The impact of current and proposed changes to general guidelines on bluetongue surveillance of the Office International des Épizooties

A.R. Cameron

AusVet Animal Health Services, 140 Falls Road, Wentworth Falls, NSW 2782, Australia

Summary

New draft guidelines for surveillance have been prepared for possible submission to the Office International des Épizooties (OIE) General Session for adoption in 2005. These guidelines are non-prescriptive and output-oriented, but also identify a series of critical elements required to effectively implement and evaluate surveillance systems. The guidelines allow for the use of a range of approaches to surveillance, including the use of non-random data sources and the combination of multiple sources of evidence. They also require transparency and the presence of basic quality assurance systems. The guidelines deal with surveillance to demonstrate freedom from infection as well as surveillance to determine the distribution and occurrence of infection. If the draft guidelines are adopted, a range of novel approaches to surveillance of bluetongue virus (BTV) may become formally acknowledged and accepted under the OIE *Terrestrial animal health code*. This may enable different countries to tailor their BTV surveillance systems more closely to their own needs and capabilities while maintaining equivalence in the outputs of the systems.

Keywords

Bluetongue – International trade – Non-random data – Office International des Épizooties – Standards –Surveillance – Surveys – Terrestrial Animal Health Code – Trade.

Surveillance for bluetongue (BT) virus (BTV) infection poses a number of challenges. Complicating factors include seasonal, climatic and environmental variations in vector and virus distribution, and the persistence of antibodies in animals moving from one area to another. If surveillance is being undertaken to estimate the risk of infection, traditional tools such as randomised cross-sectional surveys are less useful, as they are generally only able to provide estimates of seroprevalence. Estimates of incidence are more likely to be of value, but are often more difficult to measure with reasonable levels of precision. This is particularly the case in areas where transmission occurs at low levels, such as at the margins of endemic areas. If, on the other hand, the purpose of surveillance is to substantiate zone or national claims of disease freedom, traditional cross-sectional survey approaches used in isolation are now recognised as often being expensive and inefficient. Combination of survey data with other existing sources of evidence may be able to generate the same level of confidence at lower cost. Surveillance systems need to be flexible enough to take into account available sources of evidence, as well as differences in production systems and environmental conditions.

Over the last four years, the Office International des Épizooties (OIE), through ad hoc groups, has been involved in a process of revising its guidelines for general surveillance. Separate guidelines have been developed for aquatic animals and terrestrial animals, both based on the same set of principles. At the time of writing, the revised aquatic animal guidelines had been endorsed by the 2003 General Session of the OIE and incorporated into the diagnostic manual, and the draft terrestrial animal guidelines were under consideration for possible submission to the 2005 General Session. If endorsed by OIE members, these terrestrial guidelines will have an impact on the approach to surveillance for all OIE listed diseases, including BT. When planning long-term approaches to BT surveillance, it may therefore be useful for member countries to be aware of some of the principles in the current draft guidelines.

Draft Office International des Épizooties guidelines

Background

The philosophy behind the draft guidelines is important to understand. It is consistent with the approach taken in the chapter on risk analysis. In order to demonstrate disease status, or to determine the distribution or impact of disease or infection in a country or zone, it is necessary to have an effective surveillance system. However, if the outputs of a surveillance system are to be used with confidence, the reliability of the surveillance system must be able to be evaluated – hence the need for international standards.

In the past, OIE standards have often been relatively prescriptive. This is more evident in the *Aquatic animal health code* where in many cases sample sizes, sampling frequencies, and methods of analysis have all been specified. This prescriptive approach has the advantage of providing detailed guidance in the planning of surveillance activities, and allowing simple objective assessment of compliance with the standards. The disadvantage of this approach lies in the assumption that there is only one valid way to conduct surveillance activities, and that this one approach will be valid in all countries of the world. In the last decade or two, there has been a dramatic increase in research on epidemiological techniques for disease surveillance, and the analysis of surveillance data. As a result, approaches that may have seemed adequate several years ago can now be recognised as being either technically incorrect due to false assumptions, or inefficient. There is no reason to assume that the advances in the field of surveillance techniques will cease in the near future. The range of more precise, practical and efficient approaches to surveillance that have appeared offer countries the opportunity to adopt different techniques, selecting the ones that are best suited to their own situation, be it economic, cultural, climatic, geographic or biological. This opportunity has brought with it two problems for international trade: first, the new techniques are not formally recognised as valid approaches to surveillance in the existing *Code* standards (1); and second, it is much more difficult to assess the validity and compare the outputs of a range of different surveillance systems in order to establish equivalence.

The draft guidelines were formulated to address these issues, with the somewhat contradictory aims of:

1) being non-prescriptive to allow the application of the most appropriate surveillance techniques to a particular situation
2) providing objective standards by which all such surveillance systems could be judged.

The approach taken was to assume that any current or future approach to surveillance should be considered acceptable, as long as it is able to meet a certain set of criteria. These criteria, referred to in the draft as 'critical elements', either determine standards or identify factors, which must be taken into consideration. For example, the first critical element identified is the population. In order to be valid, the target and study populations must be identified and differences between them identified.

A second aspect of the philosophy behind the draft chapter is the creation of a mechanism to enable application of general guidelines to a specific disease. Continuing the example of populations, the draft chapter provides general guidelines as to the best way to select appropriate populations for surveillance. However, they indicate that the appropriate populations defined in the disease chapters of the *Code* should be used, where such definitions exist. This pattern is repeated in other areas, so that the guidelines provide the framework for designing and evaluating a surveillance system, as well as advice on the selection of appropriate values, while the disease-specific chapters provide detailed parameters suitable for the particular disease. This removes the need for any surveillance guidelines in many of the disease chapters, but requires the same chapters to be revised to provide appropriate parameters to be applied to the general surveillance chapter.

Another example of this is given by the choice of the value of design prevalence (also called threshold prevalence or minimum expected prevalence). A definition for design prevalence, and explanation of the importance of specifying the value selected is contained in the surveillance guidelines. However, appropriate values will vary for each disease, depending on a number of factors including the speed of transmission.

The third philosophical basis for the chapter is that it aims, as far as possible, to be output-oriented, rather than input-oriented. In other words, it aims to define what a surveillance system should be able to achieve, rather than specify what is required in order to achieve this. This approach is consistent with the aim of being non-prescriptive and recognising that there may be a number of different ways to achieve the same outcomes. While allowing considerable flexibility in the surveillance methodologies used, the guidelines are much more specific, for instance, about the level of confidence required to demonstrate freedom.

Contents

In brief, the contents of the draft guidelines are as follows.

In Section 1, there is a statement of the objectives of the document, namely to provide:

a) guidance to the type of outputs that a surveillance system should generate
b) guidelines to assess the quality of disease surveillance systems
c) guidelines for the outputs needed from surveillance systems for the risk analysis process

This is followed in section 2 by definitions of terms used in the chapter.

Section 3 deals with general principles of surveillance. A distinction is drawn between structured population-based surveys and non-random data sources that may be used for surveillance purposes. Critical elements applicable to all surveillance activities are identified followed by special considerations for surveys and for the use of non-random data. These 'critical elements' provide the mechanism by which standards are set in the draft chapter. Notes on the combination of data from multiple data sources are also included.

The critical elements identified include definitions of the population, cases and outbreaks, consideration of any tests used (including guidelines to documenting the performance of the test especially with regard to precision, sensitivity and specificity), sampling methods, sample size calculation and data analysis methods. In all cases, full transparency should be achieved through appropriate documentation. A relatively new inclusion in the area of surveillance is the requirement for demonstrable quality control systems. These may be relatively simple, but should document both the established protocols for surveillance, and be able to detect and document any departures from these protocols.

Section 4 deals specifically with surveillance to demonstrate freedom from infection, starting with general guidelines for declaring freedom, including historical freedom. It then lists general critical elements required for demonstrating freedom, and specific issues for surveys and for the analysis of non-random data sources. Section 5 is concerned with surveillance to determine the distribution and occurrence of infections, providing general guidelines, as well as guidelines for the use of surveys and non-random data sources.

The final section 6 highlights the relationship between surveillance and risk analysis, identifying the range of surveillance outputs and their role in the different components of risk analysis.

Implications for bluetongue virus surveillance

The guidelines for surveillance contained in the current *Code* chapter on bluetongue (under review) are relatively flexible, but contain a number of statements that make their interpretation and practical implementation somewhat problematic. If the draft general guidelines for surveillance are ultimately accepted, most disease chapters will need to be progressively updated to reflect the changed guidelines. This means that general statements regarding the approach to surveillance may be removed from the disease chapters, while specific information required for effective surveillance needs to be included. For instance, the requirement for both random and targeted surveillance could be removed, while the output confidence level of 95% would be retained. Design prevalence values, currently specified simply as 2%, may need to be expanded to capture the concept of clustered populations, and include both animal- and herd-level design prevalence values. More specific information may be required on the appropriate way to identify populations for targeted sampling (e.g. those adjacent to any zone of possible BTV activity).

While these and further similar changes may be required in the BT chapter, the effect of these changes on the practical implementation of surveillance will be far greater. Under the guidelines, there is no limit to the variety of approaches that may be used for surveillance, as long as they meet the requirements of the chapter (e.g. are scientifically valid and recognised), and the specified outputs (achieve a 95% confidence level). Some of the alternatives that may be possible include the following:

1) Surveillance not based on serology: the current chapter specifies that serology should be used. Newer techniques may mean that in the future other approaches to surveillance become more efficient or more practical, such as the use of polymerase chain reaction (PCR) on trapped *Culicoides* to detect BTV.
2) Quantitative combination of multiple sources of evidence: instead of depending on a single source of evidence, such as serological surveys, to provide all the confidence required for a free zone, it may be possible to combine a number of different sources of evidence (sentinel sites, cross sectional surveys, vector trapping data, etc.) to

produce a single, quantitative estimate of the combined confidence achieved.

3) The use of quantitative approaches to the analysis of data from targeted surveillance: most sentinel herd systems (a commonly used approach to surveillance for BTV) represent a form of targeted rather than random surveillance, due to the targeted placement of the herds in areas of particular interest (e.g. high risk areas). This approach is acknowledged in the current chapter, but traditional analytical techniques make it impossible to quantitatively evaluate the confidence that can be gained from non-random data. Newer approaches currently under development may enable data from sentinel sites to provide valid quantitative input into the overall assessment of confidence of freedom.
4) The use of other existing non-random data sources to supplement surveillance data: an example may be provided by data from routine testing of export animals from the free zones.

These are just a few examples of different approaches that may be taken to achieve equivalent outcomes under the draft guidelines. It is important to note that, under the draft guidelines, whatever approach is used, any potential biases in the data and imperfections in diagnostic system sensitivity and specificity must be taken into account and the methods used for data analysis must be valid and internationally accepted.

Conclusion

If adopted, these guidelines are likely to have two major effects. Firstly, there is the opportunity to develop more effective and more affordable approaches to surveillance, closely matched to the differing needs and practical constraints of different member countries. On the other hand, without prescriptive guidelines, there will be a requirement for greater skilled input into the design, documentation and assessment of surveillance systems. For BT, a range of different approaches to surveillance may be available to produce equally acceptable outputs.

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Reference

1. Office International des Épizooties (OIE) (2003). – Terrestrial animal health code, 12th Ed. OIE, Paris (oie.int/eng/normes/mcode/A_summry.htm accessed on 14 August 2004).