

Aquatic Animal Health Subprogram: Establishment of a national aquatic animal health diagnostic network

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Australian Government

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1. TABLE OF ABBREVIATIONS

| | |
|-----------------------|--|
| AAH | Aquatic Animal Health |
| AAHC | Aquatic Animal Health Committee |
| AAHL | Australian Animal Health Laboratory |
| AHC | Animal Health Committee |
| AHA | Animal Health Australia |
| AQUAPLAN 2005-2010 | Australia's National Strategic Plan for Aquatic Animal Health |
| ANZSDP | Australian and New Zealand Standard Diagnostic Procedure |
| AusBIOSEC | Australia's Biosecurity System – Primary Production and the Environment; a major part of the National Biosecurity Strategy, designed to maintain or improve the management of the nation's biosecurity status in the primary production and natural resource management sectors. It builds on the specific industry and pest based strategies, legislation and operational procedures that are already in operation. |
| CSIRO | Commonwealth Scientific and Industrial Research Organisation |
| DAFF | Australian Government Department of Agriculture, Fisheries and Forestry |
| DNA | Deoxyribonucleic Acid |
| EHNV | Epizootic haematopoietic necrosis virus |
| FRDC-AAHS | Fisheries Research and Development Corporation, Aquatic Animal Health Subprogram |
| GAV | Gill-associated virus |
| NAAH-TWG | National Aquatic Animal Health Technical Working Group |
| NAADLN | National Aquatic Animal Diagnostic Laboratory Network |
| NACA | Network of Aquaculture Centres in Asia-Pacific |
| NATA | National Association of Testing Authorities |
| OCVO | Office of the Chief Veterinary Officer, DAFF |
| OIE | World Organisation for Animal Health (formerly Office International des Epizooties) |
| PCR | Polymerase Chain Reaction |
| PG | Post graduate |
| PIHC | Primary Industry Health Committee |
| PIMC | Primary Industries Ministerial Committee |
| PISC | Primary Industries Standing Committee |
| QA | Quality assurance |
| QDPI&F | Queensland Department of Primary Industries and Fisheries |
| RNA | Ribonucleic acid |
| SCAHLs | Sub-committee on Animal Health Laboratory Standards |
| TAAHL | Tropical Aquatic Animal Health Laboratory, Townsville |
| VER | Viral encephalopathy and retinopathy |
| WSSV | White spot syndrome virus |

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2. NON TECHNICAL SUMMARY

2.1 Structure and function of the National Aquatic Animal Diagnostic Laboratory Network (NAADLN)

To strengthen and support Australia's regional aquatic animal diagnostic laboratories a network has been established. The structure is two-tiered with reference and referral laboratories based on the same definitions utilised by Sub-committee on Animal Health Laboratory Standards (SCAHLs) (See Appendix 5).

2.2 Access to network database

The final location of the database for access to all member laboratories and government managers is likely to be through the Australian Government Department of Agriculture Fisheries and Forestry (DAFF) website.

2.3 Network database functions

The database permits easy searching of network laboratories for specific areas of expertise or specific test types. Contact details for laboratories will be available facilitating the exchange of test methodologies, referral of diagnostic samples and general information. Each laboratory has defined the type of samples it is willing to receive and the locations from which it is willing to receive them. The database highlights the accreditation status of the laboratory and allows searching for National Association of Testing Authorities (NATA) accredited laboratories. The front page of the database explains the limitations of the data contained within (see Appendix 3).

2.4 Database maintenance and updating

The database will have easy mechanisms for on-line annual updating, requiring only minimal input from a database network coordinator. Simple processes have been created for transferring the data profile of individuals between laboratories and removing retiring staff from the database. Each laboratory will be responsible to update its profile annually. State and Commonwealth NAAH-TWG representatives will issue reminders to laboratories and take responsibility to ensure their relevant Government laboratory information is updated annually to reflect test and staff availability. NAAH-TWG will also be responsible for determining the entry of new laboratories to the network, through its annual meetings.

2.5 Create a laboratory network

Twenty laboratories met the criteria for entry to the network. The project coordinator contacted all of the aquatic animal diagnosticians in each laboratory and entered their details into the NAADLN database. The database captures the diagnostic test capability of the laboratory as well as the human capacity across the various disciplines utilised for diagnostic tests. The assessment of personal proficiency in a discipline relied upon diagnosticians providing self-assessments of their abilities.

2.6 Facilitating transfer of knowledge and technology of aquatic animal diagnostics

The project coordinator visited most of the laboratories personally and assisted in forming and strengthening links between network laboratories. The construction of the database forms the primary mode for transfer of information between laboratories. The database permits laboratories to determine the diagnostic test options available at other laboratories and provides contact numbers for diagnosticians to communicate with colleagues. The database also allows diagnosticians to identify which laboratories have rated themselves as having expert level skills in particular disciplines.

2.7 Maintaining proficiency through ring-tests

Many of the network laboratories do not focus solely on aquatic animals and, in general, aquatic case volume is low, due to, in part, the implementation of cost-recovery by State and Commonwealth Laboratories as also noted by Frawley (2003). To maintain high levels of proficiency within the network, particularly in laboratories with low sample volumes, it was considered necessary to commence circulation of diagnostic samples preferably at a frequency of once or twice annually. This process provides a measure of quality assurance (QA) across the network and assists in providing continuing education material. Consultation with all network laboratories resolved that a multi-centric approach to the staging of proficiency tests was preferred. In this system the laboratory hosting the round would rotate between participating network laboratories. A benefit was recognised in rotating the host laboratory, as the rigour of hosting a round would enhance the focus on the individual test discipline to ensure all aspects of the test were being performed optimally within that laboratory. Most laboratories expressed the need for funding to support the host laboratory in creation, collation and reporting of the test round. The majority of laboratories were willing to participate in the testing rounds at their own expense, as part of internal QA processes.

2.7.1 Microbiology proficiency testing

For NATA accredited laboratories there is already a microbiology proficiency program in place, operated through IFM Quality Services Pty Ltd. This program is not specifically organised for aquatic animal pathogens. However, it typically includes two aquatic isolates each year. The expansion of such a program to the wider network was viewed as beneficial.

2.7.2 Histopathology proficiency maintained through “slide of the quarter” circulation

In 2005 NAAH-TWG nominated Ian Anderson (QDPI&F) to develop a methodology for quarterly generation of a histopathology slide of the quarter. This activity is coordinated by Ian Anderson and commenced in 2005. Slides

are sent to laboratories linked to NAAH-TWG. The issue of upgrading the slide of the quarter to a proficiency test was raised at the 2006 NAAH-TWG meeting. The consensus was that this slide of the quarter program should be continued in its current form, and not progressed to a full proficiency test, due to limited resources and other priority areas taking precedence. Network members can apply through their State NAAH-TWG representative to join the circulation of the slide of the quarter program.

2.7.3 Parasitology ring testing

The prospect of improving parasitology resources through a project to create a digital image library was discussed with NAAH-TWG. Circulation of images to network members could run in parallel with the histopathology slide of the quarter process. The commencement of proficiency testing in parasitology was viewed as a lower priority by NAAH-TWG and should not be considered for resourcing in the near term.

2.7.4 PCR ring testing first steps

A model for the commencement of ring-testing in PCR has been developed (see Appendix 4) and will undergo modification based on comments from the NAAH-TWG. Initially this program will be educational to determine which elements of currently used methodologies, if any, give aberrant results. Once these early problems are resolved, the testing rounds can be more appropriately applied as proficiency tests with a more intense focus on the sensitivity of testing. A mechanism for funding this project will need to be sought if it is to be progressed any further, due to the expenses of setting up and hosting a ring test. This issue should be directed to the members of Aquatic Animal Health Committee (AAHC) for consideration.

2.8 Aquatic animal diagnostician age distribution

The profiling of aquatic animal diagnosticians has documented that more than 70% are over fifty years of age. This analysis highlights an urgent need for new resources to be invested in succession planning over the next 5-10 years. This investment will ensure high levels of skill are maintained in the laboratory network and ensure that corporate knowledge is not lost. The ease of transfer of skills from other animal health areas into AAH was recognised and it was recommended that new training programs for AAH need to be synergised with general animal health post-graduate training, rather than developing courses as a separate entity.

2.9 Further network development

To take the network to the next level of functionality further development needs to be undertaken. This should involve facilitating ring testing, which will reinforce the roles and responsibilities for network laboratories. During the course of the project, some participating laboratories and members of NAAH-TWG have provided comments on further improvements, which would augment the structure that has been created. To deliver these improvements it is recommended that a part-time network coordinator be appointed. Further modifications to the database have been proposed to improve ease of use and the creation of formal assessment criteria for individuals classified as “expert” within the database. The current climate of limited Government funds for aquatic animal health laboratory services, in the face of growing demands, implies a need for enhanced efficiency of aquatic animal diagnostic service delivery. For the

network to deliver competent, timely and cost-effective aquatic animal diagnostics into the future the development of a business plan is required. This would require the input of an accounting professional and significantly greater engagement of the laboratories. The foundation for this business plan has been created through the initiation of the network in this project.

3. ACKNOWLEDGEMENTS

We would like to thank all those laboratory staff who contributed to database design and participated in telephone, email and in-person interviews and workshops around Australia. We are grateful for the input into the draft from the National Aquatic Animal Health Technical Working Group. We also extend our thanks to Eva-Maria Bernoth for input from the Office of the Chief Veterinary Officer (OCVO) to inform design of the database. We wish to recognize and acknowledge earlier efforts to capture laboratory information on capability and capacity through the Department of Agriculture, Fisheries and Forestry Australia projects and work by Iain East. Work on specialist competencies by Tiina Hawkesford from QDPI&F has also been incorporated into this new database.

4. BACKGROUND

The establishment in 2002 of the AAHC has provided a forum for discussion of aquatic animal health priorities by industry and government representatives. To support AAHC, the NAAH-TWG was established to provide AAHC with technical advice as well as to advise AAHC on any aquatic animal health issues of concern, in a similar manner that Animal Health Committee (AHC) receives advice from the SCAHLS. In fact, in areas of mutual interest (c.f. SCAHLS Workshop – Molecular Diagnosis and PCR Related Technologies for Pathogen Detection in Veterinary Diagnostic Laboratories, 25-27 November 2003 at CSIRO Australian Animal Health Laboratory (AAHL)) linkages between SCAHLS and NAAH-TWG facilitate consistency in advice to their respective committees.

NAAH-TWG discussed the need for a diagnostic network at their meeting 25-27 May 2004 (Agenda items 14 and 15). NAAH-TWG confirmed that there is a strong case for a regional diagnostic laboratory network, as opposed to a centralised system (Resolution 6) and endorsed a two-tier concept of recognising “referral laboratories” and “reference laboratories” for specific diseases.

AAHC at their 22 June 2004 meeting agreed with NAAH-TWG’s recommendations about the value and ongoing necessity for maintenance of the regional diagnostic laboratory system for aquatic animal health diagnostics, and requested that NAAH-TWG provide further advice on how a network would operate (Resolution 10.1).

The FRDC Aquatic Animal Health Subprogram (AAHS) Strategic R&D Plan 2002-2007 lists as key priority projects:

- Continue ring testing for white spot virus
- Ring testing for viral encephalopathy and retinopathy (VER), epizootic haematopoietic necrosis virus (EHN), and crayfish plague.

AAHC recognises the need for an aquatic animal health diagnostic network that would enhance Australia’s diagnostic capability and capacity. The establishment of such a network for aquatic animal diseases is also a priority under the Australian Government’s Securing the Future – Protecting Our Industries from Biological, Chemical and Physical Risk initiative that extends over the fiscal years 2004-05 to 2007-08. In addition, the project aligns with SCAHLS Strategic Plan 2004-2008.

At the 2005 NAAH-TWG meeting a workshop was undertaken to discuss and agree on the model for the network. The University of Sydney was also represented as an observer at this meeting. Those State and Territory Governments present and The University of Sydney agreed to participate in formation of the network. Through the course of the project 20 laboratory centres have joined the network (see full list below: 13.2). All State and Territory Government laboratories, major private veterinary laboratories, veterinary universities and universities offering aquaculture courses with significant aquatic animal health components were invited to participate during the course of the project.

5. NEED

The lack of many recognised serious diseases is perceived as one of Australian aquaculture's prime competitive advantages to contribute to supplying future global seafood demand. Maintenance of this high health status through initiatives that reduce the risk of disease incursions and facilitate early detection and response to emerging disease problems is seen as critical to continuing industry expansion. The range of commercially significant aquatic animal species, and their diseases, is increasing steadily. It is clear that due to limited resources, diagnostic laboratories cannot develop proficiency in the diagnosis of all significant diseases, for example those listed in the Australian National List of Reportable Diseases of Aquatic Animals. Appropriately, State laboratories, in support of local industries, concern themselves with local aquatic animal species and their significant diseases and have developed expertise in those areas. Rather than duplicate this effort, AAHL's involvement and expertise focuses on exotic diseases of concern to Australia, as well as new or emerging endemic diseases. As a consequence, expertise in specific diseases has developed in different laboratories throughout the country. To take advantage of this development, to ensure that expertise in different diseases is available Australia-wide, and to create a consistent system of aquatic animal disease diagnosis and reporting, it is proposed that a national network of laboratories should be established for the diagnosis and monitoring of aquatic animal diseases underpinned by a quality assurance program. Through a consultation process, uniform data standards and reporting formats need to be developed and adopted by all jurisdictions. Standard diagnostic tests and operating procedures also need to be developed and subsequently adopted by laboratories within the network. In May 2006 an Australian Government funded workshop on Australia and New Zealand Standard Diagnostic Procedures (ANZSDPs) re-stated their value for Australian laboratories undertaking tests on aquatic animals. A report on this workshop will outline how to progress development of more ANZSDPs for aquatic animal pathogens.

Thus this project is concerned with the establishment of the network and commencement of activities, including proficiency tests ("ring tests") designed to assist laboratories in further developing their diagnostic capabilities and/or to allow demonstration that performance of a particular test is at a nationally accepted standard, using ANZSDPs. In this way confidence of stakeholders in the quality of diagnoses provided is increased. The project contributes to the implementation of Strategy 1 (Enhanced integration and scope of aquatic animal health surveillance in Australia) of AQUAPLAN 2005-2010.

6. OBJECTIVES:

- Objective 1. Make recommendations on the structure and function of the network of referral and reference laboratories
- Objective 2. Establish a network for aquatic animal disease diagnosis
- Objective 3. Facilitate transfer of knowledge and technology in aquatic animal diagnostics
- Objective 4. Develop a model for national laboratory proficiency (ring) testing as a mechanism to enhance the proficiency of the established diagnostic network.

7. METHODS

A. Project presentation and workshop with NAAH-TWG: May 2005.

Commitment by representatives from AAHL, State and Territory Governments, and the University of Sydney to an aquatic animal disease diagnostic network was affirmed at the 2005 meeting of NAAH-TWG. South Australia and Northern Territory government representatives were not at that meeting. However, they subsequently confirmed their support. Discussions on the membership structure, management and operations of the network were included at this meeting. The content of the proposed database, such as listings of specific antibodies and bacterial reference strains was also discussed and referred out-of-session for ongoing discussion. The workshop also raised the issues surrounding standards for undertaking proficiency testing by network laboratories and mechanisms for information transfer between laboratories.

B. Creation of the National Aquatic Animal Disease Laboratory Network (NAADLN)

A project coordinator was appointed, Mr Matt Landos, an experienced aquatic animal health veterinarian with laboratory and national level committee experience. Laboratories were visited by the project coordinator to discuss diagnostic capability and capacity with laboratory staff and their role and responsibilities in the network. This information has been used to populate an entirely new database of Australian laboratory diagnostic expertise for diseases of aquatic organisms, replacing the old database from FRDC Project 2003/647. The age profile of diagnosticians was also collected to inform succession planning. Methods for on-going maintenance of the network were developed.

C. Communication and extension strategy

To facilitate the development of the project and extension of results a network communications strategy was developed. In addition to this, the network coordinator developed linkages between network members and with NAAH-TWG, SCAHLS, AAHC and FRDC AAHS.

D. Updating aquatic animal pathogen and diseases database

Through the NAAH-TWG group discussions, a mechanism has been developed to enable updating of the Aquatic Animal Pathogens and Diseases Database (FRDC Project 2003/646)

E. Project presentation and review at NAAH-TWG meeting, May 2006.

In consultation with NAAH-TWG, options for administration and implementation of inter-laboratory proficiency tests were developed. Considerations included cost recovery and sustainability within an overall objective to have implementation of the tests managed by expert laboratories (e.g. TAAHL for nodaviruses, University of Sydney for EHNIV, AAHL for white spot syndrome virus (WSSV)), coordinated by the network coordinator. The first rounds of proficiency testing will be planned for molecular diagnostics for aquatic animal diseases. A mechanism for the development of proficiency testing material for parasitology was discussed. Drafts of the results, this report and the database were provided to NAAH-TWG and considered out of session. Final comments were received from NAAH-TWG on 2nd November 2006 and were incorporated into this report.

8. RESULTS AND DISCUSSION

Objective 1

1.1 Structure of network

The 2005 NAAH-TWG workshop and subsequent discussions confirmed that all State, Territory and Commonwealth laboratories and the University of Sydney would participate in the initial development of the network. The meeting also recommended that the network membership be open to all laboratories undertaking diagnostic tests on aquatic animals. This was specifically to include non-NATA accredited laboratories, and sole operator laboratory diagnostic services. Based on this consultative process a two-tier system of laboratories (Referral and Reference Laboratories) has emerged. A formal process has not been necessary to designate laboratories as “Referral” or “Reference”, as there have not been diseases recognised that would warrant creation of a Reference Laboratory as described by the SCAHLS - Policy Document: Reference Laboratories (see Appendix 5). Hence the network has a flat structure of referral laboratories around Australia. A referral laboratory is considered to be any laboratory that nominates itself to undertake a specified diagnostic test on aquatic animal samples referred from another laboratory. The University of Sydney and CSIRO Australian Animal Health Laboratory (AAHL) are special cases, as they are already OIE Reference Laboratories - the University of Sydney for EHNIV and AAHL for both EHNIV and Yellow Head Disease. In addition, AAHL is the NACA Regional Reference Laboratory for Koi herpes virus infection. By default these laboratories serve as reference laboratories in the network for these pathogens, according to the guidelines in Appendix 5. In the future, should a need arise for a Reference Laboratory, then NAAH-TWG can determine the validity of the claim of expertise according to the criteria laid out in Appendix 5. Resolution of many of these issues will occur as the network evolves and is beyond the scope of this initial project.

1.2 Access to the network

Laboratories seeking to be added to the network will be considered by NAAH-TWG at its annual meeting, through an agenda item drafted by the executive officer. The network will remain open to any competent laboratory undertaking diagnostic tests on aquatic animals.

The database which has been created has personal data and public data sections. The final location of the database for access to all member laboratories and government managers is likely to be through the Australian Government Department of Agriculture Fisheries and Forestry (DAFF) website. The information available will include contact details for all laboratories, lists of tests available at each laboratory and a guide to the expertise available at each laboratory. Only the network database coordinator would have access to the depth of information which includes the individual diagnostician’s profile of skills and personal information.

Objective 2

2.1 Network database creation and functionality

The diagnostic tests routinely offered by laboratories have been recorded on the NAADLN database (see Appendix 6 cd-rom). This database enabled diagnosticians to participate in a self-assessment of their competencies across the range of disciplines and techniques involved with delivery of aquatic animal disease diagnostic tests. In effect this has provided a skills register within the laboratory database. There is a clear need for this to be updated annually for it to remain relevant and useful. In the “live” public version, the skills of laboratory staff are aggregated to provide an outline of the skills at the laboratory level. The skill profile of individuals is maintained confidentially and not available to the general network. The database will incorporate a search function which will facilitate enquiries as to the location of expertise and where particular tests for individual disease agents may be undertaken. The database also notes the level of internal quality control within the laboratory e.g. NATA accreditation for the performance of certain techniques.

The database has simple mechanisms for on-line annual updating, requiring only minimal input from a part-time database network coordinator. Simple processes have been created for transferring the data profile of individuals between laboratories and removing retiring staff from the database. Each laboratory will be requested to update its profile annually. This updating process will take the form of individual personal email reminders with a web-link and advice on how to complete an online update of the individual profile. It is anticipated that the network database coordinator will be required to log some of the updating information annually.

State/Territory and Commonwealth NAAH-TWG representatives will issue reminders to laboratories and take responsibility to ensure that their respective Government laboratory information is updated annually to reflect test and staff availability.

Objective 3

3.1 Facilitate transfer and knowledge of aquatic animal diagnostics

The network coordinator has been able to foster some improved communication between laboratories through providing contact details for diagnosticians with particular expertise around the country. This has largely been a result of raising the awareness of the depth of expertise that exists within many of the network laboratories. The creation of the network database will assist aquatic animal diagnosticians around Australia to determine the availability of different test types around Australia. The search functions of the database make it easy to locate and contact laboratory staff with particular expertise. The contact point provided for search responses will be the general telephone switch number of the relevant laboratory. Ongoing communications and technology transfer within the network will be achieved using the communication tools already in place for the FRDC AAHS viz. FRDC website, *Health Highlights* newsletter and the FRDC AAHS Scientific Conferences, and for NAAH-TWG (annual NAAH-TWG meetings and Out Of Session papers coordinated by the executive officer).

Objective 4

4.1 Create proficiency testing model

All network laboratories have agreed in principle to participate in proficiency testing, providing that some form of resourcing to cover the costs of hosting proficiency rounds is identified and applied. Non-host participating laboratories agreed to cover the costs of completing the tests within existing operating budgets as part of their own internal quality assurance processes.

4.1.1 Microbiology proficiency

Proficiency testing in microbiology is already in place within NATA accredited laboratories through a commercial provider. An offer was made at the 2006 NAAH-TWG meeting, from the fish health laboratories at WA Fisheries and Mt Pleasant Tasmania, to increase the circulation of important isolates and appropriate media. NAAH-TWG members were encouraging of this approach. However, NAAH-TWG recognised that no funding mechanism was currently available to support this.

4.1.2 Histopathology proficiency

In 2005 NAAH-TWG nominated Ian Anderson (QDPI&F) to develop a methodology for quarterly generation of a histopathology slide of the quarter. This commenced in 2005 and is currently sent to laboratories linked to NAAH-TWG. The slide of the quarter is aimed at education rather than attempting to operate as a true proficiency test. The laboratory preparing the sections rotates on a quarterly basis amongst participating laboratories. Participating laboratories were initially only government laboratories linked to NAAH-TWG. This has now been expanded to include one private laboratory. At the 2006 NAAH-TWG meeting a proposal to upgrade the slide of the quarter to a full proficiency test was considered and deemed not to be an immediate priority. It was the consensus of NAAH-TWG that the current format should be maintained into the near future. Laboratories can apply through their State NAAH-TWG representative to join the circulation for the slide of the quarter. To minimise costs for the host laboratory this may involve the forwarding of material between laboratories within the one State or Territory.

4.1.3 Parasitology proficiency

Development of parasitology reference material and proficiency testing was also discussed by NAAH-TWG at the 2006 meeting. The parasitologist from Queensland Museum had indicated a willingness to participate in a project to develop proficiency testing material, as part of the creation of a database of images of common parasites from aquatic animal species in aquaculture in Australia. NAAH-TWG considered that the project did not rate a high priority for funding and the proposal was not supported.

4.1.4 PCR proficiency

Extensive discussions with laboratory diagnosticians from all disciplines led to the creation of the proposed proficiency testing model for PCRs (See Appendix 4). NAAH-TWG determined at their 2006 meeting that PCR testing was the highest priority area for proficiency test development. The proposed methodology incorporates some elements of the first WSSV ring test, hosted

by AAHL. The new protocol attempts to overcome some of the impediments encountered in the first PCR ring test round, through initially seeking to define the problem areas of operation of particular PCR assays. The problem areas will then be addressed through a group teleconference with a facilitator coordinating an action plan to resolve difficulties. A funding source is required to facilitate the commencement of the PCR proficiency model.

5.1 Aquatic animal diagnostician age distribution

Through collection of personal data for the compilation of the NAADLN database some analysis of laboratory based aquatic animal diagnosticians in Australia was made possible. Although not specifically included in the objectives of this project, the findings were such that the authors felt they should be included, as they underpin the operation of the NAADLN into the future. The profiling of aquatic animal diagnosticians found that more than 70% were in excess of fifty years of age. (See Figures 1 & 2.) This analysis highlights an urgent need for new resources to be invested in succession planning over the next 5-10 years. This urgency is further highlighted by the findings from FRDC project 2005/641, which noted that the vast majority of survey respondents (73%), from all stakeholder groups, agreed or strongly agreed that demand for aquatic animal diagnostic services will increase over the next 5-10 years. This investment will ensure high levels of skill are maintained in the laboratory network and ensure that the current aggregation of significant, individual knowledge is not lost due to retirement of experts. At the 2006 NAAH-TWG meeting it was recognised that this problem is not unique to aquatic animal health (AAH) diagnostic resources, but in fact was symptomatic of all animal health laboratory resources around Australia, referring to the report of Frawley (2003) and Sims (2003). The establishment of the network is one part of addressing this looming problem. The final report for FRDC 2005/641 makes several other recommendations to address this issue. The ease of transfer of skills from other animal health areas into AAH was recognised and it was recommended that new training programs for AAH need to be synergised with general animal health post-graduate training, rather than developing courses as a separate entity.

Figure 1: Age distribution of aquatic animal disease diagnosticians in Australia

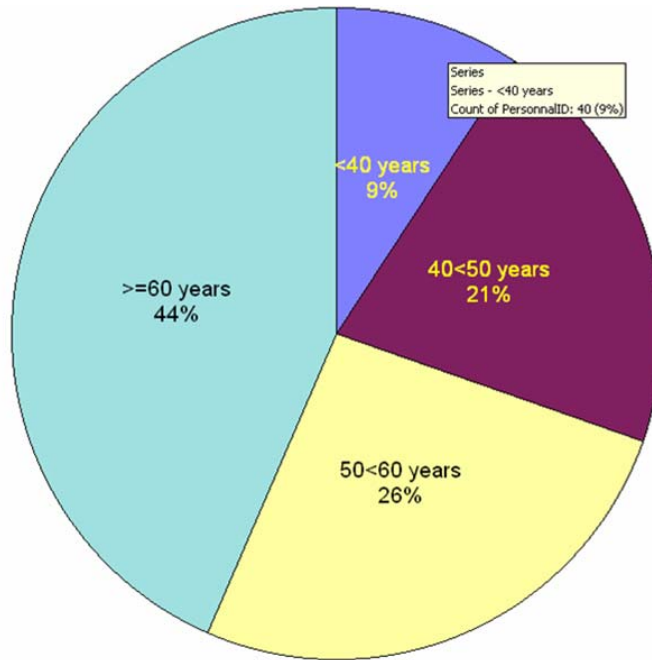
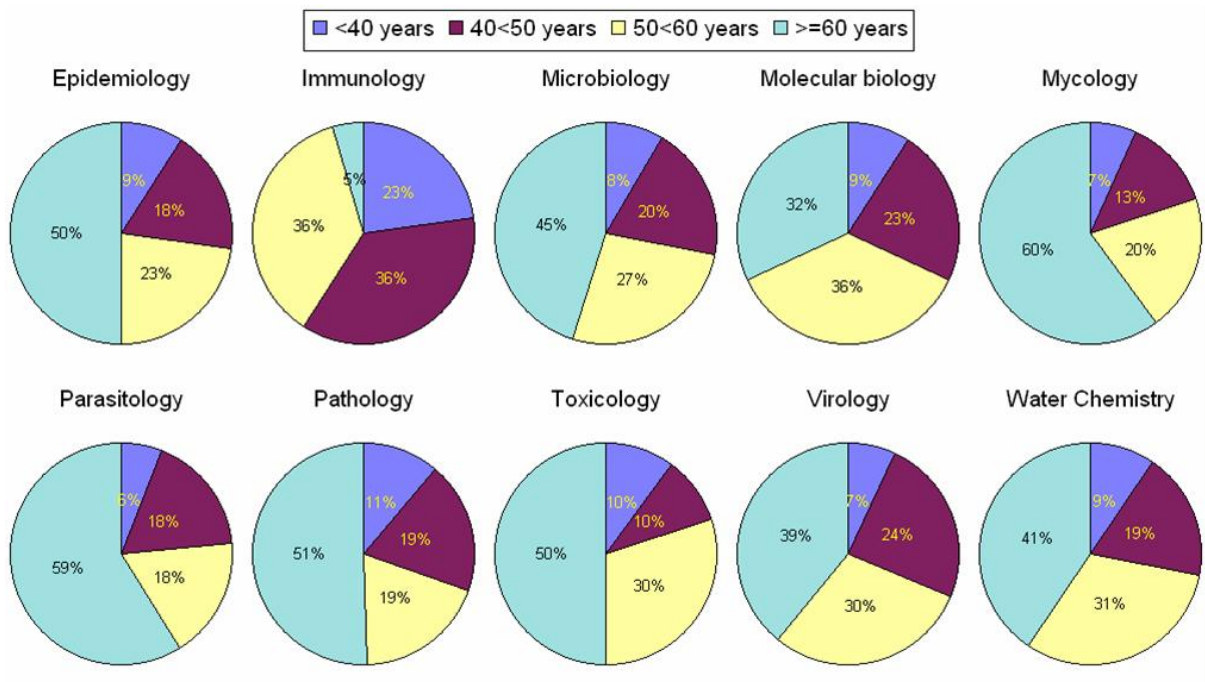


Figure 2: Age distribution of aquatic animal diagnosticians by discipline



9. BENEFITS AND ADOPTION

The degree of expertise in different diagnostic disciplines and across different aquatic species varies throughout NAADLN laboratories. At completion of this project there will be a direct benefit to individual laboratory services, through the increased ease of access to diagnostic methods and expertise from the array of NAADLN member laboratories. The improved linkages between laboratories through the commencement of the network will facilitate more rapid dissemination of new diagnostic techniques and refinement of older techniques.

In addition, there is a broader benefit to stakeholders who utilise aquatic animal diagnostic services, in having a robust national network of laboratories that produce consistent, accurate results from the most up to date validated methods. The implementation of the full proficiency testing program proposed, underpins the confidence in the quality of diagnostic outputs from laboratories.

The seafood and aquaculture sectors are also beneficiaries of outcomes from this project. The quality of diagnostic outputs is pivotal in acting as the first line of early recognition of new disease incursion, forming a key component of Australia's aquatic animal disease surveillance. In turn, these surveillance results from laboratories form the basis of Australia's quarterly report on aquatic animal disease status to the OIE, setting the grounds for Australia's international trading status on a range of seafood and live fish products.

The database resource, which will be hosted on a website by The Australian Government Department of Agriculture Fisheries and Forestry, will support a new level of enquiry, through the search functions for specific tests and skills amongst Australia's aquatic animal diagnostic laboratories.

Finally, provided that resources are available to support the updating of the NAADLN database, it will remain a useful tool to assess the demographics of aquatic animal diagnosticians in Australia. This may prove valuable as a performance indicator of future policy and resourcing strategies designed to target aquatic animal diagnosticians, for the purposes of succession planning.

10. FURTHER DEVELOPMENT

The implementation of the model for a PCR proficiency ring-testing program is a critical next step in improving the outcomes from NAADLN laboratories. NAAH-TWG confirmed this as a priority at their recent meeting in May 2006. This will require a full project to be worked up into an application and funds sought from available sources.

For the network to attain full functionality further investment is necessary. The network which has just been created should be viewed as the first step in the process of creating the National Aquatic Animal Diagnostic Laboratory Network. The next steps suggested below are outside the scope and budget of this initial project and are dependent on further funding and appointments.

- 10.1.1** Development of a business plan by a part-time network coordinator and an accountancy professional to deliver the activities outlined below. Such a business plan would necessitate that the States, Territories and the Commonwealth support the maintenance of the database and further network development, and accept the in-kind costs that will accrue to the individual laboratories.
- 10.1.2** Funding for the initiatives and activities described to be identified
- 10.1.3** Individual network laboratory managers to review their staff self-assessment competency ratings and update the NAADLN database.
- 10.1.4** A network coordinator to review the level 5 (expert) rated diagnosticians, requiring them to meet a criteria list and provision of evidence to justify their level 5 status. It was broadly recognised throughout the network, that the presence of level 5 experts was essential to the functioning of the network. However the cost of operating as a level 5 expert (signing on to the commitments below) must be accounted for in funding provisions. The laboratory manager should be required to sign off in agreement that the criteria are able to be met.

As an example some level 5 commitments might include:

- The laboratory will accept material for second opinion assessment
- The laboratory will maintain an up to date scientific understanding in the nominated discipline and be willing to distribute this knowledge
- The laboratory will be willing share technical information on diagnostic test development and optimisation
- The laboratory is willing to store and distribute reference material and reagents to permit use of the test or diagnostic technique.
- The laboratory is part of an existing proficiency testing program for the nominated discipline or test.
- The laboratory will host a proficiency test round in the nominated discipline.

- 10.1.5** Full definition of roles and obligations of member laboratories to the network to be documented and signed off by laboratory managers.

11. PLANNED OUTCOMES

1. Creation of a network of aquatic animal diagnostic laboratories with enhanced competency across a wider range of aquatic animal diseases than was previously available.
2. Improved quality control through participation in network proficiency testing programs.
3. Laboratories with expert competency will be identifiable through the database, and more readily available to confirm laboratory results.
4. Improved technology transfer and avoidance of unnecessary effort duplication in the area of new test development.
5. Increased provision of resources for more visionary succession planning in key aquatic animal diagnostic disciplines, based on evidence on the seriously aging demographic of aquatic animal diagnosticians.

12. OUTCOMES ACHIEVED TO DATE

1. The structure and functions of a national network of aquatic animal diagnostic laboratories has been defined.
2. Twenty laboratories from all States and the Northern Territory have joined the network (listed below) and had their details entered on the NAADLN database.
 - AAHL Fish Diseases Laboratory, CSIRO Livestock Industries, Geelong
 - Berrimah Veterinary Laboratory, NT
 - CSIRO Livestock Industries, Crustacean Disease Laboratory, Brisbane
 - Digsfish Services
 - Future Fisheries Veterinary Services
 - Gribbles Pathology - Adelaide
 - Gribbles Pathology - Clayton, Melbourne
 - IDEXX Thebarton, Adelaide
 - James Cook University
 - NSW Department of Primary Industries - Elizabeth Macarthur Agriculture Institute
 - NSW Department of Primary Industries - Regional Veterinary Laboratory, Wollongbar
 - Primary Industries Research, Victoria, Department of Primary Industries, Victoria
 - QDPI&F Biosecurity Services Laboratory - Yeerongpilly
 - QDPI&F - TAAHL
 - Queensland Museum
 - The South Australian Museum, Parasitology section
 - The University of Sydney - Faculty of Veterinary Science, Farm Animal Health, Camden,
 - University of Queensland, Centre for Marine Studies
 - University of Tasmania, School of Aquaculture
 - WA Department of Fisheries - Fish Health Unit
3. Communications between laboratories have been improved initially through a visit by the project coordinator to engage laboratories in the network. Subsequently, improved communications will be fostered through accessing the contact information for all laboratories in the NAADLN database.
4. Laboratory expertise has been defined by discipline and aquatic animal species groups within each laboratory. Through the NAADLN database this information can be searched and expertise identified, and contact details provided.

13. CONCLUSION

The project has created the NAADLN database of aquatic animal diagnosticians and diagnostic tests available at laboratories around Australia. It has also created a communication tool through the network database to foster improved inter-laboratory exchange of expertise and methodologies. This should be viewed as the first step in commencing a network. The model of Reference and Referral Laboratories has been chosen to structure the network. Applications for changes to laboratory status within the network are to be considered by NAAH-TWG at their annual meeting. Twenty laboratories have been engaged to join the network and contributed to the formation of the NAADLN database.

Proficiency testing in all major disciplines has been reviewed, with the priority area of PCR proficiency testing being identified. A model to develop this proficiency testing has been created, and once actioned, will enhance the proficiency of molecular testing across the network.

Further investment in the development of PCR proficiency testing is strongly recommended.

To gain full value from the network further development needs to be undertaken to define the specific roles and obligations of member laboratories. It is recommended that a network coordinator and professional accountant be appointed to develop a business plan that will support the desired functions of each network laboratory to ensure continued supply of competent diagnostics at an acceptable cost to industry and Government.

14. PROJECT CONTRIBUTORS

NAAH-TWG members at the 2005 and 2006 meetings.

Comments on a draft report were received from:

Written responses -

Mark Crane - AAHL

FRDC AAHS

Ian Anderson - QDPI&F

Nick Moody - QDPI&F

Belinda Wright - OCVO/DAFF

Brian Jones - WA Fisheries

Verbal responses-

Marty Deveney - PIRSA

Kevin Ellard - Tasmanian DPIW

John Humphrey - Northern Territory DPI

Andrew Gregory - SCAHLS executive officer

15. REFERENCES

Frawley Report on Rural Veterinary Services. (2003) Department of Agriculture, Fisheries and Forestry, Australia and Commonwealth Department of Education, Science & Technology: Canberra.

OIE. (2006). Epizootic Haematopoietic Necrosis In: Office International des Epizooties, Paris, OIE Manual of Diagnostic Tests for Aquatic Animals, Pp. 82-103.

Sims LD (2003). Supply of Veterinary Laboratory Specialists. A Report to the Sub-Committee of Animal Health Laboratory Standards. Asia Pacific Veterinary Information Services.

16. APPENDIX 1: INTELLECTUAL PROPERTY

The database runs using Microsoft Access. The public version is attached as a CD-ROM.

17. APPENDIX 2: STAFF

Matt Landos: The University of Sydney
Navneet Dhand: The University of Sydney
Marion Saddington: The University of Sydney
Richard Whittington: The University of Sydney

18. APPENDIX 3: DISCLAIMER FOR DATABASE CONTENT

The National Aquatic Animal Diagnostic Database contains information on the tests available at individual diagnostic laboratories around Australia. These are updated only once a year and serve only as a guide to the capability of an individual laboratory. Laboratories should be contacted to determine if the specified test is still available before submitting diagnostic material.

The level of proficiency reported for a laboratory has been compiled from data provided through a self-assessment process. The figure provided for the laboratory is the composite of all diagnosticians' responses, with the highest score being used to represent that laboratory's capability. These data have not been scrutinised to determine their accuracy and have been entered in good faith with the assumption that participants have not over- or under-stated their expertise. Please note the limitations of this part of the database. The basis for scoring is detailed below:

- 1 Very basic understanding: would need to review methods, and receive significant assistance to perform the test (likely had performed a few tests some time ago - so has familiarity and low level skills)
- 2 Basic understanding - would need assistance in performing test and interpreting result
- 3 Competent individual to perform test, however result and interpretation would be supervised before going out of laboratory
- 4 Highly competent, capable of running the test unassisted, and produce and interpret a result without it being supervised to go out of the laboratory
- 5 Expert, reference person for second opinions, published in the area

19. APPENDIX 4: PCR RING TEST MODEL

Project: National Aquatic Animal Educational PCR round as part of participation in the National Aquatic Animal Diagnostic Laboratory Network (NAADLN)

Network Co-ordinator

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Purpose and Outcomes of the Project

To run a PCR test on standardised material across participating laboratories within the network. Over the course of three training rounds, testing three different viral agents, (e.g. EHNV, Gill-associated virus (GAV) and NNV), determine the most appropriate format for proficiency testing. The overall aim being to enhance the consistency and quality of PCR results across the NAADLN for key agents.

Project Synopsis

Background

A proficiency testing round for WSSV PCR revealed several difficulties with the use of this type of test. The proposed educational rounds are designed to determine which test methodologies provide valid results and which methodologies are unreliable and should be upgraded on a pathogen-by-pathogen basis. NAAH-TWG will agree on the priority pathogens at the 2007 meeting in May.

Tests other than the OIE method are able to be used provided validation work has been completed within the laboratory concerned.

Objectives

1. Ensure all laboratories within the network generate the same result from standardised, homogenised material.
2. Utilise an open collaborative problem-solving approach within the network, to resolve any technical difficulties that arise through the educational rounds from unexpected test results.
3. Build personal links between laboratory staff with expertise in operating and interpreting aquatic animal molecular diagnostic tests.
4. Develop a template for the operation of routine proficiency tests within the NAADLN for PCR tests on key pathogens of national significance.
5. Develop appropriate documentation for reporting test results to and from participating network laboratories.

The Network Approach

Laboratories within the NAADLN will volunteer to become repositories for positive control nucleic acid and where possible field material relevant to their area of expertise and geographic proximity to diseases of significance. This will need to be maintained over time, and periodically tested (annually) to ensure viability of the material.

Ideally positive control material will be taken from animals with natural infections, typical clinical signs of disease and histopathology consistent with the condition. AAHL will act as the positive control depot for exotic disease agents.

The initial rounds of tests will not be utilised for the purpose of true proficiency testing and as such, will not involve/engage NATA, and will not affect laboratory certification irrespective of the results obtained.

The following key steps have been identified as points for potential breakdown and aberrant results to be generated

- 1) Sample preparation
- 2) DNA/RNA extraction
- 3) Amplification (contamination)
- 4) Loading gel
- 5) Reading/interpreting result

Three consecutive correct test results should be documented on positive and negative control material and known positive sample material, before the host laboratory can distribute the ring test material.

Round One

The material circulated will not be designed to test extreme sensitivity. It is also designed not to be necessarily restricted to laboratories that are currently delivering a test for the specified agent. This round is to examine components of running a basic PCR test. It is designed to set a baseline that can be built on for subsequent rounds.

Host laboratory: The University of Sydney, overseen by Richard Whittington.

Participating laboratories: All network laboratories with PCR capability.

Method: Published OIE method for identification of EHNV using the major capsid protein gene.

Round Two

Host laboratory: Tropical Aquatic Animal Health Laboratory - Oonoonba.

Material: killed viral material - nodavirus of barramundi.

Participating laboratories: All network laboratories that are set up to run PCR tests for VER.

Method: To be advised by host laboratory

Laboratories will use extraction technique of their choice

Laboratories will use the primer set of their choice.

Laboratories will follow a denaturation and annealing protocol provided.

A full protocol to be developed after completion of round one will incorporate any required changes to ensure smooth operation of the round.

Round Three

Host laboratory: CSIRO Livestock Industries - T.B.A.

Material: GAV infected prawn tissue.

Participating laboratories: Laboratories with GAV PCR capability.

Method: To be advised by host laboratory

Laboratories will use extraction technique of their choice

Laboratories will use the primer set of their choice.

Laboratories will follow a denaturation and annealing protocol provided.

Full protocol to be developed after completion of round one and two and will incorporate any required changes to ensure smooth operation of the round.

20. APPENDIX 5: SCAHLS REFERENCE LABORATORY POLICY

REFERENCE LABORATORIES

The role of Reference Laboratories

The role of Australian National Reference Laboratories is designed to harmonise with the OIE definitions of a Reference Laboratory (with regional and international responsibilities), as follows:

- to function as a centre of expertise and to facilitate standardisation of techniques relevant to the specified disease(s);
- to store and distribute biological reference products and any other reagents used in the diagnosis and control of the specified disease(s);
- to develop new procedures for the diagnosis, control and exclusion testing of the specified disease(s);
- to gather, process, analyse and disseminate epidemiological data relevant to the specified disease(s);
- to participate in scientific and technical studies in collaboration with other laboratories or organisations;
- to publish and disseminate information on laboratory testing for the specified disease(s);
- to provide scientific and technical training for laboratory personnel in other Australian laboratories

While not all Reference Laboratories may be able to provide all of these functions, the list should act as a guide as to the expectations of a National Reference Laboratory.

Criteria for endorsement as an Australian National Reference Laboratory:

To carry out the role requirements as outlined above, an Australian National Reference Laboratory is required to comply with the following:

- Employ scientific staff recognised as experts in the specified disease(s) and have an available range of diagnostic tests for the disease(s), including those not ordinarily available at other Australian laboratories;
- Where appropriate, be able to supply biological reference products and any other reagents used in laboratory testing for the specified disease(s);
- Conduct research to evaluate new laboratory tests for the specified disease(s) and encourage collaborative studies with other laboratories;
- Evaluate data submitted in support of SCAHLS approval of new commercial test kits for existing laboratory tests, for the specified disease(s);
- Gather, process, analyse and disseminate data relevant to the laboratory aspects of the specified disease(s);
- Assist the Australian National Quality Assurance Program (ANQAP) to conduct proficiency testing where appropriate.

Access to Reference Laboratory Services

Australian National Reference Laboratories will provide expertise and services to other Australian and New Zealand laboratories on a cost recovery basis deemed appropriate by that laboratory.

Reporting requirements:

All Australian National Reference Laboratories will submit a brief annual report of activities to SCAHLS. This will include confirmation of expertise, data on testing levels, a summary of research including publications, and a record of training activities. The report will follow the same format as the annual OIE report. OIE Reference Laboratories may submit their annual OIE report to SCAHLS rather than prepare an additional report. In the event of a significant change in the ability of an Australian National Reference Laboratory to meet its requirements (e.g. the loss of designated “expert”) the laboratory is required to advise SCAHLS of its intentions to retain or relinquish Reference Laboratory status.

SCAHLS review process

SCAHLS will annually review the ability of each laboratory to meet the requirements of an Australian National Reference Laboratory. When an Australian National Reference Laboratory fails to meet the requirements or relinquishes its Reference Laboratory status, SCAHLS will require a statement justifying retention of Reference Laboratory status, or invite new tenders respectively. If new tenders are called, all laboratories (via the members) will be invited to make submissions. When there is more than one submission for a given Reference Laboratory SCAHLS members will assess each of the submissions on their merit and vote accordingly. All aspects of this review will occur “in session”.