

# Quality assurance applied to animal disease surveillance systems

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## Summary

Monitoring and surveillance systems (MOSS) are essential activities for official Veterinary Services. In addition, the increased trade in animals and animal products over recent years has increased the importance of international disease reporting. A reliable surveillance system is the key to early warning of a change in the health status of any animal population. Such a system is also essential for providing evidence about the absence of diseases or in determining the extent of a disease which is known to be present. The authors discuss a set of methods and approaches for evaluating the quality of surveillance and survey systems. Certain steps are required when assessing the quality of a service or product. Various approaches for quality assessment are available and the suitability of each method depends on the objective of the evaluation. An essential basic requirement is, however, to use an objective, transparent and systematic approach. The evidence collected and the analyses used to reach conclusions must be of such high quality that the results are acceptable to both the management of the MOSS and the assessor. Repeated discussions and negotiations may be necessary to reach consensus, particularly if the judgement affects activities between trading partners. Well-documented MOSS with specified objectives and integrated quality assurance mechanisms are likely to be easier to evaluate.

## Keywords

Animal disease surveillance system – Fault tree – Monitoring and surveillance system – Performance of surveillance system – Quality assurance – Scenario analysis – Veterinary epidemiology.

## Introduction

Surveillance for animal diseases has been extensively used by epidemiologists and other animal health professionals to assist in monitoring and controlling health-related events in animal populations. A reliable surveillance system is the key to early warning of a change in the health status of any animal population. It is also essential in providing evidence about the absence of diseases or in determining the extent of a disease which is known to be present. The two terms 'surveillance' and 'monitoring' are often used interchangeably in animal health programmes. Animal disease surveillance involves watching an animal population closely to determine if a specific disease or group of diseases enters that population. Monitoring of animal diseases focuses on identifying a disease or group of diseases to

ascertain changes in prevalence and determine the rate and direction of disease spread. For this paper, the authors will use the term 'monitoring and surveillance systems' (MOSS) to reflect both monitoring of diseases and surveillance of animal populations.

Monitoring and surveillance are essential activities for official Veterinary Services. However, in recent years, increased trade in animals and animal products has increased the importance of international disease reporting. The Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization (WTO) (10) recognises the OIE (World organisation for animal health) as the international organisation responsible for drafting international animal health standards. The SPS Agreement requires that animal health decisions be scientifically based.

This has placed disease surveillance systems, and veterinary epidemiology in general, at the core of animal health related decisions (11). Today, efficient disease surveillance and monitoring systems are the basis for trust in international trade in animals and animal products.

The information that a MOSS generates must increase understanding of the occurrence of disease and be used to improve animal health through appropriate actions. In other words, disease surveillance is the tool which provides information for planning disease control and eradication programmes.

A MOSS is usually established for specific purposes, which are stated at the initial stage of planning the system. The data generated for a MOSS should be used to document the health status of a livestock population and to initiate or 'trigger' action. Often the objective is to facilitate trade, usually in accordance with the SPS Agreement (10). The data collected for any MOSS must be reliable and of sufficiently high quality to satisfy the demands of trading partners or other users of these data. Quality assurance and evaluation methods must, therefore, be applied to the MOSS. The method of quality assurance should be considered at the early stages of designing a MOSS, as well as in the later stages of its implementation. In this paper, the authors will describe a set of methods and approaches to evaluate the quality of various MOSS.

## Objectives of quality assessment

The objectives of quality assessment can vary between tasks and projects.

The objectives of the quality assessment should be clearly defined before the task is begun. Either a single MOSS can be assessed in terms of its quality or the relative quality of several systems can be compared at once. There are several possible reasons for initiating a quality assessment of a MOSS, including the following:

- a) to design a new MOSS
- b) to enhance the quality of an existing MOSS
- c) to improve cost-effectiveness
- d) to determine the reliability of the data produced by a MOSS
- e) to determine equivalence between two or more MOSS in the context of international trade.

Possible questions that may be asked at the start of a quality assessment of a MOSS include the following:

- is the MOSS effective enough to achieve its purpose?
- are the data and results produced by the MOSS of sufficiently high quality?

– how could the MOSS be improved?

– is one particular MOSS (MOSS-x) preferable to another MOSS (MOSS-y)?

– are MOSS-x and MOSS-y equivalent?

Under the SPS Agreement (10), the question of equivalence is a relevant issue as importing countries have the right to define their appropriate level of disease protection and to request that the exporting country applies equivalent disease control measures. However, different countries are likely to have very different ideas on what constitutes equivalence of protection and consensus may be difficult to reach.

The Codex Alimentarius Commission has been dealing with this issue and recommends that, in order to reach a consensus, a 'transparent analytical process that is objective and consistent' should be used (3). This requirement can be formulated more generally. For whatever purpose an assessment is conducted, the approach used must be systematic, objective and transparent (i.e., easily explained, with no hidden elements).

## Approaches to quality assessments

Certain steps are required when conducting a quality assessment. The first step is a detailed description of the system under investigation. This description should include the purpose and operation of the MOSS, in particular the following elements:

- the objectives of the MOSS
- the event under surveillance (case definition)
- the relevant legislation and/or regulations covering disease control for the MOSS
- the authorities involved in the system and their responsibilities
- the components of the system
- the resources allocated.

Once this description is available, the assessment can proceed. Basically, graphical, textual and numerical approaches can all be used to assess a MOSS. As some MOSS may be complex, it may be necessary to use a combination of these methods.

The Centers for Disease Control and Prevention (CDC) have published guidelines for the evaluation of a public health MOSS (1, 2). The CDC and World Health Organization (WHO) list several criteria for assessing the performance of the system (9). Table I summarises these criteria (8). The person or team applying this protocol should have considerable expertise and competence in the field of MOSS. The key activity in this

**Table 1**  
**Criteria for assessing the performance of a monitoring and surveillance system**

Criterion	Function
Usefulness	Describes the contribution of the system to the prevention and control of diseases
Simplicity	Describes the ease of operating the system. Surveillance systems should be as simple as possible while still meeting their objectives
Flexibility	Describes the ability of the system to adapt to changing information needs or operating conditions with little need for additional time, personnel or allocated funds
Quality of data	Refers to the completeness and validity of the data recorded by the surveillance system
Acceptability	Reflects the willingness of people and organisations to participate in the surveillance system
Sensitivity	Refers to the proportion of cases of a disease (or other health-related event) detected by the surveillance system. Alternatively, sensitivity can refer to the ability to detect outbreaks, including the ability to monitor changes in the number of cases over time
Predictive value positive	Proportions reported cases that actually have the health-related event under surveillance
Representativeness	Describes the occurrence of a health-related event over time and its distribution in the population by place and species
Timeliness	Reflects the speed between steps in a surveillance system
Stability	Refers to the reliability (the ability to collect, manage and provide data properly, without failure) and availability (the ability to be operational when it is needed) of the surveillance system

Source: adapted from Centers for Disease Control and Prevention (2) and Thacker *et al.* (8)

approach is to gather reliable evidence on the performance of the system. This approach also starts with describing the system. The CDC guidelines define a set of criteria for assessing the performance of a MOSS (Table 1). Data to support or assess these criteria are collected from people and documents as well as through observations. The data are then organised, analysed and interpreted. Eventually, this analysis leads to a final judgement. The result or 'output' of this type of evaluation is a report and recommendations.

The most challenging process during the evaluation is analysing the data. Analysis transforms data into information, and it is often said that information is power. This is true but only if the information flows freely from the sources to the users and vice versa. The accumulation of information with no useful purpose is pointless and will erode the trust placed in the MOSS. It is important to organise the information so that patterns and important findings can be identified. Fault trees are one graphic tool used in the processing industry (e.g. meat or food) to identify a series of events which will lead to an undesired event (the 'fault'). These trees are useful for an in-depth description of a complex system with the objective being to identify things that can go wrong. This method has a 'top-down' structure and

the branches are connected with so-called 'AND' and 'OR' gates. At an 'AND' gate, both conditions leading to the gate must be fulfilled for the event to happen. At an 'OR' gate, either of the conditions or both may be fulfilled for the event to occur. Fault trees can be used to investigate events leading to an unsatisfactory MOSS. Figure 1 suggests the elements of a fault tree which may lead to a MOSS of insufficient quality. In this context, the 'AND' gates are of particular interest.

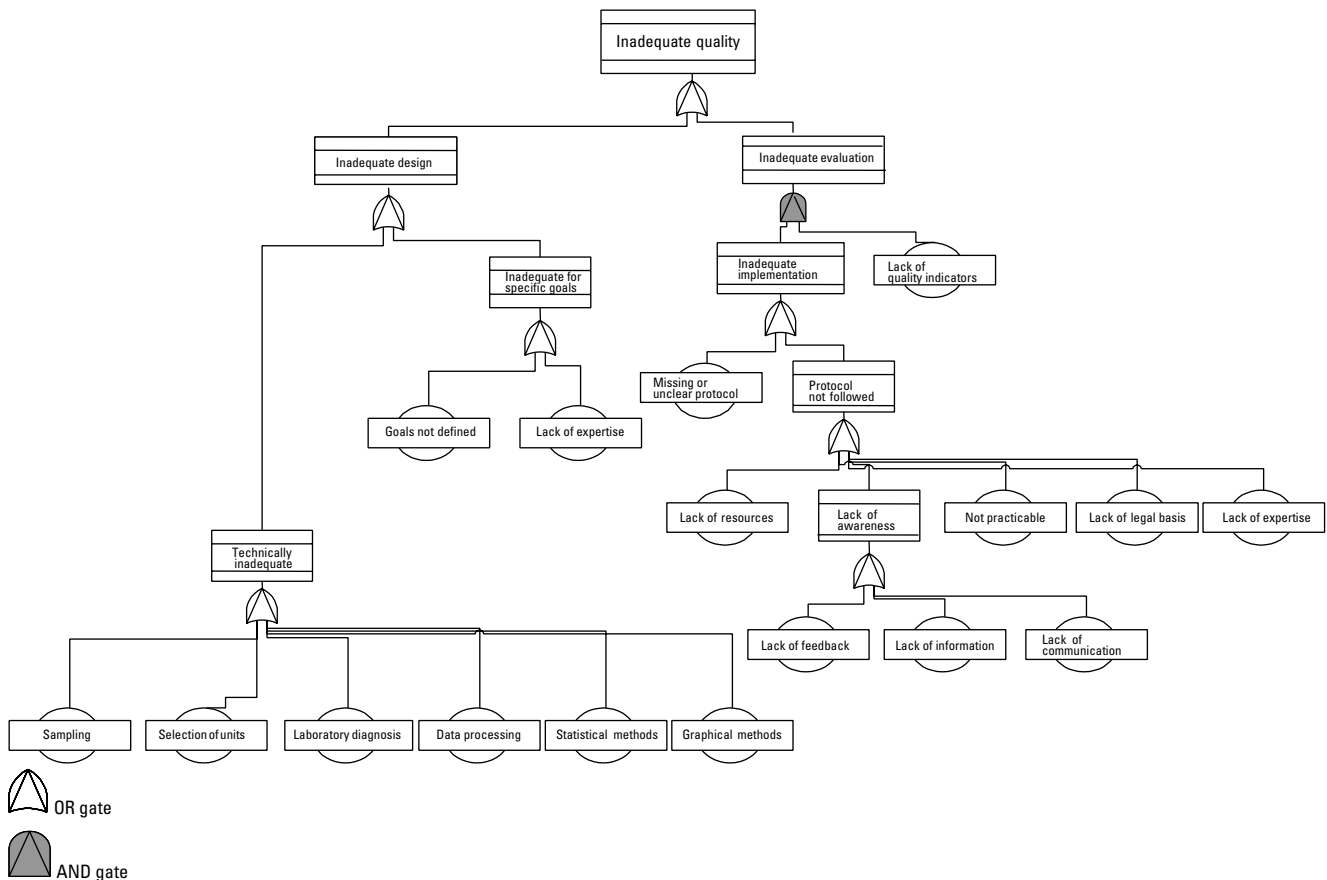
The advantage of the fault tree is that it supports a systematic and complete analysis of the system. In addition, the fault tree helps to clarify interactions between events and the influence of such interactions on the quality of the MOSS. Fault trees are particularly useful in identifying weaknesses in a system. They have also been criticised for this, as they may promote scepticism by over-emphasising the negative aspects of a MOSS. Decision-makers who are not familiar with fault trees may then over-estimate the probability that the undesirable top event, which is a system of unsatisfactory quality, will occur.

A second graphic approach is the scenario analysis. A scenario is a chronology of events that may follow from the occurrence of a particular event, for example, the occurrence of a case of disease to be registered in a MOSS. Given the design of the MOSS, the subsequent events (e.g. the detection of the disease case, sampling, confirmation of the case, reporting of the case) can be determined and integrated into the programme. This method is suitable for providing a structured description of a complex MOSS and can also be used quantitatively, if the necessary data are available (6).

Another possible method is the characterisation of a MOSS through its different elements, specifically the following:

- the objectives of the MOSS
- the target population(s)
- the design (sampling scheme and organisation)
- the diagnostic methods used
- the data management system
- the method of analysing data
- the method of feedback
- the dissemination of results.

These elements can be used to classify surveillance systems according to pre-proposed classification rules. Such a classification may be useful for the direct comparison of surveillance systems, for example, when assessing the degree of equivalence of various systems applied in different countries. However, the result will be limited in that equivalence in quality can still exist, even though the systems may not be composed of exactly the same elements. On the other hand, equivalence in design and structure is not necessarily sufficient to determine equivalence in quality.



**Fig. 1**  
**An example of a fault tree, describing the events which lead to a surveillance and monitoring system of inadequate quality**

Fault trees, scenario analyses and classifications of MOSS may be suitable for assessing systems by description and for simple comparisons of several MOSS. However, in some instances, quantitative information may also be required. For this purpose, scoring systems have been suggested, which express quality numerically (4). In this method, the critical control points of the MOSS are identified and awarded a numerical score (Table II). A maximum score is assigned for each control point, thus expressing their relative importance, with a total of up to 100 points. When evaluating a MOSS, a detailed manual is used to determine the actual score for each element. This procedure allows the weaknesses of a particular MOSS to be identified. The end scores of several MOSS can be directly compared, and the system achieving the highest score is the most effective.

Quantitative information can also be derived by using quality or performance indicators. Performance indicators have been used as quality assurance tools and integrated into the designs of some MOSS, for example, in the Global Rinderpest Eradication Programme (7). Performance indicators are often simple ratios or proportions which can be measured against a

defined target. These indicators can also be used to compare several MOSS, provided that they can be applied to various proposed programmes.

As a MOSS is often a complex structure with numerous components, and thus has many factors which may influence its quality, assessors may have to use a combination of the methods and approaches described above. The concept of risk assessment may be useful in this context. Risk assessment essentially provides a framework for organising information in a standardised way to reach a synthesis of the evidence. The quality of a MOSS is defined as sufficient if the risk of certain events is smaller than a target value. A risk assessment approach involves the identification of hazards or hazardous events, a description of the scenario pathways leading to an undesired event, the collection of evidence and, finally, a qualitative or quantitative assessment of the probability of this event and its consequences, including their estimated uncertainty. This approach is now routinely used by importing countries to assess the risk of introducing infectious agents through the importation of food, animals or plants.

**Table II**  
**A scoring system to assess the quality of a monitoring and surveillance system for exotic diseases**

Element	Maximum score
1. Aims	15
2. Sampling	20
3. Co-ordination and awareness	15
4. Environmental factors	4
5. Screening and diagnosis	20
6. Data collection and transfer	10
7. Data processing and analysis	10
8. Information dissemination	6
<b>Total</b>	<b>100</b>

Source: simplified, based on Dufour (4)

## Relevance of quality for surveillance and monitoring systems

Quality assurance should be an integrated part of the design of any MOSS to ensure that it is capable of serving its purpose. Quality assurance systems have been developed and are now widely used in many processing and production industries. Some general principles of quality assurance are equally applicable to MOSS. Among these are the need for documentation and monitoring.

Documentation is a prerequisite for evaluating the quality of a MOSS. All protocols on methods and procedures should be documented in detail. This includes all the following steps:

- sampling
- processing the samples
- recording the data
- laboratory analysis
- statistical analysis.

A written manual with detailed instructions for all participating parties is desirable, particularly when collecting data on multiple sites.

The performance of a MOSS can also be monitored through routine procedures established in the design document. Furthermore, the MOSS designer can define performance indicators for certain aspects of the system. For example, one such indicator might be the number of disease reports received from nominated districts within a targeted time period. These indicators can then be regularly calculated and monitored for increasing or decreasing trends.

'Users' find it much easier to evaluate a MOSS when quality assurance mechanisms are integral parts of the system. A fully documented system can also be audited easily and this is as useful as conducting repeated evaluations of the quality of the system.

The MOSS designer must define the type of data that the system will collect, and should also clearly define the proposed uses of the information before the system is implemented. Different users usually expect different outputs from the system. An ideal MOSS for an animal disease should gather data on the agent, the host and the environment (5). At the very least, the collected data should include the following:

- the number of cases of the disease
- the animal species affected
- the population at risk
- the type of production system in which the cases were found
- the geographical location of the cases
- whether there is laboratory confirmation of the disease
- the type of test used for confirmation.

The MOSS must have a legal framework, i.e., legislation or regulations, to support its implementation. Different countries have different legal systems but, generally speaking, animal health legislation provides the broad framework for the operation of Veterinary Services, including disease monitoring and surveillance.

This broad legal framework should include more detailed regulations which clearly describe the activities performed by the MOSS. These regulations should also include a list of notifiable diseases. The composition of this list may vary between countries. Ideally, a list of notifiable diseases should include the following:

- diseases which are exotic to the country
- diseases which have an official control and/or eradication programme
- diseases which it is important to monitor.

Traditionally, conducting MOSS has been considered a crucial part of the intelligence gathering of any Veterinary Service and thus an activity which is not susceptible to privatisation. However, although the primary responsibility for MOSS lies with the official Veterinary Service, private sector participation is also essential in ensuring a rapid response to the MOSS. The role of each party involved in the implementation of a MOSS should be documented to aid in assessing the system.

## Conclusion

Assessing the quality of a MOSS is a routine task conducted by the MOSS 'owners' as well as the MOSS 'users'. Various approaches are available and the suitability of any given approach depends on the objective of the evaluation. One essential basic requirement, however, is to use an objective, transparent and systematic approach. The evidence collected and the analyses used to reach any conclusions should be so reliable that the results are acceptable to both the managers of

the MOSS and the assessors. Repeated discussions and negotiations may be necessary to reach consensus on the quality of a MOSS, particularly if the judgement affects activities between trading partners. A well-documented MOSS with specified objectives and integrated quality assurance mechanisms is likely to be easier to evaluate. ■

## Application de l'assurance qualité à un système de surveillance des maladies animales

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### Résumé

Les systèmes de suivi et de surveillance sont des éléments indispensables aux Services vétérinaires officiels. L'intensification du commerce des animaux et des produits d'origine animale au cours des dernières années a par ailleurs accru l'importance de la déclaration des maladies au niveau international. L'existence d'un système efficace de surveillance s'avère déterminante pour assurer la détection rapide d'une modification du statut sanitaire d'une population animale. En outre, un système de ce type apporte une contribution primordiale, dans la mesure où il permet d'obtenir les preuves de l'absence de maladies ou de délimiter l'aire de répartition d'une maladie existante. Les auteurs passent en revue un ensemble de méthodes et de dispositifs destinés à apprécier la qualité des systèmes de suivi et de surveillance.

L'évaluation d'un service ou d'un produit passe nécessairement par plusieurs étapes. L'évaluation qualitative est réalisable selon diverses modalités, qui dépendent chacune de l'objectif poursuivi. Toutefois, le choix d'une démarche objective, transparente et systématique constitue une exigence fondamentale et essentielle. Pour être recevables à la fois par les responsables du système de suivi et de surveillance et par les évaluateurs, les conclusions finales doivent se fonder sur des données et des analyses de qualité irréprochable. L'obtention d'un consensus exigera sans doute plusieurs séances de discussion et de négociation, notamment si la décision finale risque d'avoir un impact sur les activités des partenaires commerciaux. Les systèmes de suivi et de surveillance établis sur la base d'informations détaillées, d'objectifs précis et de mécanismes intégrés d'assurance qualité seront vraisemblablement plus faciles à évaluer.

### Mots-clés

Analyse de scénario – Arbre de défaillances – Assurance qualité – Efficacité des systèmes de surveillance – Épidémiologie vétérinaire – Système de suivi et de surveillance – Système de surveillance des maladies animales. ■

## El aseguramiento de calidad aplicado a un sistema de vigilancia zoonosanitaria

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### Resumen

La aplicación de sistemas de seguimiento y vigilancia es una de las funciones básicas de los Servicios Veterinarios oficiales. En los últimos años, además, con la intensificación del comercio de animales y productos de origen animal, la notificación internacional de enfermedades ha cobrado una importancia todavía mayor. Disponer de un sistema de vigilancia fiable es la clave para detectar con rapidez todo cambio en la situación sanitaria de una población animal, y es esencial también para demostrar la ausencia de enfermedades o determinar el alcance de cualquiera enfermedad existente en un país. Los autores examinan una serie de métodos y criterios para evaluar la calidad de los sistemas de seguimiento y vigilancia.

Hay ciertos pasos obligados a la hora de determinar la calidad de un servicio o producto. Existen además diversos métodos, y la conveniencia de utilizar uno u otro dependerá del objetivo que persiga la evaluación. Ante todo conviene tener en cuenta que, con independencia del método que se elija, es condición indispensable que sea objetivo, transparente y sistemático. Las pruebas obtenidas y los análisis empleados para extraer conclusiones deben ofrecer un nivel de calidad suficiente para que los resultados del proceso no admitan dudas para los administradores del sistema de vigilancia ni para los evaluadores. Es posible que para lograr un consenso hagan falta varias rondas de discusión y negociación, sobre todo cuando las conclusiones puedan influir en los intercambios comerciales entre varias partes. En principio no debería ser muy difícil evaluar un sistema de seguimiento y vigilancia que cuente con dispositivos de información eficaces, objetivos bien definidos y un sistema incorporado de garantía de calidad.

### Palabras clave

Análisis de hipótesis – Árbol de fallos – Aseguramiento de calidad – Epidemiología veterinaria – Rendimiento de los sistemas de vigilancia – Sistema de seguimiento y vigilancia – Sistema de vigilancia zoonosanitaria.



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