacting animals and their corresponding epidemiological units were to be performed, the sampled animals should be well identified (if no clear identification system is in place, then use specific ear tags to identify sampled animals). The farmers should agree to keep the animals for a specified period when serological results will be obtained and follow-up studies will be performed. It should also be agreed that farms (units) included in the survey should not vaccinate until survey results are obtained (first survey or follow-up investigations in case of epidemiological units with reactors).
- Timing for sampling: If mass vaccination is applied and a serological test (DIVA, if available) is used where some low level of vaccine-induced cross-reactions are expected, then the period for sampling should be carefully considered. If vaccination is performed systematically twice yearly (two fixed periods), then the cross-sectional survey could be performed 4–5 months after the last vaccination and 1–2 months before the next vaccination round. This would minimize the risk of vaccine cross-reactions in the diagnostic test. Also, specific characteristics of the production system in different countries would determine the best time for sampling (e.g. seasonal movement of herds for grazing, access to water or market, or weather conditions).

5.6.3 Risk-based surveys

Risk-based surveys, introduced earlier in this document (Sections 2 and 4), can be an effective and efficient surveillance component in this stage when prevalence is being estimated for low-prevalence populations.

In designing a risk-based survey and estimating the required sample size, in addition to information on the design prevalence, the confidence level and the diagnostic test performance, we need to know:

- The expected risks (relative risk) of the sections/categories of interest (risk categories). For example, in zone D in the example given in Table 5.2, we could assume that, based on studies performed during PCP stages 1 and 2, the risk in subregion D1 is two times higher than the risk in sections D2 and D3 (the last two have the same risk).
- The proportion of the population in each risk category. For zone D it would be 0.56, 0.22 and 0.21 for sections D1, D2 and D3, respectively.
- The sampling coverage one would like to have for each of the risk categories should account for the lack of reported outbreaks in the previous 2 years.

In a practical sense, there is some justification for achieving higher confidence in detecting virus circulation by increasing sampling efforts in the subregion with expected higher risk (D1). Therefore, planners could decide to allocate 50 percent (or 0.5) of the sampling to D1 and split the other 50 percent between D2 and D3 (25 percent each).

Software tools are available for determining sample size and allocation (see Annex 1). After providing the hypothetical country situation above and using the same design prevalence, confidence and diagnostic performance assumptions listed in section 5.6.2, we would require sampling the following number of epidemiological units in zone D: D1 = 173, D2 = 87, and D3 = 86 epi units, for a total of 346 units sampled in zone D (first three columns of Table 5.2).

Hypothetical results of the planned survey are summarized in the last six columns of Table 5.2. The hypothetical results include the actual number of epidemiological units sampled and the number of units with at least one sero-reactor. Section 5.6.4 describes the process for follow-up investigations for the epidemiological units with at least one sero-reactor, and the complexities of interpretation.

5.6.4 Follow-up investigations and interpretation of (sero)survey results

The design of the example provided in section 5.6.2 assumed perfect specificity, which may not be the case; therefore, all sampled epidemiological units with at least one confirmed reactor (seropositive) should be further investigated (Table 5.2).

The objective of the follow-up investigations is to confirm or refute whether the seropositive results identified in the first survey are due to virus circulation (transmission) by confirming the sampled epidemiological unit is positive.

Details of the follow-up investigations are explained in the WOAH Terrestrial Code at https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_fmd.htm. Table 5.2 displays the hypothetical results of the confirmatory survey. Maximum prevalence can be estimated even in the case of no confirmation of cases as well as the probability of the zone or subregion being free from disease.

In summary, the follow-up investigations and information/evidence to be collected from epidemiological units with seropositive results include:

- clinical examination of study animals;
- virological examination of reactor animals (first survey): probang samples or saliva or nasal swab samples taken for PCR and virus isolation testing (Nelson *et al*., 2017);
- paired serology – all properly identified animals in a previously identified seropositive herd are resampled to assess changes in the number of seropositive animals;
- clinical examination and serological testing of unvaccinated susceptible animals present in the epidemiological unit (if only cattle are vaccinated, but there are also sheep or goats in the farms, these unvaccinated animals could be sampled); and
- use of unvaccinated sentinel animals.

TABLE 5.2

Hypothetical results of an NSP serological survey for assessment of virus circulation in different geographical zones. For zones A, B and C, we used a random two-stage sampling approach with a design prevalence of 1 percent. This design prevalence means that the sampling is intended to detect an epidemiological unit prevalence of ≥ 1 percent. For zone D, we used a risk-based design assuming the same design prevalence.

Zone/ subregion within the zone	Unit (epi unit) population	Estimated sample size	No. epi units sampled	Epi units with at least one sero-reactor	(Sero)Positive epi units following confirmation (%)[b]	Maximum expected prevalence (%)	Virus positive epi units	Probability of disease freedom
A	8 308	307	320[a]	10	0 (0.0%)	0.93	0	0.96[c]
B	874	261	251[a]	5	3 (1.2%)	3.1	0	0.21
C	15 570	312	366[a]	31	7 (1.9%)	3.63	1	0
D1	4 893	173	174	3	1 (1.2%)			
D2	1 944	87	69[b]	0	0 (0.0%)			
D3	1 845	86	73[b]	2	0 (0.0%)			
D total	**8 682**	**346**	**316**	**5**	**1 (0.3%)**	**1.5**	**0**	**0.78**

[a] In these regions the additional epi units sampled were non-random selected farms considered at high risk (either herds with low vaccination coverage or herds that had outbreaks in previous years).

[b] For logistical reasons, the required sample size could not be reached in these regions.

[c] This number represents the confidence (1-p) that the population is free at an expected minimum prevalence of 1 percent given a null hypothesis of "the study population is endemic". The p value for this example was p = 0.04. This means that we reject the null hypothesis. In this case, we could state the confidence in freedom is 0.96 (or 96 percent).

These investigation approaches may lead to many potential results that should be evaluated carefully (Table 5.3). When the prevalence is very low or the zone is free of disease, conclusions on seropositive results alone have severe limitations, particularly in mass vaccinated populations where some level of vaccine-induced seropositive results can be expected. It is very difficult to determine the meaning of small numbers of reactors within and among epidemiological units as an indicator of virus circulation at epidemiological unit levels.

In Table 5.3, we describe scenarios with potential results of the follow-up investigation, an interpretation of these results, and actions to confirm or rule out infection in the unit being investigated (virus circulating).

Once the results at the epidemiological unit level are confirmed, inferences can be made at the zone level. If all epidemiological units are confirmed negative, the probability of freedom can be evaluated (e.g. zone A, Table 5.2). One tool for this evaluation is FreeCalc (https://epitools.ausvet.com.au/freecalcone). If virus (or virus antigen or genome) is not detected, but serological results indicate virus circulation (zones B and D, Table 5.2), these results can be used to designate the maximum expected prevalence in the zones, continue assessing the risk of virus circulation, and guide both implementation or optimization of risk mitigation measures and the design of future surveys.

5.7 SURVEILLANCE COMPONENTS TO MEET INFORMATION NEEDS FOR STAGE 3 OUTCOME 5

Outcome 5. There is a body of evidence that FMD virus elimination in domestic animals within the country or zone is being progressively achieved

All the previously discussed surveillance activities conducted in PCP stage 3 will be used to develop substantial evidence of virus elimination with the addition of vaccination evaluation and wildlife surveillance. Combining the evidence from the range of surveillance activities and results can be very complex. Examples of approaches to combining information from multiple activities are demonstrated in *Risk-based disease surveillance – A manual for veterinarians on the design and analysis of surveillance for demonstration of freedom from disease* (FAO, 2014).

5.7.1 Post-vaccination monitoring

Detailed practical guidelines on how to monitor vaccination programmes have been provided in *Foot-and-mouth disease vaccination and post-vaccination monitoring* guidelines written by FAO and WOAH (Ferrari *et al*., 2016). When using prophylactic vaccination, it is extremely important to check the quality of the vaccine. This aspect is covered in Chapter 1 of the guidelines on vaccine attributes (how to select a vaccine). Chapter 2 provides guidelines on implementing a vaccination programme and monitoring vaccination coverage. Finally, Chapter 3 provides the guidelines on evaluation of the immune response. Of particular importance for stage 3 of the PCP are the studies on evaluating immunity at population level (herd immunity). We encourage you to read the examples provided on design and interpretation of serological surveys to help assess herd immunity.

As defined in Section 2 of this guideline, a key concept of surveillance is to provide information to "take action". The assessment of vaccination as a prevention and control tool will dictate surveillance actions. Table 5.4 summarizes monitoring activities (studies) to assess coverage and herd immunity, and the risk mitigation actions that study results could lead to.

5.7.2 The wildlife–livestock interface

When control of a disease is approaching eradication, the role of wildlife as a reservoir and a source of re-infection becomes a higher priority, and wildlife surveillance may be considered at the wildlife–livestock interface, although it is challenging. The importance of wildlife in the disease epidemiology varies around the world, depending on the pathogen circulating, prevailing domestic animal management practices, and the wildlife species present. For example, in parts of Africa, an FMD endemic cycle involves free-living African buffalo (*Syncerus caffer*), the primary carrier host of FMDV, predominantly the southern African territory serotypes (Jolles *et al*., 2021), in the African savanna.

Although FMDV can infect many other cloven-hoofed wildlife species (e.g. impala *Aepyceros melampus* and kudu *Tragelaphus* sp.) and camelids, the epidemiological role of many wildlife species is unclear. Carrier African buffalo have been shown to be a source of infection for other susceptible wildlife and domestic species with variable transmission from carrier buffalo to cattle reported (Hedger, 1972; Vosloo *et al*., 2002).

The demonstrated source of transmission from carrier African buffalo contrasts with the unknown epidemiological significance of carrier cattle. In areas of the subcontinent where free-living buffalo do not occur, it is possible to establish internationally recognized FMD-free zones (International Animal Health Code of the WOAH), and this has already been achieved in Botswana, Namibia and South Africa, as well as in North Africa. In regions other than Africa, wild boar (*Sus scrofa*) have shown involvement with FMD outbreaks affecting cattle, buffaloes, sheep, goats and pigs in Bulgaria.

The latter was a short-duration disease event, although occasional introduction of FMD from wildlife to livestock may have occurred (Alexandrov *et al*., 2013; EFSA, 2012).

TABLE 5.3
Scenarios describing potential results of follow-up investigations at epi unit level, interpretation and actions

Scenario	Clinical examination	Virological examination	Paired serology: increased	Paired serology: same reactor(s) confirmed	Paired serology: old reactor NEG; new reactor POS	Unvaccinated animals (serology)[a]	Required additional information and interpretation	Actions
1	+	1,411	NA[b]	NA	NA	NA	Confirmed outbreak/ virus circulation in epi unit and study zone	Report outbreak; implement control measures and outbreak/epi investigations
2	-	+	NA	NA	NA	NA		
3	-	-	+	NA	NA	NA	Confirmed virus circulation within the epi unit and potentially between epi units in the study zone	Longitudinal follow-up to detect virus by enhanced clinical surveillance and periodic sampling for PCR testing in epi unit and nearby epi units, or epi units in study zone with history of seropositive results. Could consider use of unvaccinated sentinels.
4	-	-	-	+	NA	+	Assess presence of other nearby reactor epi unit(s) (geographical clustering of epi units). Assess history of vaccination coverage or results of herd immunity in region. If vaccination or herd immunity levels were low and/ or there are other reactor epi units nearby, then this scenario indicates virus circulation.	Longitudinal follow-up as in scenario 3. If additional information does not help confirm virus circulation (high vaccination coverage, no geographical clustering), apply enhanced clinical surveillance and include this epi unit in future surveys (risk-based). Assisted vaccination of this epi unit.
5	-	-	-	+	NA	-		
6	-	-	-	-	+	-		
7	-	-	-	-	+	-	This is a challenging result which could be due to either test specificity issues resulting in false positive results or an indication of virus circulation. The additional information as in scenarios 4–6 can be used to assess this epi unit.	Apply enhanced clinical surveillance and include this epi unit in future surveys (risk-based). Assisted vaccination of this epi unit.
8	-	-	-	-	-	-	Epi unit negative	

[a] In this scenario only a few (one or two) of the total sampled susceptible animals (e.g. sheep) were seropositive.
[b] NA = Not applicable.

TABLE 5.4
Overview of vaccination monitoring activities (studies), study design and potential risk mitigation actions triggered by the monitoring results

Type of study	Objective	Design/approaches	Interpretation/decision
Vaccination coverage following a mass vaccination campaign	Measure the proportion of units (herds/communities/ animal owners) vaccinating, animals vaccinated and the age distribution of vaccinated animals at different geographical strata, zones or compartments	Records on vaccine doses acquired and distributed in the zone/country. Summarize indicators from vaccination cards/certificates. Match records of vaccines distributed with vaccination cards and records from animal movements to update population size data. If farmers are responsible for the vaccination, random visits by veterinary officers when planned date of vaccination is reported by farmer to audit vaccination and assess coverage post-vaccination. Participatory rural appraisal methods	Zones with low level of coverage: Enhanced clinical surveillance and target these regions if serological surveys to assess virus circulation are planned. If vaccination is done by the farmers, in the next vaccination campaign, vaccination is assisted by veterinary officers. Units that did not vaccinate (no vaccination card/ certificate): Restricted animal movements and enhanced clinical surveillance (visits by veterinary officers) until next vaccination campaign
Pre-vaccination evaluation of immunity at population level	Overview of herd immunity and identification of populations at risk (zones, regions with high proportion of units not adequately immune) before mass vaccination (one month)	At each targeted zone: The unit of the study is the epi unit (herd, community, etc.). Design: Two-stage random sampling: first, select epi units; second, select animals (young animals, if cattle 12–24 months) within each unit. (See Ferrari *et al*., 2016, for a detailed explanation of the design.)	If vaccination is performed by farmers, assisted vaccination by veterinary officers in regions/ herds with low immunity
Post-vaccination evaluation of immunity at population level (herd immunity)	Assessment of vaccination effectiveness (herd immunity following vaccination)	At each targeted zone: The unit of the study is the animal. Design: Stratified random samples to assess proportion of animals assumed protected. Or The unit of the study is the epi unit. Apply two-stage random sampling as described above.	Zones/herds with low herd immunity post vaccination: Enhanced clinical surveillance and target these regions if serological surveys to assess virus circulation are planned

It should be noted that following the principle of compartmentalization, identification and reporting of a TAD in wildlife, but not in livestock, should not impact the free status and trade.

At this stage of the PCP, implementation of wildlife disease surveillance activities can complement a national animal disease programme. However, as with all surveillance, the planning phase must consider any possible action that can result from surveillance information. Prevention and control options in wildlife populations can be problematic. There are two surveillance strategies – active and passive/ opportunistic – that can help in understanding the disease situation in wildlife. Although a thoroughly designed active surveillance scheme will be beneficial to understanding the disease situation in wildlife, it is expensive, time-consuming, and not always practical in vast endemic and resource-poor regions. Opportunistic surveillance schemes (sampling and testing hunted or dead animals, reports of animals found ill or dead, etc.) may have a low probability of detecting an infected individual in wildlife but will eventually identify risks of hazard introduction originating from wildlife.

The design of an active surveillance plan should consider the estimated wildlife population in a specific geography or region and the agricultural practices in that region, as well as livestock densities and human activity at the wildlife–livestock interface. The presence of free wildlife in areas where farmers graze their livestock often results in problems between farmers and wildlife. Infections will spread more commonly where domestic herds and wildlife co-exist. Fine-scale geographical features such as rivers and other water sources also need to be considered points of interaction between wildlife and livestock. Such areas should be the focus for both wildlife and livestock surveillance.

5.8 SURVEILLANCE COMPONENTS TO MEET INFORMATION NEEDS FOR STAGE 3 OUTCOME 7

Outcome 7. Some FMD control activities are combined with other TAD control activities

The implementation of an official prevention and control programme to enter PCP stage 3 for FMD with corresponding surveillance activities will also strengthen surveillance for other TADs. Surveillance activities that can be directly used for multiple TADs include disease reporting by farmers, clinical inspections at the herd level or aggregation locations, and environmental surveillance (Colenutt *et al.*, 2021). Surveillance for multiple pathogens will make the programme more cost-effective and is most likely to also ensure implementation of control measures that address farmers' perceived priorities, improving their engagement with the surveillance programme. The serological surveys performed at PCP stage 3 are less flexible for multiple use, since the study population tends to respond to predefined characteristics (e.g. only bovines younger than 24 months) and the study design is for disease detection.

5.9 SUMMARY

Surveillance in PCP stage 3 is intended to provide information on declining prevalence of disease in at least one zone and to better understand virus circulation in terms of herd immunity. During this stage, the focus of surveillance objectives and associated components must change over time as the prevalence of disease becomes lower and virus circulation decreases. The specific surveillance components (disease reporting and clinical inspections, random and risk-based serological surveys, environmental and wildlife surveillance) are more complex in design and implementation than in earlier stages and need to be used in combination to provide evidence of decreased prevalence or freedom from disease. Methods such as scenario tree models combine the evidence from various surveillance components to assess both the sensitivity of the surveillance system and the probability of disease freedom.

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Annexes

Annex 1

Resources, tools and background for surveillance planning, design, analysis and evaluation

A1.1 INTRODUCTION

Implementing a surveillance programme can be a daunting, complex and expensive undertaking. Typically, the process of planning surveillance through reporting should involve a team with a diverse background and skills to address a broad set of topics. A wealth of surveillance design, analysis and reporting information on methodologies and tools is available to users. This annex provides background on some resources and tools to develop, implement and evaluate surveillance for specific conditions. We highlight and describe some resources and tools that are either previously mentioned in this document or that can directly support users of this document. The tools and information are divided into four categories: (1) planning; (2) design; (3) analysis; and (4) evaluation. Many resources and tools have components that cover many categories but primarily will be presented in Table A1.1, the last page of this annex. The resources and tools have been developed for specific purposes over an extended period, so please consult the paper by Hoinville *et al*. (2013) for a discussion of terms and concepts associated with surveillance.

A1.2 PLANNING

Surveillance planning can be viewed at two levels. The first level is the strategic or broad overview of the surveillance system objectives. The second level is the actual surveillance plan. Many tools and resources can assist in both levels of surveillance planning. Recently, a joint effort by Food and Agriculture Organization of the United Nations (FAO), World Organisation for Animal Health (WOAH) and World Health Organization (WHO) developed an operation tool, the Surveillance and Information Sharing Operational Tool (SIS-OT), which guides users through a process to establish or strengthen the capacity for coordinated, multisectoral surveillance and information sharing for zoonotic diseases within their country (Table A1.1). The SIS-OT includes a stepwise assessment tool for users to evaluate the existing capacity within their country according to a framework of indicators, ultimately creating a roadmap and a workplan to establish or strengthen their surveillance and information systems.

An important component of the SIS-OT that is relevant to the purpose of this annex is a curated toolbox describing existing resources for surveillance and information sharing. The toolbox includes templates and applications for data collection, evaluation and reporting. The toolbox also includes workshop guides and other tools, guidance documents, and instructive materials (WHO, FAO and WOAH, 2022). As of January 2023, the toolbox listed 86 elements (see the Excel spreadsheet at https://www.who.int/publications/i/item/9789240053250). The description of each tool identifies the SIS-OT-defined five stages of surveillance development: pre-planning, gap assessment, planning, implementation, and monitoring and evaluation. The workplan developed through the SIS-OT process identifies specific tools from the toolbox that can strengthen capabilities within the five respective stages.

A second tool, the Joint Risk Assessment Operational Tool (JRA-OT), like the SIS-OT, was developed to support the Tripartite Zoonoses Guide. The JRA-OT facilitates the identification, assessment, management and risk reduction of zoonotic diseases through coordination and collaboration between a country's ministries and other agencies that are responsible for various aspects of human health, animal health, and the environment. Strategic and operational planning for PCP and the associated surveillance can be enhanced with a thorough understanding of the risks by a broad range of stakeholders.

A third tool, SurvTools (developed under RiskSur), has three components: surveillance system, design tool, and evaluation tool. The design and evaluation tools are discussed below. In relation to planning, the surveillance system part of SurvTools systematically leads the user through the processes of identifying the hazard, surveillance objectives, geographical area, susceptible population, and risk characteristics. Several other resources with practical information on surveillance planning are listed in Table A1.1. For example, both the *Guide to terrestrial animal health surveillance* and the *Manual of basic animal disease surveillance* give brief, practical approaches to planning surveillance (see Table A1.1). The *Guidelines for designing animal disease surveillance plans* provides a detailed listing of the components of a surveillance plan. FAO *Guidelines for surveillance of pandemic H1N1/2009 and other influenza viruses in swine populations* provides a good example of a completed surveillance system plan, including a site visit questionnaire.

TABLE A1.1
List of surveillance tools and resources, including purpose, online access and areas of application in surveillance

Tool name	Purpose	Location	Application area in surveillance			
			Planning	Design	Analysis	Evaluation
Surveillance Evaluation Tool (SET)	Developed by FAO to provide countries with a comprehensive and standardized way to evaluate animal disease surveillance system capacities	http://www.fao.org/3/i9143en/I9143EN.pdf	x			x
Risk-based strategic plan for control of foot-and-mouth disease	Template for development of the risk-based strategic plan required for progression from PCP-FMD stage 1 to stage 2	https://www.fao.org/3/cb1866en/cb1866en.pdf	x	x		
Epitools	Practical utilities to assist in survey design and analysis (including calculators) in developing and developed countries	https://epitools.ausvet.com.au		x	x	
SurvTools (previously called RiskSur)	Provides developers with science-based frameworks guiding them through the process of design and evaluation of surveillance systems (including risk-based). Includes three tools: a design tool, an evaluation tool, and a statistical tool. Reflects the sequence of steps involved in the development of a surveillance system and its associated components, including defining the target hazard and surveillance objective, target population, surveillance enhancements, testing protocol, study design, sampling strategy, data generation (sample collection), data/sample transfer, data translation (sample analyses), epidemiological analyses, dissemination of results and surveillance review.	https://survtools.org/ https://www.fp7-risksur.eu/	x	x	x	x
ECoSur	A semi-quantitative tool to evaluate the organization and functioning of collaboration in a multisectoral surveillance system. Includes evaluation of the key function of collaboration for an effective and sustainable multisectoral surveillance system.	https://survtools.org/wiki/surveillance-evaluation/lib/exe/fetch.php?media=files:guidance_v2.pdf#:~:text=ECoSur%20is%20a%20semi-quantitative%20tool%20that%20aims%20to,system%20and%20to%20analyse%20its%20strengths%20and%20weaknesses				x
Risk-based disease surveillance	Manual for planning and analysing risk-based surveillance for the purpose of demonstrating freedom from disease	http://www.fao.org/3/i4205e/i4205e.pdf	x	x	x	

Cont.

Tool name	Purpose	Location	Application area in surveillance			
			Planning	Design	Analysis	Evaluation
FAO guidelines for surveillance of pandemic H1N1/2009 and other influenza viruses in swine populations	Guidelines for surveillance planning for H1N1/2009 for detection, supporting disease absence and general surveillance	http://www.fao.org/3/ak738e/ak738e.pdf	x	x		
Guide to terrestrial animal health surveillance	Facilitates the design, implementation and evaluation of animal health surveillance systems for disease, infections and residues	https://www.woah.org/en/a-new-oie-guide-to-better-surveillance-and-detection-of-health-risks-related-to-animals/ (Not available free to public online)	x	x	x	
Manual of basic animal disease surveillance	Assists in the development of animal disease surveillance by establishing a framework for deciding on the best approach to surveillance and by examining the strengths and weaknesses of key surveillance tools. Provides a step-by-step guide to implementation of basic animal disease surveillance.	Nairobi, AU-IBAR. ISBN 978-9966-1659	x	x	x	x
Guidelines for designing animal health surveillance plans	Supports national veterinary services in designing comprehensive animal disease surveillance plans by highlighting important components	http://www.fao.org/fileadmin/user_upload/remesa/library/FAO%20Guidelines%20for%20designing%20animal%20disease%20surveillance%20plan.pdf	x	x		
Training manual on surveillance and international reporting of diseases in wild animals	Training material including a theoretical overview and practical exercises on wildlife disease surveillance and reporting	https://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/WGWildlife/A_Training_Manual_Wildlife_2.pdf	x	x		
Wild bird highly pathogenic avian influenza surveillance: Sample collection from healthy, sick and dead birds	Provides brief guidelines on the sampling methods to use when conducting wildlife surveillance or a morbidity/mortality investigation	http://www.fao.org/3/a0960e/a0960e00.htm		x		
Surveillance and Information Sharing Operational Tool (SIS-OT)	The tool's core capacity-building guide provides a stepwise approach for users to assess national capacity and identify activities, requirements and necessary resources to develop a coordinated zoonotic disease surveillance system.	https://www.woah.org/en/document/surveillance-and-information-sharing-operational-tool/	x			
Manual 5: Surveillance and epidemiology	General information on types of surveillance, strengths and weaknesses of different surveillance tools, activities, and epidemiological analysis	https://rr-asia.oie.int/wp-content/uploads/2020/02/seacfmd-manual-5.pdf		x	x	

Cont.

Tool name	Purpose	Location	Application area in surveillance			
			Planning	Design	Analysis	Evaluation
Challenges of animal health systems and surveillance for animal diseases and zoonoses	Overview of operation, characteristics, objectives, conceptual design, needs and future directions for national, regional and global animal health surveillance and information systems. Examples of surveillance and information systems are discussed.	https://www.fao.org/3/i2415e/i2415e00.htm	x	x		
Surveillance Evaluation Framework (SurF)	Surveillance evaluation in the animal, plant, environment and marine sectors, including case studies. Four major components are conducted: motivation, scope, design and implementation, and reporting and communication.	https://www.mpi.govt.nz/dmsdocument/18091/direct				x
Open Epi	Free and open-source software for epidemiological statistics	https://www.openepi.com/Menu/OE_Menu.htm		x	x	
Event Mobile Application (EMA-i)	Facilitates data collection, real-time reporting and data analysis and visualization for high-impact animal diseases and zoonoses. Includes Emergency Prevention System (EMPRES).	https://www.fao.org/3/CA1078EN/ca1078en.pdf			x	
Epicollect	Allows users to create projects and forms, collect data online or offline, and view, analyse and export data	https://five.epicollect.net/			x	
Epi R	The manual provides R basics and information on data management, descriptive analyses, univariate and multivariable analyses, data visualization, reports, and dashboards.	https://epirhandbook.com/en/download-handbook-and-data.html#download-handbook-and-data			x	

A1.3 SURVEILLANCE DESIGN

Surveillance design includes the selection of surveillance components or activities that will comprise the surveillance system and be integrated into the surveillance plan (see Table A1.2). Once the surveillance components are identified, the specific implementation of the activities is determined, whether cross-sectional, case-control, two-stage or other design. There are good resources to assist in both aspects of the design and some practical aspects of sampling to be considered for domestic agriculture and wildlife surveillance.

A1.3.1 Surveillance components

Surveillance components have been described in many different resources, and we have selected a few for a brief overview (see Table A1.2). The references cited provide more detail on the specific components. For example, the *Manual on basic animal disease surveillance* (MBADS) provides specifics on farmer reporting systems, representative surveys, and risk-based surveys that include a step-by-step guide to developing each component and a description of components and their usefulness, objectives, common problems and suggestions for improvement.

A1.3.1.1 Purpose of disease investigations

Disease or outbreak investigations are another important component used in the first three PCP stages. Disease investigations can be on-farm visits to a suspected or reported case to gather biological samples for diagnostic testing, clinical observations of animal health, and collection of information on animal management, movement practices and other potential disease risk factors. The purposes of the investigations differ in the PCP stages:

- stage 1 – understanding the temporal and spatial distribution of the disease and gathering information on circulating virus strains; investigation of risk factors;
- stage 2 – stage 1 purposes, with the addition of better understanding the dynamics of the outbreaks and the effectiveness of intervention measures; and
- stage 3 – rapid detection and response and disease infection trends.

A1.3.1.2 Steps in disease/outbreak investigations

The document *A Field Manual for Animal Disease Outbreak Investigation and Management* (FMADOI) provides a comprehensive overview of the steps involved in an outbreak investigation and management process (see text box). Perhaps the most critical part of the process is the preparation for a disease/outbreak investigation. Processes must be developed to allow for reporting of a potential outbreak and for the standardized collection and testing of biological samples, as well as development of a questionnaire.

Many of the surveillance components described above can be sources of preliminary reports for disease/outbreak investigations. Consequently, case definitions must be developed for on-farm clinical observations as well as laboratory-based testing. These case definitions should be shared broadly along with the process for reporting situations that meet the case definitions. Questionnaires and biological sampling

TABLE A1.2
Brief description and references for common surveillance components

Component	Brief description	References
Passive/farmer reporting	Farmers identify sick animals and report to a veterinarian	1, 2, 3
Aggregation points (abattoir, markets, watering places)	Collection of clinical information and biological samples, including animal and environmental samples, when animals are congregated that allows for information from many farms or villages	1, 2, 3
Sentinel herds	A selected group of herds that are visited and animals tested on a regular basis	1, 2, 3
Representative surveys	A survey for measuring the population-level prevalence of disease/infection and risk factors without bias	1, 2, 3
Risk-based surveys	Surveys focused on higher-risk populations to increase the probability of detecting disease	1, 2
Syndromic	Collection of specific signs or groups of signs such as individual clinical signs, syndromes (e.g. respiratory, gastrointestinal or neurological) or indirect signs (e.g. food consumption, milk production)	2, 3
Negative reporting	A type of passive surveillance in which routine veterinary staff visits to farms or villages allow farmers to be questioned and animals to be examined for transboundary animal diseases (TADs)	1, 2, 3
Participatory surveillance	A set of methods, including semi-structured interviews, scoring, ranking, and visual tools, that allows the participants to express themselves in their own knowledge system and provide direction to the interview process	2, 3

1. **Cameron, A.** 2012. *Manual of basic animal disease surveillance*. Nairobi, AU-IBAR. ISBN 978-9966-1659-1-6.
2. **FAO.** 2014. *Risk-based disease surveillance – A manual for veterinarians on the design and analysis of surveillance for demonstration of freedom from disease.* FAO Animal Production and Health Manual No. 17. Rome. http://www.fao.org/3/i4205e/i4205e.pdf
3. **OIE.** 2018. *Surveillance and epidemiology. Manual 5.* Paris. https://rr-asia.woah.org/app/uploads/2019/09/seacfmd-manual-5.pdf

procedures should be prepared in advance of the site visits. The questionnaire should include information on the animals present and management practices (see Annex 3 for a sample questionnaire). The logistics of the collection (electronic or paper) and consolidation of data are important aspects to consider prior to site visits. The collection of biological samples, as with any field study, requires a detailed protocol for the actual collection (type and number of samples, transport/collection), as well as the transmission of the sample to the laboratory and the diagnostic testing procedures (see EuFMD as an example of a collection procedure for FMD: https://eufmdlearning.works/pluginfile.php/8030/mod_page/content/5/sampling_onepager.pdf).

Disease investigations are valuable because they can provide information on the spatial and temporal distribution of disease, disease dynamics in an infected herd, circulating viral strains and risk factors. However, farms/villages where outbreak investigations are conducted may not represent all infected farms/villages. The lack of representation can be due to many factors, including hesitancy of farmers to report disease, absence of clinical signs, and lack of diagnostic testing capacity/capabilities. Integrating information from disease investigations with that from other surveillance components can help overcome some limitations.

A1.3.2 Detailed design of surveillance components

The selection of surveillance components and the detailed design for implementation can be complex. Involving a multidisciplinary team will help ensure that methods are appropriate for the questions being posed, that results will be meaningful, and that resources are allocated wisely. The design tool included in SurvTools can be useful in following a stepwise approach to address detailed designs of individual surveillance components (see Table A1.3).

A1.3.2.1 Sampling considerations

The choice of sampling design and strategy deserves specific attention since the approaches must receive practical consideration in terms of feasibility. Of special note is the requirement for a sampling frame from which to randomly select the epidemiologic units (typically farm or village). Representation and randomization allow inference to be made to the population of interest. Often a list of epidemiological units – termed a list frame of farms or animals – will not be available to use for the selection process. Some alternatives have been used to overcome this limitation. One suggestion is use of a proxy such as geographic location. Tempia *et al*. (2010) conducted a serosurvey of nomadic pastoral systems using randomly selected geographic coordinates and locat-

Outbreak investigation steps
(adapted from FMADOI)

- Prepare for an outbreak investigation
- Receive a report and collect initial information
- Visit site to collect biological and questionnaire data
- Evaluate possible causes of the outbreak
- Make an initial assessment of the extent of the outbreak
- Gather information to guide further investigation and control measures

TABLE A1.3
SurvTool steps in detailed design of surveillance components

Design element	Tool function
Objective and target population	Guides through the process of defining the population
Suspicion of disease	Consider how a suspected case of the hazard (disease) of interest is defined and reported
Enhancements	Consider enhancement or incentives to improve participation and results
Study design	Define target population, sampling unit, sampling design and sensitivity/specificity of the testing protocols
Sampling strategy	Consider information needed for calculating the number of samples needed (design prevalence, confidence level, power level, sensitivity, specificity)
Sample collection process	Consider who will collect samples, how, when and how often; also training needs
Transfer means	Transfer of biological samples or data from point of collection to point of analysis
Data translation	Who will convert data into surveillance information, how and when
Epidemiological analyses	Who will accomplish an epidemiologic analysis of biological samples/data, how and when
Dissemination of results	Who will disseminate the results to a defined group of recipients
Surveillance evaluation and performance monitoring	Who will perform surveillance evaluations, how and when

ing the nearest farm to the coordinate. A similar approach would be to make a list of villages and then use the selected villages to identify nearby farms.

There are many alternative ways to design the sampling approach depending on the intent of the design. Some of the more common designs, as well as their pros and cons, are listed in Table A1.4.

As mentioned in section 2.2.2, surveillance can also be based on the knowledge of risk. Risk-based and conventional (simple random sampling) surveillance approaches essentially differ in the way in which units are selected in a population. With a conventional approach, all units in a population have the same selection probability that is independent of disease risk. With a risk-based approach, the unit's selection depends on the specific level of likelihood to show the disease or detect infection.

The actual definition of disease risk depends on the surveillance objective and availability of reliable information about risk factors. For instance, if the pathogen is absent and surveillance aims to detect its early incursion, the likelihood of the pathogen being introduced into the country or region through given units could be considered as a criterion for their selection. If the pathogen is present and the surveillance aims to detect cases and reduce their contribution to disease dissemination, the selection of units could be based on their likelihood of both becoming infected and spreading the infection to the rest of the population.

In practice, the selection of units for risk-based surveillance relies on the availability of information about: (1) unit characteristics associated with the defined disease risk; and (2) the distribution of these unit characteristics within the target populations. These characteristics – or risk factors – may relate, for instance, to the age or breeds of animals or to the type, geographical location (which is likely to be affected by environmental conditions) or trading patterns of premises.

A1.4 TOOLS FOR SAMPLE SIZE DETERMINATION AND DATA ANALYSIS

A1.4.1 Sample size calculation for estimating prevalence and detecting disease

Sample size determination and data analysis can be very complex, and a full discussion is beyond the scope of this document. However, it is important to understand some concepts for sample size determination and it is also important to list some tools to assist sample size calculation and data analysis.

The goal of many surveillance components is either to estimate a population characteristic or to detect disease if it is present. In the former, the planner must initially determine several ingredients (see Table A1.5). This prevalence can be determined from existing data from similar disease situations or expert opinion. When estimating prevalence, the most variability in estimates occurs when the prevalence is close to 50 percent. Thus, the sample size requirement will be highest for an assumed prevalence close to 50 percent and lower for any lower or higher prevalence selected for estimation. The goal of estimating apparent prevalence and true prevalence should also be considered in calculating sample size. If an imperfect test is being used and the goal is to estimate the true prevalence, then the test sensitivity

TABLE A1.4
Sampling designs used in surveillance

Name of sampling design	Description	Pros	Cons
Simple random/targeted	Every sample of size *n* has the same probability of being sampled	Simplicity, conventional formulas, simple sample size formulas	List frame or proxy needed, can be relatively expensive, may not be as efficient as other designs
Stratified random sampling	Random sampling within defined strata (e.g. regions, geographic areas)	More efficient than simple random sampling when units are similar within strata; can readily make estimates within strata, estimation formulas are familiar	May not be effective if epi units across strata are more similar than within strata; sample size estimates depend on strata characteristics that may be difficult to obtain
Systematic sampling	Starting selection randomly from a list or order of epi-units then selecting the units at a fixed interval	Convenient; can be implemented without a list frame such as animals in a village or farm, formulas same as for simple random sample	Does poorly if there is systematic tendency in data; clustering could affect results
Cluster sampling	Selection of groups as epi units and then sampling all the elements within the group (all animals in a herd)	Can reduce travel and list frame development costs; useful when elements within a cluster are different	Not as effective in agriculture settings when animals may be similar within a farm or village. Formulas are not as well known
Two-stage sampling (see Annex 3)	Selection of groups as epi units and then selection of a subsample of the elements within the group (all animals in a herd)	Same benefits as cluster but is useful when animals within an epi unit are similar	Sample size needed for both stages of selection; formulas for estimation are different and, if ignored, can lead to errors

Source: Adapted from Salman, Wagner and Gardner 2003.

TABLE A1.5
Ingredients for calculating a sample size for estimating a proportion (e.g. disease prevalence) assuming a simple random sample

Ingredient	Description
Expected prevalence	Level of disease or another characteristic expected to be present
Margin of error	The precision associated with the estimate (usually the width of a confidence interval)
Confidence level	Confidence that the true value lies in the confidence interval (typically 95% or 90% but could be lower for initial exploratory surveillance such as in progressive control pathway [PCP] stage 1)
Population size	Number of epi units in the population
Test sensitivity	Probability that a test will identify a true positive as a test positive
Test specificity	Probability that a test will identify a true negative as a test negative

TABLE A1.6
Hypothetical sample size for estimating apparent and true prevalence for a test with 90 percent sensitivity and 98 percent specificity in EpiTools

Input variable	Apparent prevalence	True prevalence
Expected prevalence	0.2	0.2
Margin of error	0.05	0.05
Confidence level	95%	95%
Population size	1200	1200
Test sensitivity	NA	0.90
Test specificity	NA	0.98
Calculator used	https://epitools.ausvet.com.au/oneproportion	https://epitools.ausvet.com.au/prevalencess
Sample size	205	313

and specificity should be included in both the sample size calculation and, ultimately, the analysis. An example of both apparent and true prevalence sample size calculation and estimation using Epitools (https://epitools.ausvet.com.au) is shown in Table A1.6.

The Survey Toolbox, a practical manual and software package for active surveillance in developing countries, has valuable background detail on the methods and the calculators (https://epitools.ausvet.com.au/static/SurveyToolbox.pdf). Detection techniques typically are used to find disease in a population that may be free from the disease. Analysis of surveillance data for detection calculates the probability of the surveillance to detect disease if present at a specified level (FAO, 2014). The level of disease being detected is often referred to as the design prevalence. In contrast to estimating disease, the sample size typically decreases with the increasing prevalence of disease you are trying to detect in a population. Intuitively, it makes sense that if more animals are infected, it will require sampling fewer animals to find an infected animal. Unlike estimation, the design prevalence level is often set by international standards, trading partner requirements, biology, or other practical considerations (risk-based surveillance). Ingredients for calculating the sample size for detection are like those needed for estimating true prevalence, with the exceptions of use of design prevalence instead of estimated prevalence, the use of type I and type II errors, and removal of margin of error (see Table A1.7). Type I and type II errors are based on hypothesis testing. With disease detection, hypothesis testing is the basis, and there is the alternative hypothesis that disease is present at levels below the detection level, versus the null hypothesis that the disease is present at levels above the detection level. Hypothetical sample sizes for detection prevalence of 20 percent and 5 percent demonstrate both the lower sample size for detection at 20 percent prevalence (compared with estimation) and the increase in sample size with decreasing prevalence for detection (see Table A1.8).

Two-stage sampling, as described above, is a very useful approach in surveillance. Two-stage sampling is described in Annex 2, but it is useful to note that in the second stage of sampling, either the estimation or detection approach can be used, depending on whether the goal is to estimate prevalence at both the epidemiological unit level (first stage) and the sub-unit level (second stage, usually animal level).

TABLE A1.7
Ingredients for calculating a sample size to detect disease for a given design prevalence assuming a simple random sample

Ingredient	Description
Design prevalence	Level of disease or another characteristic that is desired to detect
Type I error	The probability of rejecting the null hypothesis when it is true
Type II error	The probability of accepting the null hypothesis when it is false
Population size	Number of epi units in the population
Test sensitivity	Probability that a test will identify a true positive as test positive
Test specificity	Probability that a test will identify a true negative as a test negative

TABLE A1.8
Hypothetical sample size to detect disease for 20 percent and 5 percent design prevalence, respectively, for a test with 90 percent sensitivity and 98 percent specificity

Input variable	Apparent prevalence	True prevalence
Expected prevalence	0.2	0.05
Margin of error	0.05	0.05
Confidence level	0.05	0.05
Population size	1200	1200
Test sensitivity	0.90	0.90
Test specificity	0.98	0.98
Calculator used	https://epitools.ausvet.com.au/freecalctwo	https://epitools.ausvet.com.au/freecalctwo
Sample size	30	198

A1.4.2 Surveillance analytical tools

Analysis of surveillance information is a critical step which can be complicated and should include input from experienced epidemiologists, statisticians and data scientists. For this document, the objective will be to highlight the range of tools available. Analytical tools such as R, SAS and SPSS allow for descriptive and analytical analyses that can appropriately handle complex survey data (e.g. two-stage, clustering, stratified, and stratified with different selection probabilities). In R, a free open-source software package, an epidemiologic package called Epi-R has specific analyses for epidemiologists. Tableau software focuses on visualization and allows for creation of custom dashboards.

Less complex software tools are available for planning surveillance (sample size calculators, selection of samples), collecting data (questionnaires, data transmission) and analysing results. Several of these tools are listed in Table A1.1 (Epitools, SurvTools, Open Epi, Event Mobile Application and Epicollect).

As with software, many sources provide background information on analysing surveillance data. While there are many journal articles and notable texts, we restrict the references here to several that are readily available and appropriate for surveillance in the PCP context. Manuals are listed in Table A1.1, including *Risk-based disease surveillance, Guide to terrestrial animal health surveillance, Manual of basic animal disease surveillance* and *Surveillance and epidemiology: Manual 5.*

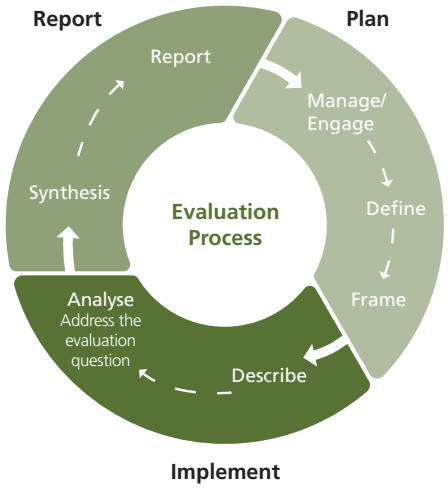
A1.5 EVALUATION OF SURVEILLANCE SYSTEMS: THE PROCESS

Each evaluation should follow a process that includes three phases:

1. the plan phase, where the evaluation plan is developed and framed;
2. the implement phase, where the objective under evaluation is defined and assessed; and
3. the report phase, where the evaluation information is communicated to those who need to know and act on it (see Figure A1.1).

If a pre-existing tool, guideline or framework is selected to conduct the evaluation, material and processes covering some or all these phases may already be included. When possible, it is recommended that the first phase (plan) described below is completed before the tool is selected, to determine which resource is most appropriate.

FIGURE A1.1
The cycle of the evaluation process
(adapted from Peyre, Roger and Goutard, 2022)



Source: Authors' own elaboration.

A1.5.1 Plan phase

In this first phase, the scope of the evaluation should be defined and the evaluation plan developed. This phase will require participatory engagement with people involved in or benefiting from surveillance, such as those who plan, design or coordinate surveillance; those involved in surveillance activities when they are being implemented; and those who use surveillance and/or evaluation information. Where possible, these stakeholders should be consulted on the evaluation needs related to the surveillance objective. The evaluation plan needs to account for the logic frame of the surveillance, including its inputs, activities, outputs, outcomes, expected impact and unintended consequences. Evaluation planners should determine the reason and the intended audience for the evaluation information. As part of this determination, the planners should also characterize the context for the evaluation as outlined in Table A1.9. This table includes the resources available for the evaluation. Sufficient resources should be made available for surveillance evaluation in the same way they are planned for the surveillance prioritization, planning, design and implementation. The description of the evaluation context, through an examination of the elements, can provide a full overview of the evaluation expectations and possibilities.

Finally, the evaluators should decide which surveillance attributes (sometimes referred to as categories or areas) to focus on, considering the evaluation purpose and questions. Many evaluation attributes have been identified and described previously by multiple authors, including CDC, Drewe *et al*. (2015), Hoinville *et al*. (2013) and Peyre *et al*. (2022), and include frameworks and protocols such as OASIS, Serval, SurvTools, SurF and FAO SET (see Table A1.1).

Attributes are commonly grouped into the following categories:

- *situation and operation of a surveillance system:* objectives/scope, central institutional organization, field institutional organization, laboratory, surveillance tools, surveillance procedures, data management, training, communication, evaluation;
- *organizational attributes:* risk-based criteria definition, surveillance system organization;
- *functional attributes:* availability and sustainability, acceptability and engagement, simplicity, flexibility, adaptability, compatibility, multiple hazard;
- *effectiveness attributes:* coverage, representativeness, false alarm rate (inverse of specificity), bias, accuracy, precision, timeliness, sensitivity (detection probability and detection fraction), positive predictive value, negative predictive value, robustness;
- *value attributes:* cost, benefit, cost-effectiveness, cost–benefit; and
- *integration (One Health):* One Health collaboration and integration mechanisms (e.g. coordinative capacity, database interoperability).

Before moving to the next phase, the roles, responsibilities and selection of evaluation tools or frameworks must be established. If resources permit, the external evaluators may choose a pre-existing tool, guide or framework (see Table A1.1) that fulfils the needs of the evaluation plan. If the evaluation will be conducted internally by surveillance planners or other stakeholders within the system, their selection, terms of reference and possibly training to conduct the evaluation must be determined.

A1.5.2 Implement phase

Once an evaluation plan has been generated, it can be implemented according to the steps described below. This process will include collection of both primary and secondary data (qualitative, quantitative and/or mixed) and the analysis of these data in line with the evaluation objective. As general principles, the following steps should be considered:

- collecting and organizing evaluation data systematically following good practice that reduces bias and ensures validity;
- using qualitative and/or quantitative data to establish baselines, patterns and trends, and/or to draw comparisons;
- if relevant, comparing costs and benefits (monetary or non-monetary) in a cost–benefit analysis;
- interpreting the findings, ensuring bringing in relevant stakeholders; and
- employing existing or expected standards to formulate conclusions.

TABLE A1.9
Definition of the context elements in the evaluation process

Context elements	Relevance
Surveillance objective	Impact on the selection of evaluation attributes
Hazard name	Provides information on the disease under evaluation which will impact the complexity of the evaluation (e.g. between animal disease and zoonotic diseases)
Geographical area	Provides information on the scale of evaluation
Legal requirements	Provides information on the need to meet an effectiveness target or not
Strengths and weaknesses of current approach	Provide summary information on the rationale behind the decision to evaluate
Stakeholder concerns about current approach	Provide information on the involvement and interest of decision makers in the evaluation process
Alternative strategies to consider	Provides information on the type of evaluation required (based on a counterfactual or not)
Do you want to evaluate or change the system or some components in the system?	Provides information on the level of evaluation
How many components will you include in this evaluation?	Provides information on the number of counterfactuals considered
Are you considering risk-based options?	Relevant for the inclusion of the attribute risk-based criteria definition in the evaluation plan
Will you consider the costs of surveillance in your evaluation?	Provides information on the interest of economic evaluation
Do you know the current cost of your system and/or components?	Provides information on the data required
Do you have a budget constraint?	Provides information to define the economic evaluation (meeting a budget target or not)

Source: Peyre, Roger and Goutard 2022.

For example, if a cost-effectiveness analysis of a surveillance strategy is to be conducted, data will need to be collected on the inputs into surveillance and the outputs it produces (both for the baseline and the counterfactual), as well as the valuation of these (e.g. monetary units for the costs and a non-monetary effectiveness unit for the outputs), followed by a comparison in a cost-effectiveness analysis. The results of the analysis would be interpreted using established economic evaluation criteria.

Lastly, the use of a strengths and weaknesses assessment of the evaluation approach is recommended.

A1.5.3 Report phase

For surveillance systems, an evaluation will commonly produce multiple pieces of information (e.g. on several attributes and the strengths and weaknesses of the system) that will need to be integrated to communicate the merit or worth of the surveillance and to formulate recommendations. Recommendations should be defined with or reviewed by multiple stakeholders to ensure prioritization and ensure that they are realistic and feasible. The recommendations should be developed into a time-bound action plan that holistically addresses the identified weaknesses and defines roles and responsibilities that enable surveillance activities to inform PCP objectives to assist in the progression along the PCP. When pre-existing tools, guidelines or frameworks are used to conduct the assessment, evaluators are encouraged to adapt automatically generated reports to meet the needs and objectives of the surveillance system being evaluated. The evaluator will present the results in line with the evaluation purpose and evaluation questions and choose suitable presentations for the target audience (e.g. a traffic light system as used in SurF would allow comparison of performance over time and highlight where improvements may need to be made).

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Annex 2

Guidelines for conducting a serological survey to assess the distribution of FMDV virus in a population

Overview and key points

This annex describes the basic steps required to design and implement an NSP serosurvey to estimate the prevalence (proportion) of epidemiological units with evidence of previous infection with FMD within a defined population.

Key points are:

- Recording the age and vaccination status of the sampled animals is very important
  - NSP antibodies can persist in an animal for months or years, therefore young animals should be sampled to estimate the prevalence of recent infection
  - Animals that have been repeatedly vaccinated may be positive for NSP, even if they have not been infected.
- The NSP serosurvey should be accompanied by a questionnaire to identify risk factors for FMD.
- To ensure that the survey results are as reliable and informative as possible, an epidemiologist should be involved in the design and analysis of the survey.

A2.1 BACKGROUND

Serological tests are widely used to monitor the immune status of animals exposed to foot-and-mouth disease virus (FMDV) or FMDV vaccines. Serological tests for FMD can be divided generally into two types: those that measure antibodies to structural proteins (SPs) and those that measure antibodies to non-structural proteins (NSPs). When FMD infects a cell, it replicates, and two types of FMDV proteins are produced: the SPs that are components of the virus coat (capsid), and the NSPs that are generated during virus replication either during infection of an animal or in vitro during vaccine production (Figure A2.1). Following infection, the immune response produces antibodies directed at both the SPs and the NSPs, whereas following vaccination, the immune response should elicit antibodies directed at the SPs only. The latter is because high-quality vaccines are purified to remove most of the NSPs. However, the lack of vaccine purity may result in positive NSP tests, particularly in animals that have been repeatedly vaccinated (WOAH, 2021). The difference in the immune response between vaccinated and unvaccinated animals has been used to develop a DIVA (differentiating infected from vaccinated animals) approach. On this basis, NSP serosurveys are commonly used to assess and monitor the distribution of FMD infection in a population where vaccines have been applied, but they also have application in non-vaccinated populations. The serosurveys can also be an important source of evidence to demonstrate population-level freedom from infection. This annex provides guidance for researchers who intend to conduct a serosurvey to assess the distribution of FMD infection in a population.

A2.2 STEPS TO DESIGN AND IMPLEMENT AN NSP SEROSURVEY

The section below describes the general steps to design and implement an NSP serosurvey. For further information about any of the steps, refer to the further reading list at the end of this annex.

Step 1. Identify survey objective(s)

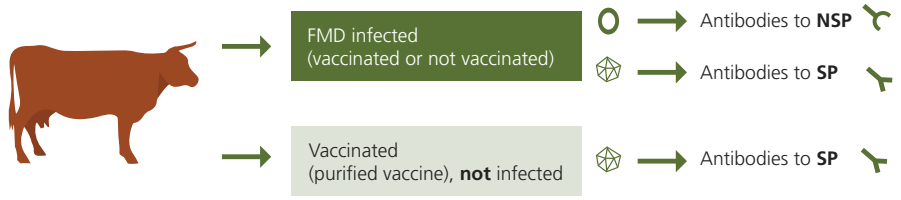
The primary objective of conducting an NSP serosurvey is usually to estimate the prevalence (proportion) of *epidemiological units* (epi units) with evidence of previous infection with FMD within a defined population.

An epi unit consists of animals that share the same environment (and therefore likelihood of exposure to FMDV if it is circulating). Often this would be either a farm or a village (when animals with different owners within a village have relatively close contact with each other, such as during common grazing).

Because FMD is so contagious, especially in a naïve population, if one animal within an epi unit is found to be infected, the entire unit is considered infected. Therefore, it is usually more informative to use the epi unit, rather than individual animals, as the unit of analysis.

NSP antibodies can persist for months or years, so a positive result is not necessarily an indicator of a recent infection. Therefore, if the objective is to estimate the prevalence

FIGURE A2.1
Non-structural and structural proteins that result from infection or vaccination



Source: Authors' own elaboration.

of recent exposure, the survey should be restricted to young animals, where recent exposure would have necessarily occurred. However, for surveys in endemic countries early in PCP stages, analysis of the prevalence in the different age groups can be used to estimate the infection rate and the age at which animals are likely to become first infected.

Depending on the situation, other objectives may also be defined such as the identification of risk factors at the animal and epi unit levels.

Step 2. Define the population of interest (target population)

The geographical scope of the survey, as well as the species and husbandry type(s), must be clearly defined.

Step 3. Choose the survey design

A survey built on a two-stage sampling design is often used, meaning that first the epi units are selected (farms or villages) and then a subset of animals within the selected epi units is sampled. If a subset of animals within an epi unit is small, such as may happen when restricting the sample to young animals, then all eligible animals may be tested, and the sampling design is referred to as cluster sampling.

The method of selecting epi units to be sampled will depend on whether a reliable list of all the epi units (sampling frame) is available:

- If a list of all epi units (farms and/or villages) is available, the desired number of units should be chosen using simple random sampling.
- If a list of all epi units (farms and/or villages) is *not* available, random coordinate geographic sampling (RCGS) may be used to select random geographic coordinates, and epi units near these coordinates are then sampled (Tempia *et al.*, 2010).

Step 4. Determine the sample size

Determination of the sample size is one of the most complex issues faced when planning a serosurvey. There is no single "right" approach for determining the sample size; the researcher must balance the objectives of the study with logistical and financial considerations. One approach is to calculate the sample size in two steps:

1. Determine the number of epi units required by using the formula for "sample size required to **estimate prevalence** in a large population".
2. Determine the number of animals to sample in each epi unit by using the formula for "sample size to **detect disease**".

There are sample size calculators[1] available that can greatly assist with determining the sample size. Several parameters are required:

- The desired level of precision (acceptable error), which is often set at ± 5 percent or 10 percent. When reporting the results, this precision is reflected in the confidence interval.
- Confidence level, which is a measure of how certain we are that the true value lies within the confidence interval. By convention, 95 percent is usually used, although sometimes 90 percent or 99 percent is specified.
- Expected frequency of disease (also called design prevalence): An estimate should be made based on the best available knowledge. For the first stage of sampling, this refers to the expected proportion of positive epi units; for the second sampling stage, it is the minimum expected prevalence of sero-conversion within an epi unit. If the epi unit prevalence is unknown, an estimate of 50 percent will maximize the sample size.
- The size of the population: In the first stage, population size refers to the number of epi units (farms/villages), whereas in the second stage, it will refer to the approximate number of animals on each epi unit.
- Sensitivity and specificity of the test: The sample size formulae can be adjusted to account for imperfect

[1] Available sample size calculators include: Sergeant, E.S.G. 2018. ***Epitools epidemiological calculators***. Fremantle, Australia, Ausvet (http://epitools.ausvet.com.au); Scotland's Rural College Online Applications (https://epidemiology.sruc.ac.uk/apps/); and WinEpiscope (http://www.winepi.net/uk/index.htm).

diagnostic tests. An evaluation of commercially available NSP tests showed that they generally have very high specificity, but that sensitivity can be reduced over time (>100 days post infection), especially in vaccinated cattle that are subsequently infected (Paton *et al.*, 2006).

Step 5. Consider stratification

Stratification means dividing the population into separate, exclusive groups (strata) and then randomly sampling units from each stratum. This approach can be used to ensure that each group in the population is represented in the survey. Additionally, if epi units within a stratum tend to be more similar than across strata, stratification can improve the accuracy of a survey.

For NSP serosurveys, stratification may be done by:

- geographic area (e.g. to ensure that all regions or districts are included);
- husbandry type or farm size (e.g. commercial or smallholder); and/or
- species or production type (e.g. sheep, pigs, beef, dairy).

Proportional allocation is often used to ensure that each stratum is properly represented. This allocation means that the number of units selected is proportional to the number in each stratum. For example, if a nationwide survey is to be carried out, the number of farms selected from each district would be proportional to the number of farms in each district, to ensure that no district is over- or under-represented. The researcher may further apply stratification to ensure that both commercial and smallholder farms (or different production types) are represented within each district strata. Sampling at a higher rate in specific stratum can be conducted, but this approach results in a complex sampling design that requires specific analytical approaches, and an epidemiologist should be consulted to help with design and analysis.

Step 6. Plan for data collection

Data collection is a critical step that can be broken down into two parts: (1) identify which data will be collected; and (2) define how the data will be recorded. An NSP serosurvey is an excellent opportunity to collect data that can provide information about risk factors for FMD at both the epi unit (farm/village) and animal levels (see Table A2.1).

Data collection materials should be carefully designed. If a questionnaire is to be used, it should be pre-tested (piloted) to ensure that each question is clear and answerable. Questions should have mutually exclusive answer categories unless the respondent is permitted to provide more than one answer. A practical approach is to develop the shell of the intended report to ensure the questions will meet the reporting objectives. Ideally the survey team will collect the data electronically using a smartphone or tablet; electronic collection reduces the need for a second step of transferring data from a paper form into a computer. Applications are available that can facilitate digital data collection, including freely available ones such as EpiCollect and ODK. The use of tick boxes (paper) or dropdown menus (electronic) speeds data recording, reduces errors and facilitates the eventual analysis.

The investigators must also ensure that there is a clear and user-friendly system to label the samples so that the laboratory test results can be matched with the correct demographic and risk-factor data from each animal. A spreadsheet should be prepared for eventual storage of the data. To ensure all the necessary data are collected, it can be helpful to design the spreadsheet before the data collection form, and to base the latter on the former. Consult the textbox for some important rules for designing the spreadsheet that will greatly facilitate analysis.

Step 7. Conduct the survey

A full description of issues related to the implementation of the survey is beyond the scope of this document, and the guidance will vary according to the country context. Activities should include:

Case study

An NSP serosurvey was conducted to determine the proportion of vaccinated farms (epi units) that had been infected with FMD in the past 2 years. The test was assumed to have a 75 percent sensitivity and perfect specificity.

First-stage sampling (farms)

In a large population of farms (>10 000), the expectation was that 35 percent of epi units would have NSP seropositive animals, and a 5 percent margin of error and 95 percent confidence were specified. Based on these values, 350 farms should be sampled.

Second-stage sampling (animals)

On each farm, if FMD was present, it was assumed that at least 30 percent of the animals would become infected and seroconvert. An average farm size of fewer than 200 animals was assumed. Again, specifying a 95 percent confidence level, 13 animals should be sampled on each farm to be 95 percent sure to select at least one positive if the farm had been infected.

Therefore, the number of serum samples required would be 350x13 = 4 550.

- preparing equipment and logistics (including data collection sheets, transport, restraint, specimen collection and processing);
- training survey teams;
- visiting selected farms and/or villages and conducting an interview – at this point, data on epi unit-level risk factors can be gathered, and a sampling frame for the animals can be built;
- visiting selected livestock owners (if in a village) and collecting the serum samples and data on animal-level risk factors; and
- sending the specimens to the laboratory.

Step 8. Analyse and report the results

Laboratory

For each sample, it is recommended that the laboratory records the "raw" result (percentage inhibition or optical density) as well as the final result (positive or negative). This recording is particularly important if the animals sampled could have been vaccinated with a non-purified vaccine, in which case some NSP seroconversion could be attributed to the vaccine. In this case, the use of different cut-offs may be explored in the analysis (Emami *et al*., 2015).

Descriptive

The key result from the survey will be an estimate of the **prevalence of epi units with NSP-positive animals**, meaning that they have been infected with FMD in the past. As NSP antibodies can persist in an animal for years, the age of the animals sampled may be the best indicator of how long ago the infection could have occurred. The prevalence estimate should be reported along with a 95 percent confidence interval, which is roughly interpreted as being 95 percent confident that the true prevalence lies within this interval.

If stratification was used, separate prevalence estimates and confidence intervals should be reported for each stratum; these confidence intervals will usually be very wide, as the number of animals within each stratum may be relatively small.

Risk-factor analysis

A full description of analytical epidemiology is beyond the scope of these guidelines. Involvement of a trained epidemiologist is recommended. For further information, the reader is directed to the "Further reading" list. Briefly, risk factors can be identified through the comparison of the NSP prevalence in groups *with* ("exposed to") and *without* the risk

TABLE A2.1
Example of risk-factor data that could be collected as part of an NSP serosurvey

	Risk factor	Example of data to record
Epi unit-level factors	Location of epi unit	x, y coordinates
	Livestock population	Number of each FMD-susceptible species
	Production type	Select from defined categories: e.g. • Dairy/beef/mixed • Intensive/extensive • Commercial/smallholder
	Clinical signs compatible with FMD in the past 12–24 months?	Yes/No If yes, date
	FMD vaccination history in last 24 months	Date, number of animals vaccinated, and vaccine used
	Replacement stock and new introductions	Number and frequency of new animals introduced to herd
	Contact with other herds while grazing?	Yes/no
Animal-level factors	Age of animal	In months
	Species	Cattle/buffalo/sheep/goat/pig
	Purpose	Dairy/meat
	Prior FMD vaccination?	Yes/No If yes, date and vaccine used
	Born in this epi unit?	Yes/No
	Contact with other herds while grazing?	Yes/No
	Ever had signs of FMD?	Yes/No If yes, when?

factor (e.g. vaccination status, age group, production type). This involves the calculation of ratios such as relative risk and odds ratio, which measure the magnitude of a statistically significant association between risk factor and disease. Contingency tables (e.g. 2×2 tables, see Table A2.2) can facilitate calculation of these ratios. A Chi-square test can be used to test for statistical significance – that is, to determine whether the difference observed in the level of disease between the different groups is unlikely to have occurred by chance. As for sample size, online tools are available to assist with these calculations.[2] To control for confounding and bias, more advanced multivariable analytical techniques such as logistic regression may be used to analyse the survey data and identify risk factors.

Rules for spreadsheet design

- One research project = one datasheet.
- Each row represents the most basic unit measured – in this case, an animal.
- Each row requires a unique identifier (ID number).
- Each column represents a variable – e.g. animal ID, epi unit ID, date, species, district, test result, etc.
- One answer (piece of information) per cell. Consider all possible kinds of answers beforehand – e.g. if you are recording "species present", define categories first (e.g. cattle, sheep, mixed).
- No blank rows, no blank cells and no merged cells. Include a "." if missing information.

TABLE A2.2
Example of a 2x2 table to see if intensive husbandry is a risk factor for NSP-seropositivity

Generic 2x2 table			
	Disease +	**Disease -**	**Total**
Exposed to risk factor	a	b	a+b
Not exposed to risk factor	c	d	c+d
Total	a+c	b+d	

2x2 table completed with survey results			
	Epi units with NSP-positive animals	**Epi units with no NSP-positive animals**	**Total**
Intensive husbandry	65	205	270
Extensive husbandry	10	70	80
Total	80	270	350

Prevalence in intensive husbandry group: 0.24 (95 percent CI: 0.19–0.3)
Prevalence in extensive husbandry group: 0.12 (95 percent CI: 0.06–0.22)
Odds ratio:[a] 2.22 (95 percent CI: 1.08–4.56)
Chi-square: 4.91; p-value 0.027

Interpretation: Epi units practising intensive husbandry are 1.93 times more likely to have NSP-positive animals than epi units with extensive husbandry. This value is statistically significant ($p<0.05$ means less than 5 percent chance that the difference observed would be due to chance alone).

[a] Relative risk is calculated according to the formula: [a/b)]/[c/d]

[2] Available tools include: Sergeant, E.S.G. 2018. *Epitools epidemiological calculators*. Freemantle, Australia, Ausvet (http://epitools.ausvet.com.au – choose studies<<summary statistics from a 2x2 table); and WinEpiscope (http://www.winepi.net/uk/index.htm – choose "risk estimation").

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WOAH. 2021. Infection with foot and mouth disease. In: *Terrestrial Animal Health Code.* Chapter 8.8. Paris. https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/

FURTHER READING

More information and designing and analysing surveys

Cameron, A. 1999. *Survey toolbox: A practical manual and software package for active surveillance of livestock diseases in developing countries*. Fremantle, Australia, Ausvet. https://epitools.ausvet.com.au/static/SurveyToolbox.pdf

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Thrusfield, M. 2018. *Veterinary epidemiology*. John Wiley & Sons.

Thrusfield, M. 2018. *Veterinary epidemiology.* John Wiley & Sons

EXAMPLES OF SEROSURVEYS

Knight Jones, T.J.D., McLaws, M. & Rushton, J. 2017. Foot-and-mouth disease impact on smallholders What do we know, what don't we know and how can we find out more? *Transboundary and Emerging Diseases,* 64(4): 1079–1094. (See table 2 in the paper for a summary of serosurvey results from various countries.)

Tekleghiorghis, T., Weerdmeester, K., van Hemert-Kluitenberg, F., Moormann, R.J.M. & Dekker, A. 2017. Foot-and-mouth disease seroprevalence in cattle in Eritrea. *Transboundary and Emerging Diseases*, 64(3): 754–763. https://doi.org/10.1111/tbed.12434

INFORMATION ABOUT NSP TESTS

WOAH. 2021. Foot-and-mouth disease. In: *Manual of diagnostic tests and vaccines for terrestrial animals.* Chapter 3.1.8. Paris. https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-manual-online-access/

Annex 3

Questionnaire form examples

A3.1 EXAMPLE OF AN OUTBREAK INVESTIGATION REPORTING FORM

Adapted from OIE South-East Asia and China Foot-and-Mouth Disease (SEACFMD) Campaign, 2018. *A field manual for animal disease outbreak investigation and management*

Investigation Reporting Form

Reporting Form ID: _____

Investigating Official: _____

Position Held: _____

Signature: _____

Investigation Date: _____/_____/_____

Section 1: Outbreak reporting

1.1 The officer was informed of this outbreak by:

☐ Owner

☐ Livestock volunteer in village or subdistrict

☐ Village or subdistrict headman

☐ Other (please specify):_____

1.2 Reporting Date: _____/_____/_____

Section 2: Index case

2.1 Name and address of owner of the first case:

_____

i) Village Name:_____

ii) Subdistrict/District/Province:_____

iii) Coordinates: X _____ Y _____

2.2 Date the first signs of disease were noted: _____/_____/_____

2.3 Species of the first case:

☐ Cattle ☐ Buffalo ☐ Pig

☐ Sheep ☐ Goat

☐ Other (specify species):_____

2.4 If the first case was introduced from another area, please provide details:

Specify date of introduction: _____/_____/_____

Specify source location: _____

2.5 Owner managed diseased animals by (answer all applicable options):

☐ Slaughter (specify location)_____

☐ Consumption or distribution (specify location)_____

☐ Carcass disposal (burial or burning) (specify location)_____

☐ Treatment (specify treament)_____

☐ Other (specfy)_____

Section 3: Individual case description

Owner Name:
Village Name:
Village ID Number (*if applicable*):
Subdistrict:
District:

Species		
Total number susceptible		
Number affected		
Number of deaths		
Number slaughtered/destroyed		
Date first animal affected		
Date last animal affected (if applicable)		
Vaccination history	Vaccinated date(s)	
	Vaccinated times	
Specify origin if introduced		

Section 4: Clinical investigation

4.1 Clinical signs

☐ Fever
☐ Bleeding/haemorrhage
☐ Drooling saliva
☐ Anorexia
☐ Respiratory signs
☐ Diarrhoea
☐ Jaundice
☐ Abortion
☐ Blisters on mouth/feet/udder
☐ Neurological signs
☐ Other (specify) _____

4.2 Autopsy findings – please attach results (*if applicable*)

4.3 Sample collection (*if applicable*)
Sample ID: _____
Laboratory: _____
Sample Type: _____
Submission Date: _____/_____/_____

4.4 Laboratory findings – please attach results (*if applicable*)

Section 5: Environment

5.1 Animal husbandry in outbreak area (choose all applicable answers)

☐ Farm ☐ Pen or stable

☐ Grazing in defined area ☐ Free-grazing

☐ Other (specify) _____

5.2 Please provide details of any shared water sources within the outbreak area:

_____

5.3 Name all livestock markets, slaughterhouses and animal collecting centres within a 10 km radius of the outbreak (*if applicable*)

Section 6: Risk factors and aetiology

6.1 Have animal herds within the outbreak area received vaccination?

☐ No

☐ Yes

Date of vaccination _____/_____/_____

Lot _____

6.2 Have animal herds within a 5 km radius of the outbreak area received vaccination?

☐ No

☐ Yes

Date of vaccination _____/_____/_____

Lot _____

Others:

_____

6.3 Movement of possible reservoirs

Type of possible reservoir	Date of movement	Origin	Destination
Animals:			
Carcass or meat product:			
Animal feed:			
Farmers, traders or other people:			
Vehicles:			
Others (specify):			

6.4 If an outbreak of this nature has occurred within a 10 km radius previously, please provide details:

i) Date of last outbreak _____/_____/_____

ii) Location of last outbreak _____

iii) Disease and serotype confirmed by laboratory (*if applicable)*_____

Please attach map(s) of outbreak location, water sources, livestock markets, slaughterhouses and animal collecting centres within a 10 km radius of the outbreak area.

A3.2 EXAMPLE OF A SEROPREVALENCE QUESTIONNAIRE FORM

Adapted from FAO. 2012. *Prevalence and risk factors for FMD-NSP antibodies in cow and buffalo calves, and small ruminants in Egypt: Result from a nationwide serosurvey May–December 2011.* Rome (*C. Bartels, personal communication, commissioned under MTF/INT/003/EEC1*).

Name of owner _____

Village _____

Municipality _____

District _____

Governorate _____

Location of local clinic (circle one) 0 Same village 1 Different village

PART 1

IDENTIFICATION -Fill out yourself-	QUESTIONNAIRE IDENTIFICATION	- UVN -
		X-COORDINATE
		Y-COORDINATE

1 What are the geocoordinates (decimal degrees) of the village?

X _____

Y _____

PART 2

VILLAGE **– ask local veterinarian –**	**QUESTIONNAIRE IDENTIFICATION**	**- VVV/GGG -**
		X-COORDINATE
		Y-COORDINATE

1. Is there a ruminant market in this village?
(Only one answer possible)

0 No
1 No, but in same municipality
2 No, but in same district
3 Yes

2. Have there been clinical signs for FMD seen in the last 12 months?
(Only one answer possible)

0 No
1 No, but in same municipality
2 No, but in same district
3 Yes

3. Have animals been vaccinated against FMD in the last 12 months?
(Only one answer possible)

0 No
1 Yes, 1 time, *month* (_____)
2 Yes, 2 times, *months* (_____)

4a. What is the estimated number of cattle in this village? Cattle _____

4b. What is the estimated number of buffaloes in this village? Buffaloes _____

4c. What is the estimated number of sheep in this village? Sheep _____

4d. What is the estimated number of goats in this village? Goats _____

PART 3

SAMPLE SHEET				QUESTIONNAIRE IDENTIFICATION		- VVV/GGG -
				X-COORDINATE		
				Y-COORDINATE		
Serial number[a]	Age in months	Sex = male = female	Species = cattle = buffalo	Born at owner = yes = no, in village = no, in municipality = no, in district = no, in different governorate	Owner	Coding for household questionnaire
UVN/01/01						
UVN/01/02						
UVN/02/03						
UVN/02/04						
UVN/02/05						
UVN/02/06						
UVN/02/07						
UVN/02/08						
UVN/02/09						
UVN/02/10						
UVN/02/11						
UVN/02/12						
UVN/02/13						
UVN/02/14						

[a] Please note that for each new owner there is a new number, sequential up to a maximum of 8. This identification is also used for the "owner's questionnaire". Please note that number for animals is a sequential number from 1 to 15. So this number does not restart when an animal is from another owner.

PART 4

HOUSEHOLD – ask owner –	**QUESTIONNAIRE IDENTIFICATION**	**- VVV/GGG -**
	X-COORDINATE	
	Y-COORDINATE	

1. Where did large ruminants go for drinking in the last 12 months?
(more than one answer possible)

0 At the house
1 Within village
2 Around village
3 In nearby village

2. Where were large ruminants fed in the last 12 months?
(more than one answer possible)

0 At the house
1 Within village
2 Around village
3 In nearby village

3. Were large ruminants introduced/purchased in the last 12 months?
(more than one answer possible)

0 No
1 Yes, from this village
2 Yes, from this municipality
3 Yes, from this district
4 Yes, from this governorate
5 Yes, from other governorate (_____)

4. For what purpose(s) are large ruminants raised?
(more than one answer possible)

1 Milk production
2 Fattening
3 Other

5. How did you treat the manure in the last 12 months?
(more than one answer possible)

1 Kept for self
2 Given to neighbours in the same village
3 Sold out of the village

6. Have you sold any ruminants in the last 12 months?

0 No
1 Yes

7. Did you buy/introduce large ruminant manure from other farms in the last 12 months?

0 No
1 Yes

8. Are there, or have there been in the last 12 months, sheep or goats in this household?

0 No
1 Yes

PART 4b – small ruminants

HOUSEHOLD **– ask owner –**	**QUESTIONNAIRE IDENTIFICATION**	**- VVV/GGG -**
		X-COORDINATE
		Y-COORDINATE

1. Where did sheep or goats go for drinking in the last 12 months?
(more than one answer possible)

0 At the house
1 Within village
2 Around village
3 In nearby village

2. Where were sheep or goats fed in the last 12 months?
(more than one answer possible)

0 At the house
1 Within village
2 Around village
3 In nearby village

3. Were sheep or goats introduced/purchased in last 12 months?
(more than one answer possible)

0 No
1 Yes, from this village
2 Yes, from this municipality
3 Yes, from this district
4 Yes, from this governorate
5 Yes, from other governorate (_____)

4. For what purpose are sheep or goats raised?
(more than one answer possible)

1 Milk production
2 Fattening
3 Other

5. How did you treat the manure in the last 12 months?
(more than one answer possible)

1 Kept for self
2 Given to neighbours in the same village
3 Sold out of the village

6. Have you sold any sheep or goats in the last 12 months?

0 No
1 Yes

7. Did you buy/introduce sheep or goat manure from other farms in the last 12 months?

0 No
1 Yes

8. Are there, or have there been in the last 12 months, large ruminants in this household?

0 No
1 Yes

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Progressive control pathways provide a stepwise, measurable approach to disease control and, potentially, eradication. Surveillance systems must be capable of providing useful information to document programme progress, assessing intervention efforts, and the achievement of interim outcomes. This document demonstrates a practical surveillance approach that progresses from measuring broad disease epidemiology and risk factors to specifically evaluating intervention options and documenting low disease prevalence. The process focusses on aligning practical surveillance components with disease programme outcomes while focusing on foot-and-mouth disease as an example.

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