UPDATE ON NAHLN ACTIVITIES

NATIONAL ANIMAL HEALTH LABORATORY NETWORK COORDINATORS
U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES
OCTOBER 2016
Overview

NAHLN Restructure
Codification
AMR
NLRAD
Lab Messaging

Brief Update on NAHLN Operations
NAHLN Restructure

APHIS and NIFA worked in conjunction with NAHLN Coordinating Council on details, transition and implementation of NAHLN restructure, based on 2012 NAHLN Concept Paper

Overall Transition Process:

- Self-Assessment by labs – completed September 2014
- External Review (NAHLN and NIFA) – completed Dec 2014 and repeated June 2015
- Needs Evaluation (based on modeling work with CEAH) – completed April 2015
- Recommendations for Laboratory Distribution – completed April-September 2015
- Implementation – completed January 2016
NAHLN Restructure

Successful Implementation!

Infrastructure funding provided to all laboratories designated Level 1, 2 and 3

Next for 2017:

- Laboratories will complete a self-assessment
  - Demonstrate any major changes to last year’s assessment (Oct 2016)
- Assessments will be reviewed by APHIS and NIFA
- Each laboratory will be evaluated through the decision matrix to determine if any change in designation
- Funding will be distributed in Spring/Summer 2017.

For 2018:

- Overall network evaluation of needs, process and decision criteria will be completed for 2018
NAHLLN Laboratory Designations—August 2016

Please refer to lab list for testing capabilities.
NAHLN Codification

Codification Work plan has been finalized and submitted through APHIS management for clearance.
- This process included defining and formalizing many processes across NAHLN and within the NAHLN Program Office

Next step: submission to Office of Management and Budget (OMB) for approval.
- Once cleared by OMB, language will be drafted for publication as a proposed rule.

Draft NAHLN Program Standards being finalized:
- Anticipate circulation to stakeholders for review and input by December 2016
Antimicrobial Resistance (AMR) Surveillance Pilot – Veterinary Diagnostic Laboratories

Accomplishments

- Finalized survey of US vet diagnostic labs to assess current practices used to detect antibiotic resistance, and to determine how information regarding antimicrobial resistance is shared.
  - Survey administered through AAVLD in 2015
  - Manuscript submitted to JVDI

- Developed a pilot project targeting veterinary diagnostic laboratories that includes recommendations on best practices for AMR testing, standardization, data collection and reporting
  - Draft plan completed and is being circulated to additional stakeholder groups for comment

- Plan will not be implemented until designated AMR funding allocated
Antimicrobial Resistance (AMR) Surveillance Pilot – Veterinary Diagnostic Laboratories

Part of the overall White House National Strategy USDA

- **National Strategy for Combating Antimicrobial Resistant Bacteria (CARB)**
  
  **Plan Goal 2**: Strengthen National One-Health Surveillance Efforts to Combat Resistance

- **USDA Proposed Surveillance Plan Objective 2**: Implement routine antibiotic susceptibility testing of selected animal pathogens and collate and report data across veterinary diagnostic laboratories.

- VS also supporting through planning of NAHMS and longitudinal studies, One Health communication and the National Veterinary Accreditation Program

- Collaborating with FDA Vet-LiRN for coordinated efforts in vet labs
National List of Reportable Animal Diseases

Cross-VS effort that addresses many different aspects of NLRAD

Comprehensive document that includes the following sections:

- SOPs for maintaining and updating NLRAD List
  - Review and approval processes- routine and emergency/emerging disease
- Laboratory role in NLRAD
  - Disease and Case definitions
- NLRAD communication
  - Who reports to whom
  - When disease should be reported
  - What is to be reported
- Data management
  - Reporting needs
  - Mechanism for reporting
- Confidentiality issues
  - Process
  - Intellectual Property
National List of Reportable Animal Diseases
NLRAD, including Emerging Diseases

Formed a joint working group with NAHRS Steering Committee and NAHLN Coordinating Council to develop a detailed implementation plan for NLRAD and emerging diseases in labs.

Draft plan addresses known and unknown agents including:
- Case definitions,
- Timelines and triggers for reporting, and
- Information sharing details such as data flow, proposed mechanism, and data standards

Lab implementation component incorporated into overall NLRAD Framework
- Published for comment via APHIS Stakeholder Registry
Proposed Data Flows for NLRAD Diagnostic Results

State A Database (e.g. USDA/APHIS, SCS)

State A

Laboratory State A

Laboratory State B

State B Database

State B

LMS

SALMS

EMRS

Web-entry

Emergency/FADs

Monitored [NAHRS-like]

Data system to support CIS

Non-FADs

Emerging

VSL

Web-entry

Regulated

SCS

Web-entry
Laboratory Electronic Messaging

18 NAHLN labs and NVSL actively messaging
  - Additional 5 labs prepared to message
Messages can now be received for 10 diseases
  - IAV-A, IAV-S, ASF, BSE, CSF, FMD, PEDV, PRV, VSV
NVSL messaging routinely
Integration of results into other VS systems that collect field data
  - EMRS and VSLS
2017 messaging priorities include:
  - Continue to expand number of labs with capability to message
  - Expand messaging to include Scrapie and AMR data
  - Support implementation of NLRAD
  - Integration with other internal VS systems
  - Enhance utility of messaging standards
LMS Messaging

<table>
<thead>
<tr>
<th></th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tests</td>
<td>3</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Messaged</td>
<td>2</td>
<td>16</td>
<td>19</td>
</tr>
</tbody>
</table>

Legend:
- Diseases
- Labs
- Total tests messaged (x1000)
Update on NAHLN Operational Activities
NAHLN Support of Outbreak Testing

H7N8 HPAI/LPAI – commercial turkeys, IN (Jan 2016)
  ◦ 9 flocks affected, ~250,000 birds
  ◦ Testing supported by IN NAHLN laboratory (Purdue)

H5N1 LPAI – commercial turkeys, MO (April 2016)
  ◦ 39,000 birds affected
  ◦ Testing supported by MO Dept of Ag NAHLN laboratory

H5N2 LPAI, NY & NJ Live Bird Markets (June 2016)
  ◦ Testing supported by the following NAHLN laboratories;
    ◦ Cornell University Animal Health Diagnostic Center
    ◦ PA Dept of Agriculture and NJ Department of Agriculture

Wild bird surveillance-- 2nd year of enhanced surveillance
  ◦ Testing supported by 8 NAHLN laboratories
  ◦ Target 35,000 samples
Quality Management System Support--Training

Training based on AAVLD, ISO 17025 OIE standards
14 trainings have been conducted since 2010
542 participants

Interactive learning environment
- Document control, records, internal auditing, management review, corrective actions, root cause analysis, equipment
- Workshops: Root cause analysis, SOP and associated document development, QMS Jeopardy game
- Mock audit: Application of skills- auditing, reporting, responding

Regional Training
- 35 participants from 2 states

Gap Analysis
- Visit or document review
## Surveillance and Response Testing in NAHLN labs

<table>
<thead>
<tr>
<th>Disease/Agent</th>
<th>FY15</th>
<th>FY16 (through 3rd qtr unless noted)</th>
<th># of NAHLN Laboratories Currently Approved for Testing</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Samples or Animals Tested</td>
<td></td>
</tr>
<tr>
<td>BSE</td>
<td>40,809</td>
<td>25,811*</td>
<td>4</td>
</tr>
<tr>
<td>CSF</td>
<td>5,516</td>
<td>3,807</td>
<td>41</td>
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<tr>
<td>IAV-S</td>
<td>27,474</td>
<td>12,621</td>
<td>38</td>
</tr>
<tr>
<td>PRV</td>
<td>25,670</td>
<td>15,710</td>
<td>14</td>
</tr>
<tr>
<td>SCRAPIE</td>
<td>38,135</td>
<td>28,117</td>
<td>19</td>
</tr>
<tr>
<td>HPAI</td>
<td></td>
<td>78,625**</td>
<td>19 have tested</td>
</tr>
<tr>
<td>PEDV</td>
<td></td>
<td>341,347***</td>
<td>20 have tested (no approval)</td>
</tr>
<tr>
<td>PDCoV</td>
<td></td>
<td>181,980***</td>
<td>20 have tested (no approval)</td>
</tr>
<tr>
<td>VSV</td>
<td>208</td>
<td>181</td>
<td>5 tested</td>
</tr>
</tbody>
</table>

*complete FY16


No approval indicates that any NAHLN laboratory can test for this disease
NAHLN Portal

NAHLN
National Animal Health Laboratory Network

When a large-scale animal-disease outbreak occurs, tracking its progress and performing diagnostic tests on thousands of diagnostic samples is a big challenge. To get the job done, it is very important that all the parties involved—Federal agencies and laboratories managed by State governments and universities—communicate and collaborate effectively. The National Animal Health Laboratory Network (NAHLN) now forms part of a nationwide strategy to coordinate the work of all organizations providing animal disease surveillance and testing services.

LOG ON

ABOUT NAHLN | CONTACT US | ABOUT US | NAHLN NEWS
### NAHLN
- Avian Influenza Virus (AIV)
- Avian Paramyxovirus (APMV-1)
- African Swine Fever Virus (ASF)
- Bovine Spongiform Encephalopathy (BSE)
- Chronic Wasting Disease (CWD - ELISA)
- Classical Swine Fever Virus (CSF)
- Foot and Mouth Disease Virus (FMD)
- Infectious Salmon Anemia Virus (ISA)
- Pseudorabies virus (PRV)
- Scrapie/CWD (IHC)
- Swine Influenza Virus (SIV)
- Vesicular Stomatitis Virus (CF)
- Vesicular Stomatitis Virus - PCR
- Viral hemorrhagic Septicemia – PCR

### APHIS
- Anaplasmosis cELISA
- Avian Influenza Serology Proficiency test
- Blue Tongue
- Bovine Leukosis
- Bovigam
- Brucella Ovis
- Brucellosis
- Contagious Equine Metritis
- Equine Viral Arteritis
- Johne's Direct PCR
- Johne's Direct PCR - Pooled
- Johne's Liquid Media
- Johne's Liquid Media - Pooled
- Johne's Solid Media Culture
- Johne's Solid Media Culture - Pooled
- Johne's Milk ELISA
- Johne's Serology
- Leptospira Check Test
- Piroplasmosis Equine
- Pseudorabies virus (PRV)
- Scrapie Genotyping
- Salmonella Type D
- Salmonella Serotyping

### NPPLAP
- HLB - Huanglongbing
- PPV-Plum Pox
- PRAM- Phytophthora ramorum
Proposed template for the new entry page into the portal

General Information about the purpose and usage of Portal or about testing, i.e.:

When a large-scale animal-disease outbreak occurs, tracking its progress and performing diagnostic tests on thousands of diagnostic samples is a big challenge. To get the job done, it is very important that all the parties involved—Federal agencies and laboratories managed by State governments and universities—communicate and collaborate effectively.

APHIS Participant Laboratories

- Description of APHIS Proficiency Tests with embedded links
- Contact Info
- Link to NVSL page
- Info on APHIS certification

NAHLN National Animal Health Laboratory Network

- Description of NAHLN with embedded links:
  - NAHLN Website
  - Info on joining NAHLN
- Link – Contact Us
- Link

National Plant Protection Laboratory Accreditation Program

- Description of NPPLAP with embedded links
- Contact Info
Exercises and Drills Working Group

Comprised of lab directors, section heads, emergency planners from NAHLN labs and VS (open membership)

Accomplishments:

- Informational webinars and meetings
  - Lab Capacity Estimation Model (LCEM)
  - Barcoding successes and challenges
- 2 Immediate Response Drills
- Planning bar-coding hands on drill for 2017
Methods Technical Working Group

Accomplishments

Implemented new membership structure- Core and General Membership

Strategic Discussions

◦ Network challenges
◦ Recommendations for FY2017 priorities for validation and methods comparison projects

Completed Methods Comparison Projects and Reviewed Validation Dossiers
2017 Priorities for NAHLN

Complete codification of the NAHLN

Begin implementing pilot activities for NLRAD and AMR surveillance (dependent on funding)

Continue to increase electronic messaging capacity and capability
  ◦ Increase data integration
  ◦ Support NLRAD
  ◦ Support AMR surveillance

Complete validation projects
  ◦ Oral fluids for swine FADs
  ◦ Equivalency testing on PCR platforms
  ◦ Methods standardization projects
Questions?
Portal Working Group

Current: Laboratory users are providing input on guidance documents and user friendliness of Portal

Future: Expand responsibilities and membership of the group to create a more permanent Portal Working Group
  ◦ Workgroup members will help identify, develop requirements, and recommend Portal improvements
Veterinary Services Integrated Surveillance Modules (VSISM) Conceptual Overview
NAHLN Approved Laboratories

* Bovine Spongiform Encephalopathy (BSE)
* Newcastle Disease (ND)/Influenza A Virus in Avian (IAV-A)
** Scrapie/Chronic Wasting Disease (CWD)
* Classical Swine Fever (CSF)/Foot and Mouth Disease (FMD)
  - Influenza A Virus in Swine (IAV-S)
  - Vesicular Stomatitis (VS)
  - African Swine Fever
  - Pseudorabies Virus (PRV)
  - Viral hemorrhagic septicemia (VHS)
  - Infectious salmon anemia (ISA)

*For specified agents, not all laboratories are currently participating in surveillance testing
** Multiple assays conducted for this agent, refer to specific disease map/list for assay options.

July 20, 2016