USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Guidance on How to Design a Surveillance Scheme in U.S. Animal Health

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Note: If you are in the middle of a response and urgently need a scheme designed, contact the Surveillance Design and Analysis (SDA) unit in the Center for Epidemiology and Animal Health (CEAH) for assistance at VS.CEAH.Surveillance@usda.gov.

Introduction to Developing a Surveillance Scheme

Animal health surveillance is the process of collecting, analyzing, and interpreting animal health data to support animal health hazard management goals by providing information that results in taking action. For outbreaks, the animal health hazards of concern are diseases. Strategies for managing the animal health hazards are described in response plans outlining the response goals and objectives. The information from outbreak surveillance results in a specific action or set of actions related to management of the disease. The information gathered through surveillance can include characteristics about (a) the disease agent, (b) the animals, and (c) the environment animals live in, including the people who interact with the animals. A variety of tools are used to collect data for surveillance, such as questionnaires, visual observations, thermometers, scales, and, of course, a variety of laboratory procedures including diagnostic tests. The questions of how much data to collect, how many animals, barns, or farms to visit, how frequently to collect data, and how long the data collection process needs to continue are key elements of designing a scheme. The answers to these questions are dependent on other elements, such as surveillance objectives, data collection tools, and available resources.

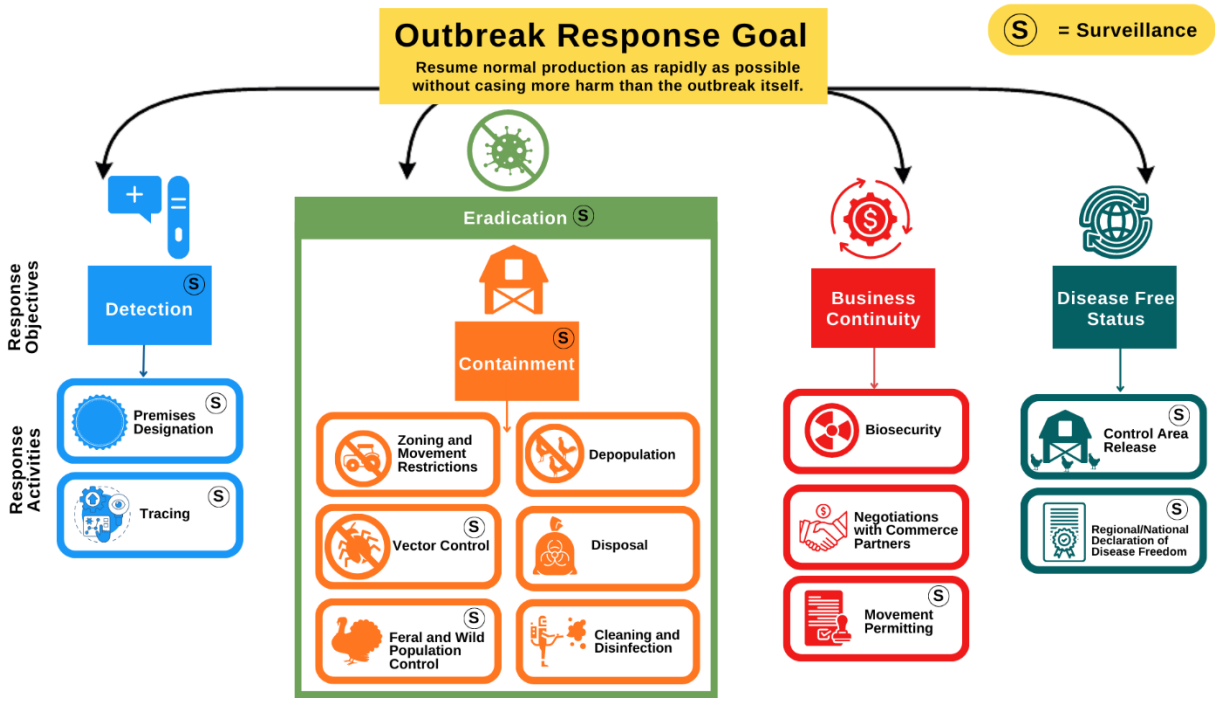


Figure 1. The role of surveillance in outbreak response. This diagram illustrates one way to picture an outbreak response. The overarching goal is attained through a set of concrete, measurable response objectives. Numerous activities (common examples shown) take place during the outbreak response to achieve the objectives. Surveillance is an activity that occurs at different times during the outbreak response and supports different objectives or other response activities. Surveillance is appropriate any place and any time actionable information is needed.

Instructions for Using the Guide to Surveillance Scheme Design

This guide is built around one specific example to provide a practical illustration of the steps in the process along the way. In this example, a surveillance designer named “Desi” has been asked to design surveillance for the Surveillance Zone (SZ) surrounding the established Control Area (CA) during the outbreak response to an incursion of foot-and-mouth disease (FMD) in the fictitious State of Commonplace. The fictitious outbreak was caught very early and is very localized in the fictitious county of Countryside. At the time that Desi was asked to design this surveillance, it had been more than 15 days since the outbreak was confirmed, a single CA in Countryside County had been established, and the extent of the outbreak was believed to be known. The purpose of this SZ surveillance is to provide ongoing evidence that control actions have been effective, and disease has been contained to the CA. Other surveillance to determine the extent of the outbreak has been conducted in the SZ prior to this period and FMD has not been detected in the current SZ to date. The SZ contains commercial swine operations (all-in-all-out, grow-out, and breeding), beef cattle feedlots, dairy farms, cow-calf operations, large sheep feedlots, goat (meat) farms, small wool-sheep operations, and small goat dairies.

Note that this particular surveillance scheme was selected for this guide to illustrate some specific features of surveillance design, not because it is more or less important than other surveillance that should be conducted in an FMD outbreak. Figure 2 below is a repeat of Figure 1 showing that this specific example is just one surveillance scheme of many schemes supporting outbreak response and plays the role of supporting the containment objective.

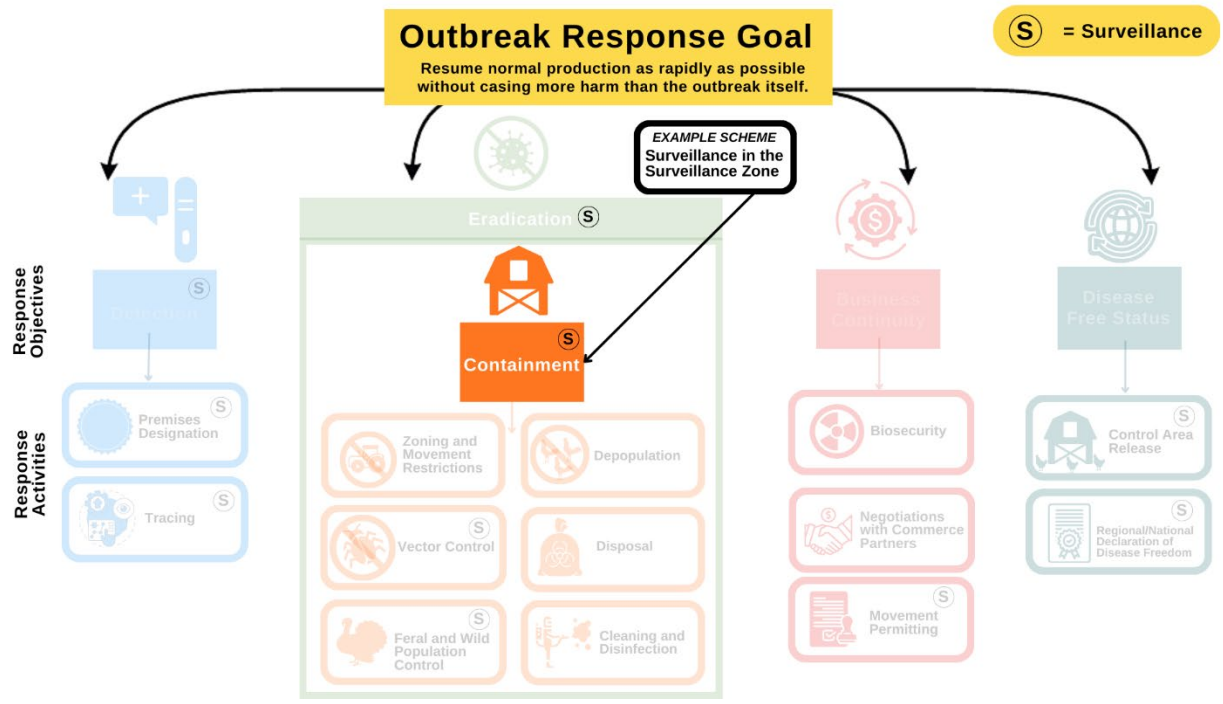


Figure 2. Context for the example surveillance scheme used in this design guide. The example scheme shown in this guide provides evidence that the control measures applied thus far in the response are working. This scheme gathers data to demonstrate that disease has not spread to premises in the Surveillance Zone. It is applied approximately 15 to 20 days into the outbreak after the Control Area has been established and the extent of the outbreak is well understood. This scheme is not the only scheme used to provide evidence that control measures are working. Surveillance in the Control Area and in the Free Area beyond the Surveillance Zone also provide evidence of successful control measures. The surveillance scheme example in this guide is just one of many surveillance schemes needed to support the outbreak response.

To design a surveillance scheme, start by identifying and describing the nine surveillance design elements given below (Figure 3). **If you struggle to fill in some parts of the elements, move on to other elements and return to the difficult ones later.** Use other surveillance schemes as examples or analogs to provide a starting place and document any assumptions you need to make so they can be addressed in the design process. **Do your best, but do not leave parts blank**.

After the base information is gathered, you will need to go back and forth (iterate) between some of the elements to design the final scheme. Unit selection, number of units, and frequency and duration of sampling are nearly always involved in this iterative process, but other elements may need to be reconsidered as well.

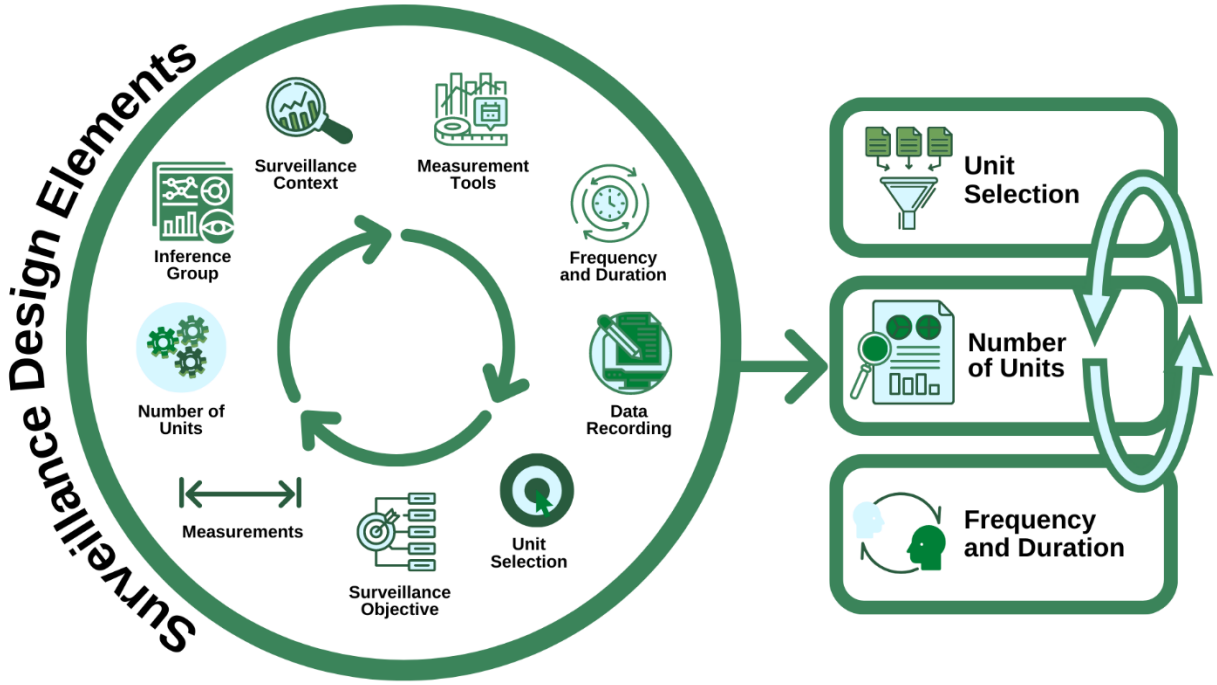


Figure 3. The nine surveillance design elements and iterative nature of the process

Once you have finalized the scheme design, a short summary of the information can be written for sharing with others. We recommend that this summary include information related to all nine elements, but they do not need to follow the order they are listed within this document, nor does all of the detail gathered in the process need to be shared. (See the Example Surveillance Scheme below.) The information gathered, including the thought process used to develop the scheme, is important and should be saved as a separate internal document.

The scenario used here is not intended to be realistic. The fictious outbreak was kept small to focus on one SZ surrounding one CA. For outbreaks with many CAs and SZs, the same approach is used and generalized across the different sized zones. This guidance document was written to help people use available information to make the best decisions possible. It focuses on the process and the decisions that need to be made along the way. The first time through will likely be slow, but it does become quicker as one gains familiarity with the process. Surveillance design is complex. Reach out to **VS.CEAH.Surveillance@usda.gov** for assistance.

Surveillance in the Countryside County Surveillance Zone (SZ) in the State of Commonplace after control actions have been in place for two weeks

This surveillance scheme supports the **response goal:** Resume normal production as rapidly as possible without causing more harm than the outbreak. More specifically, this scheme provides information to support the **response objective:** to contain foot-and-mouth disease (FMD) to the identified and established Control Areas (CA) through the **surveillance objectives:** (1) provide evidence demonstrating with 95 percent confidence that FMD prevalence is less than 10 percent among commercial cattle dairy premises in the SZ for premises having prevalence of 15 percent or more and (2) understand factors potentially involved in spread should disease be detected.

This surveillance scheme targets:

- Commercial cattle dairies in the Surveillance Zone (SZ) not designated as a contact premises (CP) or suspect premises (SP). CP and SP will be involved in surveillance as part of foreign animal disease (FAD) investigations.
- Cattle showing any non-specific clinical signs including mild signs such as low milk yield, low feed intake, or lameness.
- Cattle from areas in the premises where exposure is more likely such as near entrances, vents, or areas with high potential for fomite transmissions, because we do not expect cases of FMD in the SZ.

Select a subset of 26 premises (of the 97 total in the SZ) for active surveillance at random every 21 days with at least 2 rounds of testing occurring after lifting of the CA. When repeating the random selection process, remove premises previously selected from the list until surveillance has been conducted on all premises in the SZ, then start the process over with the full list of premises. Each round of surveillance achieves 0.95 probability of detecting at least one infected premises when at least 10 percent of premises in the SZ are infected when the probability of detection on each premises is 0.95.

For premises with 3,200 head or more, select 20 cattle exhibiting non-specific clinical signs from each separate bio-secure area (epi unit) on the premises. A premises will form one epi unit in most cases. If mild signs are common, select “cattle showing signs from each pen, barn, or other grouping” from each epi unit “with priority given to areas near entrances, vents, and areas with high potential for fomite transmission” (USDA–APHIS–VS, 2020). If there are only a few cattle with non-specific clinical signs, select them first, followed by selecting cattle from priority areas distributed across the epi unit as described above. Selecting 20 cattle results in a 0.95 probability of detecting at least one infected animal when 15 percent of the cattle in the epi unit are infected assuming a 95 percent sensitivity testing protocol. If less than 20 cattle are tested, the probability of detection will be less than 0.95, increasing the number of premises required to achieve 0.95 probability of detection at the SZ level. For premises with less than 3,200 head, use the Animal Sample Size Table to determine the exact sample size for these smaller premises. Observation of case-compatible clinical signs require an FAD investigation rather than continuing with SZ surveillance sampling.

Send specimens (oral swabs or Probang samples) to NVSL or an approved NAHLN laboratory for rRT-PCR testing. If the rRT-PCR is positive at a NAHLN laboratory the sample will be sent to FADDL for confirmation (USDA–APHIS–VS, 2015). Submissions to NVSL must contain a hard copy of the completed 10-4 Form (USDA, 2022). Each NAHLN laboratory has its own submission form; locate and use the correct form for the choice of laboratory. Refer to the FAD PReP Foreign Animal Disease Investigation Manual (USDA, 2022) for sample labelling and submission details.

Include a unique specimen identifier (bar code) and Premises ID on each specimen container. Include the Premises ID, the unique specimen ID, date and time of collection, and unique animal ID on the submission form. Enter each unique animal ID into the EMRS2Go app associated with the Premises ID and date of collection, and for each animal include the unique specimen ID, animal age, clinical signs observed, any subgroup, barn, or pen identifier and/or special locations such as near an entrance, vent, or other high-risk area. Include reason for collection, total number in susceptible populations on premises by species, the presence and total population of other livestock species, and key biosecurity practices in the EMRS2Go app associated with the Premises ID and collection date.

Response activities will continue unchanged if no positive detections occur for the premises tested in the SZ. Negative test results for all specimens provide evidence that control actions are working. Movement restrictions for premises in the CA and for network premises should prevent spread to the SZ. There are no movement restrictions within the SZ to halt further spread in this zone should it occur. Early detection of an introduction in the SZ depends heavily on passive surveillance and industry involvement in enhanced passive surveillance activities to detect specific signs associated with FMD.

A confirmed positive disease detection will result in the designation of new Infected Premises (IP) and initiation of associated response activities and trigger a need for additional information. That is, separate surveillance will likely be required to determine and understand pathways of introduction.

References

U.S. Department of Agriculture (USDA–APHIS–VS). 2015. Foot-and-mouth disease (FMD) response ready reference guide - overview of FMD diagnostics. https://www.aphis.usda.gov/animal_health/emergency_management/downloads/fmd_rrg_diagnostics.pdf.

U.S. Department of Agriculture (USDA–APHIS–VS). 2020. Foot-and-mouth disease response plan the red book. FAD PReP foreign animal disease preparedness & response plan, 222. https://www.aphis.usda.gov/animal_health/emergency_management/downloads/fmd_responseplan.pdf.

U.S. Department of Agriculture (USDA). 2022. Foreign animal disease (FAD) investigation manual.

Design notes for example

Blue boxes with this icon  contain notes provided by a typical surveillance designer (we'll call her "Desi"). Like you, Desi may not have all the information, or all the details needed to design a surveillance scheme the first time through. You will see that the information quality and details will improve as Desi works through the design process. You will also see her change her mind about scope and eventually see her adjust her design to balance feasibility with the need to avoid consequences of erroneous decisions. You will need to go through this process too when you design surveillance schemes.

Guidance

Tan boxes like this are included to provide you with additional information and specific guidance for each step.

Elements for Surveillance Design

1. Surveillance Objective

1.1. Describe the hazard management goal and the response objective or activity supported by the surveillance. State the specific surveillance objective with a measure of precision.

1.2. State the measurable outcome of the surveillance scheme. Describe the action that will result from the information gathered through surveillance.

1.3. Describe the consequences of making a wrong decision using the surveillance information.

Surveillance Objective

1.1. Overarching outbreak response goal for the entire outbreak response: *Resume normal production as rapidly as possible and regain disease-free status without causing more disruption and damage than the disease itself.*

Surveillance Objective *In 1.1., Desi has more knowledge and information than would ordinarily be expected. We helped her out with 1.1. because it is important to illustrate the ideal information that belongs here.*

It is not unusual to find yourself designing surveillance without knowing the outbreak response objective or activity that the surveillance informs, let alone having a clear understanding of the overarching outbreak response goal. You may have to simply make some reasonable assumptions in this section, such as assuming the overarching response goal is something like "disease control and eradication" or perhaps "containment and managing impact."

Specific response objective supported by this surveillance: Contain FMD to the identified and established Control Areas (CA).

Outbreak response objective *This is only <u>one</u> response objective among many in this outbreak response that supports the overarching outbreak response goal. It is <u>the</u> response objective supported by <u>this</u> specific surveillance scheme. Disease control and eradication are two closely tied response objectives. Because many response activities support both objectives, control and eradication are often treated as if they are one objective. The example surveillance scheme described here supports the control or containment objective, but it does not provide information to support an eradication objective. Therefore, we only list the containment objective here to be clear about what the surveillance can achieve.*

Again, this may be difficult for you to determine. Because surveillance is the process of collecting information for action, ***you cannot design effective surveillance if you don't know what actions the surveillance supports****. So, if you skip this step, come back to it before you finalize your design.*

Surveillance Objective *(continued)*

Surveillance Objective: Provide evidence demonstrating that FMD is below a specified prevalence threshold (to be determined) in the Surveillance Zone (SZ) during the period of surveillance with a 0.95 probability of detection if FMD is present at this prevalence threshold or above.

Surveillance Objective

You may need to start with outcomes and actions (1.2.) and then come back to fill in objectives (1.1.) based on the outcomes and actions. To work backward this way, ask yourself, "What information will the surveillance provide?", "What actions will that information trigger?", "Why are those actions important?", and "What response activities or response objectives are supported by the information from the surveillance?"

Describing the objectives and actions supported by the surveillance is essential to surveillance design. A specific surveillance objective that includes the level of precision is necessary to determine the sample size required to meet the objectives.

It is also important to describe what you think the overarching response goal(s) and objective supported by the surveillance are. If later, you find your surveillance is not meeting someone's needs, it will likely be because their response goals and objectives differ from your assumptions.

During an active outbreak, you may be able to obtain response goals and objectives from the Incident Management Team (IMT). (Be aware that people may use the terms, "goal" and "objective" differently from how we have defined them here. Here we are looking for both the abstract overarching goal of the response and the specific measurable objectives of the response that help achieve the goal.)

For this FMD example, it may also be useful to look at the Foot-and-Mouth Disease Standard Operating Procedures: Surveillance and the Foot-and-Mouth Disease Response: Ready Reference Guide -FMD Surveillance SOP. Keep in mind that these documents were written prior to development of the current surveillance design guidance documents and many concepts and terms have not yet been aligned.

Surveillance Objective *(continued)*

1.2. Measurable outcomes and associated actions

Individual premises selected from the SZ will either be FMD Detected and Confirmed according to the FMD Case Definition or FMD Not Detected.

Decisions or actions resulting include:

1) If FMD is **Detected and Confirmed** on **any** premises in the SZ
   - Response actions will be initiated including depopulation, defining a new CA, trace investigations, and similar.
   - There may be a need for additional information, such as a separate surveillance scheme designed to determine and understand mechanisms for spread.
2) If **all** premises tested in the SZ are **Not Detected**, then response activities will continue unchanged. The negative results provide evidence that control actions are working.

Measurable outcomes and associated actions *It is useful to work this out in a stepwise fashion. Consider the data that you think you will be collecting and the reason for that collection. From there, identify the decisions and associated actions that the information will lead to. Often the decision is one of two choices, but there can be more than just two options depending on the data collected. This may be the first place that you will loop through steps to refine your design. You may write down the type of information you expect to collect only to find that this information is insufficient to make the decision needed and then adjust your scheme to include other information.*

1.3. Consequences of errors

1) If FMD is detected when FMD is not present, unnecessary and costly actions will be triggered.
2) If FMD is not detected when FMD is present, then FMD is not contained in the CAs and disease is spreading. (Or it may have been present there prior to the CA establishment.) Furthermore, FMD will continue to spread from this undetected premises.

Consequences of errors *Think carefully through the errors in the decision-making process in 1.2. and the actions that follow. Identify the level of concern you have with each of the errors. In this example, the chances of making the conclusion that a premises is infected when it is not, are low and are reduced by confirmation testing and epidemiological investigations. The other error, failing to detect disease when it is actually present, is a very serious error. The chances of this error can be reduced by designing surveillance with the best choice of diagnostic test possible to achieve a high probability of detection (0.95) at a prevalence threshold that is not of concern for spread, even if it were missed, and by repeating rounds of surveillance to detect missed cases in a reasonable amount of time. Costs and practical considerations will need to be balanced with the proposed surveillance needs and the impact of missing cases. In this situation, the consequences of a false negative can be reduced by good biosecurity and careful observation of clinical signs by producers, i.e., preventing spread through other actions.*

2. Surveillance Context

2.1. Describe the setting in which surveillance is carried out. Include:

- The species of animal
- The production type or environment in which the animals are found, including the region or State(s) that are the focus of this surveillance
- The health hazard of primary concern
- Historic presence/absence of the health hazard
- All response actions that are in place at the time of the surveillance (such as biosecurity measures, movement restrictions, isolation periods, and similar).

2.2. Indicate items from the list above that impact the level of surveillance needed to achieve the surveillance objective.

Surveillance Context

2.1. Setting

The SZ(s) are areas surrounding identified and established CA(s).

- This surveillance focuses on cattle, swine, sheep, and goats in the (fictitious) State of Commonplace. The current surveillance scheme will focus on premises with susceptible species that engage in commerce. Backyard operations will be the focus of a different surveillance scheme. For the current scheme, the premises of interest include ~~commercial swine operations (all-in-all-out, grow-out, and breeding),~~ ~~beef cattle feedlots,~~ **dairy farms,** ~~cow-calf operations,~~ ~~large sheep feedlots, goat (meat) farms, a number of small wool sheep operations, and numerous small goat dairies~~.
- FMD is the primary concern. VSv and SVv can look like FMD and though infrequent in the state of Commonplace, these viruses are possible differential diagnoses to consider. The incubation period for FMD is 2–14 days and can vary by species, dose of virus, and on the route of infection. Morbidity can be up to 100 percent, but mortality in adults is typically 1–5 percent. Younger animals are more likely to die from FMD, often due to inflammation of the heart. Clinical signs commonly occur in the following manner:
  - ♦ **Cattle:** Typically present with fever, anorexia, and reduction in milk production; excessive salivation can often occur. After 2–3 days, lesions can be observed on mucous membranes, interdigital spaces, and on the coronary band; these will rupture after approximately 1 day. Recovery comes after 8–15 days.
  - ♦ ~~Pigs: Severe lesions occur on feet and also may be on the snout, udder, hock, and elbow.~~
  - ♦ ~~Sheep and goats: Signs are fewer or less obvious, but can include lesions on mouth, heel bulbs, and coronary bands.~~

Desi: "I am concerned that designing surveillance for all of these species is going to be too complex. I'm going to reduce the scope to cattle and work on surveillance for pigs and for sheep and goat at another time. In fact, I'll build this for dairies first and expand to other cattle operations later, as well."

- The state of Commonplace was historically free of FMD until the current outbreak.
- In the SZ, premises managers should be on heightened awareness for the presence of FMD in their area and should be following the FMD Redbook, secure food supply guidelines, or other incident guidelines for best biosecurity practices. There are no movement restrictions in the SZ, so keep this in mind when considering mitigations that might reduce the impact of false negative results.

Surveillance Context *(continued)*

2.2. Factors impacting surveillance

During the period of time when this SZ surveillance scheme will apply, there will not be an overarching standstill and there are no movement restrictions in the SZ. Strict movement controls should be in place in the CA. FMDv spread from infected premises by way of animal or product movements, or fomites is limited by the movement restrictions placed on the infected premises, on vehicle traffic, and on other premises within the CA. Airborne spread between premises is limited at this time (more than 2 weeks out from initial detection and the IP has been depopulated). ~~Airborne spread from infected farms or passing infected trucks is possible, but we should make sure that this has been limited by zoning and movement restrictions.~~

Desi: "I checked on this concern about spread from passing vehicles and found that beyond the boundary of the CA, this type of transmission is unlikely in the SZ. Contaminated trucks or trucks carrying infected materials should not be traveling outside of the CA without cleaning and disinfecting nor without a movement permit."

There are no vaccinations taking place at this stage in the outbreak response.

There are no movement restrictions or movement permit requirements in the SZ; the SZ is part of the Free Area (FA).
At this point in the outbreak, it is believed that all FMD infected premises have been found and that spread from the original cases (in CA's) is not occurring. We do not expect FMD in the SZ. In our design we will need to balance the need to detect FMD infected premises (an avoid false negatives) with the costs and feasibility of the sampling.

Factors related to risk:

- Operations with more traffic onto and off the operation are higher risk (frequent buying and selling; more service-related visits including feed delivery, veterinarians, and similar; and number of farm workers entering and exiting the operation daily).
- Swine are considered virus amplifiers, but clinical signs appear slightly later and are less severe than in cattle.
- Sheep and goats tend not to show obvious clinical signs and are more likely to spread before detection.

Surveillance context *Describe what you know to the best of your ability and request information from anyone who has seen the situation first-hand. Think about the consequences of errors (1.3.) as you fill in the setting (2.1.) and particularly the mitigations impacting surveillance (2.2.). What are the risks associated with false negative findings in the particular context for the surveillance? What special activities or circumstances are in place that either reduce the probability of a false negative occurring, perhaps by reducing the risk that positives exist, OR that reduce the consequences of a false negative? For example, consequences of a false negative are reduced when movement restrictions are in place compared to a situation where there are no such restrictions.*

3. Inference Group

3.1. Carefully define the inference group (the group of units the surveillance provides information about), making it clear which units are included in the inference group and which ones are not.

3.2. Note if the inference group differs in any way from the population included in the hazard management goal, what those differences are, and why there is a difference.

Inference Group

3.1. Define group

The inference group includes all commercial premises (premises that engage in commerce by selling animals or product and moving them off the premises, or buying animals or product and moving them onto the premises) with **cattle,** ~~bison, swine, cervids, sheep or goats~~ in the State of Commonplace. ~~Feral swine in holding facilities or those being trapped and held for movement should be included~~.

Desi: "I'm limiting the scope for this scheme."

3.2. Differences

The outbreak response goal and response objective identified in 1.1. applies to all operations with susceptible species where outbreak response activities are used to manage FMD spread. This surveillance scheme focuses only on commercial cattle dairy operations. Surveillance for other cattle production types and other species will be developed separately. For premises involving dairy cattle that do not participate in commerce but play a role in the FMD outbreak, we depend on awareness and reporting through passive surveillance for these types of premises in the SZs. That said, we included premises with as few as 2 dairy cows in our 97 identified premises for this surveillance. Wild populations of susceptible species and exotic animal facilities in the SZ are also excluded from this surveillance scheme and need to be addressed separately.

It is important to identify which group of animals the surveillance will make inference to. Be specific about which animals are included in this inference group and which animals are not.

It is often easier to design surveillance for a narrowly defined inference group. A scheme for one inference group can be used as the starting point for the scheme for a new group. Schemes for different inference groups can always be combined later into one document, when doing so will not cause confusion.

4. Unit Selection

4.1. Identify the specific units (animals, pens, barns, premises, areas, zones, and similar) to collect measurements from.

4.2. Describe the hierarchy of units to select and measure. For example, to collect measurements about disease on a premises might require selecting barns within the premises, pens within the barns, and animals within the pens.

4.3. Explain the processes for selecting units at each level in the hierarchy, such as selecting all units (census), random selection, targeted selection, or a combination.

4.4. When using targeted selection, describe and justify the use of the targeting criteria.

Unit Selection

4.1. Units to measure

Measurements will be collected on (1) individual cattle, (2) barns, pens, or subgroups of cattle on the premises where disease spread is limited or restricted because of the grouping (epidemiologically separated), and (3) premises. The primary measurement (diagnostic test) will be collected on individual cattle while contextual information will be collected on barns or pens and on premises.

This surveillance scheme was selected as the example for this guide because it involves zone-level surveillance rather than just focusing on individual premises level surveillance. That is, this surveillance requires the designer to determine how many premises to select from the SZ, how many barns or pens to select from each premises, and how many animals to select from each barn, pen, or other group that can be considered an epidemiological unit.

Unit Selection *(continued)*

4.2., 4.3., and 4.4. Hierarchy of units measured, selection processes, and targeting

Premises – Using the complete list of all 97 commercial dairy premises in the Countryside County SZ, select a subset of premises at random without replacement. This process will likely be repeated multiple times. If all premises in the SZ have been selected, start over with the full list frame of 97commercial dairies.

Barns, pens, or subgroups - Most commercial premises will have multiple barns or pens of varying sizes. Surveillance should ideally be conducted for every barn or pen on the premises, particularly if these units are considered epidemiologically separate (disease spread is restricted or limited between units in some way). If only a subset of barns, pens, or subgroups are to be selected, target barns, pens, or subgroups with the most case-compatible clinical signs first, followed by groupings with the highest risk of exposure.

Individual cattle should be selected using appropriate targeting criteria. First target case-compatible clinical signs, secondly, target factors that could result in increased risk of exposure, and thirdly, on factors that could result in an increase in susceptibility. (The number of premises, subgroups, and animals to select is determined in Element 7.)

SZ's can contain a large number of premises and it will likely be impractical to conduct surveillance on all premises in the SZ at one time, thus a subset of premises will need to be selected. We will be returning to the SZ to sample premises until the associated CA is released. It makes sense to visit different premises in the SZ each time and only returning to those selected previously when all premises in the SZ have been tested at least once. This is the reason for sampling without replacement. However, if there are known differences in the risk of introduction to any of the premises in the SZ, targeted selection could be considered. The first round of SZ surveillance could be conducted in the highest risk group and the selection process could return to this set of premises before testing all of the premises in the SZ, if the risk warrants it.

Random sampling is necessary for unbiased estimates in research. However, for many surveillance objectives, biasing results can make achieving the surveillance objectives more efficient. Selecting a target subgroup of animals (or even premises as was suggested above) can increase the opportunity for detection when diagnostic testing is the primary measurement (See Element 5 below). Just remember that using a targeted selection process prevents the data from being used to generate unbiased statistical estimates for the general inference group.

5. Measurements

5.1. List the primary measurements required to achieve the surveillance objective.
5.2. List additional measurements (contextual data) required.

Measurements

5.1. Primary measurements

The primary measurement of interest for this scheme is the diagnostic test result of an FMD rRT-PCR conducted on vesicle fluid, oral, or lesion swabs or a PCR of a Probang specimen. Because we do not expect to see vesicles or lesions, Probang specimen are likely to be the most common specimen type.

5.2. Additional measurements

Premises data: Unique premises ID, date of visit, reason for collection and submission (SZ surveillance), premises type (dairy), herd-level observations of case-compatible clinical signs or other indicators of herd health status, total number of dairy cattle on the premises, total number of other livestock on the premises by species, key biosecurity practices, and a list of animal ID's for the cattle sampled at that visit.

Desi: "The measurements underlined are not necessary for the original objective. These details require minimal effort to add and would be invaluable if disease spread occurred to understand the mechanism of spread."

Animal data: Unique animal ID (official USDA tag), date and time of specimen collection, species of animal (bovine), clinical signs or other indicators of health status observed on each animal, age of animal, any subgroup, barn, or pen identifier and/or special locations such as near an entrance, vent, or other high-risk area for the animal, unique specimen identifier (bar code), and unique premises ID.

Specimen data: Unique specimen identifier (bar code), date and time of specimen collection, unique animal ID, and unique premises ID.

Note that although this is not expected in the SZ at this point in the outbreak, certain clinical signs at the herd-level would be sufficient to designate a premises as a Suspect Premises (SP), triggering a confirmatory Foreign Animal Disease (FAD) investigation.

It is important to clearly specify all of the data required to make use of the primary surveillance measurement to meet the objectives. It's easy to think only the test result and associated premises are needed. A positive test associated with a premise would achieve the primary objective – we could be very sure that control actions are not working, and disease has spread. But for a collection of negative test results, data analysis is necessary to demonstrate that the level of precision needed for the surveillance objectives has been achieved. If negative test results can't be connected to specific places and times, the surveillance information cannot serve its purpose.

*Beyond the primary objective, **if a positive is detected in the surveillance zone**, understanding how the spread occurred will become a new objective. Having information about biosecurity practices and environmental conditions would support this need. Desi has chosen to include additional measures for this purpose.*

6. Measurement Tools

6.1. Describe the tools (instruments, devices, processes) to be used to take the measurements.

6.2. Provide references to other material as necessary so that the measurements can be collected correctly.

Measurement Tools

6.1. Describe tools The FMD diagnostic test used is the rRt-PCR and can be applied to serum, oral swab or Probang, epithelial tissue, or vesicular fluid. See fmd_rrg_diagnostics.pdf (usda.gov). This test has a mean diagnostic sensitivity of 95 percent and a mean diagnostic specificity of 97 percent when using cutoff CT values of 45 per the National Veterinary Service Laboratory (NVSL). Because FMD is not expected in this region, most of the specimens will be oral swabs or Probang.

No specific survey instrument exists for observational measurements on specimens, animals, and premises. This type of information can be capture in the Emergency Management Response System (EMRS)2Go mobile app. If EMRS2Go is not being used, data will need to be captured on paper, but ultimately, all of the data collected must be entered into EMRS for an FAD like FMD.

Specimens are submitted to NVSL or an approved National Animal Health Laboratory Network (NAHLN) laboratory for testing. Unique specimen identifier (bar code), date and time of specimen collection, unique animal ID, and unique premises ID should be captured on the lab submission form for the selected NAHLN laboratory or the 10-4 submission form for NVSL. When using EMRS2Go, submission forms can be created automatically.

Provide details in the surveillance scheme on the specimen type(s) and tests that meet the needs of the surveillance. It may also be helpful to describe initial detection processes versus detection processes later in an outbreak. Non-negatives must be confirmed at NVSL before declaring them as positives. There may be a shift during an outbreak allowing some control actions to occur for a NAHLN laboratory non-negative result. Be sure to check the case-definition for the disease and incorporate how a case is defined into your scheme either here as part of the measurement tool or as part of Element 1 and the decisions made because of the surveillance.

Detailed information about a specimen is required on the laboratory submission forms so that diagnostic test results can be linked to the correct animal and premises once the results are final. Linking test results to the correct records in EMRS requires that the same identifying details are entered into EMRS as well as on the laboratory submission form.

Finally, remember that surveillance includes data other than diagnostic testing. Data observed on the animals (species, clinical-sign, location on the premises, and similar) and their environment (groupings or housing, group risk factors such as pen exposure to wildlife, weather conditions, overall herd or flock health, production type, premises-level risk factors such as movements or visitors, and similar) are important for meeting the surveillance objectives.

Many data collection tools (electronic forms, mobile information apps, and similar) are still being developed, so note where tools are needed, where existing tools require additional fields or other improvements needed to support accurate data collection.

Measurement Tools *(continued)*

6.2. References for correct use of tools

See the Foreign Animal Disease (FAD) Investigation Manual for guidance from NVSL on the proper methods for collecting the specimen, proper handling for shipping the specimen, and completing submission forms. Visit the General NVSL Information USDA webpage to find further details about laboratory submissions.

Use initial contact forms and other fields provided in EMRS2Go to collect data about the animals, about the pens, barns, pastures, or other animal groupings on the premises, about the premises, and about the weather or other environmental conditions.

It is important that any tools for taking the measurement be used correctly to get the most accurate measurements possible. Always provide guidance on the use of measurement tools or include a link to detailed information about the measurement tools and their use.

This is especially important for accurate measures of disease presence/absence. The diagnostic sensitivity and specificity depend on proper collection and handling of the specimen. Provide instructions on specimen collection, appropriate containers, and media, and on special handling instructions. Alternatively, provide a link to laboratory guidance on these procedures.

7. Number of Units

7.1. Provide the number of units (at all levels of the hierarchy) to collect measurements from to achieve the surveillance objective(s).

7.2. Include the level of precision or uncertainty in the inference or predictions. Specifically, state the chances of making a wrong decision using the surveillance information provided by this scheme and list the conditions that could result in an error.

7.3. Describe how quickly the measurements need to be collected (the period of time for taking the key measurements) to be considered one measurement event.

Number of Units

7.1. and 7.2. Each level in the hierarchy

Number of animals: For the rRT-PCR, the diagnostic sensitivity is 95 percent. If the prevalence in the target group is at or above the prevalence threshold and we test the number of animals as given in the table below, at least one infected animal will be observed with 0.95 probability. This table is for an epidemiological unit of 3,200 or more cows per premises. The number of animals tested could be less for smaller premises, especially at the lower prevalence threshold values.

Number of animals to select from premises with 3,200 or more cows per premises to achieve 0.95 probability of detection for various prevalence threshold values.

Prevalence Threshold for Target Group	Number of animals tested
0.20	15
0.15	20
0.10	30
0.05	62

This particular surveillance scheme was selected for this guide because it involves zone-level surveillance rather than just focusing on individual premises level surveillance. Thus, Desi must decide how many premises to select from the surveillance zone, how many barns or pens to select from each premises, and how many animals to select from each barn or pen.

Number of animals *Starting with the number of animals, use the Animal Sample Size Table and enter the rRT-PCR diagnostic sensitivity of 95% into the "Diagnostic Test Protocol Sensitivity" cell. For "Confidence Level" use the default 95.00% value. Sometimes we set confidence to 99%, but only when we need the detection probability to occur 99 times out of 100.The table of values provides an array of sample sizes for "Total number of animals in the epidemiological unit" containing from 1 to 100,000 animals and for "Prevalence Threshold of Disease" levels from 0.01% to 95.00%.*

Desi has captured four sample sizes for 20, 15, 10, and 5% prevalence thresholds, respectively, for an epidemiological unit with 3,200 or more cows. She's created a small table of options to help her decide on an appropriate design, knowing that the sample sizes are smaller for smaller farms.

Number of Units *(continued)*

7.1. and 7.2. Each level in the hierarchy (*continued)*

Number of premises: The Countryside County SZ contains 97 dairy premises. If surveillance is sufficient to achieve confidence of 95% on each premises, then a 0.95 probability of detection (detect at least one infected premises 95 times out of 100) can be achieved for the prevalence levels shown in the table below when testing is conducted on the number of premises given.

Number of premises to select for active surveillance out of 97 dairy premises in Countryside County, in the State of Commonplace for various prevalence thresholds (or number of infected premises among the dairies).

Number of infected dairy premises in the Surveillance Zone	Prevalence among premises in the SZ	Number of premises selected for active surveillance
3	3/97 ≈ 3%	66
5	5/97 ≈ 5%	47
8	8/97 ≈ 8%	32
10	10/97 ≈ 10%	26

Number of premises *Using the Premises Sample Size Table, leave the "Confidence Level" at the default 95.00%. Assuming that sampling of animals on the premises is adequate (as designed above), the "Probability of detection within the premises (based on number of animals tested)" is set to 95%.*

Desi has calculated the approximate prevalence of 3, 5, 8, and 10 infected premises among the 97 premises in her SZ and created a table to help her determine the best design.

The sample size table provides an array of values and an array of sample sizes for "Number Premises in the Zone or Area" containing from 1 to 100,000 animals and for "Prevalence Threshold of Disease" from 0.01% to 95.00%.

Scroll down until you find the row for 97 under "Number of Premises in the Zone or Area". Find the columns for 3%, 5%, 8%, and 10% under "Prevalence Threshold of Disease". You will see the values found by Desi {66, 47, 32, and 26} for the sample sizes.

Number of Units *(continued)*

7.1. and 7.2. Each level in the hierarchy (*continued)*

Number of epidemiological units: There are 97 dairy-premises in Countryside County of various size. Most of them are small with 71 premises having less than 100 milking cows and 19 with 100 to 499 cows. There are 3 premises with 500 to 999 cows, 2 with 1,000 to 4,999 cows, 1 with 6,436 cows and 1 with 9,527 cows. Most of these dairies have one milking parlor for all their cows, so even if cattle are housed in separate pens or barns, the premises forms one epidemiological unit (exposure to disease does not differ among animals in different pens or barns). A few of these premises do have multiple milking parlors and keep subsets of their cows in separate bio-secure areas (epidemiological units). (There are four of these on the biggest premises for example.) On these premises, surveillance must be conducted in all epidemiological units and the number of cows selected for testing in an epidemiological unit should be equivalent to the number of cows selected for testing on separate premises.

Number of epidemiological units: *In this example, all the epidemiological units on a premises will be selected for surveillance because there are at most four epidemiological units per premises.*

If the number of epidemiological units is large and conducting surveillance in all epidemiological units is overly burdensome, select a subset of epidemiological units for surveillance. Using the Premises Sample Size Table and treating separate epidemiological units on a premises like "Premises in the Zone or Area", leave the "Confidence Level" at the default 95.00% and assume that sampling of animals on the premises (or epidemiological unit in this case) is adequate to achieve a 95% probability of detection.

7.1 and 7.2 Recap

The sample size to consider ranges from 15 to 62 cows per premises or epidemiological unit on about one-half to one-third of the premises in the SZ for each round of sampling. The impact of prevalence threshold and conditions for making an error hasn't been fully explored yet.

Desi: "There is a lot to think about here. Once the initial information is captured, I want to come back and consider several options. For each option, I'll calculate the total sample size, the probability of detection (or more importantly, the circumstances that could result in an incorrect decision), and consider the consequences of an error balanced against feasibility and resources." See notes under Iterative Design Process.

Number of Units *(continued)*

7.3. Measurement events or rounds of testing

Data collection (specimen collection and other observations of the animals and their environment) on each individual premises must be completed within one day and data collection on the entire set of selected premises needs to be accomplished in less than five days to make a claim about the disease status of the zone at one point in time. Conducting surveillance on the entire selected subset of the 97 premises is considered a single measurement event, or one round of SZ surveillance, and will be repeated in time to provide continued support that control actions are working.

Data collection can often be spread across time for practical reasons and still achieve the surveillance objectives. One mathematical assumption is that the phenomena being observed is fixed or not changing. The practical application of this assumption when one of the measures is the presence/absence of a disease agent is to collect data with a time frame during which disease prevalence is relatively static.

Information from a single measurement event can hold value over time when there is a negligible risk of introductions that allow an accumulation of information over time. During an outbreak of a highly transmissible FAD, risk of introduction is nearly always a concern. In this specific case, in which a Control Area has been established with all the associated quarantines and other control actions and no new cases have emerged in the Surveillance Zone for a period of time, one could argue that risk of introduction is minimal and that a single measurement event for surveillance could be spread over an extended period of time.

Desi has chosen to select a subset of premises to visit within 5 days and repeat this process in 21 days with 2 rounds of testing after the lifting of the Control Area to demonstrate that the Surveillance Zone remained free of disease. Alternative approaches are certainly possible although specific surveillance objectives will likely be different.

8. Frequency of Repetitions and Duration

8.1. Explain whether the measurement event needs to be repeated and how often.

8.2. Explain the duration of surveillance (or number of repeats) to achieve the surveillance objective(s).

Frequency and Duration

8.1. Frequency

To continue to demonstrate that control actions are working, measurement events in the SZ must be repeated periodically as long as there is a CA associated with that SZ. Typically, this type of surveillance is conducted once an incubation period (~14 days for FMD) or if control measures appear to be working well, once every 21 days may be appropriate.

8.2. Duration

Surveillance should continue in the SZ for two measurement events or rounds of testing lifting the CA.

The frequency of repeated measurement events in a scheme depends on the surveillance objectives, the disease transmission parameters, and risk of introductions. Some surveillance objectives only require one or two separate measurement events to make a conclusion with the necessary level of confidence, while other objectives may require on-going surveillance for an extended period of time. In an outbreak, the duration for some surveillance schemes depends on the duration of the quarantine. Often there is a need for one or more measurement events after quarantine has lifted to fully demonstrate that there is no disease spread.

9. Data Recording

9.1. Describe any processes or systems for recording data such as approved forms, electronic forms on hand-held devices, or official data systems.

9.2. Provide details on how specific data fields should be entered or provide a link to special instructions for each official system.

Data Recording

9.1. Data recording systems used

There is no survey instrument for capturing the required observational measurements on the animals, barns or pens, and premises. Information to be collected on the premises, the animals, and the specimens are listed in Element 5. All the data detailed in Element 5, except the diagnostic test result, should be captured in the EMRS system.

9.2. How data should entered

Specific instructions and guidance on data entry can be found in the training section of EMRS. Information is either captured on paper and entered into EMRS later, or entered directly into the EMRS2Go system (a mobile device tool for entering data in a field setting.)

The unique specimen identifier (bar code), date and time of specimen collection, unique animal ID, and unique premises ID should accompany the specimen laboratory submission to ensure that the diagnostic test result for each specimen can be linked to the animal and premises in EMRS. Details can be found in the FAD PReP Foreign Animal Disease Investigation Manual (USDA, 2022).

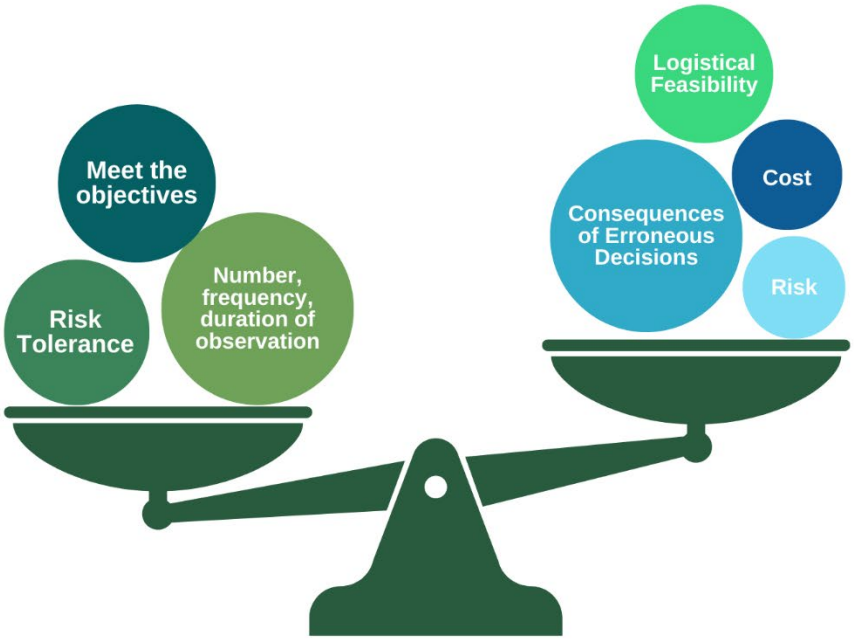
EMRS is the official record keeping system for FAD outbreaks. The Disease Reporting Officer (DRO) on an incident is responsible for reviewing laboratory results and creating the appropriate statuses in the system. When developing a surveillance scheme, a DRO should be included in the discussions to provide input on specific data needs and procedures.

Reports on surveillance progress can be created and/or extracted from the EMRS system, and visual displays can be generated by using chart and advanced mapping capabilities. EMRS can also be used to assign and manage the surveillance work and EMRS2Go is a user-friendly data entry interface that simplifies much of the data capture process at the field level - use of this app is highly recommended. If you are unfamiliar with EMRS, consult with EMRS Network Associates and EMRS Specialists for further guidance.

Specimens are submitted to NVSL or an approve NAHLN laboratory for testing and must be accompanied by the laboratory submission form for the selected NAHLN lab or the 10-4 submission form for NVSL. Laboratory submission forms should not be viewed as record keeping or measurement tools. Detailed information is required on these forms so that diagnostic test results can be linked to the correct animal and premises once the results are final.

Iterative Design Process

Once information on all nine elements has been gathered, it is time to reconsider some of the elements. Revisit any and all elements as necessary.



It is particularly important to balance the proposed number and frequency of data collection required to meet specific surveillance objectives with the cost and logistical feasibility of the surveillance proposed.

A typical set of questions to ask at this stage include:

1. Is the inference group (3.1.) and surveillance context (2.1.) defined so that one surveillance scheme addresses the entire group in the given context?

   If you are struggling with different surveillance needs for different subgroups, times or phases of the outbreak, or zones, consider splitting into separate schemes as needed for simplicity and clarity. You can always combine the schemes into one document later, if doing so would not result in any confusion.

2. What are the errors and consequences of errors associated with using this surveillance to make decisions (1.3.)? How likely are these errors considering the surveillance objectives and precision level proposed (1.1.) and the surveillance context (2.2.)?

   In general, the larger the volume of data, the more precise the estimates, and the less likely there are to be errors in decisions based on the surveillance. For surveillance focusing on disease presence/absence, the consequences of an error change as you change the prevalence threshold. Consequences are minimized for smaller prevalence thresholds because disease is detected at a lower prevalence level and closer in time to the initial exposure. As the prevalence threshold increases in the surveillance design, disease prevalence is higher, time since exposure is longer, and consequences are likely to be more severe.

Disease transmission patterns and the likely prevalence of disease in the target group (4.2.) can help you think about the impact of your choice of sample size (7.1.) and precision (7.2.). Contact experts in disease spread and impact to help guide your decision and refer to any risk assessments that are available.

3. How feasible is it to collect the sample size proposed (7.1.)? Can one round of surveillance be conducted in the required time frame (7.3.)? Are the total costs (including 7.1., 8.1., and 8.2.) reasonable considering the consequences and the likelihood of missing disease? Are there other mitigating factors (2.2.) that reduce either the chance of an error or the negative consequences?

Once you have decided on the final details in your surveillance scheme, write a short summary of the information to share with others that includes all nine elements in an order that suits the needs. Although you may write out multiple pages of notes during the design process, the summary of the scheme should fit on two pages or less in most cases.

It is not necessary to share all the details gathered and processed as you designed the scheme, but information related to all nine elements should be included to ensure that you have described a complete surveillance scheme. We also recommend that you save (as an internal pre-decisional document) the detailed information you gathered, including any thought processes you captured as you developed the scheme. Such a document can be invaluable when adjusting the current design and can provide you with a starting place for future design processes.

Although your scheme is itself a product, it may be included as part of an SOP (a document designed for field staff that describes the response framework, along with the steps for conducting the surveillance) or it may be part of a document used to communicate with trade partners. For different audiences, more or less detail may be required for some elements. For example, more detail about the measurements and measurement tools is important for implementing the surveillance in the field, while more detail about choice of sample size and frequency to support the surveillance objectives in a given context is more important for communicating the value of the surveillance to partners in commerce.

As you become more skilled at designing surveillance, the tendency is to skip some of the elements, especially when a new scheme involves the same disease, inference group, or targeting criteria. It is a Surveillance Design Standard to address all nine elements every time. Providing partial information can lead to misunderstandings, confusion, and even result in collecting insufficient data to meet the objectives.

You may find that schemes to achieve different objectives can be combined into one scheme and still meet all the objectives. Combining schemes can simplify communications, but it can be dangerous if combining schemes can lead to not fully meeting one of the objectives. It is a best practice to design surveillance for one objective at a time, addressing all elements each time. Combine separate schemes into one scheme only when doing so will not jeopardize meeting any of the objectives. When multiple schemes are combined into one document, list all the objectives supported by the surveillance scheme and be explicit about the objective that requires the most surveillance.

Revisiting Element 3: Inference Group

FMD has very different transmission patterns for cattle, swine, and sheep and goats. To avoid confusion, let's limit the scope of this scheme to cattle, and to dairy cattle in particular. We can design schemes for beef cattle, feed lots, or cow-calf operations next, and use what we've designed here as a starting place. If it won't be confusing, then we can combine these separate schemes into one document.

Schemes for swine and sheep and goat are likely to be very different. See Figure F-3 below taken from USDA–APHIS–VS (2020) FMD Red Book.

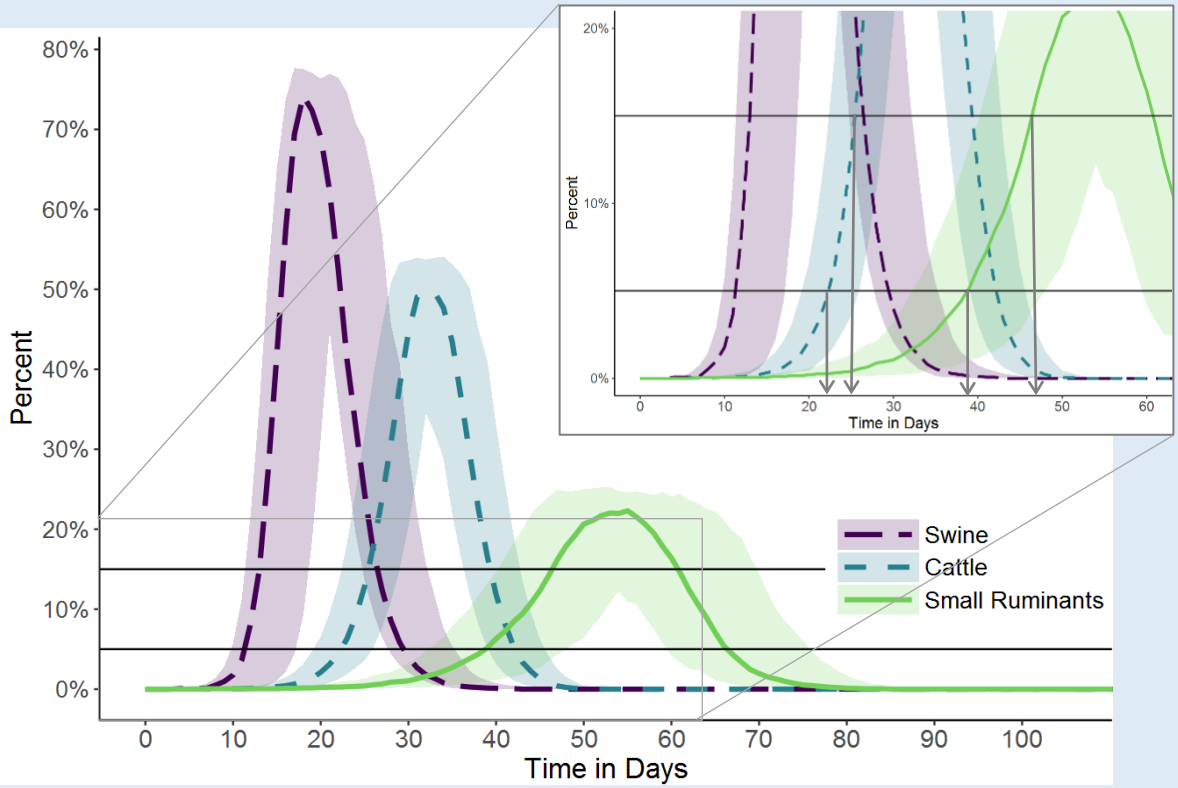


Figure F-3. Percent of animals in a small ruminant, cattle, or swine herd in the infectious stage for high R_0 values with inset showing detail of curve from 0 to 60 days and less than 20 percent infection. Parameters are based on information from publications by Mardones et al. 2010, Chis Ster et al., 2012, and de Rueda et al. 2014. (Product of USDA cooperative agreement with University of Minnesota.)

Another decision made early on was to limit the period of this surveillance scheme (context) to about 15 to 20 days after the CA was established. Prior to this, we depended on other surveillance to identify any cases in the SZ.

Random surveillance in the SZ early in the outbreak to determine the outbreak's extent could be very useful, but it could also be very costly. Instead, we focused on conducting surveillance on traced direct and indirect contacts between the IP premises and other premises with susceptible species for this purpose.

Revisiting Element 7: Number of Units

Consequences of errors: The error of detecting FMD on a premises when FMD is not actually present would have severe consequences, triggering a new control area and all the associated response actions. However, we protect against this by requiring a FAD investigation and confirmatory testing.

The error of failing to detect FMD on a premises when FMD **IS** present could result in additional disease spread. Given our education and awareness campaign, and the heightened state of alert on the dairy farms in the SZ, it is unlikely that FMD would go unnoticed on a premises for very long. It is also less likely that FMD would be spread from the CA to the SZ given the quarantines and movement restrictions.

Surveillance Objective: Provide evidence demonstrating that FMD is below a specified prevalence threshold (0.05, 0.10, 0.15, or 0.20?) in less than (50%, 30%?) of the premises in the Surveillance Zone starting approximately two weeks after the CA was established and ending with at least two rounds of surveillance after lifting of the CA.

Number of animals to select from premises with 3,200 or more cows per premises to achieve 0.95 probability of detection for various prevalence threshold values.

Prevalence threshold for target group	Number of cows to test	Most likely to observe this prevalence threshold
0.05	62	19 to 26 days post exposure
0.10	30	21 to 28 days post exposure
0.15	20	22 to 29 days post exposure
0.20	15	24 to 31 days post exposure

Number of premises to select for active surveillance out of 97 dairies for various prevalence thresholds (or number of infected premises among the dairies)

Number of infected dairies in the SZ	Prevalence threshold (among premises)	Number of premises to select
5	5%	47
8	8%	32
10	10%	26

Surveillance in the SZ at this point in the outbreak is not to delimit the extent of the outbreak like it would be in the first few days of the outbreak, nor is it for early detection of an introduction in the SZ. Rather the purpose of this surveillance is to demonstrate that the control actions implemented are working. This supports our own understanding of the outbreak response and also provides evidence to assure neighboring States and domestic and international trade partners of the effectiveness of the response actions.

Collecting specimens from 20 cows from each premises (or epi unit on a premises) is adequate for this purpose. Increasing the number of cows tested will not appreciably reduce the time to detection. Testing approximately one-third of the premises in the SZ will result in surveillance on nearly every premises given that we will be doing one round of surveillance as soon as possible and, once the CA has been lifted, there will be two more rounds of SZ surveillance each round on a new set of premises, for a total of three rounds. This should provide adequate evidence that disease is not present in the SZ.

Annotated Example Surveillance Scheme

On the next page, you will find a repeat of the example surveillance scheme presented at the beginning of this document. In this version of the scheme, click your mouse anywhere in the scheme and then hover over highlighted areas to see pop-up text describing the associated surveillance element. Click on the phrase and it will return you the surveillance element associated with that highlighted phrase. Clicking Alt + left-arrow-key will return you to your previous position.

Surveillance in the Countryside County Surveillance Zone (SZ) in the State of Commonplace after control actions have been in place for two weeks

This surveillance scheme supports the **response goal:** Resume normal production as rapidly as possible without causing more harm than the outbreak. More specifically, this scheme provides information to support the **response objective:** to contain foot-and-mouth (FMD) to the identified and established Control Areas through the **surveillance objectives:** (1) provide evidence demonstrating with 95 percent confidence that FMD prevalence is less than 10 percent among commercial cattle dairy premises in the SZ for premises having a prevalence of 15 percent or more and (2) understand factors potentially involved in spread should disease be detected.

This surveillance scheme targets:

- Commercial cattle dairies in the Surveillance Zone (SZ) not designated as a contact premises (CP) or suspect premises (SP). CP and SP will be involved in surveillance as part of foreign animal disease (FAD) investigations.
- Cattle showing any non-specific clinical signs including mild clinical signs such as low milk yield, low feed intake, or lameness.
- Cattle from areas in the premises where exposure is more likely such as near entrances, vents, or areas with high potential for fomite transmissions, because we do not expect cases of FMD in the SZ.

Select a subset of 26 premises (of the 97 total in the SZ) for active surveillance at random every 21 days with at least 2 rounds of testing occurring after lifting of the CA. When repeating the random premises selection, remove premises previously selected from the list until surveillance has been conducted on all premises in the SZ, then start the process over with the full list of premises. Each round of surveillance achieves 0.95 probability of detecting at least one infected premises when at least 10 percent of premises in the SZ are infected when the probability of detection on each premises is 0.95.

For premises with 3,200 head or more, select 20 cattle exhibiting non-specific clinical signs, from each separate bio-secure area (epi unit) on the premises. A premises will form one epi unit in most cases. If mild signs are common, select "cattle showing signs from each pen, barn, or other grouping" from each epi unit "with priority given to areas near entrances, vents, and areas with high potential for fomite transmission" (USDA–APHIS–VS, 2020). If there are only a few cattle with non-specific clinical signs, select them first followed by selecting cattle from the priority areas distributed across the epi unit as described above. Selecting 20 cattle results in a 0.95 probability of detecting at least one infected animal when 15 percent of the cattle on the premises are infected assuming a 95 percent sensitivity testing protocol. If less than 20 cattle are tested, the probability of detection will be less than 0.95, increasing the number of premises required to achieve 0.95 probability of detection at the SZ level. For premises with less than 3,200 head, use the Animal Sample Size Table to determine the exact sample size for these smaller premises. Observation of case-compatible clinical signs require an FAD investigation rather than continuing with SZ surveillance sampling.

Send specimens (oral swabs or Probang samples) to NVSL or an approved NAHLN laboratory for rRT-PCR testing. If the rRT-PCR is positive at a NAHLN laboratory the sample will be sent to FADDL for confirmation (USDA–APHIS–VS, 2015). Submissions to NVSL must contain a hard copy of the completed 10-4 Form (USDA, 2022). Each NAHLN laboratory has its own submission form; locate and use the correct form for the choice of laboratory. Refer to the FAD PReP Foreign Animal Disease Investigation Manual (USDA, 2022) for sample labelling and submission details.

For each specimen, include a unique specimen identifier (bar code) and Premises ID on each specimen container. Include the Premises ID, the unique specimen ID, date and time of collection, and unique animal ID on the submission form. Enter each unique animal ID into the EMRS2Go app associated with the Premises ID and date of collection, and for each animal include the unique specimen ID, clinical signs observed, any subgroup, barn, or pen identifier and/or special locations such as near an entrance, vent, or other high-risk area. Include reason for collection, total number in susceptible populations on premises by species, the presence and total population of other livestock species, and key biosecurity practices in the EMRS2Go app associated with the Premises ID and collection date.

Response activities will continue unchanged if no positive detections occur for the premises tested in the SZ. Negative test results for all specimens provide evidence that control actions are working. Response activities will continue unchanged if no positive detections occur for the premises tested in the SZ. Negative test results for all specimens provide evidence that control actions are working. Movement restrictions for premises in the CA and for network premises should prevent spread to the SZ. There are no movement restrictions within the SZ to halt further spread in this zone should it occur. Early detection of an introduction in the SZ depends heavily on passive surveillance and industry involvement in enhanced passive surveillance activities to detect specific signs associated with FMD.

A confirmed positive disease detection will result in the designation of new Infected Premises (IP) and initiation of associated response activities and trigger a need for additional information. That is, separate surveillance will likely be required to determine and understand pathways of introduction.

References

U.S. Department of Agriculture (USDA–APHIS–VS). 2015. Foot-and-mouth disease (FMD) response ready reference guide - overview of FMD diagnostics. https://www.aphis.usda.gov/animal_health/emergency_management/downloads/fmd_rrg_diagnostics.pdf.

U.S. Department of Agriculture (USDA–APHIS–VS). 2020. Foot-and-mouth disease response plan the red book. FAD PReP foreign animal disease preparedness & response plan, 222. https://www.aphis.usda.gov/animal_health/emergency_management/downloads/fmd_responseplan.pdf.

U.S. Department of Agriculture (USDA). 2022. Foreign animal disease (FAD) investigation manual.

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