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SCAHL S

NEWSLETTER

SUB-COMMITTEE ON ANIMAL HEALTH LABORATORY STANDARDS

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The LEADDR Project

Last year it was proposed to adopt a more national approach to exotic disease diagnosis and the response to an exotic disease outbreak through developing a network approach in this area. Termed 'Laboratories for Emergency Animal Disease Diagnosis and Response' (LEADDR), a workshop was held by SCAHLS to develop a concept paper for the Animal Health Committee (AHC). This was endorsed by the AHC, but with the proviso that it is business as usual until such time as LEADDR develops operational activities that can be considered by AHC.

Following the August 2008 meeting of SCAHLS, a one day workshop examined progress on the concept of the LEADDR network. It was agreed that transparency, openness and trust in reporting was crucial, as

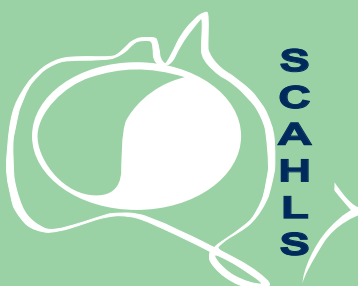
was the early establishment of a quality assurance program to underpin the testing undertaken. Given the need to manage biosecurity and biosafety it was agreed to focus the next stage of development on testing for avian influenza, Newcastle disease and bluetongue. Non-pathogenic AI and ND viruses are endemic in Australia but the detection of virulent agents would signal an exotic disease outbreak. It was agreed that for these three agents, standard operating procedures, standardized diagnostic tests and commonality of equipment would need to be developed over the coming months. As a starting point, it was agreed to establish the network in State Laboratories and to convene monthly tele-conferences to monitor progress.

Pathology Program on Track

The Australian Animal Pathology Standards Program (AAPSP) is now on track for self-sufficiency, thanks to Federal Government and Animal Health Australia (AHA) support supplementing member's subscriptions during its first four years. The program provides proficiency testing in histopathology, a national pathology archive, a second-opinion service, assistance for trainee veterinary pathologists and an annual series of continuing education workshops. The workshops, each year based on a different body system, are presented in every Australian State and the Northern Territory by eminent veterinary pathologists from Australia or USA.

The national pathology archive is now 'on-line' for subscribers. It provides digital images of hundreds of histopathology sections of diseased tissue for most production animal species, and more are being added. The next step is the development of ancillary information and pathological descriptions for each of the cases in the collection. The web site also contains a growing list of thematic information packages to assist trainees.

The AAPSP is jointly managed by AHA, SCAHLS, the Australian Society for Veterinary Pathology, NSW Department of Primary Industries and the Australian Veterinary Schools. For more information, see www.animalhealthaustralia.com.au/aahc/programs/ahsp/aapsp.cfm



Equine Influenza – Lessons Learned

While exotic disease exercises are helpful in maintaining our preparedness for emergency animal disease outbreaks, there is nothing like the ‘real deal’ to sharpen up our responses. Last year’s Equine Influenza outbreak certainly did that. Elsewhere in this Newsletter there is discussion of the Laboratories for Emergency Animal Disease Diagnosis and Response (LEADDR) initiative. The development of LEADDR is largely a response to the lessons learned during the EI outbreak.

Some of the issues identified during the outbreak were:

- Transport of specimens to AAHL remains a problem. Urgent samples seem to find their way
- Differences in test results between laboratories can create considerable tension and uncertainty. Test validation, adequate proficiency testing and sharing internal quality control data will all need to be in place before the next outbreak.
- Disease control managers frequently ask technical questions of laboratory staff. The answers would be more useful if each issue was first discussed by a group of laboratory based specialists.
- Some new laboratory diagnostic technologies (such as the real-time PCR used for EI) do not involve replication of infectious agents and can be conducted in regional laboratories with appropriate biosecurity.
- Laboratories that use these technologies in ‘peace time’ for routine high-volume testing (e.g. export testing) are in a better position to ‘scale up’ the operation to handle the large sample numbers expected during an outbreak.

There are encouraging signs that the LEADDR Project will result in a broader range of improved test results for emergency disease diagnosis. Communication between laboratories is seen as the key to solving the issues identified above.

Security Sensitive Biological Agent (SSBA) Regulatory Scheme

SCAHLs was recently briefed by Letitia Toms from The Department of Health and Ageing (DHA) on the Security Sensitive Biological Agent (SSBA) Regulatory scheme.

The regulatory scheme is built around a two-tiered list of SSBA's. The list was derived from intelligence information and an analysis of the impact and feasibility of these agents being used in a terrorist act. The regulatory scheme requires all entities and facilities holding SSBA's to register with the national authority. Tier 1 agents will be regulated from January 2009, and Tier 2 agents from January 2010.

The DHA will be conducting an education and awareness-raising campaign covering the proposed security requirements, data collection systems, and coordination with existing schemes. This national road-show for stakeholders will be a major component of the education and awareness-raising campaign.

The road-show will provide stakeholders with updated information about the SSBA regulatory scheme, including the National Health Security Act 2007, the NHS Regulations, the SSBA standards, guidelines and data collection. The information provided at the road-show will help to ensure that affected stakeholders are prepared for, and able to comply with, the new regulatory scheme when it is introduced in 2009.

Training for stakeholders will be held later this year to assist in understanding the requirements for compliance with the scheme.

For further information on the SSBA Regulatory Scheme please go to the Department's web site: www.health.gov.au/ssba. For enquires, or if you would like to register to attend a road-show, e-mail: ssba@health.gov.au.

New Test Evaluation Working Group

This group manages the process of independent review of new test methods and validation data. The aim is to facilitate the development and adoption of new diagnostic methods.

Templates for validation dossiers can be found on the SCAHLS website (www.scahls.org.au). These cover serological tests, nucleic acid detection tests and extensions to existing tests. For some methods (e.g. bacterial culture and pen-side tests) these templates may need to be adapted to suit the particular characteristics of the test. The fee for consideration of assay validation data is A\$3,000.

Approval through SCAHLS should be sought for new tests when they apply to:

- National disease control, eradication and surveillance programmes,
- Health Certification Programmes (for livestock destined for international export), and
- Exotic disease diagnosis.

At the August 2008 SCAHLS meeting, revisions to the New Test Evaluation Policy and the New Test Evaluation Procedures were approved. These are now available on the SCAHLS website and provide further guidance for submitters of validation dossiers. Lists of approved assays and assays under development are also available on the website on the 'Test Register'.

Tests may be submitted as extensions to an existing assay where proposed minor changes are not expected to significantly affect the fitness for purpose of the assay involved. These extensions, if accepted for consideration, attract a reduced fee of A\$2,000.

Dossiers may be submitted to the SCAHLS Executive Officer at: jbirrell@agric.wa.gov.au

Use of non NATA accredited laboratories

At the August 2008 SCAHLS meeting, the increasing occurrence of samples being submitted to laboratories not accredited by NATA for veterinary testing was noted with some concern.

NATA accreditation provides a way of determining and recognising the competence of laboratories to perform a specific range of testing, including diagnostic veterinary testing. Importantly, it also provides laboratory customers (veterinarians) and their clients (animal owners and managers) with confidence in the reliability of the test results being issued.

Laboratories accredited by NATA must demonstrate that they meet international standards and have a commitment to quality management systems and, accordingly, continuous improvement. Accredited laboratories undergo regular audits which take into account all aspects of their operation. These include an evaluation of the suitability of management systems, staff, supervision arrangements, test methods, equipment, equipment maintenance and calibration, quality control procedures and performance in external proficiency testing (quality assurance) programs.

All of these measures provide confidence that an accredited laboratory can report accurate, reliable and reproducible results.

Progress of the new national animal health laboratory strategy (NAHLS)

The NAHLS structure is slowly taking place with the formation of a ten person Reference Group, chaired by AHA chairman Roly Nieper, charged with overall strategic direction of the program. The Reference Group will report to the Board of AHA. Beneath the Reference Group is a Senior Managers Group (SMG), chaired by Catherine Ainsworth of DPI Victoria, containing representatives from all States and the NT. The SMG will guide and direct a number of working groups of which there are currently two: one developing deliverables and key performance indicators, the other looking at a national training scheme. All State government and NT laboratories will trial the proposed KPIs for the system based on data drawn from 2007-08. The data will reflect national laboratory capability and will assist with the first gap analysis conducted for Australia.