

NAHLN Coordinating Council Meeting  
June 15-16, 2010  
Ames, IA

Attending:

Bruce Akey	X	Bill Johnson	X	Dustin Oedekoven	X
Gary Anderson	X	Elizabeth Lautner	X	Lanny Pace	X
Tom Baldwin	X	Bill Layton	X	Muquarrab Qureshi	X
Bill Barton	NA	David Marshall	X	Mark Robinson	X
Arthur Davis	X	Barb Martin	X	Beverly Schmitt	X
Larry Granger	*	Terry McElwain	X	Gary Sherman	NA
Heather Hirst	X	Tom McKenna	X	Bill White	X
Wally Hoffman	X				

(X = Present; NA = Absent; \*= Represented by another person)

Visitors: L. Granger represented by Emi Saito

Recorders: Jill Brown, Stephanie Hadsall, Traci Imlau, Alison Krogh

**Welcome:** Beth Lautner, Muquarrab Qureshi, and Gary Anderson welcomed the members and thanked them for attending the first National Animal Health Laboratory Network (NAHLN) Coordinating Council (CC) meeting.

**Introductions of NAHLN CC Members:** Members in attendance introduced themselves and the organizations they represented.

**Opening Comments:** John Clifford, Deputy Administrator of Veterinary Services (VS) and Meryl Broussard, Deputy Administrator of Plant and Animal Systems thanked the CC and are looking forward to feedback from the group as they determine the next steps needed to move the program forward. Highlighted efforts of the NAHLN include:

- Conducting surveillance for endemic and foreign animal diseases
- Participating in pandemic H1N1 validation and quick work on deploying approved assays
- Hosting the first quality management system course in August, 2010

**Open Discussion:** – Facilitated by Gary Anderson

- Input and activities of United States Animal Health Association/American Association of Veterinary Laboratory Diagnosticians (USAHA/AAVLD) Joint Committee on the NAHLN
  - *The USAHA/AAVLD Joint Committee on the NAHLN has expressed an interest in obtaining a better understanding on how decisions are made in the United States Department of Agriculture (USDA). E.g. how does the USDA determine which laboratories can conduct different tests.*

Depending on disease, multiple documents can be used to provide guidance for decisions from VS Memorandums, VS notices, and the Code of Federal Regulations (CFR). VS is in the process of codifying language concerning NAHLN, but the process is expected to take 18-24 months.

All surveillance efforts take time and resources to develop and support. Decisions are made based on risk and the following questions:

- what is the National need for testing,
- does the State Animal Health Official support testing in the state,
- does the state have the infrastructure to support participation,
- is the lab currently in the NAHLN, and
- if not, do they meet the criteria to be a NAHLN laboratory?

VS does review surveillance program goals on an annual basis, but there is a need to review the development and implementation of existing surveillance programs to establish better defined procedures for implementation of surveillance programs.

CC members requested more communication and transparency, an opportunity for input in the decision making, and a better understanding of the decision making process related to when laboratories are able to test for new diseases and when changes are made in the testing procedures when laboratories have already been approved for some testing. Examples of testing situations where better understanding was requested included piroplasmiasis, CEM and gamma interferon. Concerns about reporting were discussed. It needs to be clear what results go into EMRS and how results are confirmed.

The group expressed it was helpful to learn the complexities of the decisions and agreed that better communication is needed. The NAHLN CC can be used as a sounding board and other communication tools such as conference calls, webinars and e-mail can be used when appropriate. State representatives to the Coordinating Council explained the following important aspects of being able to test samples in their states:

- Industry stakeholders don't understand why tests aren't run in-state where they can get fast results from a laboratory in which they have frequent testing performed, have trust in results, and communication networks established.
- State laboratories can lose the confidence of stakeholders when samples have to be shipped out of state.
- There may be a "regional need" for testing, versus having a lab in every state to run every test.

The impact and challenges of including all interested labs/states in specific testing needs to be determined. It may be that the limitations can be overcome with State stakeholder support. The State representatives expressed an interest in participating in the discussion and decision making process when determining which states/labs will be conducting testing.

○ *Reimbursement –*

Blanket Purchase Agreement (BPA) – The BPA process includes establishing a Performance Work Statement, price negotiation to establish a price schedule, a BPA call or order for services, and invoicing. An advantage to the BPA is that funding can be adjusted during the fiscal year. A disadvantage is that the funding must be spent in that fiscal year.

Cooperative Agreement (CA) - The CA process includes establishing a work and financial plan. CAs can be extended for up to a year after the initial agreement. New CAs, with Member laboratories include language that allows the money to be used to add IT and other NAHLN needs if the number of samples cannot be met. This same language is being incorporated into new VS CAs to increase flexibility.

Sharing information with laboratory and University personnel on BPAs and CAs is important for timely and accurate reimbursements. Webinars outlining details of new agreements have been conducted for the new Member laboratories with success. Other trainings are also available at the regional and Headquarters level. VS will modify processes to include webinars for State and university budget and fiscal personnel involved in CAs and BPAs.

○ *Need increased awareness of NAHLN in industry groups -*

The NAHLN Quarterly Newsletter has grown from 200 to over 1000 and includes industry groups in its distribution. Communications need to be provided to the National Institute for Animal Agriculture and Animal Agriculture Collation to raise awareness of NAHLN.

Fifteen FMD Exercises are planned throughout the United States. Hosting laboratories can invite industry representation to the exercises to observe the interaction of the participants.

**Council Activities from Charter:** - Facilitated by Muquarrab Qureshi

Request was made for the NAHLN CC to review the charter carefully for any revisions.

Amendments to the Charter will be discussed in Session 3.

**Session 1:** Review and comment, at least annually, on the specific criteria that defines a NAHLN Laboratory - Facilitated by Beth Lautner

- **Laboratory Review Process and approval/continued approval -**  
In response to the NAHLN review and changes made to VS memorandum 580.4, changes were made to the NAHLN Checklist. The NAHLN Checklist is now completed by each laboratory on an annual basis. At the time the completed NAHLN Checklist is submitted, laboratories must also provide documentation of their quality system. If a laboratory is accredited, they must submit a copy of their accreditation certificate. If laboratories are not accredited, they must submit their current quality manual and other quality management documents and participate in a NAHLN site visit. Laboratories will lose NAHLN status if a quality management system is not in place.

The NAHLN Program Office has worked with AAVLD and the Accreditation Committee to develop the process for the NAHLN Site visits. The intent of the audit is to be instructional and helpful. The site visit report contains factual information on commendations, nonconformances, and recommendations.

The NAHLN Site visit audits are as comprehensive as an AAVLD audit since the audit team has more time to focus on the specific NAHLN efforts. One laboratory has lost its NAHLN status because a quality management system was not implemented.

The CC reached consensus on support for the laboratory review process and endorsed removal of NAHLN status for laboratories that do not meet the AAVLD, ISO OIE standard.

- **Laboratory Responsibilities**  
The Laboratory Designation chart outlines the different levels of responsibilities for each designation. The chart was developed so Laboratory Directors would have the requirements on paper to refer to.

The CC reached consensus that the criteria that define a NAHLN Laboratory, as listed in the table, are reasonable but the laboratory designation definitions need to be refined from a network perspective.

**Session 2:** Discussion of those policies that relate to the NAHLN that do not infringe on the statutory authority of the Federal or State governments - Facilitated by Gary Anderson

- **NAHLN Checklist and policy documents -**

The checklist started in 2004 and was modeled on the Laboratory Response Network checklist. In 2006 a summary checklist was sent out to increase understanding of NAHLN activities with Area Veterinarian in Charge (AVICs) and State Animal Health Officials. Due to the modifications to VS Memorandum 580.4 and the need to ensure the quality management systems have been implemented in each NAHLN laboratory, the checklist was modified in 2008 and distributed to NAHLN Laboratory Directors for comments. The NAHLN Checklist is now completed annually by each laboratory.

The CC supports the annual distribution of the checklist. The CC will also be given the opportunity to review the checklist and provide input to the NAHLN Program Office.

- Surveillance programs, testing activities, and determination of laboratory participation - NVSL has received \$16 million for swine influenza virus (SIV) testing with approximately \$12 million available for testing in the NAHLN laboratories. The use of the \$12 million is defined for SIV testing and can't be used for infrastructure support. NVSL has received additional funding from the Centers for Disease Control (CDC) for the SIV pilot surveillance project.

A surveillance plan for vesicular diseases was developed to begin with foot and mouth disease (FMD). The plan has not been implemented because of a lack of funding. Negative cohort studies are being conducted in NAHLN laboratories for FMD, African swine fever, and Rinderpest.

**Session 3:** Review and comment as necessary on any other programmatic or operational issues of relevance to the NAHLN in an effort to enhance the effectiveness of the Network - Facilitated by Muquarrab Qureshi

The President has requested agencies propose programs for a 5% budget cut for the FY12 budget. The President's intention was to discontinue programs that were no longer effective or necessary and did not want agencies to reach the 5% with across the board cuts. It is not known what proposed cuts will make it into the President's budget.

- Discussion of Funding:
  - National Institute of Food and Agriculture (NIFA) Funding - Funding levels for fiscal year 2010 are flat from 2009. NIFA has been directed that the \$4.4 million of funding in the Cooperative Agreements must include up to 10% of the agreement in indirect costs.

The CC reached consensus to provide NIFA information that could be helpful in a draft Request for Application (RFA) to utilize NIFA funding, for funding beyond

core laboratories. Members of the CC who are interested to work with Terry McElwain on the information for the RFA are asked to e-mail to the co-chairs expressing their interest. The information provided for consideration in the RFA could detail possible deliverables based on funding levels.

**Action Item:**

**2010.06.001** - Terry McElwain will work with a sub-committee to draft information to provide for an RFA to utilize NIFA funding for funding beyond core laboratories.

**2010.06.002** - CC Members interested in working on the sub-committee to draft information to provide for the RFA will e-mail the CC co-chairs.

**2010.06.003** – CC co-chairs will provide list of sub-committee members to Terry McElwain.

- Animal and Plant Health Inspection Service (APHIS) Funding -  
The budget for 2011 is flat and there is a request to reduce the 2012 budget. The funding listed in the NAHLN background materials does not cover NVSL support for NAHLN initiatives such as training, proficiency tests, reference materials, and confirmatory testing. NAHLN funds through VS have been used to start programs. The goal is to move surveillance costs to AHMS so NAHLN funds can remain flexible and be used to support new initiatives necessary to meet the NAHLN mission.
- NAHLN Working Groups updates and discussion including charge, charter and membership:
  - NAHLN Methods Technical Working Group (MTWG) -  
This group came into existence after the first dossier review. The group meets quarterly, by conference call or face to face meetings and reviews method comparisons, evaluates the performance of assays over time by looking at reagents and controls, and allows NVSL and NAHLN personnel to work through issues together. Terry McElwain and Barb Martin serve as co-chairs of the working group.

The NAHLN Coordinator has been invited to present the process and educational material on methods comparison and validation to an FAO and OIE supported meeting in September.

The CC reached consensus that this group needs to continue and requests the co-chairs to continue and serve as liaisons. The Co-chairs will use the existing purpose statement to develop a charter and charge for the working group and provide documents to the CC for review.

**Action Item:**

**2010.06.004** – Barb Martin and Terry McElwain will work with members of the MTWG to develop a charter and charge.

○ Exercises and Drills Working Group -

This group was formed prior to the AI tabletop exercises to provide input into NAHLN exercises. The group is addressing recommendations from the avian influenza tabletop exercise summary report and has had input into the FMD exercises taking place this summer. One goal of the group is to develop drills for all laboratories.

The group will continue to focus on gaps that are identified by the exercises conducted. Co-chairs for this group are Pat Blanchard and Chris Clothier.

The CC reached consensus that this group needs to continue and Barb Martin will serve as the liaison for the working group. The working group is requested to draft a charter and charge for the working group and provide both documents for the CC to review.

**Action Item:**

**2010.06.005** – Barb Martin will work with the members of the Exercises and Drills Working Group to develop a charter and charge.

○ Information technology (IT) Working Group -

This group was formed to provide input on IT development to Veterinary Services. Members of this group have developed messaging guidelines and are available to offer their expertise to aid other laboratories as they develop the capability to electronically message diagnostic test results.

The proposal was made that a conference call be scheduled between John Picanso and the members of the IT working group. This would allow Mr. Picanso to provide the overall USDA IT strategy and define how NAHLN fits into the strategy. Then the group could develop a charge and charter.

The CC reached consensus that this working group needs to continue and Bruce Akey will serve as the liaison for this CC. The group is requested to schedule a conference call with John Picanso and then provide a draft charge and charter for the working group to the CC for review.

**Action Item:**

**2010.06.006** – Bruce Akey will coordinate a conference call between John Picanso and the members of the IT working group.

**2010.06.007** – Bruce Akey will work with the members of the IT Working Group to develop a charter and charge.

- Toxicology Working Group  
This is a USAHA special committee working group.

The CC reached consensus that this group is important. Since this group is not a NAHLN working group a request will be sent to the group expressing interest that a member of the NAHLN CC join the group to serve as a liaison..

**Action Item:**

**2010.06.008** – CC co-chairs will submit a request to the USAHA Toxicology Working Group expressing an interest in having a member of the CC to join their group to serve as a liaison for the CC.

*The remaining items in Session 3 were facilitated by Beth Lautner.*

- Standardizing PT processes -  
The scope of NVSL proficiency testing has broadened with NAHLN. A standard operating procedure was developed in place that outlines the minimum criteria for conducting molecular proficiency tests. The NAHLN Program Office is currently working with the NVSL Pathobiology Laboratory to come up with a standardized way to conduct PTs for the transmissible spongiform encephalopathies.
- FMD Exercises -  
Fifteen FMD exercises are scheduled between July and September 2010. While the primary focus is on the laboratory it's important to include representation from the AVIC, State Animal Health Official (SAHO) office, field personnel, and industry at the exercise. This involvement helps to identify the needs of the different groups involved in an outbreak situation.

Approximately two weeks prior to the exercise a conference call will be scheduled with each host to gather information that is unique to the state so the exercise can be tailored to include those circumstances. Individual after action reports will be provided after each exercise and a summary report will be written to summarize the findings of all 15 exercises.

The NAHLN Program Office is working on a document that contains details from the Kansas and Iowa FMD exercise that the host laboratories can use as background information when they invite people to participate.

- NAHLN Activation -

The FMD exercises provide an opportunity to review the current NAHLN Activation plan and provide an opportunity to improve the plan. A color coded system has been developed to designate different levels of activation and will be provided to all the NAHLN laboratories for their input.

- Implementation of VS Memorandum 580.4 -

Since the changes to VS Memorandum 580.4 there have been samples from several Foreign Animal Disease Investigations (FADI) that have been sent to the NAHLN laboratories for testing. In order to summarize what's working and where there is room for improvements, it would be helpful to develop an after action report for samples tested in NAHLN laboratories. It is important to note that laboratories doing routine testing are also a part of the overall FAD detection process.

Flow charts for VS Memo 580.4 have been developed and distributed to increase understanding of the memorandum. Additional training is needed to increase awareness. Training will be provided as part of FADD training as well as continuing education.

- NAHLN capacity modeling needs -

In order to be prepared to respond to an adverse animal health event an assessment of diagnostic testing capacity needs to be conducted at regular intervals. The CDC developed a complex spreadsheet that collects capacity information. The NAHLN Program Office is currently working to use the principles of the CDC's spreadsheet to develop a capacity calculator that can be used annually by each of the NAHLN laboratories. A prototype of the calculator is expected in 6 months. NAHLN laboratories will have the opportunity to work with the developers of the calculator. The calculator could be used to inform the NAHLN Program Office what is really needed in your laboratory or in your region.

- NAHLN communications -

The NAHLN Quarterly Newsletter distribution has grown to over 1000 people. A survey was recently sent out to gather input from readers.

NAHLN PowerPoint Presentations are available to present at meetings. Shorter presentations, containing 3 key points, can be developed to target specific groups such as industry and SAHOs.

**Action Item:**

**2010.06.009** – Barb Martin will oversee the development of a short NAHLN PowerPoint presentation targeted to SAHOs.

- NAHLN CC charter review -  
The CC reached consensus that an electronic version of the charter will be shared to collect modifications using track changes. The items initially identified to be modified include:
  - Change references to Cooperative State Research, Education, and Extension Service to NIFA throughout the document
  - Amend Dr. Broussard title in Appendix A to his current title in the NIFA structure.
  - Clarify wording around the State Partners responsibilities as a co-chair and involve the co-chair in the Executive Committee when appropriate. For example, the State representative cannot be present during budget discussions.

Session 4: New Areas for the NAHLN – facilitated by Gary Anderson

- One Health:  
A recent letter from the Secretary announced the need to organize a One Health group on the policy level across USDA. A technical group has been formed along with APHIS and VS One Health Groups. There is increased understanding that dealing with the agriculture side promptly, decreases the impact on the human health side.

Participation in One Health groups, and publishing in forums that also contain a public health audience are ways to bring our expertise to a broader audience.

- Emerging Diseases:  
NVSL is currently funded disease by disease; however, APHIS is looking at changes in the overall budget structure to better respond to current and future needs. In addition, the laboratory LIMS systems are designed to support specific functions, not to capture unlimited data. To address emerging diseases, thought needs to be put into what data are collected and how it will be used.

The CC brainstormed approaches for the future direction of the NAHLN. One approach discussed was to develop information to better convey the three roles of the NAHLN:

early detection, rapid response and appropriate recovery and the current status of its capability for both foreign and emerging including zoonotic diseases. Responsibility #1 for NAHLN is detection and surge capacity for high consequence foreign animal diseases. We need to define what we currently have for capability across NAHLN laboratories for detection and capability including the regional laboratory concept for surge capacity. Responsibility #2 for NAHLN could be the detection and response to emerging diseases including zoonotic diseases. This would bring in the One Health concept and the role of NAHLN. It was noted that for this role, it is important that a broad range of laboratories have capacity to participate as early detection of emerging diseases is critical and any NAHLN laboratory regardless of case load or primary species focus could be the laboratory where samples may first come in. Some basic level of laboratory support and an IT system capable of capturing this data is needed for Responsibility #2. Responsibility #3 was identified as supporting food safety and toxicology laboratory work in conjunction with other governmental entities in addition to VS and NIFA.

The CC reached consensus on further exploring how to better define the requirements and the needs for the NAHLN to accomplish all three Responsibilities.

**Action Item:**

**2010.06.010** - CC members interested in participating in a subcommittee to better delineate roles and needs to meet the three responsibilities were asked to contact Gary Anderson with their interest.

Session 5: Review and comment, at least annually, on goals, strategic plan, and operational objectives of NAHLN – facilitated by Gary Anderson

There is a need to show that the NAHLN is a good steward of the money provided but also to identify those objectives have not been met including:

- modeling to identify bottlenecks that impact our capacity
- educate stakeholders on the laboratories base support and what it provides
- communicating the needs and requirements for comprehensive surveillance
- the need for reference materials, serum banks, and support for the NVSL

**Action Item:**

**2010.06.011** - Members of the CC that are also members of the USAHA/AAVLD Joint Committee on the NAHLN, will ask the committee to provide updated information on infrastructure support provided by the laboratories to the CC.

A suggestion was made for the next face to face meeting held in Washington D.C.

A suggestion was made that conference calls be scheduled on a regular basis; if there aren't agenda items to discuss the call could be cancelled.

**Action Item:**

**2010.06.011** - Barb Martin will pool the group on possible times for regular conference calls.

Meeting Adjourned