Veterinary diagnostic laboratories in developing countries: the challenge of credibility

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Summary
The problems facing veterinary diagnostic laboratories in developing countries range from simple problems, such as limited funds to keep good personnel or obtain equipment, supplies, reagents or training, to the more complex problems of designing and executing appropriate sample collection schemes for disease surveillance or evaluating the performance characteristics of a new diagnostic assay. While many developing countries are addressing these problems independently and a number of international and national organisations provide various forms of external support, the Office International des Epizooties (OIE) must continue in its critical role to provide guidelines for the most appropriate diagnostic assays for trade purposes and the development of the primary reference reagents for these assays. In addition, the OIE should take the lead in development of quality management guidelines for veterinary diagnostic testing laboratories. Without these guidelines and standards, diagnostic laboratories in developing countries will have difficulty in gaining the credibility necessary to help improve the positions of their countries in the international trade of livestock and livestock commodities.

Keywords

Introduction
The production of livestock commodities (meat, milk, poultry and eggs) has increased world-wide during the last decade due to increased demand driven by population growth, increased urbanisation and rising incomes. Virtually all of the growth in the livestock sector has occurred in developing countries, but the proportion of the world export market for these countries has actually decreased (2). For these countries to increase their share in the international trade of livestock and livestock commodities, two major barriers must be reduced or controlled: non-tariff trade restrictions and animal disease. While the first barrier is most properly within the purview of the World Trade Organisation (WTO), the gathering and dissemination of information on animal diseases, the establishment of disease definitions and diagnostic guidelines to help control and reduce the occurrence of these diseases and definition of the operational criteria for quality assurance in veterinary diagnostic laboratories have been, and remain, the primary reason for the existence of the Office International des Epizooties (OIE).

The ability of any country to use the information, guidelines and standards provided by the OIE to deal effectively with animal health problems requires at least five essential elements, as follows:

a) a cohesive national animal health regulatory authority
b) a comprehensive animal health surveillance programme conducted by (or in association with) the national authority
c) the ability of the national authority to control animal movements within and across its national boundaries
d) the ability of the national authority to take appropriate actions when animal health problems are recognised, and
e) the ability of the national authority to diagnose animal diseases accurately and efficiently.
Some developing countries have all or most of these elements, but many do not. Without the first four, a national veterinary diagnostic laboratory has little more than a descriptive role to play, limited almost entirely to reactive efforts in the face of disease outbreaks.

Assuming that the first four elements listed above are available or are at some stage of enactment by the government of the developing country, the role of the national veterinary diagnostic laboratory is clear: to provide the best evidence possible for making determinations of the disease status of animal diseases of national importance. As with many issues, this role can be extremely challenging.

The challenges

The problems which face the diagnostic laboratory of any developing country are varied and can seem endless. Each laboratory faces a unique set of problems, but in general, these can be reduced to four categories:

a) personnel
b) financial limitations
c) availability of appropriate assays, and
d) establishment of national and international credibility.

Personnel

There are many examples world-wide of national and international scientific support resulting in the establishment of world-class laboratories with few or no appropriately trained personnel to run them. This is true in the agricultural sciences as well as in many other disciplines, and the facilities stand as monuments to poor planning. In veterinary diagnostics, as in any other area, the laboratory is only as good as the people performing its work. Unfortunately for diagnostic laboratories in developing countries, the common experience is that advanced training equals a negotiable asset that is then used by the scientist for advancement to an administrative or political position. Often the training investment does not reach the laboratory, or at least not for long.

One solution adopted by several organisations is to assist in the training of trainers. Instead of trying to provide advanced training to every individual who might need it, the approach is to target known individuals in the developing countries who have a demonstrated commitment to their current work. The trainee becomes part of a package between the training organisation and the national government whereby the training organisation agrees to provide the advanced training at minimal or no cost, the trainee agrees to a multi-year, post-training commitment during which he/she will train others in the specific disciplines and techniques, and the national government agrees to provide support for the local-level training efforts. This approach pays several dividends in that the training process becomes decentralised, thus allowing better use of the resources of the training organisations, and the developing country officially recognises the need for – and invests in the sustainability of the outcome by taking ownership of – the expanded training process.

The critical element in this process is that the initial training is well considered. Too often a training investment has been made when there was no immediate purpose for it to serve, simply because objectives beyond 'capacity-building' were not considered in an appropriate time-frame. The common result is that the expertise is not exercised by the trainee and has been lost by the time it is needed.

Financial limitations

Money plays a part in so many of the functions of a good diagnostic laboratory that a full consideration of the problems generated by limited finances is beyond the scope of this article and is somewhat pointless as well. However, it must be stated emphatically that an inadequate budget for salaries will reflect directly on the quality of data produced. Why should a well-trained scientist or technician stay in a poorly paid government position when there are better opportunities elsewhere at home or abroad?

Beyond that, a veterinary diagnostic laboratory can be as expensive or inexpensive a proposition as the national requirements dictate. A review of the OIE 'List of Tests For International Trade' (1) indicates that most of the assays have relatively simple equipment requirements. With the exception of virus neutralisation assays, the majority of 'Prescribed Tests' require a microscope for visual observation or immunofluorescence, or are serodiagnostics requiring a modest investment in immunoassay equipment. At present, none of the 'Prescribed Tests' or 'Alternative Tests' for Lists A and B diseases are molecular biological assays, thus relieving a basic diagnostic laboratory of the need for the relatively expensive equipment and infrastructural support necessary to these techniques.

Access to reagents, disposable supplies and technical support has always been a weak point for diagnostic laboratories in developing countries. However, this is often a problem of logistics as much as finances. With the daily improvement in global communications and commercial distribution networks and the movement towards harmonised assays with standardised internal quality controls, the access of laboratories in developing countries to the tools of their trade will continue to improve.

Availability of appropriate assays

Even when the technical competence of the laboratory staff is high and financial support is not an issue, many diagnostic laboratories are hampered in their efforts to produce relevant data because the appropriate diagnostic assay is simply not available. In this case, the word 'appropriate' is meant in the sense of 'fit for purpose'.

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Many of the animal diseases found in developing countries do not exist elsewhere, and the commercial market forces of developed countries do not play a role in competitive generation of assays for these diseases. An example of this situation is the diagnosis of trypanosomosis, an animal and human disease of developing countries in Africa, Asia and Latin America. A number of serodiagnostic and other types of assays for this disease have been developed, but none are reliable and none have become well established due to inherent problems with the assay reagents, complexities in some of the assay protocols or the biological variability among the different species of pathogenic trypanosomes and their routes of transmission. Assays for the diagnosis of animal trypanosomosis have been developed principally by institutions in developing countries, tropical veterinary institutes in developed countries and international organisations, with none of the power of the profit motive to drive this effort. While a profit motive is not essential to the development of effective diagnostic assays, the evidence for its role in the improvement of veterinary diagnostics in developed countries is overwhelming.

Where good assays for specific animal diseases are available to developing countries, they still may not be 'fit for purpose or use' – i.e., appropriate in their current form to the goal of a disease surveillance, control or eradication programme. For example, a country which has foot and mouth disease (FMD) and practices vaccination of susceptible animals has little use for an assay that yields a high percentage of positive reactions among the protected vaccinates. The assay needed is one which discriminates between uninfected/unvaccinated, uninfected/vaccinated and infected animals, whether these have been vaccinated or not. To date, several good antigen and antibody immunodiagnostics for FMD have been developed, but the appropriate test for an area with disease and vaccine control is not widely validated or available.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) between members of the WTO places responsibility on the developed countries of the world to help developing countries reduce the barriers to agricultural trade (3). The OIE, in its role as an advisory body to the WTO, needs to develop a stronger proactive role with its own members with respect to encouragement and guidance in the development of diagnostic assays for the important animal diseases of developing countries. Without the centralised international leadership of the OIE, solutions to the recognised animal disease diagnostic problems of developing countries will get no further than the paper on which they are printed.

**Credibility**

The issues dealt with above have focused on the functional aspects of a diagnostic laboratory. While it is crucial that the staff of any laboratory should be appropriately trained, perform at the highest possible level and have ready access to the materials necessary for disease diagnosis, this efficiency would mean nothing in the world of trade if it occurs in a vacuum. To develop credibility among potential trading partners, the operation of a diagnostic laboratory must be transparent and the information generated with regard to a particular animal disease must be understandable with reference to international standards. Otherwise, the information will be discounted or ignored because its quality cannot be established.

There are two equally important components to the establishment of credibility. First, the laboratory must have a quality assurance (QA) system, preferably organised according to some type of international standards. The details of the QA system should be available to, and agreed with, any 'client'. This system should contain enough elements to ensure the prospective client that the data produced by the laboratory is reliable, of high and consistent quality, and that it is generated in an objective manner. At a minimum, the QA system should have documentation on the laboratory organisation, levels of authority and responsibility, staff training, general procedures, sample handling procedures, the specific protocols used for assays that lead to diagnostic interpretations and full documentation of the internal quality controls used to measure the accuracy and precision of each assay. The system should also include sufficient documentation ('paper trails') to convince an outsider that reported data can be traced from specific samples that were handled according to the established protocols, and provision should be made so that the laboratory continually challenges itself through participation in internal and external proficiency testing. Through the organisation and use of such a QA system, the operations of the diagnostic laboratory become transparent and can be judged for quality by a client, including trading partners.

The second component to gaining credibility is the use of international standards to yield data which are comparable between laboratories and countries. This can be achieved through the use of standardised assays world-wide, so that every laboratory assaying for a particular disease would use exactly the same assay protocol and components, including internal quality control standards. Another, more realistic approach is to use harmonised assays (i.e., different in components and protocols, but similar in results) that incorporate similar internal quality control standards that are traceable to one accepted set of primary reference standards, for a particular disease.

In the physical sciences, all measurements of mass, volume, temperature and time in official testing laboratories are made in units that are traceable to the 'Système international' (SI). Different equipment, reagents and protocols are used for the same type of analysis in different official testing laboratories, but the equipment calibration and reagent composition are traceable to international standards and the different protocols have been validated locally by the users according to
international guidelines. In veterinary diagnostic laboratories, many of the reagents are of biological origin and do not lend themselves to description in SI units. However, if the assay equipment is properly calibrated, the reagents characterised and the protocols validated by the user, the incorporation of common internal quality controls with specific performance characteristics should allow the raw data generated to be normalised to a comparable standard.

At present, few assay reference standards are available to veterinary diagnostic laboratories in developing or developed countries. Most trading partners enter into bilateral or multilateral agreements which establish the required sampling and assay conditions for the exporter to meet, or the importer simply imposes these standards as a requirement for trade to happen. Often, this leaves the developing countries unable to participate in international trade.

Although the universal availability of primary reference standards for disease diagnostic assays would not solve all of the problems of livestock and livestock commodity trade, their lack of availability for many assays is a definite hindrance to the establishment of credibility by diagnostic laboratories in developing countries. The OIE, through both developed and developing country members, must ensure that these standards are developed and are made widely available at cost so that all countries can maximise their trade opportunities in livestock and livestock commodities.

Laboratoires vétérinaires de diagnostic dans les pays en développement : le défi de la crédibilité

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Résumé
Les laboratoires vétérinaires de diagnostic dans les pays en développement sont confrontés à un ensemble de problèmes allant des plus simples tels que l’insuffisance des fonds permettant de conserver un personnel qualifié ou d’obtenir des équipements, du matériel, des réactifs ou des moyens de formation, aux plus complexes tels que la conception et l’exécution de programmes appropriés de collecte de prélèvements destinés à l’épidémiométrie ou l’évaluation des performances d’une nouvelle technique de diagnostic. Certes, beaucoup de pays en développement s’efforcent de résoudre ces problèmes séparément et nombre d’organisations nationales et internationales fournissent diverses formes d’aide extérieure, mais l’Office international des épidémiologies (OIE) doit poursuivre son importante contribution en mettant au point des lignes directrices pour les épreuves de diagnostic les plus appropriées aux échanges internationaux et pour l’élaboration des réactifs primaires de référence pour ces épreuves. De plus, l’OIE devrait développer des lignes directrices relatives à la gestion de la qualité, destinées aux laboratoires vétérinaires de diagnostic. En l’absence de ces lignes directrices et réactifs de référence, les laboratoires de diagnostic des pays en développement auront des difficultés à acquérir la crédibilité nécessaire pour améliorer le niveau de leur pays dans les échanges internationaux d’animaux et de produits d’origine animale.

Mots-clés
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Resumen
Los laboratorios veterinarios de diagnóstico de los países en desarrollo se enfrentan a varios tipos de problemas, desde los más simples (como la carencia de fondos para contratar a personal competente, obtener instrumental, suministros y reactivos o procurarse formación) hasta los más complejos (concepción y ejecución de buenos programas de muestreo para la epidemiovigilancia o evaluación del rendimiento de una nueva prueba de diagnóstico). Aunque muchos países en desarrollo intentan solucionar esos problemas por su cuenta, y aunque varios organismos nacionales o internacionales les presten apoyo externo bajo diversas formas, la Oficina Internacional de Epizootias (OIE) debe perseverar en su importante labor, elaborando directrices sobre las pruebas de diagnóstico más adecuadas en el ámbito del comercio internacional y preparando reactivos primarios de referencia para dichas pruebas. Por otra parte, es preciso que la OIE lleve la iniciativa en la elaboración de directrices de gestión de calidad para los laboratorios veterinarios de diagnóstico. A falta de tales directrices y estándares, será difícil que los laboratorios de diagnóstico de los países en desarrollo obtengan la credibilidad necesaria para contribuir al progreso de sus países en lo que al comercio internacional de ganado y productos pecuarios se refiere.

Palabras clave

References

