

National Animal Health Laboratory Network



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June 12, 2012



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Presentation Overview

- Background and History
- NAHLN Activities and Capabilities
- Application of Capabilities through Surveillance
- Activities to Assess Gaps and Enhance Capabilities
- Conclusions





Background and History



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History of the NAHLN

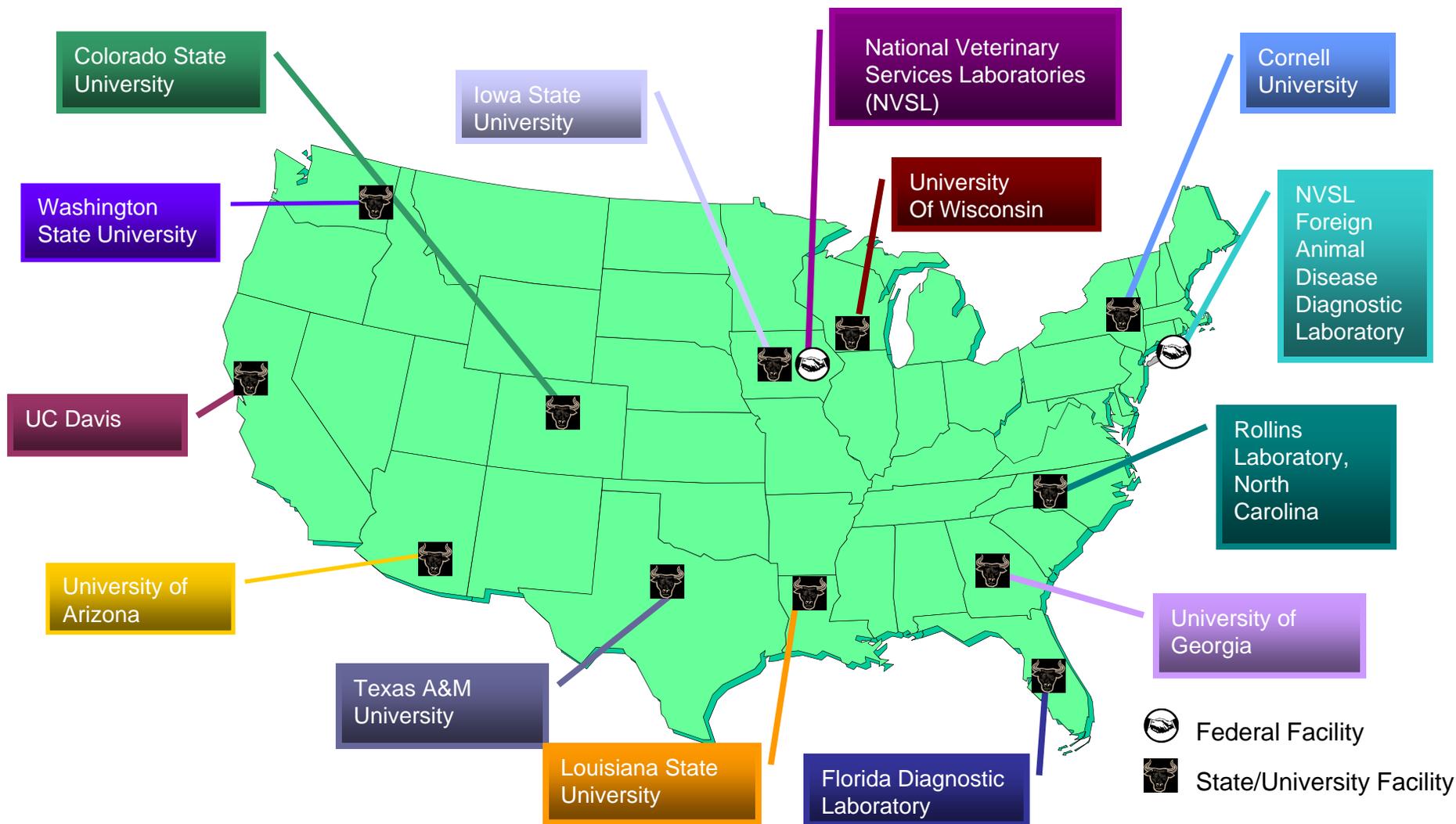
- Need identified by
 - 2001 USDA Safeguarding Review
 - 2001 FMD outbreak in UK
- NAHLN established in 2002
 - Coordinates Federal lab capacity with extensive infrastructure of State-supported labs
 - NAHLN supported through APHIS and NIFA



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The original 12 NAHLN laboratories



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The Purposes of NAHLN

- Early detection
 - Targeted surveillance based on population density & risk
- Rapid response
 - Surge capacity to test outbreak samples
- Appropriate recovery
 - Large numbers of samples tested to show freedom



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Founding Principles and Features of NAHLN

- Quality management standards
- Competency of laboratory personnel
- Standardized diagnostic techniques
- Reference materials and equipment
- Secure communications and reporting system
- Adequate facilities to ensure biosafety/biosecurity levels
- Assessment of preparedness through scenario testing

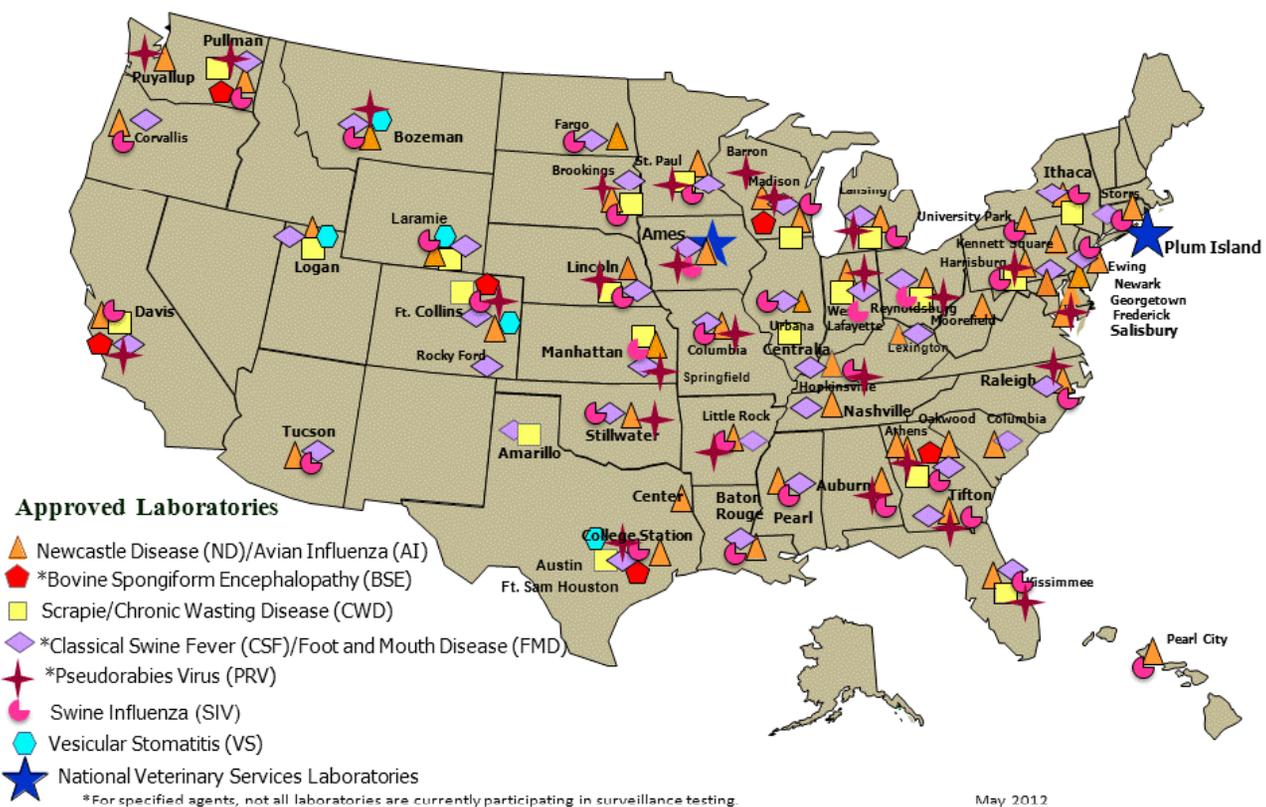


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NAHLN Labs by Disease Designation

National Animal Health Laboratory Network (NAHLN)



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NAHLN Activities and Capabilities



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Quality Management Standards

Laboratory Review and Approval Process

- Developed in conjunction with AAVLD Accreditation Committee
 - Consistent with ISO 17025/ OIE standards
 - Site visits
 - Audit report and response
 - Piloted 2008, implemented 2009
- Annual report and evaluation of processes
 - Input from audited labs and stakeholders
 - Establish annual goals and recommendations
- Development of associated audit documents
 - NAHLN Audit SOP
 - Guidance documents



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Quality Management Standards

Quality Management System Training

- AAVLD, ISO 17025/ OIE standard
 - Document control, records, internal auditing, management review, corrective actions, root cause analysis
- Interactive learning environment
 - Wet lab – application of skills
- 2010 training - 87 participants representing 52 labs
 - 40 NAHLN laboratories
 - 8 prospective laboratories
 - 3 Federal and one international lab
- Summary report and recommendations



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Quality Management Standards

Quality Management System Training

- May 2011 – Collaborated with NPDPN to provide modified NAHLN training to plant network labs
- July 2011 – Training provided to representatives from 11 east African countries
- August 2011– Training provided to NAHLN labs 5 countries
- August 2011- Development and evaluation of distance learning modules
- September 2011 – AAVLD NAHLN QMS training
- July 2012 – Training scheduled for NAHLN labs and representatives from 10 countries



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Competency of Laboratory Personnel

Proficiency Testing Program

- NVSL – National reference lab
 - Provides proficiency test panels and reference materials
- Requirement - must successfully complete proficiency test process to participate in NAHLN surveillance activities
 - Competency assessment
 - Frequency
 - ❖ 6 months to 1 year
- Diseases/agents
 - AI, ASF, BSE, CSF, CWD, END, FMD, PRV, rinderpest, scrapie, SIV, VSV



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Competency of Laboratory Personnel

Train the Trainer Program

- Established 2005 in response to need to increase number of people trained and proficiency tested to address animal health emergencies
- Incremental growth

Disease/Agent	Approved Laboratories		Approved Analysts	
	FY2004	FY2010	FY2004	FY2010
AI	15	54	28	218
CSF	12	39	24	169
END	15	52	28	207
FMD	12	40	24	174



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Standardized Diagnostic Techniques

- NAHLN Methods Technical Working Group
 - Purpose: to provide input on various aspects of methods validation and approval
 - ❖ Review of available methods and associated gaps
 - ❖ Identification of potential new technologies
 - ❖ Validation and methods comparison criteria and approval processes
 - ❖ Dossier review and assay approval process
 - ❖ Continual performance assessment of assays
- Current standardized methods:
 - AI, BSE, CSF, CWD, END, FMD, PRV, SIV, Scrapie, VSV



Secure Communications & Reporting System

NAHLN IT System

- Established a system with data and messaging standards to ensure accurate and consistent diagnostic information is quickly and securely transmitted.
 - [NAHLN IT Committee](#)
- Laboratories messaging into NAHLN IT system
 - 13 CSF
 - 12 AI
- Expanding message capability
 - SIV message
 - CSF ELISA message



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Application of Capabilities Through Surveillance

Surveillance Programs

- Established surveillance plan, procedure manual and communication guidance
- Benefits
 - Early detection
 - Increased technical proficiency
 - Improved communication
 - Improved preparedness



Classical Swine Fever

- Plan developed by National Surveillance Unit with stakeholder input
 - Target clinical signs, feral swine, slaughter condemned
 - All high risk states involved
- Implemented in January 2006
 - 38 laboratories participating
- First surveillance program for a foreign animal disease



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Swine Influenza Virus

- Implemented in May 2009
- 36 approved laboratories
- Existing assay didn't detect pandemic H1N1
 - Matrix PCR modified and deployed with assistance from ARS in 6 weeks





Activities to Assess Gaps and Enhance Capabilities

Preparedness through Scenario Testing

FMD Tabletop Exercise Series

- VS Policy Workshop
- 16 tabletop exercises in NAHLN laboratories
 - > 450 people from 34 States
- Internal NVSL exercises on FMD and AI
- Follow-up VS Policy Workshop



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Preparedness through Scenario Testing

Preliminary Findings - FMD Tabletop Exercise Series

5 General areas of preliminary findings

- NAHLN laboratory preparedness
- Communication
- Capacity
- Diagnostic development/validation
- Decision-making



Standardized, Rapid Diagnostic Techniques

Agricultural Screening Tools Workshops

- FAZD, DHS sponsored workshops to gather Stakeholder input
- AST I – Define tools, define status and ID gaps
- AST II – Industry perspective, policy gaps and priorities
- AST III – Laboratory Concept of Operations
- AST IV – Development of lab related policies



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NAHLN Diagnostic Development

Standardized Diagnostic Techniques

- Optimization of RNA extraction for early detection of FMD virus in milk from experimentally infected cows
- Enhancements to Molecular Diagnostics for FMD and CSF
- Negative Cohort studies for CBPP and LSD
- Validation and evaluation of fitness for purpose of FMD lateral flow device (penside assay)
- Developing processes and policy for deployment of CSF and FMD ELISAs to NAHLN labs



All in partnership with FADDL and NAHLN labs with funding from ARS, FAZD, and DHS

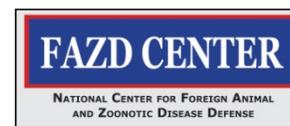


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Secure Communication and Reporting System

Laboratory Capacity Estimation Model

- Collaboration between NAHLN/FAZD/AAVLD
 - Funding from DHS
- Software tool for evaluating/monitoring NAHLN capacity
 - Daily testing and surge
- Project Objectives:
 - Improve knowledge in individual and overall NAHLN diagnostic testing
 - Prioritization of resources
 - Serve as critical tool for managing a large number of diagnostic tests simultaneously
- User testing finalized; ready for release



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Secure Communication and Reporting System

NAHLN Portal

- Modules in development
 - Secure mechanism to electronically comment on and release SOPs
 - Laboratory directory - space, personnel and equipment
 - Mechanism to monitor assay performance
 - Mechanism to submit and receive PT results
 - Mechanism to train others in the validation process
 - Work Group and collaboration space to post documents and schedule meetings and calls
- Integration with LCEM data elements
- Currently in user acceptance testing
- Applicable to multiple networks



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Preparedness through Scenario Testing

2012 Web-based Exercises

- Leverage developed resources to regularly practice outbreak response
 - LCEM
 - NAHLN Portal
 - Outbreak disease guidelines



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Conclusions

Conclusions

Successes of the NAHLN

- Strategically combines the infrastructure and expertise in the State veterinary diagnostic laboratories and the National Veterinary Services Laboratories
- Established the animal health laboratory backbone of the United States emergency response and recovery program
- Implemented national, standardized surveillance for high priority diseases
- Tremendous progress in the ability to respond



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Conclusions

Existing Needs and Gaps

- Maintain and improve quality management systems and technical expertise
- Develop and implement a comprehensive IT system
- Address personnel gaps to ensure testing needs are met
 - Technical, QA, IT, administrative
- Implement additional surveillance programs for early detection
- Ensure necessary laboratory supplies, reagents, and diagnostic tests are available



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