Central or national veterinary diagnostic laboratories

J.E. Pearson

United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Veterinary Services Laboratories, P.O. Box 844, Ames, Iowa 50010, United States of America

Summary
Information on laboratory organisational structure and roles was gathered from twenty-four national veterinary diagnostic laboratories around the world. This information was used to develop an overview of the organisation and roles of the national veterinary diagnostic laboratory. In addition, the national diagnostic laboratory for the United States of America (the National Veterinary Services Laboratories) was used as an example to provide more information on the activities of such a laboratory. The survey revealed great variation in organisation and structure among the twenty-four laboratories. A few have only one facility, others function at multiple locations, and all have different supervisory reporting systems. However, these laboratories all form a significant part of the national veterinary infrastructure. All of the laboratories contacted in the survey report to (or are at least partially under the direction of) the Chief Veterinary Officer or another senior animal health official, and most report to the Ministry of Agriculture. The national veterinary diagnostic laboratories have similar roles, and are all responsible for foreign animal disease diagnosis and for providing support to national disease eradication or control programmes. Most also play an active role in import and export testing, either performing the tests themselves or developing a quality assurance programme for other laboratories that perform the testing. In addition, the national veterinary diagnostic laboratories usually undertake research and provide training, consultation, disease surveillance information and, in some cases, vaccine evaluation.

Keywords

Introduction
The central or national veterinary diagnostic laboratory can be defined as the federal laboratory that provides laboratory support for the regulatory programmes of national Veterinary Services and for diagnosis of domestic and foreign animal diseases. Directors of eighteen laboratories from countries around the world were asked to provide information on the organisation, management and roles of their laboratories. Sixteen responded with information (see Acknowledgements). All provided information on their organisational structure and the roles of their laboratories: some gave in-depth reports while others gave only general information. The material collected allowed a good overview of the laboratories. The author also discussed this subject on a less formal basis with laboratory and animal health officials from the following countries: Japan, People's Republic of China, Argentina, Mexico, Russia, Sweden, Switzerland and Zimbabwe. The information gained from these contacts will be summarised in this paper. In addition, the national veterinary diagnostic laboratory of the United States of America (USA), the National Veterinary Services Laboratories (NVSL), is described in more detail. After summarising the information from laboratories in other countries, the author concluded that NVSL is fairly representative of many national veterinary diagnostic laboratories and can serve as an example of this group.
Organisational structure of the national veterinary diagnostic laboratory

The organisational structure of the national veterinary diagnostic laboratories varied tremendously: no two national laboratories contacted described the same organisation. In addition, the organisation of several of the laboratories had recently changed, or was in the process of changing. The laboratories were generally responsible to the Chief Veterinary Officer (CVO) or other senior animal health official for the diagnostic testing that they conducted. The Director of some laboratories, including the NVSL, reported directly to the CVO. In other cases, the laboratory reported to another official in the Ministry of Agriculture. Even in these cases, there was a close relationship between the national veterinary diagnostic laboratory and the CVO. Some of the laboratories contacted did not provide specific information regarding the authority to whom they reported; however, most laboratory Directors indicated that the CVO or senior animal health official had the authority to request the national veterinary diagnostic laboratory to perform diagnostic testing in support of government veterinary programmes.

There was some variation in the number of branch laboratories within the national veterinary diagnostic laboratory. For example, France has twelve laboratories that report to one Director, Italy has ten, Spain has three, Canada has six, Denmark has two, Northern Ireland has a main laboratory and a satellite diagnostic laboratory, Argentina has one central laboratory and eleven regional laboratories, and the NVSL has two laboratories in separate locations. All laboratories in Australia have recently been combined in one location at a high-security laboratory in Geelong, Romania, Belgium and South Africa also have laboratories in one location. Korea, Japan and the People's Republic of China have separate laboratories for domestic and import/export testing, whereas most other countries combine import/export testing with domestic testing. A number of countries maintain biocontainment laboratories for foreign animal disease (FAD) diagnostic testing. Many of these are a part of the one national veterinary diagnostic laboratory and report directly to its Director, while others (such as those in South Africa, Canada and Denmark) report directly to a senior animal health official. Branch laboratories do not always report to the same animal health official. The Director of the Institute of Animal Health in the United Kingdom (UK) reports to the Biotechnology and Biological Sciences Research Council, whereas the FAD testing is performed for the Ministry of Agriculture, Fisheries and Food. In the USA, the Chief of the Foreign Animal Disease Diagnostic Laboratory, which is located on Plum Island off the coast of New York, reports to the Director of the NVSL located in Ames, Iowa. Specific laboratories within the national veterinary diagnostic laboratory systems of Canada, Italy and France were developed as centres of excellence for specific diseases or diseases of specific species.

In conclusion, organisational structures of the national veterinary diagnostic laboratories varied greatly; however, all the laboratories contacted received some degree of direction from the CVO or other senior animal health official.

Relationship between state/district laboratories and the national veterinary diagnostic laboratory

The state/district laboratories are covered in detail in a separate paper in this issue (3). The relationship of these laboratories to the national diagnostic laboratory contributes to the organisational structure and the role of the national diagnostic laboratory. Almost every country has a separate state/provincial/prefecture or departmental laboratory system that usually does not report to the national diagnostic laboratory. The primary exceptions appear to be England and Wales, where the Investigation Centres which serve as the local laboratories report to the Veterinary Laboratories Agency, which is the national diagnostic laboratory for the UK. In Belgium, eight district laboratories report to the Ministry of Agriculture, as does the national diagnostic laboratory. The interaction between state/provincial laboratories was not reported by all countries contacted. There is great variation in the levels of interaction between the national diagnostic laboratory and state/provincial laboratories. In some countries, such as Australia and the USA, the State laboratories are autonomous and only ask for assistance if there is a very unusual case or if an FAD is suspected. Others refer all submissions of certain types (such as tuberculosis, brucellosis or rabies) to the national diagnostic laboratory. In Japan there are 195 prefecture laboratories. The National Institute of Animal Health, which is the national diagnostic laboratory for Japan, provides assistance to these laboratories if requested. The interaction of the NVSL with the State and university laboratories is probably similar to that of many other countries. In the USA there are approximately 70 State or university diagnostic laboratories. These laboratories are autonomous, and the NVSL provides the following services to them: testing for suspected FAD or emerging disease problems, testing which requires expertise/equipment that the State laboratories cannot provide, testing to confirm unusual or questionable results, and training. In addition, the NVSL supplies reagents that are not commercially available and external quality assurance samples (proficiency tests). The proficiency tests are also provided to approved private laboratories. The NVSL charges a user fee for most of these services. Additional information on the interaction between national and state laboratories is covered in the article by Gosser and Morehouse (3).
Roles of the national veterinary diagnostic laboratory

Diagnosis of foreign animal diseases

Diagnosis is a function of the national diagnostic laboratory in every country contacted. Many of those countries have excellent biocontainment facilities and are working with foot and mouth disease. In addition, most countries are working with other, less infectious exotic agents in their less secure facilities. The specimens may first be submitted to a state or local laboratory, which will forward the samples to the national diagnostic laboratory, either for complete testing or for confirmation. In some cases, if an FAD is suspected, a veterinarian employed by the federal or state government is called upon to carry out a complete investigation and submit the samples to the national diagnostic laboratory. The national diagnostic laboratory is usually responsible for providing the laboratory support for the FAD control or eradication programme. An eradication programme can result in large numbers of samples being submitted. During the 1983-1984 outbreak of highly pathogenic avian influenza in the USA, 1,000 samples per day were submitted to the NVSL for virus isolation. During the recent outbreak of classical swine fever in The Netherlands, 10,000 serum samples were submitted per day to the national laboratory to be tested for antibody. User fees are not charged by the national laboratories for these services.

Disease control programmes

The national diagnostic laboratory is usually responsible for providing support for federally funded disease control or eradication programmes. The national diagnostic laboratory may perform all the testing or may act as a reference laboratory and only perform tests on samples referred from other laboratories. As an example, the NVSL supports the Aujeszky's disease (pseudorabies) eradication programme in the USA by performing confirmation testing on samples that produce unusual reactions, performing the polymerase chain reaction test on the trigeminal ganglia, providing training, providing proficiency tests, approving laboratories to perform serological tests and helping to develop programme goals. The NVSL plays a similar role in the USA tuberculosis and brucellosis eradication programmes. In addition, the NVSL has carried out applied research projects to provide information on some problems in the programmes, such as the pathogenesis of brucellosis in bison. The Danish Veterinary Laboratory carries out comprehensive testing for subclinical Salmonella infection in poultry and pigs as part of a national zoonosis control programme, and is testing muscle fluid for antibodies from 800,000 slaughter pigs. All laboratories contacted seemed to play similar roles in a national animal disease control programme. The NVSL does not charge user fees for testing to support disease control programmes. Based on the information submitted, it appears that other national laboratories also provide this type of testing free of charge.

Diagnostic testing

Testing to diagnose domestic diseases is performed by all the national laboratories contacted. Details on this testing were not supplied by all laboratories, but it appears that in some countries the national diagnostic laboratory provides reference assistance testing for other laboratories, and in a few it is the primary diagnostic laboratory for the country. Many of the laboratories did not provide information on charges for this service, while several confirmed that they charge fees for diagnostic testing. In the USA, samples for diagnosis of domestic diseases usually go to the State laboratories, and the NVSL acts as a reference laboratory, performing the testing that the State laboratories cannot or do not want to do. This includes identifying unusual agents and performing characterisation studies such as phagetyping, toxicological studies requiring additional equipment and pathogenicity studies in animals. The NVSL usually charges a user fee for this testing. All NVSL user fees are full-cost recovery, including overhead. Samples from unusual or high-profile domestic diseases are investigated by United States Department of Agriculture (USDA) veterinarians, and such samples are submitted directly to the NVSL for in-depth diagnostic evaluation. A recent outbreak of a disease which causes reproductive problems provides an example. The problem appeared to be a more pathogenic form of porcine respiratory and reproductive syndrome (PRRS), but the pigs had been vaccinated. USDA veterinarians conducted the investigation and submitted samples to the NVSL; PRRS virus was isolated and characterised.

Import and export testing

In all countries contacted, the national diagnostic laboratory plays a major role in import/export testing; indeed, several laboratories reported that facilitation of trade has become one of their most significant roles. The General Agreement on Tariffs and Trade (GATT) and the resulting formation of the World Trade Organisation (WTO) increased emphasis in this area. The WTO requires that standard tests be used and that the methods and results be made available to the trading partners (8). In many countries, all testing to qualify animals for import or export is performed by the national diagnostic laboratory. In other countries, some of the import/export testing may be carried out by state or regional laboratories, and in a few countries, testing may be performed in private laboratories. If the testing does not take place in the national diagnostic laboratory, the national veterinary authorities must have a programme to ensure quality assurance. In most cases, this programme is administered by the national diagnostic laboratory. In the USA, all import testing is performed by the NVSL; State laboratories may perform must export tests, and private laboratories may perform export tests for a few diseases. The State and private laboratories must follow the standard procedures as outlined by the Office International des Epizooties (7), and they must adhere to the quality
assurance requirements. In the USA, a procedure to approve State and private laboratories to perform certain tests for export or interstate movement was initiated in 1973 and has continued with some modifications. There are now 280 State and private laboratories approved to perform the equine infectious anaemia serological test. The laboratories must have personnel who have been trained by the NVSL, use USDA-licensed reagents, follow the standard procedure, successfully complete proficiency tests and report all results of testing to animal health officials.

The NVSL charges user fees for all import/export testing. Japan and the Republic of Korea do not charge for this testing. Not all laboratories contacted supplied information on user fees for import/export testing; however, all the others that did respond said that they did charge for this service.

**Quality assurance**

Several laboratory Directors commented that development of a quality assurance programme is receiving high priority in their laboratory and that it is critical for maintaining credibility as a reference laboratory and for the international acceptance of their import/export test results. The European Union has a laboratory quality assurance programme which uses EN 45001 as the standard for accreditation (1). The paper by Caporale et al. in this issue covers quality assurance in veterinary diagnostic laboratories in detail (2). As mentioned above, the national laboratories are taking the responsibility for the establishment of a quality assurance programme for import/export testing that is performed in state and private laboratories. The NVSL has established a goal to seek formal accreditation compliant with ISO 9000 (4) and ISO/IEC Guide 25 (5) by 1 January 2000. According to the information supplied, the other national laboratories appear to be developing similar programmes.

**Research**

The survey data indicate that research is a part of the mission of all national laboratories. The primary mission of the national laboratories of Korea, Japan and Poland is research; however, all three laboratories also have a strong commitment to diagnostic testing. The same is true of the Institute of Animal Health in the UK. Other laboratories that responded indicated that their primary mission is diagnostic testing, and the secondary mission is applied research to develop and implement new diagnostic techniques. In the USA, the national laboratories that undertake veterinary research do not have diagnostic testing as part of their mission. These laboratories are a part of the USDA, but they are not under the direction of the CVO. The NVSL does not have research as part of its mission but does, however, perform studies on validation of new techniques, and if no diagnostic techniques are available, studies are undertaken to develop new techniques. In addition, animal studies will be undertaken to reproduce a disease syndrome observed in the field and to study the pathogenicity of an agent that is isolated.

**Consultation**

The laboratory Directors contacted did not provide specific details about consultation. However, based on subsequent discussions with other laboratory Directors, the author is of the opinion that this is a significant role of the national diagnostic laboratory. The staff of the national diagnostic laboratory is often called upon to provide national veterinary authorities with information needed to develop and carry out disease control programmes. National laboratories usually have scientists who are experts in most of the significant diseases of the country and who are called upon to provide information on pathogenesis, epidemiology and prevalence, as well as on diagnostic tests. A member of the NVSL scientific staff is included in the development of any USDA disease control, prevention or eradication programme. In addition, an NVSL pathologist is included in a three-person team to investigate an unusual or emerging disease problem.

**Training**

The national laboratories play two roles in training. They organise and carry out training in their laboratory, and their scientists are also asked to assist in training courses provided by others, including lectures at universities. The NVSL training programme appears to be typical of many national laboratories. The NVSL has a training office with a staff of two people. In fiscal year 1997, the NVSL conducted 18 formal laboratory training courses and trained a total of 332 people. Most of the courses offered are designed for five to fifteen people to learn specific laboratory technique(s) and last from two to five days. As an example, a two-day course is offered to train laboratory technicians on export test procedures for bluetongue, bovine leukosis and equine infectious anaemia. Twelve people are trained at one time, and the course was conducted eight times in fiscal year 1997. Another example can be seen in the FAD courses. Three two-week courses are provided each year; these courses are for up to 30 people and include lectures on (and demonstrations of) the more significant FADs. The NVSL also provides training to individuals who want to learn specific techniques or who want to have an overview of a number of techniques. A user fee is charged for most training on diagnostic techniques, but not for FAD training.

**Supply reagents**

The NVSL produces and supplies diagnostic reagents for most tests for which no commercial reagents are available. The USA State diagnostic laboratories rely on this service as they do not have the capability to produce many of the reagents needed. Only one of the other national laboratories contacted mentioned this as a service they provided. This service is supported by user fees.

**Surveillance testing**

As a result of GATT and the formation of the WTO, there is a need to be able to provide information to trading partners on disease incidence. Also, the WTO allows the establishment of regions that are recognised as free of disease; however, the
establishment of these regions must be based on a disease surveillance system. The NVSL provides the diagnostic support for this programme, for example, by performing surveillance testing for bluetongue on samples obtained from northern and northeastern USA to monitor a region that is recognised as being free from bluetongue.

**Testing of veterinary biologicals**

The testing of veterinary biologicals is a role of a national laboratory in most countries, but it is usually not performed in the national laboratory that is responsible for diagnostic testing. However, five of the national laboratories contacted listed testing vaccines as one of their roles. The paper by Makie in this issue covers this subject (6). In the USA, the Centre for Veterinary Biologics-Laboratory (CVB-L) tests veterinary biologicals. This laboratory is located in the same facility as the NVSL, and the NVSL provides many of the support functions for the CVB-L. The functions of the CVB-L are as follows:

- to test master seeds and cells for purity and safety; test new serials of vaccines for purity, safety, potency and efficacy
- to test licensed vaccines for purity and potency
- to develop reagents to evaluate vaccines
- to conduct testing in response to reports of problems with vaccines
- to develop new techniques to evaluate vaccines.

In many countries, limited testing of veterinary biologicals is performed by the national laboratory. The programmes for approval are based more on establishing good laboratory practices to be used in the manufacturing process and less on testing on the final product.

**Conclusion**

In spite of the wide variation in organisation, there are many similarities between the national veterinary diagnostic laboratories around the world. All receive direction from senior animal health officials and play a significant role in the infrastructure of the national veterinary authorities of their countries. All are instrumental in preventing the introduction of exotic diseases, in carrying out the national disease eradication and control programmes, and in ensuring that the import/export testing meets the WTO requirements. Most laboratories also support the diagnostic capability of the country by providing training, consultation and surveillance testing.
Laboratoires vétérinaires centraux ou nationaux de diagnostic

J.E. Pearson

Résumé

Vingt-quatre laboratoires vétérinaires nationaux de diverses régions du monde ont été interrogés sur leur mode d'organisation et sur leurs fonctions. Les données ainsi collectées ont permis d'avoir un aperçu de l'organisation et des fonctions des laboratoires vétérinaires nationaux de diagnostic. L'auteur a, par ailleurs, pris pour exemple le laboratoire national de diagnostic des États-Unis d'Amérique (National Veterinary Services Laboratories), afin de donner plus de détails sur les activités de ce type de laboratoire. L'enquête a fait ressortir des différences significatives d'organisation et de structure parmi les vingt-quatre laboratoires interrogés. Quelques-uns d'entre eux concentrent leurs activités sur un seul établissement, d'autres fonctionnent sur des sites multiples et les systèmes de déclaration aux fins de supervision varient de l'un à l'autre. Cependant, tous ces laboratoires occupent une place importante dans l'infrastructure vétérinaire nationale. Tous les établissements contactés dans le cadre de l'enquête dépendent du Directeur des Services vétérinaires ou d'un autre responsable officiel de la santé animale (ou sont, tout au moins, placés sous leur tutelle), et la plupart rendent compte au ministère de l'Agriculture. Les laboratoires vétérinaires nationaux de diagnostic ont des fonctions comparables, qui comprennent le diagnostic des maladies animales exotiques ainsi que l'appui apporté aux programmes nationaux d'éradication ou de prévention. La plupart de ces laboratoires prennent également une part active dans les analyses effectuées à l'occasion des importations et des exportations, soit en effectuant eux-mêmes les tests, soit en mettant au point des programmes d'assurance qualité pour les laboratoires qui s'en occupent. De plus, les laboratoires vétérinaires nationaux de diagnostic mènent également des activités de recherche et de formation et fournissent des services de consultation, d'information sur la surveillance des maladies et, dans certains cas, d'évaluation des vaccins.

Mots-clés
Diagnostic – Laboratoires – Santé animale – Standardisation.

Laboratorios veterinarios centrales (o nacionales) de diagnóstico

J.E. Pearson

Resumen

Tras recabar datos sobre la estructura organizativa y las funciones de veinticuatro laboratorios veterinarios nacionales de diagnóstico de distintas partes del mundo, se vertió esa información en una descripción general de lo que deben ser la organización y las funciones de un laboratorio veterinario central de diagnóstico. Por otro lado, para completar la información sobre las actividades que realiza un laboratorio de esa índole, se utilizó a modo de ejemplo el laboratorio nacional de diagnóstico de Estados Unidos de América (National Veterinary Service Laboratories). La encuesta puso de manifiesto una gran disparidad entre los veinticuatro laboratorios en cuanto a su estructura y organización. Mientras unos pocos centralizan sus actividades en una única sede, otros las reparten entre diversos establecimientos, y cada uno funciona con sistemas distintos de comunicación y supervisión. No obstante, todos ellos
pertenecen de manera significativa a las infraestructuras veterinarias de sus respectivos países. Todos los laboratorios con los que se estableció contacto durante el estudio dependen (o están parcialmente bajo la dirección) del Jefe de los Servicios Veterinarios o de algún otro responsable de la Sanidad animal, y la mayoría de ellos están encuadrados en el Ministerio de Agricultura. Todos esos laboratorios tienen funciones parecidas, y a ellos compete diagnosticar las posibles enfermedades exóticas de los animales y prestar apoyo a los programas nacionales de control o erradicación de enfermedades. La mayoría participan también activamente en la realización de las pruebas de diagnóstico que se han de efectuar en el marco de importaciones o exportaciones, ya sea realizando ellos mismos las pruebas o elaborando un programa de garantía de calidad para los laboratorios responsables de hacerlo. Además, los laboratorios veterinarios centrales de diagnóstico suelen llevar a cabo investigaciones y ofrecer servicios de capacitación, consultoría, información sobre vigilancia sanitaria y, en algunos casos, evaluación de vacunas.

Palabras clave

References


