



SCA·H·L·S

NEWSLETTER

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SUB-COMMITTEE ON ANIMAL HEALTH LABORATORY STANDARDS

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Export tests workshop

For new tests, SCAHLS has a rigorous approval process involving the completion of validation templates and submission of data for review by peers. However, many older tests, embedded in ASDTs as 'standards', have not been through a similar approval process. These tests have generally been accepted as 'fit for purpose' by virtue of their perceived performance over many years.

SCAHLs is now pursuing a process by which those tests used for AQIS export health certification can be formally accepted as fit for purpose, without requiring submissions to the New Test Evaluation Committee. However, for some of these tests there are no gold standards for comparison. Consequently, SCAHLS convened a workshop in August 2007 to discuss alternative approaches. The participants were epidemiologists with experience in test validation and scientists involved in the distribution of test reagents or provision of proficiency testing services.

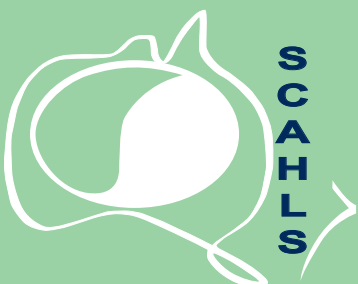
Two methods were considered. The first is the 'reliability coefficient method', in which no attempt is made to determine sensitivity or

specificity. Rather, this method aims to determine how reliable the test is when samples or group of samples are tested repeatedly over an extended period and in different environments. The second method is to use a 'latent class model' – Bayesian inference being preferred. This method uses sophisticated computer models where assumptions regarding the status of test sera are run thousands of times with test results from two or more unrelated tests. These models produce estimates of sensitivity and specificity. Bayesian inference methodologies overcome the difficulties associated with finding a 'gold standard' and are becoming more widely accepted in the scientific community.

As a result of the workshop, SCAHLS will commission a pilot study in which one or more of these 'export' tests will be examined by both 'reliability coefficient' and 'Bayesian inference' methods. It is hoped that the study will provide a template by which other tests can be examined. It will also provide the opportunity for the methodologies to be promulgated through the veterinary laboratory community.

NCRIS/ABIN Pathology Pilot

The proposed Australian Biosecurity Intelligence Network (ABIN) will contain a pilot module for veterinary pathology in the early stages of its development. The ABIN will provide a virtual shared workspace for pathologists operating in veterinary laboratories around Australia, enabling them to share databases, archives and other information related to biosecurity. The initiative will help trainees and experienced pathologists by facilitating on-line discussion and providing access to a truly national collection of information. The project will also assist the Australian Animal Pathology Standards Program (AAPSP) and the proposed National Training Scheme for laboratory specialists.



SCAHLs AB-CRC Update

The Australian Biosecurity Cooperative Research Centre for Emerging Infectious Disease (AB-CRC) is now almost 4 years into its first term, and research projects continue to mature.

The Centre has exceeded its education recruitment targets: as at 31 July 2007, 53 postgraduate research scholarships had been awarded. Additional applications are under consideration and a further four projects are awaiting the appointment of students. There is increasing activity in the Application and Linkage Program, where the results of research findings progress to development, technology transfer, adoption and/or commercialization

Three provisional patents have been lodged to date, and a number of stakeholder workshops and 'Adoption Forums' have been held

to facilitate communication between researchers and end-users. Of particular interest to the laboratory network, the real-time PCR assay developed for avian influenza that was transferred to state, NT and New Zealand laboratories in 2006 has been used effectively in the national response to the equine influenza outbreak.

An economic analysis of the centre's research outcomes has been commissioned and the development of a business case to support a Biosecurity CRC Mark II is underway. Considerable interest in participation in a new CRC has been forthcoming from both health and public health sectors, and it is likely a new centre would have expanded membership from both these sectors, particularly from public health.

Calls for preliminary project proposals to form part of the new business plan have been made and are due by 29 October 2007. Further details on the rebid planning progress can be found on the AB-CRC website (see <http://www1.abcrc.org.au/pages/AboutUs.aspx?MenuID=34>) or by contacting Lisa Adams or Moira McKinnon (joint Directors of Research Development) or CEO Stephen Prowse.

Update on New Test Approvals

One of the functions of SCAHLs is to coordinate evaluations of new tests to determine if they are "fit for purpose", and for inclusion in ANZSDPs. Currently, this work is handled by the New Test Evaluation working group, with members from many Australian states and New Zealand. Review of submitted validation dossiers includes examination by technical experts (information on the process for submitting assays for review can be found on the SCAHLs website).

After a quiet two years, the last year has seen a marked upsurge in new assays being submitted for review. Recent developments include the approval of a pooled faecal culture method for Johne's disease in goats and a PCR for Anthrax. Several other assays are under consideration.

While technical review of assays proposed for acceptance is essential, there is also a need for input from the wider SCAHLs group. This is because technical reviewers are likely to be most conversant with the background of their own state, but may not be aware of all relevant issues from other jurisdictions. Input from each SCAHLs representative is vital to

NAHLs Workshop

Twelve SCAHLs members recently debated the deliverables and key performance indicators for the National Animal Health Laboratory Strategy during a day-long workshop in Townsville. Consensus was reached on eight deliverables and 27 KPIs were identified. The agreed deliverables are:

- Diagnostic service,
- In-depth disease investigation,
- National programs,
- EAD management,
- Research and development,
- Training and continuing education,
- Technical and strategic advice, and
- Standards, quality assurance and biosecurity

In addition, an estimate was given of the relative contributions to be made by veterinary laboratories across the range of sectors involved, including government, CSIRO, private sector and universities.

ensure all factors are taken into account. At the September meeting SCAHLS further developed mechanisms to achieve this broader review following recommendations from the working group.

Also discussed at the meeting was the potential for extensions to existing assay approvals. It was agreed that while these were possible, they would need to be sufficiently minor that they did not affect the assay's fitness for purpose. Several potential types of extension were discussed and the collective view was that each proposed extension would be likely to raise unique issues. It was resolved that any proposals for extension will be examined on a case-by-case basis. SCAHLS will develop a methodology for applications for such extensions.

National Bioscience Centre

The National Bioscience Centre is an initiative by the Victorian Government to establish a new National Bio-science Centre within the La Trobe University site in Melbourne. Some \$210 million have been allocated to build the centre which will undertake research and diagnosis across the broad scope of agriculture.

This will include animal health and is likely to involve the diagnostic capabilities currently located at the Attwood veterinary laboratories. As part of the arrangements it has been proposed to use the PC 3 and PC 4 laboratory facilities at AAHL, which are being established under the NCRIS program. It is envisaged that this new facility will be commissioned in 2011.

Policy on Specimens Sent Overseas

SCAHLS is currently developing a policy to help minimize the risk to Australia's animal trade and animal health status associated with the transfer of non-human biological specimens to overseas laboratories for disease testing. The release of test results by overseas laboratories, as experience has shown, can have a significant socio-economical impact in Australia.

Following discussion of a draft paper in May 2007, a survey was conducted to obtain feedback from those likely to be affected by the policy. In addition, the survey collected data on current practice relevant to the policy. The respondents included organisations across different states and territories including government and private animal health laboratories, universities, research institutes and companies involved in animal research and veterinary services, wildlife sanctuaries and zoos. Both group and individual returns were received, and some participants also provided additional views by telephone.

Overall, the results indicated strong 'in principle' support for the policy but some modifications were suggested to make it more effective and enforceable, especially where it may affect certain specimens and work types. A more focussed and clearly defined scope was also suggested, together with improved communication with those laboratories affected by the policy. At the SCAHLS meeting in Townsville, the Committee noted the survey results and decided to redraft the policy to satisfy these objectives.

Equine Influenza UPDATE

Whilst equine influenza is endemic throughout most of the world, Australia and New Zealand have remained free until late August this year. The disease was first detected in the AQIS quarantine station at Eastern Creek, followed within days by confirmation at several locations around NSW. By mid-October the disease had been confirmed on a large number of properties in eastern NSW and south-east QLD. All other States and Territories remained free.

From a SCAHLS perspective, the experience has highlighted the crucial need for State Veterinary Laboratories and AAHL to work together in order to best meet the technical and resource requirements inherent in a major exotic disease outbreak. Interestingly, the outbreak has also demonstrated the value (and the limitations) of RT PCR technology in large-scale diagnosis and surveillance. Whilst this technology has been crucial, at the State level, in identifying new infected animals and premises, it has proved difficult to clearly link the detection of RNA (as determined by such assays) with the presence of infectious virus – essential in the control and recovery phases of the outbreak.

There is little doubt that this particular disease outbreak illustrates the need for strong and effective partnerships between State Veterinary Laboratories and AAHL, but equally it is helping to determine the best use of modern molecular diagnostic systems within the framework of a national EAD response.