# “A Wing and a Prayer” Summary and analysis of the NAHLN HPAI exercise program

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# Summary

To address action items assigned to it in the implementation plan for the *National Strategy for Pandemic Influenza*, the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS) initiated an exercise program to examine the integral connections between field actions and laboratory response during an avian influenza outbreak. To carry this out, USDA-APHIS asked CNA to design a tabletop exercise and deliver it to member laboratories of the National Animal Health Laboratory Network (NAHLN). In total, we conducted 38 exercises from February to October 2008. The exercises involved more than 700 participants, representing 45 States and numerous Federal, State, and local agencies as well as the poultry industry.

USDA-APHIS further asked CNA to examine the lessons learned from this exercise series to conduct a system-wide analysis of the NAHLN. To do so, we examined three main themes that were discussed in detail at all of the NAHLN exercises: laboratory operations, laboratory-field coordination, and notification and communication. Our analysis resulted in recommendations for the coordination of animal health laboratory response capabilities across the United States that address resource management, process alignment, notification and warning, and knowledge management strategies for the NAHLN, its component laboratories, and their interface with field operations.

Overall, we found that all but four of the NAHLN laboratories would have sufficient capacity to handle the first few days of testing for scenarios that were presented in this exercise program. As might be predicted, laboratories in States with a high density of commercial poultry operations were the most likely to quickly receive more samples per day than they could process. However, the reasons for this were somewhat counter-intuitive. The overwhelming number of laboratory samples resulted from outbreak surveillance among commercial farms and marketability testing that far exceeded the testing workload for locations with sick birds. Conversely, once full surveillance of backyard farms was underway, all of the individual laboratories could be overwhelmed with testing of individual birds and small flocks.

We also found a surprising amount of variation in how the NAHLN laboratories would handle the increased workload. These differences were as dependent on the administrative structure and organization of the labs as they were on specific capabilities and capacities for testing. This presents a notable challenge to NAHLN leadership, which must coordinate response operations across a network of laboratories that are not managed by USDA or any single agency.

To help meet these challenges, we recommend that USDA-APHIS and NAHLN do the following:

- Assist States with developing tailored laboratory response plans that account for handling overflow samples—whether from infected locations, outbreak surveillance, or routine testing—during an avian influenza outbreak.
- Identify and document how laboratories will be compensated for conducting overflow testing.
- Continue working with the National Veterinary Stockpile program to include laboratory resources.
- Continue efforts to electronically link the NAHLN data repository with the Emergency Management Response System that is used for field operations.
- Revise the definition of NAHLN "activation" and clarify the process of activating individual laboratories as well as the entire network.

We also recommend that State-level animal health agencies should:

- Further integrate laboratory requirements into the incident command system—for example, by having a laboratory liaison and incorporating laboratory resource requirements into the staffing and budgeting processes.
- Re-examine surveillance and sample prioritization plans in order to better coordinate them with laboratory operations.

Finally, we recommend that individual NAHLN laboratories work with State animal health officials and NAHLN for recovery planning.

# Highlights of the exercise program

## Introduction

On November 1, 2005, the President of the United States issued the *National Strategy for Pandemic Influenza* (NSPI) to outline the coordinated U.S. Government effort to prepare for pandemic influenza. In 2006, an implementation plan for the NSPI was issued to clarify the roles and responsibilities of government and nongovernment entities in carrying out the national strategy. To address action items assigned to it in the implementation plan (specifically, items 7.1.1.1 and 7.1.3.2), the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS) initiated an exercise program to evaluate, train, and enhance resources and readiness of the animal health community. To carry this out, USDA-APHIS asked CNA to design an exercise that would examine the integral connections between field actions and laboratory response during an outbreak of highly pathogenic avian influenza (HPAI) and to conduct a series of exercises with the National Animal Health Laboratory Network (NAHLN).

USDA-APHIS further asked CNA to synthesize the lessons learned from each of these exercises in a broad meta-analysis. Analysis of the overarching lessons learned will allow USDA-APHIS and the NAHLN to understand response capabilities across the United States, to better coordinate with all levels of government, and to improve and refine emergency policies and response plans.

This document is organized as a summary report that presents our recommendations and appendices that synthesize lessons learned across the exercise program. In the following sections, we describe highlights from the exercise program and provide recommendations for the next steps that USDA-APHIS and NAHLN, State animal health agencies, and individual NAHLN laboratories can take to enhance overall NAHLN preparedness.

## Tasking and approach

USDA-APHIS asked CNA to design and deliver a tabletop exercise to examine the integral connections between laboratory operations and field actions during an HPAI outbreak. We worked with the NAHLN Coordinator and NAHLN Steering Committee to create a board game that examined HPAI response, and then developed an exercise program that incorporated this game.[1] By using this board game as the foundation for tabletop exercises throughout the country, we could examine and highlight the variations among States and regions, and the subsets or patterns that exist in laboratory plans and capabilities.

The features of this exercise program—most notably, the use of a common format in many different locations—enable USDA-APHIS and NAHLN to analyze the animal health laboratory response system in a way that no single exercise would allow. CNA analysts facilitated each exercise and then documented the key events and decisions in after-action reports for each State or region. We then reviewed our findings, as well as participants' feedback, and analyzed the entire exercise program to identify recommendations for USDA-APHIS and NAHLN, for State animal health agencies, and for NAHLN laboratories.

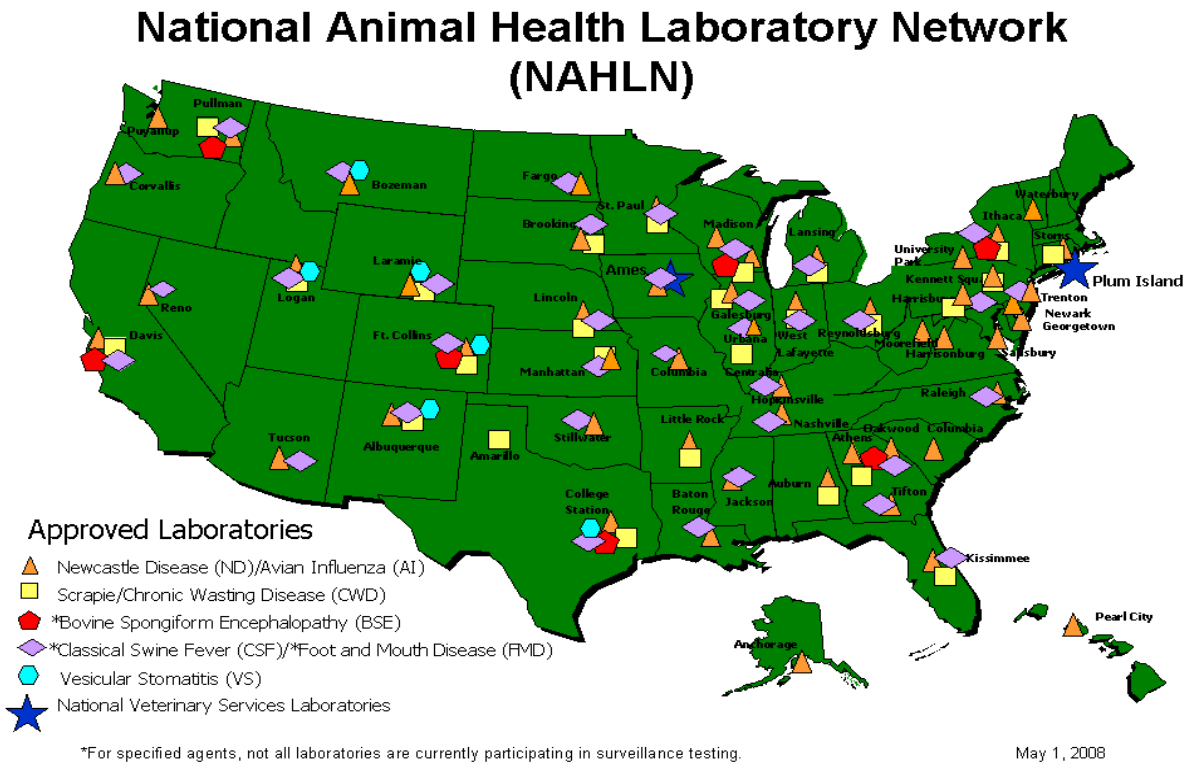
## Participants and locations

In total, we conducted 38 exercises from February to October 2008. They involved all but one of the NAHLN laboratories (see figure 1).[2] Thirty-two exercises involved a single laboratory, or multiple laboratories within a single State. Five exercises included two or more laboratories from neighboring States, and one exercise included representatives from a neighboring State that has no NAHLN laboratory to perform AI testing. Overall, more than 700 participants, representing 45 States and numerous Federal agencies, participated in the exercise program.

The laboratory director served as the host for each exercise. Participants typically included senior staff from various laboratory divisions/sections and several representatives from State and Federal

1. Appendix A describes our game components in detail.
2. The remaining laboratory did not respond to invitations to host an exercise.

Figure 1. Locations of NAHLN laboratories (map courtesy of USDA-APHIS)[a]




a. All NAHLN laboratories were invited to participate in the exercise program.

animal health agencies, such as the State animal health official (or representative), and the USDA-APHIS Area Veterinarian in Charge (AVIC) and/or Area Emergency Coordinator (AEC). Most exercises also included representatives from one or more other local, State, or Federal agencies, such as the:

- State and/or local department of health
- State and/or Federal agency for wildlife
- State emergency management agency.

In addition, many exercises included representatives from the commercial poultry industry, such as leaders from a State poultry federation or veterinarians from individual poultry companies.

Several exercises were attended by personnel from other Federal Government agencies. These included the Department of Homeland Security (DHS); the Federal Bureau of Investigation (FBI); and the National Wildlife Health Center, which is run by the Department of the Interior (DOI). A number of students and visitors also observed the exercise at some locations. The list of participants was determined by each exercise host, in coordination with animal health officials for that State. A summary of exercise locations and participants is provided in appendix E.

## Scenarios

All but two of the exercises began with the same scenario, in which increased mortality and respiratory signs are observed in susceptible poultry (not wild fowl).[3] We deliberately started the scenario at the very first report of clinical signs—which could be several days prior to official confirmation of HPAI by the National Veterinary Services Laboratories (NVSL)[4]—because the NAHLN laboratory would likely be involved at this early stage of an outbreak. The scenario for 25 of the 38 exercises began with clinical signs observed among birds at a commercial poultry facility. Alternatively, we began the scenario at a backyard farm for States that are primarily concerned about backyard flocks. Specifically, these scenarios were as follows:

- Scenario 1: The company veterinarian at a commercial facility observes increased mortality (perhaps only a few percent above the normal daily mortality rate) and birds with respiratory distress. The company veterinarian either:
  - — contacts the State animal health official, who dispatches a foreign animal disease diagnostician (FADD) to collect samples for laboratory testing, or
  - — submits additional samples directly to the laboratory after noticing the ill birds.

3. In two exercises, the scenario began with positive laboratory results from routine surveillance testing.
4. Confirmation of HPAI generally entails virus isolation and sequencing, the results of which are available between 5 and 14 days after NVSL receives the samples.

- Scenario 2: A farmer arrives at the laboratory with several dead chickens, and reports that about half of his remaining flock have respiratory signs.

Laboratory staff were familiar with both of these scenarios. Reportedly, it is not unusual for a farmer to bring several dead birds directly to the laboratory, or for a company veterinarian to submit additional samples for testing. Exercise play proceeded from one of these starting points, with participants discussing the next steps they would take for diagnostic testing and notification of results. Participants decided the day of the week on which the scenario would start, and exercise play continued for several additional scenario days. Each exercise lasted for about 4 hours, including an introduction brief, exercise play, and a hot-wash review.

## Timelines of key events

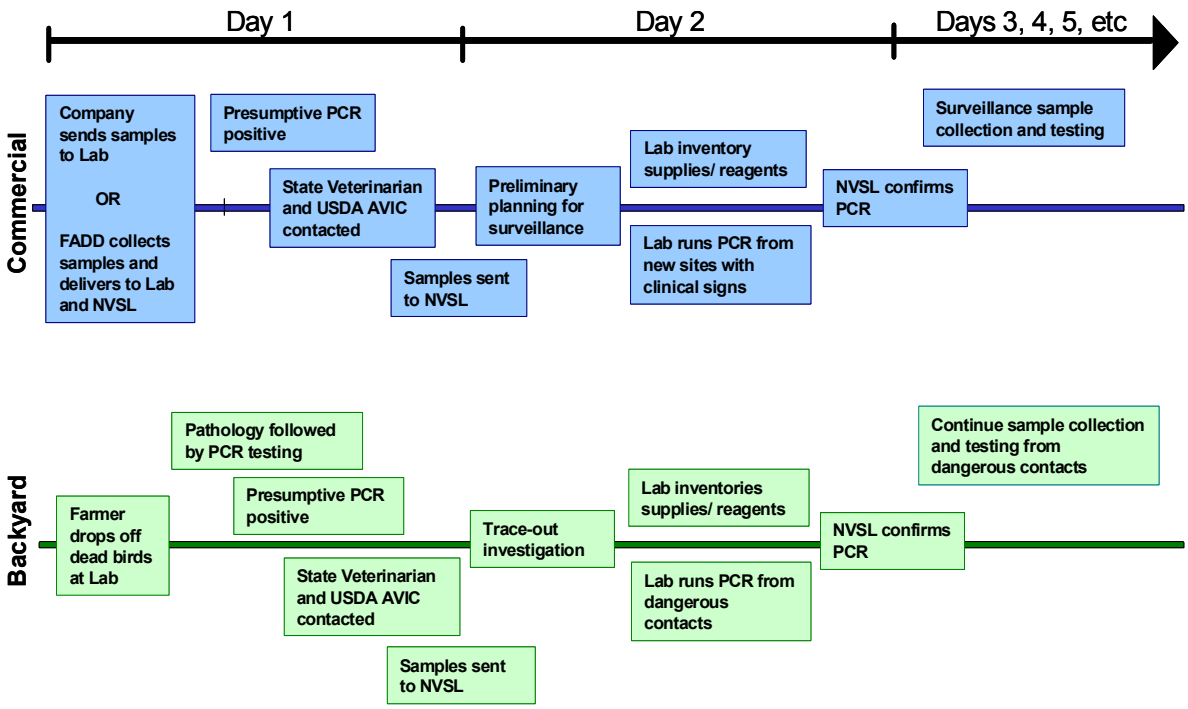
We reconstructed the exercise scenario, events, and participants' decisions in after-action reports for all of the individual exercises. We further developed a conglomerate reconstruction that describes the key events for each scenario (figure 2). Below, we summarize the common events and decisions that took place in the commercial scenario and in the backyard scenario.

### Commercial scenario

As described above, samples were submitted to the laboratory either by a commercial poultry veterinarian or by an individual (typically, but not always an FADD) who was dispatched by the State animal health official. Once the NAHLN laboratory received the samples on Day 1, they were generally able to provide a presumptive diagnosis of avian influenza to State and Federal regulatory officials within four to six hours after receiving the samples.[5] Samples were then sent to NVSL for further screening and testing, either late on Day 1 or early on Day 2.

5. Screening tests run by NAHLN labs are polymerase chain reaction (PCR) tests. These tests include the matrix test, which screens for all AI viruses, and the H5/H7 test, which screens for the H5 and H7 subtypes.

Figure 2. Timeline of the commercial and backyard scenarios




On Day 2, State and Federal officials, in coordination with commercial facilities, began making preparations to begin outbreak surveillance operations. This generally included one of two strategies:

- Collect samples from poultry at all locations within a specific radius of the index farm.
- Collect samples from all commercial poultry facilities that are on the same network as the index farm (e.g., all egg-layer operations).

Depending on the capabilities of the State animal health agency and the commercial facilities, the laboratory could expect the first wave of samples to arrive either late on Day 2 or on Day 3. In the meantime, laboratory staff said they would conduct an inventory of supplies and reagents. The lab would also run any samples collected from other facilities that had birds with clinical signs. In this scenario, NVSL would likely have completed preliminary PCR testing and initiated virus isolation and sequencing[6] by the end of Day 2.[7]

From Day 3 until the end of the timeframe for this exercise scenario, the laboratory would mostly focus on testing outbreak surveillance samples from commercial facilities. State animal health agencies might also begin area surveillance of backyard flocks within a specified radius of the index farm, depending on the number of personnel available to do so. Due mostly to the outbreak surveillance testing of commercial operations, the number of samples coming into the laboratory could easily exceed the lab's capacity by this time.

## Backyard scenario

As described earlier, the backyard scenario began when a concerned farmer or local veterinarian brought dead birds directly to the laboratory.[8] Once the NAHLN laboratory received samples, they were generally able to provide a presumptive diagnosis of avian influenza to State and Federal regulatory officials within four to six hours after receiving the samples. Upon notification, State and Federal officials would typically contact the farmer and deploy a team to investigate, collect additional samples, and begin an epidemiological investigation. Then, either late on Day 1 or early on Day 2, the field team or the NAHLN laboratory (or sometimes both) would send samples to NVSL for further screening and testing.

On Day 2, State and Federal officials would request preliminary results from the epidemiological investigation. Depending on the number of personnel available, they would send teams to investigate any other flocks with direct contact to the infected birds and collect samples. However, new premises that had birds with clinical signs typically would take precedence over direct contact premises. In most of the exercises, the laboratory staff anticipated that they could manage

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6. In addition to the aforementioned PCR screening tests, NVSL can run an N1 test, which screens for the N1 subtype. After the screening tests, NVSL conducts confirmatory testing, which may include virus isolation and genetic sequencing.
7. Variations in the timeline for NVSL confirmation depended on when, and how, the NAHLN laboratory could transport samples to Ames, IA.
8. In some States, the samples may have initially arrived at a branch laboratory and then been transported to the NAHLN lab.

these samples. The number of arriving samples that the lab could process was limited not by laboratory capacity but by the number of field personnel available to collect them. In the meantime, the laboratory would conduct an inventory of supplies and reagents. As in the commercial scenario, NVSL would likely have completed preliminary PCR testing and initiated virus isolation and sequencing by the end of Day 2.

Beginning on Day 3 and continuing through the end of the timeframe for this exercise scenario, the laboratory would focus on testing samples from new premises with clinical signs and from dangerous contacts identified through the epidemiological investigation. Participants agreed that once additional field personnel deployed to the area (from either USDA or neighboring States), the number of outbreak surveillance samples collected would quickly rise and the laboratory could become overwhelmed. However, this would likely not occur before Day 5 or 6; thus, the labs and NAHLN would have time to make necessary preparations for managing overflow samples.

## Outcomes and analysis

After completing after-action reports for all of the individual exercises, we reviewed and compared the lessons learned in order to assess their commonalities and differences. We looked for subsets and patterns in the issues that were discussed during each exercise. We also created a database to track information about the exercise program, including the list of participants, key events and decisions during each exercise, lessons learned, recommendations, and feedback comments.

To derive the lessons that arose across the entire exercise program, we defined a set of categories that would provide a common basis for analysis. We grouped the categories into three main themes that were discussed in detail at all of the NAHLN exercises: laboratory operations, laboratory-field coordination, and notification and communication.[9]

9. In contrast, issues that were specific to field operations (e.g., appraisal or mass depopulation) were not discussed in detail at all exercises because of variations in the types of field personnel who participated.

The appendices of this report present our synthesis of the lessons learned on the following topics:

- Laboratory operations (See Appendix B)
  - surge capacity
  - supplies and reagents
  - bio-security
- Laboratory-field coordination (See Appendix C)
  - prioritization of samples for laboratory testing
  - transport of samples
  - integrating laboratory response into the incident command structure
- Notification and communication (See Appendix D)
  - activation of NAHLN
  - information management
  - interagency support.

Overall, we found that only four NAHLN laboratories would be overwhelmed by the scenarios that were presented in this exercise. Laboratories in States with a high density of commercial poultry operations were the most likely to quickly receive more samples per day than they could process. This was a consequence of outbreak surveillance of commercial facilities and marketability testing that far exceeded the testing workload for locations with ill birds. However, once full outbreak surveillance of backyard farms was underway, any of the laboratories could be overwhelmed with testing of individual birds and small flocks.

We also found a surprising amount of variation in how the NAHLN laboratories would handle the increased workload. These differences were as dependent on the administrative structure and organization of the labs as they were on specific capabilities and capacities for testing, and resulted mostly from such issues as funding sources, overtime regulations, and safety concerns. This high degree of variation

presents a notable challenge to NAHLN leadership, which must coordinate response operations across a network of laboratories that are not managed by USDA or any individual agency.

States that have branch laboratories were better able to handle the surge in samples that results from continuing routine testing in addition to conducting outbreak testing. Similarly, individual NAHLN laboratories that have working agreements with other individual NAHLN laboratories were better able to distribute the workload. These results highlight the benefit of having a laboratory network such as NAHLN, where member laboratories that meet the same quality standards can work together to meet the nation's needs for rapid response and recovery testing.

# Recommendations

Each exercise was part of an overall exercise program focusing on the integration of laboratory response and field operations during an avian influenza outbreak. A key component of this program is the identification of overarching lessons that will allow USDA-APHIS and NAHLN to better understand and coordinate laboratory response capabilities across the United States. The appendices to this report present our synthesis of the lessons learned and best practices that arose during the program. Below, we list, and discuss our rationales for, our recommendations for further enhancing the emergency preparedness of NAHLN, its member laboratories, and State animal health agencies. [10]

## Recommendations for USDA-APHIS and NAHLN

**Assist States and regions with developing tailored plans for overflow sample testing during an emergency.**

As described above, the NAHLN exercise program revealed that all but four laboratories have the capacity to manage the additional samples that would be expected during the first three days of an HPAI outbreak. However, within a few days later—depending on the number of outbreak surveillance samples and the availability of field personnel to collect them—**all** laboratories will likely have more samples than they can manage on their own

NAHLN leadership should work with each of the member laboratories to identify alternative laboratories that can handle overflow routine, commercial marketability, and/or wildlife samples. The plans will need to be tailored, since each laboratory has a different set of compet-

10. Recommendations for individual laboratories and agencies are included in the after-action reports from each exercise.

ing priorities for overflow testing. For example, prioritizing poultry samples over wild bird samples could affect existing agreements and relationships between USDA-APHIS Wildlife Services and NAHLN laboratories. Decision-making guidance and identification of trigger points will help each laboratory identify when, and how, to send out overflow samples. The plans should also address the NAHLN Coordinator's role for identifying appropriate laboratories to receive overflow samples, or whether individual MOUs should be in place.

For some areas of the country (such as New England or the Delaware/Maryland/Virginia peninsula), a regional plan may be more appropriate than a State plan, and should be considered. In those cases, the NAHLN Coordinator, in consultation with State animal health officials, could pre-identify the laboratories that are most likely to be placed on alert for activation in the event of an AI outbreak in that region. MOUs could then be established between those labs and other member labs to facilitate coordination for diagnostic testing.

**Identify how laboratories will be compensated for conducting overflow testing, whether of outbreak samples or routine samples, during an HPAI outbreak.**

Response plans should also identify how laboratories will be compensated for testing samples over the course of the outbreak. During the NAHLN exercises, participants had a number of questions about reimbursement for expenses related to continuing routine testing along with conducting outbreak testing. For example, USDA-APHIS and NAHLN leadership should address whether, and when, the Federal Government will/could pay for the following measures that may occur in conjunction with NAHLN activation:

- Administrative and shipping costs for sending outbreak samples, including diagnostic samples from ill birds and outbreak surveillance samples from healthy birds, to another NAHLN laboratory
- Receiving and processing costs for the receiving NAHLN laboratory to test outbreak samples
- Travel and salary costs for NAHLN-trained personnel to go to a member laboratory in order to expand its capacity for outbreak testing

- Administrative and shipping costs for sending routine samples (not potential AI samples) to another NAHLN laboratory so that the primary laboratory can dedicate its own capacity to outbreak testing
- Receiving and processing costs for the receiving NAHLN laboratory to test those routine samples.

In turn, USDA-APHIS and NAHLN should distribute this information to member laboratories so that they can decide how to incorporate it into their own response plans.

**Continue working with the National Veterinary Stockpile program to include laboratory resources in the NVS.**

In a number of exercises, participants listed items that they would like to have available through the NVS. Examples of these resources are:

- Swabs
- Plasticware, including PCR testing plates and test tubes
- Virucidal chemicals
- PCR kits
- Sample collection kits for field responders
- Strip tests (e.g., Flu DETECT™).[11]

For PCR kits and other items with a limited shelf life, participants in several exercises suggested a system whereby laboratories would contract through the NVS to obtain these supplies on a regular basis, rather than procure them directly from the supplier. This could be similar to the contracting assistance that NVS provides for 3D (depopulation, disposal, and decontamination) resources. It would also enable NVS to have a supply of relatively fresh reagents on hand.

11. Mention of trademark or proprietary product does not constitute a guarantee or warranty of the product by the USDA and does not imply its approval to the exclusion of other products that may be suitable.

A number of exercise participants also suggested that USDA-APHIS use plastic test tubes for field collection, rather than the glass ones that are currently available. According to exercise participants, standardized plastic test tubes are more easily and safely handled by field and laboratory personnel.

**Develop and distribute a short description of the sample-transport services (such as the FedEx White Gloves service) that USDA-APHIS makes available to State animal health officials and laboratories.**

In many exercises, particularly those where the participants decided to begin the scenario on a Friday, laboratory and field personnel struggled to determine the best method for getting samples to NVSL for confirmatory testing. Further, only in a very few cases were participants familiar with the transport services currently available through the NVS.[12] State officials should have this information on hand so that they can consider the full range of options for sending high-priority samples to NVSL.

**Continue efforts to electronically link the NAHLN repository with the USDA Emergency Management Response System (EMRS).**

Currently all NAHLN laboratories have the potential to link their laboratory information management system (LIMS) database with the NAHLN repository, either via web-based entry or electronic messaging. However, the NAHLN repository cannot interface electronically with the USDA Emergency Management Response System (EMRS), which is the database that USDA-APHIS uses to track outbreak response operations. Therefore, we found that NAHLN laboratories would need to relay laboratory results to the unified command team via an alternative protocol set up just for the AI incident, such as by phone calls or faxes. Laboratory results would then have to be reentered by hand into EMRS.

12. If the State animal health official and AVIC agree, they can request the FedEx White Gloves service through a contract provided by the NVS. Upon activating this service, FedEx will pick up and deliver samples anywhere in the country within a few hours. Participants noted that this service is expensive and should only be used for high-priority samples.

Also, some laboratories have developed spreadsheets that assist this process and include common identifiers to link lab results with premises information. Exercise participants noted that often the only common identifier is the address of the premises. USDA-APHIS should examine which other common identifiers are already in use, and consider including them in an electronic link between LIMS, NAHLN, and EMRS databases.

**Consider revising the definition of NAHLN "activation" and clarify the process of activating individual laboratories as well as the entire network.**

For a case of AI, a NAHLN lab can make a presumptive diagnosis of whether the virus is present, and whether it is type H5 or H7. Consequently, the individual laboratory may increase its own state of readiness before NVSL confirms the result, or is even aware of the need for confirmatory testing. This scenario doesn't appear to fit with the current definition of NAHLN "activation" for outbreak testing.

During the NAHLN exercise program, we identified several scenarios that should be addressed in the definition of NAHLN activation. In these cases, NVSL and/or the NAHLN Coordinator could:

- Delegate a member laboratory to handle subsequent outbreak surveillance testing (after the first case is confirmed by NVSL for each new outbreak area). Samples would then be considered positive if the results of the screening test are positive.
- Designate other selected NAHLN labs (but not necessarily the entire network) to assist the laboratory that is primarily responsible for handling samples from the outbreak area.
- Request personnel from other member laboratories to assist a NAHLN lab that has reached its capacity.

These processes should be addressed in the formal NAHLN activation plan and communicated to all member labs.

**Examine the feasibility of several policies that were proposed during the NAHLN exercise program to increase laboratory response capacity using in-State resources.**

During most exercises, participants raised questions about NAHLN and NVSL policies. Some participants were looking for clarification of existing policies and procedures. Others brought up new ideas for helping laboratories handle the outbreak testing workload. Examples of these questions are provided below.

- **Finding additional personnel and laboratory space.** In most exercises, participants identified several in-State sources of PCR technicians and equipment—such as public health laboratories, universities, and National Guard Civil Support Teams—that could assist with testing, but are not trained and proficiency-tested (personnel) or validated (equipment) for using NAHLN protocols. Questions arose whether the personnel and equipment could be tested by NAHLN on short notice and approved for use with AI outbreak testing.
- **Changing the sequence of laboratory testing.** In many exercises, participants questioned whether the testing process could be modified once NVSL had confirmed the first presumptive positive PCR test result. For example, participants suggested using strip tests, either in the field or at the laboratory, to indicate priority for further testing (samples with a positive result from a strip test would be higher priority for PCR tests). Participants also suggested bypassing the avian influenza matrix test and conducting only the H5/H7 screening test on outbreak surveillance samples.

**Provide guidance on the required use of BSL-3 spaces for HPAI testing.**

A number of participants were unsure what triggers would require them to move testing from BSL-2 (bio-safety level 2) spaces to BSL-3 spaces. This has significant operational impact since most laboratories, including those from States with large commercial poultry industries, have much less BSL-3 capacity, and some have none at all. Decision tools and triggers should be included in laboratory emergency plans, including options for sending out samples to laboratories that do have BSL-3 capacity.

**Provide guidance on USDA's expectations of when and how State and Federal interagency partners will be notified of a potential HPAI outbreak.**

We found notable variations as to when and under what conditions the laboratory directors and State animal health officials would notify other agencies, including industry personnel, of a potential HPAI outbreak. In some States, industry and selected interagency partners would be notified of the first presumptive positive result. In others, the information would remain confidential until NVSL has confirmed the result and USDA-APHIS is about to make an announcement. These differences have implications for the speed and coordination of response operations in each State. However, the need to closely hold proprietary information must also be recognized. We suggest that USDA-APHIS provide guidance on when other agencies, and industries, should be notified, and what notifications will be the responsibility of USDA-APHIS.

## Recommendations for State animal health agencies

**Identify appropriate timelines for notifying State and Federal interagency partners.**

As noted above, we observed considerable differences among exercise participants in their plans for early notification of other agencies that may have an active role in HPAI response, such as public health, wildlife, emergency management, and poultry industry organizations. These differences appeared to exist even among States that routinely work together on commercial poultry issues. State plans should identify which agencies and organizations will be notified of a presumptive positive result, and by whom, and which response partners will be notified shortly before USDA announces a confirmed case of HPAI.

**Include a laboratory liaison position in the unified command for an HPAI outbreak.**

Having a liaison between the laboratory and the unified command has proven successful in previous animal disease outbreaks, such as the 2002-03 outbreak of exotic Newcastle disease. Personnel in this position do not necessarily need to be laboratory staff, but they should be

familiar with laboratory operations and with the incident command system (ICS). Responsibilities for this position could include:

- Training field personnel on the proper ways to collect samples
- Assisting with surveillance planning, to include route management, bio-security, handling, documentation, and transportation of samples
- Communicating the laboratory's resource needs to the command staff
- Coordinating the field's resource needs for sample collection and transport.

**Re-examine outbreak surveillance plans so that they are better coordinated with laboratory operations.**

In several of the States that participated in this exercise program, outbreak surveillance samples consisted of bird carcasses or blood samples. These types of samples can present a challenge for the laboratory, which will need to store, and later dispose of, a number of carcasses. It is generally more efficient for the laboratory to receive swab samples. In addition, protocols should be developed that facilitate coordination between field and laboratory personnel. Such protocols could include a system to provide swabs and train field personnel, a phone call to the receiving laboratory with information about the number and priority of samples, and a scheduling system that would allow for the preferred number of samples to arrive at the laboratory at one time.

Also, the frequency of outbreak surveillance sampling can quickly overwhelm laboratory capacity. Layer operations may require daily surveillance testing so that eggs can be moved from the farm. For all-in / all-out poultry operations, State officials should consider whether outbreak surveillance samples during an HPAI outbreak need to be collected daily or less often.

**Provide swab collection kits to field responders and training on how to use them.**

Reportedly, many States have swab collection kits on hand, or ready to be prepared, in the event of an HPAI outbreak. A few States have pre-distributed these kits to commercial poultry operators in order to facilitate rapid sample collection. However, we found that in some States the field staff, and especially industry personnel, were not trained or equipped for collecting swab samples. Having such kits available can reduce sample-collection time and ensure that the laboratory receives the preferred type of samples for rapid PCR testing.

**Re-examine sample prioritization plans so they are better aligned with laboratory operations.**

During an HPAI outbreak, laboratories can receive samples from a variety of sources—from sick birds, outbreak surveillance of commercial or backyard bards, routine surveillance of commercial operations, and wildlife—and the default plan may be to test them in the order they were received. A sample prioritization strategy will help the laboratory manage its workload while providing the most important information for those State officials who must make decisions regarding disease eradication. The strategy should include decision points for identifying which samples could be sent to another laboratory, if the NAHLN laboratory has an excessive workload.

**Develop a protocol for integrating laboratory resourcing requirements into ICS processes.**

At the start of most exercises, participants assumed that each laboratory would be responsible for procuring and tracking its own resources. However, during the exercise players recognized that such administrative and logistics functions could also be handled by the incident command post (ICP). This would allow laboratory staff to focus on supporting the testing process, and would centralize the expense and reimbursement tracking during an outbreak.

In this system, the NAHLN laboratory would relay its resource requirements to the ICP, and command staff (in the logistics or administrative sections) would fill those needs. USDA-APHIS,

NAHLN, and State animal health agencies need to address several issues to facilitate this integration:

- The National Information Management System (NIMS) requires a typing system, to ensure that the requested resources match the required resources. At this time, there is no system of national standards in place for animal health laboratory personnel, supplies, or equipment.
- The interface between NIMS and the major resource providers for laboratory supplies, such as NAHLN and NVS, is still in development. ICP staff will need to know that they should contact NAHLN for fulfilling laboratory personnel requests.
- Laboratory resources will need to be considered and included in an emergency budget submitted by a State animal health official.

## Recommendations for NAHLN laboratories

**Re-examine the laboratory's emergency response plan, taking into account lessons learned from the NAHLN exercise program.**

While most laboratories already have an emergency response plan in place, the NAHLN exercise program highlighted additional items that could be addressed in order to improve that plan. These included the following:

- Notification procedures and contact information for staff, and for State and Federal regulatory officials who will receive information directly from the laboratory.
- In-State resources that could be used in an emergency to augment laboratory testing capacity or administrative functions. A few resources identified during the exercise program were:
  - State public health laboratory resources (staff, supplies, and equipment)
  - University students, faculty, and laboratories
  - National Guard Civil Support Teams.

- Procedures for requesting additional supplies and reagents from the NVS (when available) or other sources, and/or for forwarding supply requests to the ICP.
- Funding sources, and how to receive reimbursements, for laboratory expenses such as:
  - Processing outbreak samples
  - Sending overflow samples to another laboratory
  - Receiving personnel to assist in the laboratory.
- Protocols for coordinating with field personnel and unified command (which should align with the State FAD emergency response plan), including a laboratory liaison to work with the unified command.
- Protocols for coordinating with NAHLN when the laboratory is activated to support outbreak testing in its home State or in another State.
- Memoranda of agreement with other laboratories to handle overflow samples.
- Steps for handling routine samples in addition to outbreak samples, such as:
  - Re-directing samples to branch laboratories within the State.
  - Working with veterinary providers to reduce the number of routine samples while outbreak testing is being conducted.
  - Seeking assistance from another NAHLN laboratory.
- Preparation and distribution of sample-collection kits to field responders.
- Identification of sources for, and steps to obtain, prophylaxis medications (such as anti-virals) for laboratory staff.
- Procedures for enhancing bio-security *outside* of the laboratory, such as erecting signs, changing traffic flow, and determining locations for curbside drop points and pressure-wash sites.

One suggestion from the exercise program was to develop an emergency response plan consisting of time-based modules, which could be activated depending on the level of the outbreak. The first stage of the plan would cover the first week or 10 days, when the response is primarily local. The second stage of the plan would provide direction for the first month or so, including strategies for managing additional personnel and an overload of samples. The final stage of the plan would detail how to maintain the level of testing required to prove that the State is free of disease, and how to maintain mental and physical health among employees.

**Work with State animal health officials and NAHLN for recovery planning.**

Many of the laboratories that participated in this exercise program expressed concern about maintaining business continuity during an HPAI outbreak. In particular, some labs are funded by fee-for-service agreements, and their staff members were concerned that they wouldn't regain those fees after outbreak testing was completed. State-wide recovery plans should include the laboratories, and, in turn, laboratories should include recovery measures in their own response plans. NAHLN can facilitate this planning by working with member laboratories to identify specific recovery issues.

# Appendix A: Overview of the exercise design

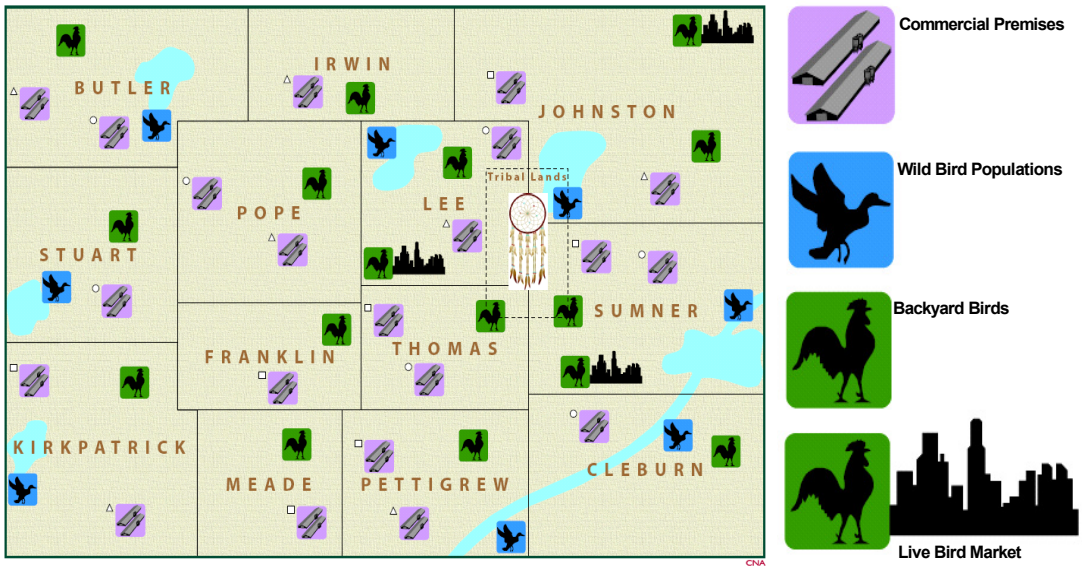
This appendix describes our game design, and explains how the board game components were used for the series of tabletop exercises with NAHLN laboratories. We drew on USDA-APHIS's current plans and experiences to represent how animal health emergency field actions and laboratory functions work together. We incorporated models, rules, and procedures that best reflect the tasks and roles the participants would engage in during an outbreak of HPAI. Our goal was to present challenging material to the participants, in order to capture the communications, conflicts, and decisions they would face in an actual event.

The objectives for this exercise program came from the *National Strategy for Pandemic Influenza* and its accompanying implementation plan, and from meetings with USDA-APHIS and NAHLN leadership. Broadly stated, the goal was to test, evaluate, train, and enhance the resources and readiness of the animal health community, and to help that community prepare to respond to an outbreak of HPAI. More specifically, the exercise focused on the interactions between field operations and laboratory response.

## Components of the board game

We produced a tabletop board game to serve as the foundation for the series of exercises with NAHLN laboratories. Note that we intentionally make a distinction between the *game* and the *exercises* that employ it. The game has a number of components that represent various facets of animal disease outbreak response. The use of those components together in a specified sequence of play can be viewed as a basic, yet interactive, model of HPAI response. We deliberately abstracted and simplified many tactical details, for both the field and the laboratory, in order to focus on the roles of the players as decision-makers. In turn, the exercise involves a number of participants who are using the game as a tool for discussing HPAI response actions and decisions.

Figure 3. Map used for the HPAI table-top exercises




## Map

The primary component is a game board that has a simplified map of a 13-jurisdiction area of an unspecified region (see figure 3). Commercial poultry operations are represented by purple squares depicting poultry houses and are distributed across the map. Backyard flocks are represented by green squares and are also distributed across the map. Wild birds are represented by blue squares and are clustered near water features. The green squares next to city skylines represent live-bird markets, swap meets, or other events where a large number of birds come together for a short period of time, intermingle, and then disperse.

Commercial poultry premises are further broken down into three networks, which are delineated by the shape (triangle, circle, or square) at the upper left of the square. Participants decide what type of poultry each of these networks represents (e.g., broilers, turkeys, or ducks), based on what makes the most sense for their State.[13] Participants also determine how large a typical commercial facility would be within each network, in terms of number of houses and number of birds per house.

For example, in one of the exercises:

- The Triangle network represented broiler operations, each with four houses of 25,000 birds per house.
- The Square network represented broiler breeder operations, each with two houses of 10,000 birds per house.
- The Circle network represented layer operations, each with eight houses of 50,000 birds per house.

Participants also determine the density of other commercial and backyard premises around those sites shown on the game board. Finally, they assign the number of birds on a typical backyard farm. In these ways, the "standard" map used for all of the NAHLN exercises is adapted to the specific types of bird populations within each State.

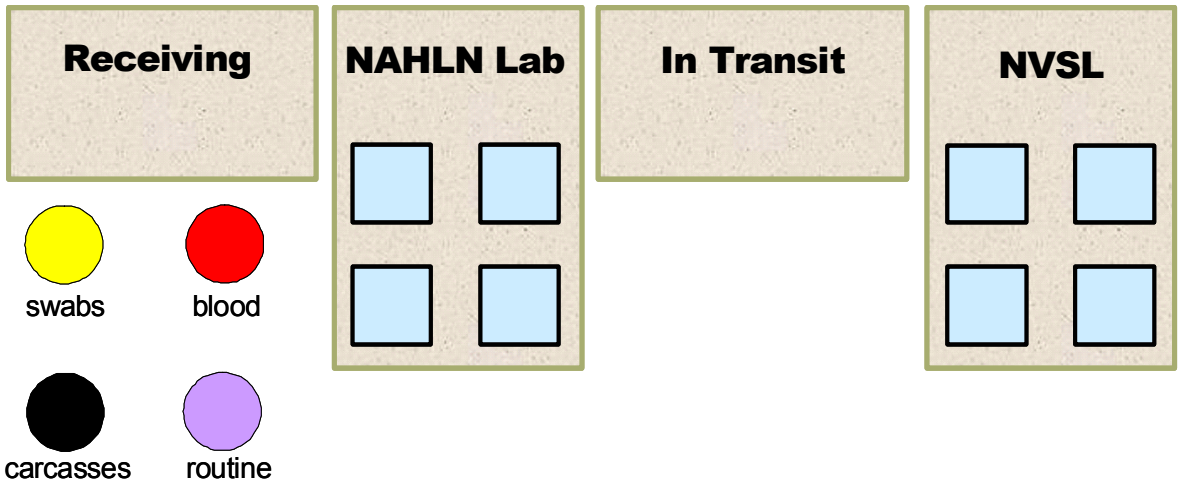
## Disease spread model

The transmission of disease between premises is determined by a disease spread model. The disease model used is the DADS model (Davis Animal Disease Simulation) that was developed to study transmission of foot-and-mouth disease in California and was adapted within CNA to model spread of disease in poultry. The general locations of the premises on the board are fed into the model, along with HPAI-specific parameters. The model then generates thousands of "adequate contacts," where disease will occur if the sender is infected; these contacts are sub-sampled for the disease spread cards.

The disease transmissions in the model are stochastic—that is, they have a random component but certain transmissions have a greater chance of occurring than others. All things being equal, the disease has a greater chance of spreading to closer premises than to those farther away. It also is more likely to spread to other premises of the same type (backyard, commercial, or wild bird). If the disease is on commercial premises, it is more likely to spread to other premises within the same network.

13. Some States do not have sufficient commercial poultry for multiple networks. In those cases, the game proceeded with fewer networks.

Figure 4. Representation of laboratory samples and assignments in the HPAI exercise.




## Laboratory representation

Laboratory components depict the process to receive, test, and transmit diagnostic samples (figure 4). Samples collected from premises are represented by colored disks (e.g. purple for routine samples; yellow for swab samples, red for blood samples, and black for carcasses). Once samples have been collected, laboratory personnel assign and prioritize them. Players can request resources to augment capacity, and/or they can decide to send some samples to another laboratory for testing.

For example, exercise participants must first define what type and number of samples are being sent to the laboratory. Once a group of samples has been collected from the field, they are placed on the board that says "Receiving," and then assigned to a laboratory unit. If those samples are later sent to NVSL for confirmatory testing, they will be placed on the "In Transit" board for a short time, and then transferred to the NVSL board.

## Response teams

This game includes a simplified sequence of actions to eradicate HPAI virus from infected premises. These steps are as follows:

- Quarantine a location that has birds with clinical signs.
- Use laboratory testing to diagnose the disease.
- Establish an ICP, as described by that State's HPAI response plan.
- Depopulate and dispose of the birds, and then disinfect the premises (3D).[14]

Because each of these steps requires different expertise—and, potentially, different personnel and equipment—the steps are represented by separate teams and actions.

Accordingly, exercise players can use the following response teams to eradicate the disease:

- **Quarantine & Tracing teams.** These teams represent the personnel, such as the foreign animal disease diagnostician (FADD), and the resources required to quarantine, begin trace-outs, and collect samples at an infected location.
- **Diagnostic teams.** These teams represent the personnel and resources required to conduct diagnostic testing on samples collected from an infected or susceptible location. Responsibilities could include collecting samples from the birds, packaging and shipping those samples, receiving and logging the samples, conducting laboratory testing, and then reporting the results.
- **Depopulation, Disposal, and Disinfection (3D) teams.** These teams represent the personnel and resources required to depopulate affected birds, dispose of the carcasses, and clean and disinfect the infected or susceptible location.

14. Other response steps, such as enforcing movement control and conducting appraisal, are not included as separate response steps in the NAHLN version of the exercise.

- **Surveillance teams.** These teams represent the personnel and resources required to conduct area surveillance by collecting samples from locations that are presumed to be uninfected.

These teams are represented by team markers that could move around the game board. Players decide which teams they will assign to the field, or to the laboratory, during each turn of the game.

### Status markers

Status markers are placed on the game board to indicate whether those premises have:

- Birds with clinical signs for avian influenza
- Been quarantined
- Birds that have been diagnosed with avian influenza
- Been depopulated and decontaminated.

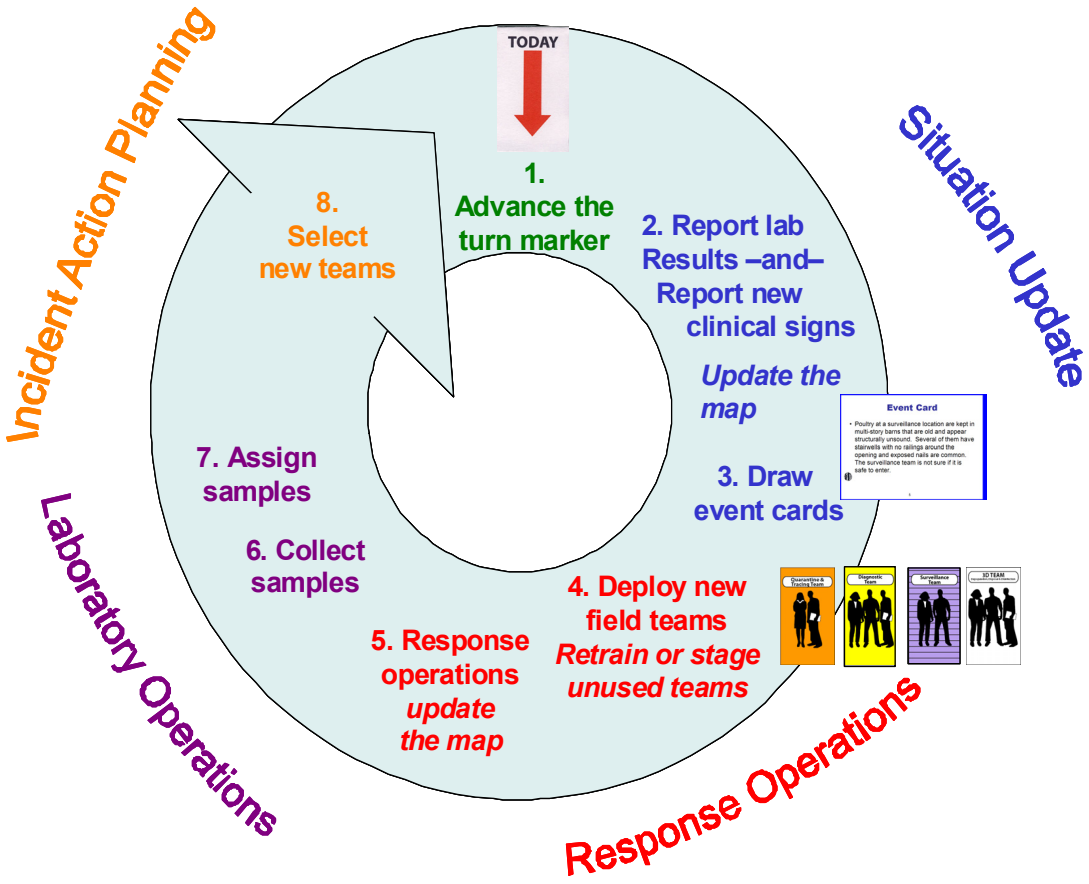
In this way, the game board with status markers is intended to represent a local area map that might be found in an incident command post (ICP) and the markings that responders would make to indicate infected locations. Status markers are updated following a report of new disease spread, of new laboratory results, and/or of actions of field teams.

## Sequence of play

The sequence of play during the exercise is intended to represent the daily "battle rhythm," or operational cycle, of an ICP of an emergency operations center (figure 5). It is roughly broken out into three phases: a situation update, operations (field and laboratory), and incident action planning. Each turn of the game represents one day of the exercise scenario.

Accordingly, each new day begins with a situation update. Participants are given reports of new clinical signs, new laboratory results, and other findings or events that may influence the HPAI response operations. Following that is an operations phase, where participants update the map based on the information provided in the situation

Figure 5. Sequence of play for the HPAI exercise




update. For example, participants may place new status markers on the map to indicate which premises have now reported birds with clinical signs for avian influenza. They may also decide where, and how, to conduct response operations (such as quarantine or 3D) by deploying new teams and carrying out their corresponding response operations.

Surveillance teams may collect laboratory samples, which the laboratory then receives for testing. At this point, laboratory representatives may assign those samples to the appropriate laboratory units. If there are any overflow samples, participants then have the option of deferring testing or shipping those samples to other laboratories.

During the final phase of each day, exercise participants plan for additional resources that will be required for subsequent days, based on what they observe on the exercise map.

Exercise play continues until the time allotted for each NAHLN exercise (usually about 4 hours) has expired. (Most of the exercises reached at least Day 3 of the scenario, and some progressed several days further.) Facilitators then conduct a hot-wash review and distribute feedback forms to solicit the participants' ideas and questions that were generated by the exercise.

# Appendix B: Lessons learned about laboratory operations

A focal point for each exercise, and for the entire program, was the examination of laboratory operations, including what steps the laboratory would take to complete outbreak testing and when those testing requests might exceed the lab's capacity. The high level of participation among NAHLN laboratories generated useful insights and lessons about laboratory emergency response. Many of the laboratory staff members had worked through animal disease outbreaks, and they added their experience to the exercise discussions.

In our review and analysis of outcomes from each exercise, we identified several overarching themes in the discussions about laboratory operations. These themes include:

- Laboratory capacity
- Supplies and reagents
- Bio-security.

In the sections below, we synthesize the discussion points and lessons learned that arose during the NAHLN exercise program across each of these topics.

## Laboratory capacity

Probably the single most frequent question that laboratory personnel raised throughout this exercise series was whether their lab has sufficient capacity to manage the volume of samples that could be generated during an HPAI outbreak. That question is generally not answered by a simple "yes" or "no." It is best answered by examining the decisions that laboratory personnel will need to make throughout

an outbreak. To do so, we separated the disease outbreak into several decision-making phases:

- The disease is first detected (presumptive phase).
- Preliminary PCR testing is completed, and the extent of the outbreak is determined (surge phase).
- The disease is contained (recovery phase).

Below, we use this construct of outbreak phases to synthesize the various insights, issues, and lessons that arose regarding laboratory capacity.

## Presumptive phase

Capacity for HPAI testing varies greatly among the NAHLN laboratories. Given this exercise scenario, we observed that all but four laboratories have capacity to manage the number of samples expected during the initial couple of days following presumptive diagnosis of AI. For the most part, therefore, laboratories will be able to manage the expected number of samples from the initial round of outbreak surveillance of commercial facilities or dangerous contacts linked to the index site.

In the initial phase of the exercise, participants began considering various ways to ramp up their own capacity. If necessary, most laboratories can ask personnel to work extended shifts to manage these samples along with routine samples that come into the laboratory on a daily basis. The exceptions could be the laboratories in those States that have a high volume of commercial poultry *and* can begin outbreak surveillance sampling very quickly. Those few labs would quickly need to investigate ways to send overflow samples to other laboratories.

The limiting factor for capacity at this point of an outbreak is not likely to be PCR testing capability, since few labs would expect to receive more samples than would fill a couple of 96-well plates. Nonetheless, exercise participants anticipated that they would become overwhelmed as outbreak surveillance got underway, due to a variety of other chokepoints. These include:

- Sample accession and data entry
- Equipment or personnel for sample extraction
- Equipment or personnel for sample PCR testing.
- Laboratory space
  - — Hood space for extracting samples
  - — BSL-3 space that may be necessary once HPAI is confirmed.

Individual laboratories varied greatly in terms of which factors would be a chokepoint. For example, some laboratories have plans in place to facilitate receiving a large number of samples while others have ample physical space.

## Surge phase

Once an epidemiology investigation begins and outbreak surveillance operations ramp up, the number of samples collected will likely exceed the capacity of all individual laboratories. However, as we observed during the exercises, the impact of this can be reduced for States or regions that have agreements in place to distribute the overflow samples to other laboratories. At this point, laboratory directors and animal health officials will need to decide on the priorities for the overflow samples, including outbreak samples, routine samples, and wildlife samples.

These decisions varied greatly in the NAHLN exercises. Some labs opted to delay the testing of routine samples and focus on outbreak samples. Others chose to continue testing nearly all routine samples and considered sending overflow outbreak samples to another laboratory. A number of factors contributed to these decisions, including the lab's ability to increase its own capacity, its funding sources, and the possibility that it will need to handle other types of samples, such as those from wild birds or those for marketability of poultry products.

### Increasing capacity

Capacity can be increased by having more personnel and / or more supplies and equipment available to conduct testing. For personnel needs, exercise players suggested a variety of in-State sources of personnel who

might be readily available at this stage of the response. These sources included:

- University students and faculty
- State public health laboratories
- National Guard Civil Support Teams.

Exercise players were quick to point out that in-State personnel would only be able to perform tasks that do not require formal proficiency training. However, in several exercises, participants questioned whether NVSL could either relax proficiency-training requirements during an emergency or develop a just-in-time proficiency training package. Players expected that eventually NAHLN would be activated and a decision would be made whether proficiency-trained personnel and certified equipment from other NAHLN labs would be deployed.

Exercise players also suggested several ways to increase testing throughput once the disease has been confirmed by NVSL, such as:

- Running only the H5/H7 screening test.
- Running strip tests (e.g., Flu DETECT™).[15]

Participants were not aware of any formal policy regarding these alternatives, and suggested that they be considered.

**Handling outbreak samples**

All labs reported that their highest priority would be samples from premises with clinical signs. Decisions about outbreak surveillance samples were more varied, often depending on the lab's decision for routine samples. In some instances, participants questioned whether the State animal health official from another State would agree to accept outbreak surveillance samples from a State with an HPAI outbreak. Other issues raised were how test results would be reported from an out-of-State laboratory and how those laboratories would be funded. Each of these topics is discussed in more detail in separate appendices of this report.

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**Handling routine samples**

The question of how laboratories would handle routine samples had a greater variety of answers than we expected. The primary driver of this difference appeared to be the need to preserve the laboratory's "market share" of diagnostic testing, both during and after the outbreak. Routine testing is the main source of funding for many laboratories, particularly those that are part of a university system rather than part of the State animal health agency. These laboratories were especially concerned about their own continuity of business needs—i.e., if they sacrificed their main line of business during an HPAI outbreak, they might not be able to be fully reconstitute it afterwards.

For our purpose, "routine samples" are defined as samples that arise from day-to-day animal health diagnostic needs within the State and *not* from the HPAI outbreak. These could be samples from private veterinarians for diagnosis of individual animals, from routine surveillance of livestock or food (such as dairy products), or from research studies. A laboratory has two basic choices: it can continue testing all of its routine samples while also testing outbreak samples, or it can send some or all of those samples to one or more other laboratories. During the exercise program, we observed labs making each of these choices, as well as including a number of other conditions to help manage their combined workload while also trying to preserve their continuity of business:

- Sixty percent of the laboratories chose to keep all of their routine samples and continue testing them in-house.
  - — Some kept them all for testing at the primary / headquarters laboratory.
  - — Others kept them within the State's laboratory system but sent them to branch laboratories.
  - — Others slowed down the number of routine samples coming in to the laboratory, so as to preserve some capacity for testing outbreak samples.
- Forty percent of laboratories chose to send out their routine samples.

We'll discuss each of these choices in further detail below, and provide some examples from the NAHLN exercise program.

*Some laboratories chose to keep all of their routine samples.*

As mentioned above, a number of NAHLN laboratory personnel expressed concern about the need to maintain their funding stream before, during, and after an HPAI outbreak. Laboratory personnel felt that the best way to do this was to continue testing as many routine samples as possible, while also meeting the diagnostic testing needs of the outbreak response. Laboratories that are part of a university system usually elected to keep all of their routine samples for in-house testing. This decision reflects their need to receive payments for individual tests in order to maintain their operating budget.

Examples of the arguments supporting this strategy are:

- "We need to maintain the funding stream for our laboratory. If we don't, we'll lose our market share to commercial labs that can pick up some of the State's testing needs."
- "We're not sure if the emergency / outbreak funding will pay for sending routine samples (i.e., not potential HPAI samples) to other laboratories. We can't pay for other labs to do this testing for us."
- "We're in a 'bovine State' and we can't drop our routine testing for cattle and dairy products. Yes, HPAI is very important, but we also need to preserve our primary industry, which is beef (or dairy, etc.)"

Laboratories were also concerned about maintaining the timeliness of testing routine samples. If routine samples need to be sent to other labs, even to those within the same State, some private practitioners and commercial operators will need to accept a delay in receiving test results.

NAHLN laboratories that are part of an in-State laboratory network nearly always elected to send routine samples to branch laboratories. In this way, the laboratory that is NAHLN-certified for HPAI testing (usually the primary, or main, laboratory) would receive all of the

outbreak samples, while routine samples for other diagnostic testing, such as for serology, would be diverted to a designated branch lab. Exercise participants gave a number of arguments to support this strategy, such as:

- "We can shuffle the workload within our State laboratory system and meet all of the testing needs."
- "We'll still be able to follow our State's protocols, keep the funding for all types of tests, and serve the needs of our animal health officials and industry with direct communication and timely test results."

Further, personnel, and even equipment, from within the laboratory system may also be shuffled to different locations in order to accommodate these plans.

Some States have a single animal diagnostic laboratory, and therefore do not have the option of sending routine samples to branch labs. An alternative decision was to reduce the number of incoming routine samples while the lab was also confronted with outbreak testing. During the exercises, lab personnel identified several methods for reducing the number of routine samples that must be tested concurrently with outbreak samples. For example, some said:

- "We'll test the high-priority routine samples now and we'll freeze the rest. We'll test those later (after the outbreak workload has diminished)."
- "The number of routine samples will be decreased anyway, because we won't be conducting as much routine surveillance if birds aren't moving (around the State)."
- "We'll communicate with the State veterinary medical association, and other practitioner groups, about holding off on sending us samples until the outbreak is finished."

Exercise participants noted that with this strategy the laboratory could still get paid for doing the routine testing, even if it occurred after the peak of the outbreak. They could also better manage and maintain the lab's workload. As the outbreak testing needs decrease, the laboratory could begin taking some of the routine samples from the freezer. This

option would allow the laboratory to maintain an increased operational tempo for staffing and use of equipment, rather than being subjected to daily dips and rises in the number of samples.

*Some laboratories chose to send routine samples to other NAHLN labs.*

In contrast, some laboratories would choose to send out their routine samples—not to branch labs, but to laboratories in neighboring States. A number of arguments supported this strategy, such as:

- "All of the outbreak samples should be handled by one lab—our State lab—if at all possible. This is best for scientific and political reasons."
- "We just don't have the capacity to do everything (outbreak and routine samples). The delay that results from sending samples to others makes more sense for routine samples than for outbreak samples."
- "It makes more sense to send routine samples across State lines than to send potential HPAI samples."

Most often, the laboratories that chose this strategy already have MOUs in place with other labs. They would not necessarily rely on NAHLN to identify labs to receive the routine samples, but would instead reach out first to neighboring labs with which they already have agreements. Also, some laboratory personnel knew that certain neighboring labs use the same LIMS database. They would want to send samples to those labs because the results could be electronically linked and thus more easily reported to animal health officials. However, it is possible that the lab in the neighboring State will also see an increase in testing samples from facilities that are trying to show they are disease-free. This will need to be considered when developing the strategy for managing overflow samples.

While the variety of strategies for handling routine samples during an HPAI outbreak was somewhat unexpected, the arguments were reasonable for each lab's individual situation. This reflects the diversity among the laboratories that are part of the NAHLN. It also presents a number of issues for officials within APHIS-VS about how best to handle the simultaneous needs for routine and outbreak testing.

### Handling wildlife samples

Wild bird samples were a wildcard during the exercises. Most of the labs conduct diagnostic testing for routine wild-bird surveillance, which is often seasonal because of migratory patterns of the wild birds. In some instances, wild birds can account for several hundred PCR tests a day, though only for a limited time each year. If the HPAI outbreak occurred at the same time as an increase in wild-bird testing, the lab could get overwhelmed much more quickly.

The solution most often mentioned for handling wildlife samples in addition to outbreak samples was to identify an alternative test site. This would help preserve the State animal health laboratory's capacity for testing of higher-priority samples. Reportedly, USDA-APHIS Wildlife Services has agreements with all NAHLN labs and could send those samples elsewhere if requested. In several exercises, players suggested that these wild-bird samples could be re-directed to another lab at the request of State animal health officials.[16]

Exercise participants also suggested that wild-bird samples could be sent to the National Wildlife Health Center (NWHC) in Madison, Wisconsin. However, NWHC representatives who participated in the NAHLN exercise program noted that this would require coordination between two Federal agencies (DOI and USDA) and possibly the sharing of emergency funds for outbreak testing. The issue of how, and whether, the NWHC could assist with laboratory testing in an HPAI outbreak among commercial poultry was not fully resolved during the exercises.

### Laboratory funding

Maintaining a funding stream is a predominant concern for most of the NAHLN laboratories that are associated with a university. Compared to laboratories operated by State departments of agriculture,

16. Wild bird submissions to the NAHLN would have to continue, as required by existing agreements in place with all 50 states. Simply prioritizing poultry samples over wild bird samples could affect these existing agreements and relationships. Therefore, the wild bird component would likely cause a greater impact on laboratory capabilities than was discussed during individual exercises.

university labs have more difficulty accommodating the expected volume of samples without clear funding arrangements. Exercise participants from these laboratories said they would first look to the State animal health agency to provide supplemental funding until the Federal response was in place, but they were uncertain how this would work and whether it was feasible. They generally agreed that a declaration by the Governor would be extremely helpful in arranging for supplemental funding.

Participants also questioned whether outbreak (i.e., "emergency") funding could be used to pay for having other labs conduct *routine* tests for the State that is affected by an HPAI outbreak, or the increased costs that might result from shuffling workload, personnel, and equipment between branch laboratories within the same State.

## Recovery phase

The number of diagnostic tests required to prove that an area is "free" of disease far exceeds the number required (only one test) to prove that the virus is present. As we observed after the exotic Newcastle disease outbreak in 2002–03, laboratories will have an increased workload for diagnostic testing long after the disease is contained. As surveillance continues past the point of finding new disease cases, the laboratory will be involved with "negativity" testing so that poultry farms can repopulate and recover.

Federal and State animal health agencies should consider the extended laboratory response time when planning for resource allocation and emergency funding. Even if the laboratory is well integrated with the incident command system, its high work load may continue after the ICP has shut down. It may face a challenge in ensuring that funding is in place for personnel and supplies to support the extended testing.

The NAHLN tabletop exercises focused on the first few days of an HPAI outbreak, and spent less time on recovery issues. Still, in most of the exercises, participants raised issues about laboratory testing for marketability and proof of negativity, and concerns about the laboratory maintaining its own "market share."

For example, in one exercise, a poultry federation representative inquired about conducting marketability testing for egg-layer operations in areas of the State that were not (yet) affected by the outbreak. Could the NAHLN laboratory receive samples from these farms, which were presumed to be negative for AI, so that they could continue marketing table eggs? If so, how often could/should those farms submit samples? Quick calculations during this exercise suggested that the marketability testing could eventually overwhelm the capacity of the entire NAHLN network. This raised concerns over the delicate balance of needing to eradicate the disease while also preserving business continuity.

A number of laboratory directors expressed concern over maintaining their own lab's business continuity. If they had to re-direct routine samples during an outbreak, would they regain those opportunities afterwards? Overall, it became clear that laboratories need to be included in continuity of business planning, both for the labs' support to industry and for the labs' own recovery efforts.

## Laboratory supplies and reagents

During the exercises, laboratory representatives frequently stated that a primary concern would be maintaining sufficient amounts of supplies and reagents for PCR testing. In almost all circumstances, laboratory staff would inventory their supplies on Day 2 at the latest (and more often on Day 1 after obtaining the presumptive positive PCR result). They would order any necessary supplies and reagents, based on estimates of the expected number of samples provided from response personnel. The labs would continue to monitor their supplies and reagents throughout the outbreak response.

Most labs are constrained in some fashion by university or State regulations that limit the amount of supplies and reagents they can purchase at any given time. Such constraints would be particularly significant in the early days of the response, when the lab's workload is rapidly increasing but the response operations have not progressed to the point where a State or USDA emergency has been declared (which would ease spending constraints). Some labs have developed work-around solutions, such as having many people in the lab ordering the maximum amount that an individual can request.

Participants made a number of additional suggestions for obtaining supplies and reagents during the initial days of an HPAI outbreak. They identified alternative sources of supplies, such as the following:

- **The State public health laboratory.** Participants cautioned, however, that the public health lab could be reluctant to provide supplies and reagents if they expect an increase in human influenza testing of the worried-well once the outbreak is known to the general public. Also, the reagents used in CDC (Centers for Disease Control and Prevention) protocols for AI testing are different from those used in NAHLN protocols, so they might not be usable for animal health diagnostic testing.
- **University laboratories.** This suggestion was most common during exercises involving a university-sponsored laboratory. Research laboratories may have supplies that could be used for AI diagnostic testing, though the research programs would need to be reimbursed.
- **NVSL.** In several exercises, participants suggested that the courier who delivers the presumptive positive samples to NVSL, could bring supplies and reagents back to the laboratories.
- **Other NAHLN laboratories.** This was the default response given by most laboratories when asked how they could obtain supplies and reagents in an emergency. During a few exercises, the staff of one laboratory contacted another laboratory and made notional arrangements for supplies and reagents to be delivered.

In many exercises, participants also questioned whether laboratory supplies and reagents were available from the National Veterinary Stockpile (NVS). Currently, laboratory supplies and reagents are not available through the NVS program; however, NVS personnel are in the process of identifying which supplies should be included and how to maintain them. Exercise participants suggested that the following items be included in the NVS:

- Swabs
- Plasticware—including PCR testing plates and test tubes
- Virucidal chemicals

- PCR kits
- Sample collection kits for field responders
- Strip tests (e.g., Flu DETECT™). [17]

Exercise participants also discussed how PCR kits could be maintained in the NVS. PCR kits have a limited shelf-life, and a system would have to be developed whereby the stocks are refreshed on a regular basis. One common suggestion was for the laboratories to purchase supplies from NVS on a rotating basis so they can be used for routine testing rather than discarded. Participants also questioned whether suppliers could keep up with the expected demand, and suggested that USDA coordinate with suppliers to conduct a feasibility study.

## Bio-security

Bio-security concerns regarding sample collection and transport were a significant discussion point in most exercises. Participants noted that they would develop a transportation route that would, as much as possible, maintain clean sample-collection methods between farms. The ICP would have responsibility for developing the sample-collection plan. In some, but not all, instances, the laboratory would participate in this planning.

While a number of methods were suggested, most exercises focused on setting up centralized collection points, where field personnel would deliver samples from infected and suspected premises. Other personnel would then collect samples from the central location and bring them into the laboratory. This set-up would also minimize the amount of traffic coming to the laboratory and would facilitate additional coordination with the lab about the numbers and types of samples that would be arriving.

In most instances, participants noted they would further limit traffic flow around the laboratory and restrict access. They would also designate an area for cleaning and disinfection of transport vehicles. This would be more challenging for some labs, such as those on university

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campuses or in densely populated areas. Those participants recognized that they would need to coordinate with their respective veterinary schools and campus safety personnel to collaborate on signs, traffic flow, and the locations of curbside drop points and pressure washing sites.

In some instances, participants suggested moving the testing to a more remote area and secure location. They felt that this would alleviate some environmental health and safety concerns the university might have about potential contamination. It would also eliminate any need to impose bio-security measures or to limit transportation in the middle of the campus.

Several of the larger laboratories have the space to set up a separate receiving area for outbreak samples, but most would use the same receiving area that they use on a routine basis. Necropsies would be performed in the same area as routine samples. Participants stated that it would not be possible to perform necropsies in a hood, as the dander would foul the ventilation system.

The initial PCR tests would be done in BSL-2 spaces. However, participants were generally unsure of regulatory requirements for the use of BSL-2 or BSL-3 spaces once HPAI has been confirmed, especially if NVSL and CDC determine that testing is too dangerous for a non-BSL-3 facility. Most labs have limited BSL-3 testing and storage capabilities, and some have none. Consequently, participants discussed several options for handling samples according to BSL-3 protocols. Some of these options are:

- Coordinate with NAHLN to send samples to laboratories that do have BSL-3 capability.
- Explore strategies to inactivate samples in a biosafety cabinet so the rest of the testing can be done within BSL-2 spaces.
- Deploy portable BSL-3 laboratories from the National Veterinary Stockpile (provided that this capability is added to the NVS) or other laboratories to augment capacity.

The third option was especially appealing to participants from laboratories located on a university campus or in a populated area. They discussed the use of portable laboratory space as a general solution for alleviating a number of bio-security concerns.

# Appendix C: Lessons learned about laboratory–field coordination

Often, animal disease exercises don't fully acknowledge the laboratory component of response operations. This exercise program, with its objective of examining the integral connections between field actions and laboratory response, provided an opportunity for field and regulatory personnel to discuss the field response and identify where better coordination with the laboratory is required. Also, this was the first opportunity for many laboratory staff to participate in an exercise. Thus, the NAHLN exercise program also provided an opportunity for laboratory personnel to better understand how the lab connects with the overall response structure.

In our review and analysis of the outcomes from each exercise, we identified several overarching themes that arose in discussions about laboratory–field coordination. These themes include:

- Prioritization of samples for laboratory testing
- Transport of samples
- Integration of laboratory response into the incident command structure (ICS).

In this appendix, we synthesize the discussion points and lessons learned that arose during the NAHLN exercise program across each of these topics.

## Prioritization of samples for laboratory testing

Diagnostic samples from sites with new clinical signs were the top priority for laboratory testing in all of the NAHLN exercises. The exercises revealed, however, that the priority of other samples, such as outbreak surveillance samples from commercial facilities, backyard

farms, and wild birds, differed across the States. Participants appeared to take a number of factors into account when assessing which samples would be highest priority, and thus be processed first. These factors included:

- The types of commercial poultry operations that were affected
- The density of commercial facilities in the outbreak area
- Whether the outbreak began in a backyard farm or on a commercial facility
- The presence and volume of migratory birds (seasonal variations).

For example, since egg-layer operations need to move products daily, those outbreak surveillance samples may be given higher priority than samples from broiler operations. Also, we noted that States with a large number of commercial poultry facilities may not begin surveillance of backyard farms until the first round of commercial surveillance has been completed. Closely connected commercial facilities, such as those that are part of the same network or in close geographic proximity, may have higher priority than commercial farms that are farther away.

If the expected number of samples exceeds the laboratory's capacity, a prioritization strategy should be established. This strategy will require coordination between laboratory and field personnel. During the NAHLN exercises, we observed that laboratory staff were generally reluctant to assume or establish a prioritization strategy on their own. They would rely on field personnel or animal health officials to indicate which samples should be tested first, or whether all outbreak samples should have the same (high) priority. Alternatively, samples would likely be processed in the order in which they were received at the laboratory.

In addition, participants recognized that the sample prioritization strategy needs to align with the laboratory's requirements for overflow samples. The strategy that is developed within each State may influence requests that are made for NAHLN assistance. For example, the unified command may feel that surveillance samples from commercial

facilities should be a high priority. However, the lab may feel compelled to complete some of its routine testing before processing outbreak surveillance samples from farms that are presumed to be negative. If the lab does not have sufficient capacity to do both within the same day, some samples will need to be delayed or sent to another laboratory.

Thus, laboratory–field coordination is needed to establish a sample-prioritization strategy for each State. We observed that exercise participants frequently made assumptions about what samples should be highest priority, but that those assumptions differed among agencies and among States. In the event that the sample-testing workload does not exceed a laboratory's capacity, all of the samples can be handled in the most timely manner. Nonetheless, it is important that the lab be a part of the planning and decision process when the sample-prioritization plan is developed. As we further discuss below, integrating laboratory operations into the ICP functions could help accomplish this.

## Transport of samples

Since we conducted exercises in locations across the country, we noticed a wide variety in decisions about how to transport samples. Local geography was a factor in these plans, as was the distance to a NAHLN laboratory or to NVSL. In this section, we discuss both of these transport concerns—shipping samples to NVSL for confirmatory testing and collecting and distributing surveillance samples.

### Shipping samples to NVSL

In many exercises, the process of shipping samples to NVSL led to a lengthy discussion, particularly if participants had decided to start the exercise scenario on a Friday. Standard protocol is for the laboratory to send any samples that are presumptive positive to NVSL for confirmatory testing via FedEx. However, many laboratories are located in rural areas or on university campuses with limited options for late evening or weekend FedEx service; therefore, the samples might not be sent until the following workday. In those instances, participants identified several ways to get samples to NVSL more quickly. These included:

- Driving samples directly to NVSL, which was an option if the State is in the Midwest and if driving would take about the same amount of time as shipping by FedEx.
- Flying samples to Ames, IA, on a commercial, charter, or government aircraft.

There is another option for getting high-priority samples to NVSL, which was discussed at only one of the NAHLN exercises. USDA-APHIS has a contract in place with FedEx, called the White Gloves service. This contract essentially makes FedEx available anytime/anywhere to pick up a package and deliver it overnight. It is costly, and USDA-APHIS recommends that it be used only for high-priority samples and/or when there are no other options. The contract is managed through the National Veterinary Stockpile. To use this service, the State Veterinarian and USDA AVIC need to request it.

## Delivery of outbreak surveillance samples to the laboratory

A frequent topic of discussion during the exercises was collection and delivery of samples to the NAHLN laboratory. Laboratory staff commented that communication from the field staff about the number and priority of samples to expect, such as a phone call from the ICP, would assist the laboratory in preparing the extraction processes, and cut down on the time necessary to run the tests once samples are received. Further, laboratory participants stressed the importance of scheduling sample collection and delivery so as to maximize the number of samples run at a time (so that the samples could be "batched" for PCR testing). Again, laboratory–field coordination would be critical for handling samples in the most efficient way.

During several exercises, participants proposed setting up sample collection stations as a means to minimize bio-security concerns. Other advantages of these stations are that the samples are collected in batches, and that a courier can call the lab when he/she reaches the collection station. In addition, some States (such as Alaska, California, and New Mexico) have courier services already established. These services are especially helpful in large States, and can be shared with the State department of health, so that samples from remote areas can be brought to the State laboratories.

Another transport concern arises when outbreak samples are sent to another State for testing. Participants at several laboratories were unsure of the processes required to send potential HPAI samples across State lines, including any bio-security requirements that would need to be made by both the shipping and receiving laboratories. Though this may be handled in the same way that samples are packaged and shipped to NVSL for confirmatory testing, the timeframe is important. After the first samples have been confirmed, subsequent samples may fall under "select agent" rules from the Department of Homeland Security, which impose further transport and handling regulations.

## Integrating laboratory response into the incident command structure

During the NAHLN exercises, a number of arrangements were mentioned for coordination between the laboratory and the unified command. We grouped these into three categories, listed here with increasing levels of coordination between the laboratory and the incident command post (ICP).

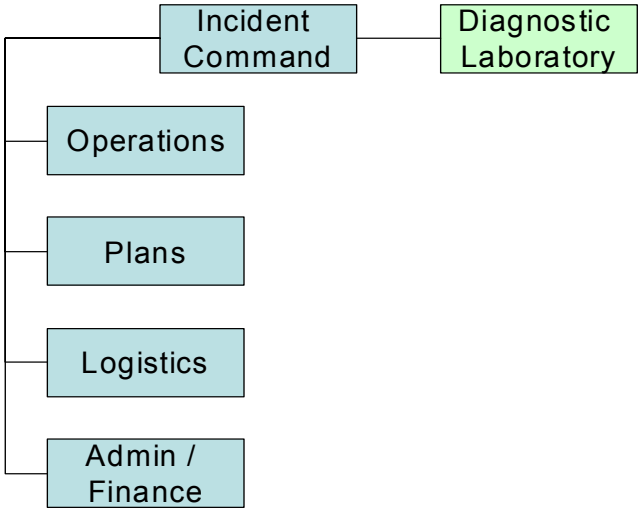
- The laboratory operates separately from the ICP, and the laboratory director communicates directly with the State animal health officials and the AVIC, who, in turn, communicate with the ICP.
- The laboratory designates a staff member to serve as the "laboratory liaison" at the ICP. In this case, either:
  - — the laboratory director still communicates directly with the State animal health officials and AVIC, or
  - — the laboratory liaison communicates directly with the incident commander(s) (who may be the State animal health official and/or the AVIC).
- Laboratory operations are fully integrated into the incident command system by including laboratory response needs in the Operations, Logistics, Planning, and Administration/Finance sections of the ICP.

Below we discuss each of these coordination levels in further detail and provide some examples from the NAHLN exercise program.

**Many labs operate separately from the ICS**

In many of the States that we visited, the HPAI response plan and/or ICS chart does not directly mention the laboratory. In these cases, communication between the laboratory and the ICP usually flows through the State animal health official and/or the AVIC, as shown in figure 6. For example, the laboratory director communicates directly with the State animal health official and the AVIC (usually through conference calls) and then those lead officials communicate with the ICP. This appears to be a "status quo" arrangement that mirrors communication lines that are in place for day-to-day operations. However, it may present challenges as the laboratory becomes involved with outbreak response.

Figure 6. Laboratory functions separated from incident command




With this arrangement, the laboratory functions largely as a stand-alone entity that supports the field response operations. For example, some exercise participants mentioned that laboratory results would be faxed to the AVIC's office, where they would be entered into the

EMRS database that is used to manage field operations. In another example, the laboratory director and the State animal health official would work together to identify which types of samples were highest priority and should be tested first. The State animal health official would then discuss this prioritization request with the ICP and relay it to field responders.

If the lab is mostly separate from the ICS, requests for additional resources would be made through one of three pathways:

- The laboratory director would make requests for personnel or other resources through NAHLN.
- The State animal health official would make requests for resources from other State agencies.
- The State animal health official and AVIC would make requests for resources from USDA-APHIS (for example, from the NVS).

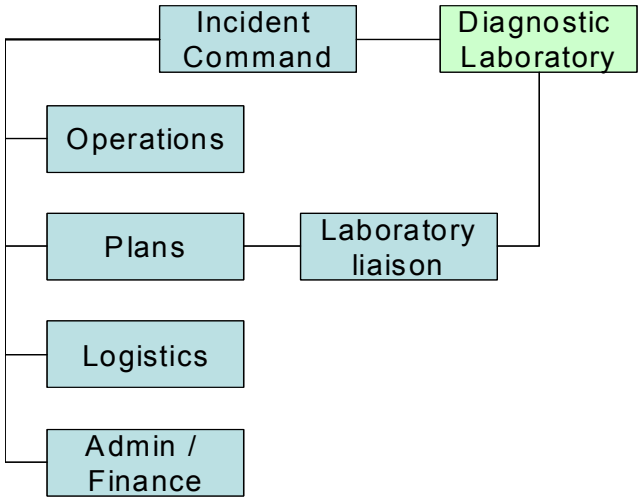
As a result, this coordination arrangement may require a greater level of communication between personnel within USDA-APHIS to ensure that the laboratory's resource needs are met, because those links are not as likely to be made within the ICP. For example, the laboratory director may have a need for additional NAHLN-trained personnel and personal protective equipment (PPE) for them to wear. These requests would be made separately if the laboratory director communicates with the NAHLN Coordinator (to request personnel) and the AVIC communicates wtih the NVS Director (to request PPE).

Also, if the laboratory is part of a university system, it may not have a direct link to communicate with other State agencies about its resource needs and may have to go through the State animal health official in order to do so. This concern arose in a number of exercises, with some participants questioning even whether all laboratory personnel would know about the outbreak. Alerts and notification messages that are sent to State agencies, or through the State EOC, may not automatically reach a university laboratory. Also, branch labs may not hear about HPAI samples tested at the main laboratory, or personnel in research divisions may not be aware of high-priority diagnostic testing that is taking place.

**Some labs identify a connection point between the laboratory and the ICP, such as a lab liaison**

One lesson that is frequently mentioned from the 2002–03 outbreak of exotic Newcastle disease (END) in the southwestern United States is the need for a laboratory liaison to serve in the ICP. During the END outbreak, the California Animal Health and Food Safety (CAHFS) laboratory had a staff member work directly with the ICP to conduct training on sample collection and packaging, to relay laboratory concerns to the incident commanders, and to respond to questions that field responders had about laboratory operations. This proved to be a useful practice and has been replicated in subsequent response operations. Several other States have similarly identified this position in their ICS organization chart for animal disease outbreaks. In general, States that have conducted a number of animal health response exercises and/or have had outbreaks of foreign animal diseases are most likely to have designated a "laboratory liaison" who serves in the ICP and provides a connection point between the field operations and the laboratory (figure 7).

Figure 7. Laboratory functions partially integrated with incident command



The lab liaison usually serves in the Planning section of the ICP and is a connection point and conduit for information flow between the laboratory and the ICP. The communications with lead officials can follow either of two pathways:

- The laboratory director still communicates directly with the State animal health official and AVIC.
- The laboratory liaison communicates directly with the incident commander(s) (who may be the State animal health official and/or the AVIC).

This coordination arrangement better facilitates a shift in communication from day-to-day situations to an outbreak response. In some States, the personnel identified to be incident commanders are the State animal health official and/or the AVIC—in this case the two pathways would essentially be identical. However, an APHIS incident management team (IMT) might be called upon to help manage field operations as the outbreak expands. If the incident command team changes, the lab liaison may need to work with both the new incident commander(s) and the lead regulatory officials (State animal health official and AVIC) in that State. The lab liaison would then communicate directly with the laboratory about changes taking place at the ICP.

With this arrangement, the lab liaison can help establish sampling and testing priorities more directly with the field responders, by working with the Operations or Planning section chiefs. The operational cycle (or "battle rhythm") of the laboratory can also be better matched to the operational cycle of the ICP. Similarly, the lab liaison can work with the Operations and Planning sections to design a sample collection and transport strategy that is better aligned with laboratory operations and requirements. Other roles and responsibilities discussed during the exercise include training field personnel on the proper ways to collect samples, and developing a surveillance plan, which would include route management, bio-security, handling, documentation, and transportation of samples.

It is also important to recognize that the lab liaison does not need to be someone from the laboratory. In fact, most laboratories will need all their personnel to manage the influx of samples and the accompanying

data management requirements. That said, the lab liaison should be someone who has a working knowledge of laboratory operations and is able to effectively communicate laboratory requirements to the ICP. If the lab liaison is filled by someone from the laboratory staff, he/she should be familiar with ICS (and probably has received some formal ICS training) and with the State AI response plan.

For those States that use this response management architecture, participants still expected that the lab would be responsible for maintaining its resource requirements, including ordering laboratory supplies, PCR kits, and personal protective equipment, as well as coordinating with NAHLN and other laboratories for additional personnel. However, as the exercise progressed, players recognized that there would be some benefit to having the laboratory more fully integrated into the ICS.

**A few labs are more fully integrated into the ICS**

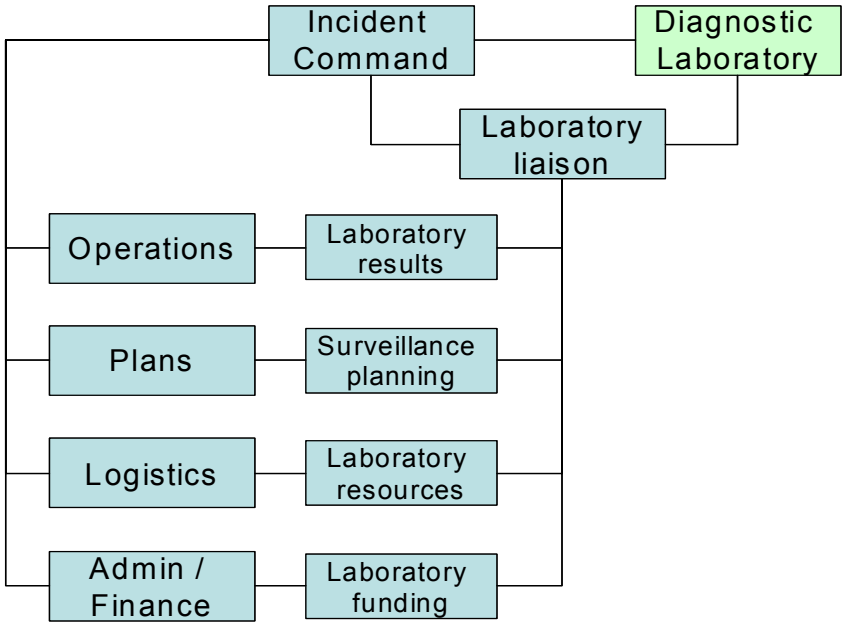
Only a handful of States mentioned that the ICP would be primarily responsible for handling resource requests for the laboratory. This was generally seen as a benefit to laboratory personnel: those who are responsible for testing could continue with that work in the face of an outbreak and wouldn't need to spend time ordering reagents or supplies. However, this arrangement requires a greater level of coordination between the laboratory and the ICP.

With this coordination arrangement, the laboratory operations are potentially connected with all sections of the ICP, and not just with a single seat in the Planning section (figure 8). For example, the laboratory can work with the ICP's:

- Planning section, for epidemiology and surveillance strategies
- Operations section, for collecting samples and setting priorities for which samples to send to other laboratories
- Logistics section, for working out sample transport and packaging requirements
- Administration and Finance section, for tracking laboratory expenses and resource requests.

This coordination arrangement may require ICP personnel, such as those as in the Logistics section, to communicate directly with NAHLN for resource ordering. They may not be aware of the resources that are available from NAHLN or NVSL, or of the constraints associated with scientific testing. They may also be more likely to consider other sources, such as EMAC (Emergency Management Assistance Compact) agreements or in-State options, such as National Guard Civil Support Teams, to fulfill the requests. For example, participants in a couple of exercises mentioned the possibility of requesting additional laboratory resources from neighboring States through an EMAC agreement. It was unclear how, or whether, those requests would be coordinated with NAHLN.

Figure 8. Laboratory functions fully integrated with incident command




Similarly, ICP personnel may be involved with tracking laboratory expenses, to include reimbursement requests to be submitted after the situation has been declared to be an emergency. This may help the laboratory regain some of its expenses for handling outbreak samples, but will require that ICP personnel understand how to document

laboratory expenditures. To continue with an example mentioned previously, a request for NAHLN-trained personnel and for their PPE could be coordinated in the ICP rather than at USDA-APHIS. This would also require the State animal health official to include expected laboratory expenses in the budget that is put together for managing the outbreak response. Therefore the lab directors should coordinate with their respective State animal health officials to develop an emergency budget for laboratory expenses prior to an outbreak situation. One suggestion was for the lab to develop a tiered-type budget with different activation levels depending on the severity of the outbreak.

Players in several exercises identified two additional obstacles to more fully integrating the lab into the ICS architecture:

- The National Incident Management System (NIMS) requires a resource-typing system, to ensure that the requested resources match the required resources. At this time, there is no system of national standards in place for animal health laboratory resources.
- The interface between NIMS and resource providers, such as NAHLN and NVS, is still in development. A significant amount of education would need to take place in order to ensure that the two structures understand each other.

Although none of the laboratories that we visited has full integration with the ICP, many are on a path to doing so. A few States have also developed a separate ICS organizational chart for the laboratory, with identified connection points for how that chart fits within the overall ICS. Reportedly, this has worked well, and might be a better arrangement for university laboratories that are not as easily integrated into the State's emergency response system.

# Appendix D: Lessons learned about notification and communication

Throughout the NAHLN exercise program, participants recognized opportunities to increase their effectiveness by calling on the support of response partners when necessary and appropriate. They also created new relationships among organizations and levels of government. To reach these objectives, the game design emphasized the need for communication, timely notification, and information sharing between the laboratory and the field, and among all response partners.

In our review and analysis of the outcomes from each exercise, we identified several overarching themes that arose in discussions about notification and communication. These themes include:

- Activation of NAHLN
- Information management
- Interagency support.

In this appendix, we synthesize the discussion points and lessons learned that arose during the NAHLN exercise program across each of these topics.

## Activation of NAHLN

One of the analysis threads that we looked at during the exercise program was the "activation" of NAHLN. This is currently defined as:

> The implementation of the state of readiness and the commitment to perform diagnostic tests up to the capacity of the laboratory as required by Federal and State officials to meet the needs for diagnostic services to contain, control, eradicate and recover from a disease event.

The NAHLN activation plan is written with foot and mouth disease (FMD) in mind, and assumes that NVSL will diagnose the first case since NAHLN laboratories do not have the reagents and/or authority to fully test for FMD. With avian influenza, a NAHLN lab will be able to make a presumptive diagnosis of whether the AI virus is present, and whether it is type H5 or H7. State officials may take response actions at this point (before NVSL has confirmed the diagnosis), which could include implementing the laboratory's "state of readiness" for further diagnostic testing.

Indeed, in almost all of the exercises in this program, we heard participants say they would take a number of steps following presumptive diagnosis, such as to conduct inventories of supplies and reagents, develop staffing plans, and enhance their bio-security measures. In some instances, commercial facilities would even begin 3D operations, and some States can provide indemnity funding based on a presumptive positive diagnosis.

All of these steps may take place before NVSL receives samples from the index case and before any other NAHLN laboratories are aware of the potential outbreak. Thus, it seems inaccurate to say that the entire laboratory network would be activated at this point, even though one of the NAHLN laboratories has implemented its state of readiness to perform diagnostic tests up to its own capacity.

Instead, during the exercise program we identified three other possible definitions of NAHLN activation that could apply shortly after an individual laboratory reaches a presumptive diagnosis of AI. These definitions are as follows:

- NVSL delegates authority to one of the NAHLN labs to conduct outbreak surveillance testing for samples within the identified outbreak area (after the first case is confirmed by NVSL for each new outbreak area). This means that new samples originating from the outbreak zone would be considered positive if the results of the screening tests conducted at the NAHLN laboratory are positive. This authority will most likely be delegated to the laboratory that handled the initial/index samples from the outbreak. In this way, NAHLN is activated because NVSL

has delegated authority to a member laboratory, and may put other laboratories on alert for future activation.

- The NAHLN Coordinator designates other NAHLN labs to assist the laboratory that is primarily responsible for handling samples from the identified outbreak area. This means that other NAHLN laboratories implement their own state of readiness to perform diagnostic testing on outbreak samples. In this way, the network is activated because additional member laboratories will help meet Federal and State needs for diagnostic services.
- The NAHLN Coordinator requests personnel from other member laboratories to help a lab that requires assistance. This means that personnel who are trained and proficiency-tested in NAHLN-approved methods for HPAI testing will travel to another laboratory to increase its throughput capacity. In this way, the network is activated because NAHLN is relying on the breadth of trained personnel among all member laboratories.

The first stage described above further extends, and perhaps provides a more concrete definition for, what it means when an individual lab is activated. But does it also mean that the network is activated? The other definitions listed above involve more than just a single NAHLN laboratory. However, the second and third possible definitions did not always manifest during exercise play. In some cases, the primary laboratory wasn't overwhelmed, and didn't need to request assistance for diagnostic testing. In most cases, lab directors chose to take one action or the other, but generally not both.

For example, not all labs can provide work space for additional personnel because of facility limitations. Instead, the lab director could choose to send samples to another laboratory. By doing so, the primary laboratory could preserve its capacity for handling routine samples along with outbreak samples. Alternatively, some labs have sufficient space for additional personnel and would request those staff from NAHLN. By doing so, they could keep all of the outbreak samples within the State and at the same laboratory.

A fourth option also arose during the HPAI exercises. Some laboratories would elect to keep the outbreak samples but send out some of their routine testing (this is discussed in more detail in Appendix B). This option doesn't appear to fit the definition of NAHLN activation, which is intended to "meet the needs for diagnostic services to contain, control, eradicate and recover from a disease event." Instead, the NAHLN activation plan obligates member laboratories to individually address "managing the routine diagnostic case load or re-directing it to another laboratory." Thus, it doesn't appear that NAHLN activation is intended to apply to the case of a member laboratory requesting NAHLN assistance with routine testing while the requesting laboratory conducts the outbreak testing. However, 40 percent of the laboratories that participated in this exercise program would have chosen this option. This raises a question of whether NAHLN should assist member laboratories with finding alternate means for completing routine testing during an outbreak.

Another point of confusion during the exercise program was whether NAHLN would provide funding to a member laboratory once it is formally activated. Exercise participants assumed that NAHLN would pay travel and salary expenses for additional personnel, and that the primary laboratory would continue to receive funding for processing the samples, in order to help pay for supplies and facility costs. Alternatively, participants assumed that NAHLN would pay for sending the outbreak samples to other member laboratories. Further, participants were unclear as to who would provide funding to laboratories to run routine samples that have to be sent out to other labs.

## Information management

When samples arrive at a laboratory, they are assigned a unique accession number and entered into the laboratory information management system (LIMS). However, the accession number does not correspond with the USDA premises identification (PremID) number coded into the USDA Emergency Management Response System (EMRS), which is used to track information about field operations. Therefore, the only way to correlate samples between the laboratory and the field is typically through other information on the label, such as the name or address, which can be difficult to read and

transcribe. Further, the PremID corresponds only to the address and therefore may not be specific enough if samples are collected from multiple houses at the same location.

Exercise participants suggested several common solutions to better correlate premises identification with their laboratory results. These included:

- Developing a barcoding system to record the laboratory accession number, the address, the USDA PremID and the laboratory's identification number. This would require the laboratory or State animal health agency to maintain a stock of sample collection kits with labels that are pre-printed with accession numbers that are already assigned. Those kits would then be distributed to field personnel. Finally, while most laboratories already use a barcoding system for wild-bird samples, many field personnel do not have barcoding equipment and would require training on the systems prior to use.
- Revising LIMS databases. Participants also agreed that their LIMS databases need to be revised, to include a section to be filled out during an emergency. It would include the address, PremID, and GPS coordinates for the specific location at which samples were collected.

Currently all NAHLN laboratories have the potential to link their LIMS database with the NAHLN repository, either via web-based entry or electronic messaging. However, the NAHLN repository cannot interface electronically with EMRS. Therefore, during an outbreak the NAHLN laboratories would need to relay laboratory results to the unified command team via an alternative protocol set up just for the emergency, such as by phone call or fax. Laboratory results would then be entered by hand into EMRS. It is our understanding that NAHLN and USDA-APHIS personnel are already developing solutions for this issue.

Finally, participants were unclear as to the information management chain if outbreak samples need to be sent to an out-of-State NAHLN laboratory. There was no consensus on whether samples in this situation would be accessioned first at the laboratory in the State with the

outbreak and then sent to another lab, or whether they would be sent directly from the field to the out-of-State lab. There was general agreement that it would be more efficient to send samples directly from the field, but in some exercises there was concern as to whether those samples would be packaged and shipped properly. All agreed that this decision would be made by State and Federal regulatory officials at the time of the emergency.

Further, once the samples have been sent to an out-of-State laboratory, participants were unclear as to what process would be implemented to send test results back. Most participants agreed that once an ICP was established, results for outbreak samples would be sent there. However, it was unclear whether those results would also be sent to regulatory officials in the State that did the testing. This is further complicated when routine samples are sent out-of-State for testing.

Some participants indicated their preference for sending samples to other laboratories that use the same LIMS database. However, they were unsure whether they would have authority to choose which State to send samples to, or whether NAHLN would be responsible for that decision. For example, officials in Indiana said they prefer to send overflow outbreak samples to Kentucky, since both States use the same LIMS database. However, the question was raised whether NAHLN would choose to send the samples to a different State because the Kentucky laboratory might start receiving an increased number of surveillance samples as well.

## Interagency support

Officials from a variety of government and private agencies, at the Federal, State, and local levels, participated in the NAHLN exercise program. Interagency representation depended largely on whom the exercise hosts had invited to participate. In some cases, the exercise included only participants from the State animal health agency, USDA, and the NAHLN laboratory. In most cases, the exercise included participants from other State-level agencies, such as the:

- State department of health
- State emergency management agency

- State department of natural resources / conservation / wildlife.
- State poultry federation (or industry representatives).[18]

Any additional Federal personnel present usually represented the USDA-APHIS Division of Wildlife Services. One of the exercises (in Wisconsin) included participants from several additional Federal agencies, including the Department of the Interior (DOI), Federal Bureau of Investigation (FBI), U.S. Agency for International Development (USAID), and Food and Drug Administration (FDA).

In this section we describe the types of questions and discussion points that arose when different agencies participated in the exercise, and the primary contributions that those agencies offered for HPAI eradication and recovery.

## Department of health

Representatives from the State and / or local department of health (DOH) participated in 25 out of the 38 NAHLN exercises. DOH officials tended to raise such exercise questions as:

- When will our agency be notified?
- What steps are taken at a commercial poultry farm to identify, investigate, and eradicate the disease?
- How can we take part in field investigations to:
  - collect epidemiological data?
  - query bird owners about the health of people in their household?
  - protect the health and safety of animal health responders?

The exercise served to educate many DOH representatives on commercial poultry operations and the bio-security measures that are already in place to protect birds, and farm personnel, from illness. We

18. While a poultry federation is not an State agency per se, these organizations are included here because they represent poultry operators across the entire State.

observed DOH officials asking industry personnel a number of questions. The opportunity for this interaction was frequently noted on participants' feedback forms as a benefit of attending the exercise.

DOH officials offered several types of assistance for HPAI eradication and recovery, such as:

- Monitoring the health of field responders and laboratory personnel
- Providing anti-viral medications for prophylaxis of field responders and laboratory personnel
- Establishing call-in lines to answer questions from the general public
- Providing epidemiologists
- Providing personnel and supplies to assist the animal health laboratory.

Animal health officials usually accepted the offers of assistance with outbreak epidemiology, public communication, and anti-viral medications. Public health personnel often volunteered assistance in terms of reagents or trained personnel, but those resources would not meet NAHLN requirements. For example, CDC protocols for AI testing focus only on the strains that are considered most likely to spread to humans. USDA protocols focus on strains that must be reported to trading partners. Also, a number of animal health officials noted that the public health laboratories in their States refuse to accept any animal samples.

In some cases, the State animal health laboratory and public health laboratory share the same building, or are nearby. In these situations, participants often noted that several personnel in both laboratories had been cross-trained and thus could assist in the HPAI diagnostic testing.

## Emergency management agency

Seven out of the 38 exercises included representatives from the State emergency management agency (EMA). In some cases, the exercise

served to increase the awareness of emergency management officials about an animal health outbreak. At other exercises, it was evident that the EMA regularly partners with the animal health agency. When emergency management officials were present, they tended to raise such questions as:

- When will our agency be notified?
- How can we (the EMA) help coordinate the HPAI response?
- What resources will the animal health agencies want to request from other State agencies?

EMA officials offered to help coordinate the response, either through the State EOC or by being part of the ICP that was established by the animal health agency. They felt the EMA should be a conduit for requests for assistance (RFAs) from other State agencies. For example, if the animal health responders needed trucks to haul 3D supplies, the EMA could coordinate a mission assignment to the State department of transportation. The EMA officials would know what other types of resources were available and how to access them.

In a few exercises, State EMA officials suggested using Emergency Management Assistance Compact (EMAC) agreements with other States as a means of obtaining additional resources. For example, they inquired about getting the following assets through an EMAC:

- Laboratory supplies, such as plasticware or reagents
- Personnel to assist in the laboratory
- Foaming machines for depopulation.

In turn, this raised questions about how NAHLN requirements would be met for the requested laboratory resources. Most of the EMA officials were not familiar with NAHLN. As a result, they might not understand the need to find additional laboratory staff that are trained and proficiency-tested in NAHLN protocols for AI testing. In Appendix C, we discussed how these resource requests might be handled if the EOC or ICP were to communicate directly with NAHLN leadership.

## Department of natural resources / wildlife

Representatives from the State and / or Federal agency responsible for wild birds participated in 19 out of the 38 exercises. These participants were much more familiar with HPAI response than either the DOH or EMA participants, because of the ongoing nationwide surveillance of wild birds for AI. They were also trained in handling birds and offered assistance in a variety of ways, such as:

- Collecting samples from live birds
- Assisting with depopulation of an affected flock
- Hazing wild birds away from commercial poultry farms
- Monitoring the health of wild birds in the outbreak area.

Animal health officials most often accepted the offers of assistance from wildlife agency participants. Some noted that wildlife specialists might not be able to assist with mass depopulation of commercial poultry because they are trained to handle individual birds, but that they could be very helpful with handling backyard flocks or game birds. Similarly, their training and experience with collecting samples from wild birds could be used to expand the surveillance efforts.

In some cases, wildlife officials noted that they would increase surveillance sampling among wild birds in the outbreak area as a result of the HPAI diagnosis among commercial poultry. This raised questions about how those extra samples would be tested—a topic that is discussed in more detail in Appendix B.

## State poultry federation

Fourteen out of the 38 exercises included representatives from a State poultry federation, or other representatives from the poultry industry. Typically the poultry industry took an active role in the field response as well as incident management. In response to an outbreak, commercial operators would enact enhanced bio-security measures. In some States, industry personnel are also responsible for collecting surveillance samples from their facilities and delivering them to the laboratory. When industry officials were present, they tended to raise such questions as:

- How should we coordinate to get samples to the laboratory?
- What types of samples are most appropriate for laboratory testing?
- How can we get additional supplies?

Industry representatives also provided information to other exercise participants about general practices within their industry, such as biosecurity measures, the roles of company veterinarians, and how they would manage disease eradication within their own facilities. They stressed the importance of timely test results for decisions they would make within the industry network. Many had surveillance plans already in place, or suggested them during the exercise, to help the industry maintain its continuity of business as much as possible.

## Interagency notification

Overall, interagency participants were most concerned about when they would be notified of the situation. We found wide differences in plans to notify other State agencies about the potential HPAI outbreak, and in the times at which that communication would take place. Notification is most likely to occur at one of three points in the outbreak response:

- Following the presumptive diagnosis of AI at the NAHLN laboratory, because the other agencies are included in a standard notification chain that is already in place
- When animal health responders want to tap into State resources, such as a Governor's jet for taking samples to NVSL or anti-viral medications for prophylaxis of laboratory staff
- After confirmation of HPAI from NVSL and shortly before any public announcement is made by USDA.

Most officials wanted to be notified as soon as possible, so they would be prepared to manage the impact of the outbreak on their own agency responsibilities. For example,

- DOH officials wanted to be notified as soon as possible, because they felt that this was necessary to protect public health. They

also wanted to be able to be prepared to handle phone calls and other inquiries from the general public about the possibility of human influenza resulting from the AI outbreak.

- EMA officials wanted to be notified so that they could respond to RFAs from other State agencies as quickly as possible.
- Wildlife officials wanted to be notified as soon as possible so that they could increase surveillance of wild birds in the vicinity of the index site.
- Industry officials wanted to be notified as quickly as possible so that they could increase bio-security measures at all facilities sharing the same network and begin increased surveillance.

When animal health officials said notification of other State agencies would be delayed, we observed a number of reasons for doing so. These reasons included concerns that:

- The agency is not allowed to release information about positive test results until it is confirmed by NVSL.
- Information would be released to the general public and generate fear of a pandemic influenza outbreak.
- Other agency priorities would interfere with, or put restrictions on, the animal health response.

Overall, the exercise program helped laboratory staff and State animal health officials become more aware of support that could be available from interagency partners. These contributions, and information on how to officially request them, can be included in emergency response plans. USDA-APHIS should be aware that notification of State-level interagency partners will occur at different times, based on plans that are in place in each State.

# Appendix E: Summary tables

In total, we conducted 38 exercises from February to October 2008. Overall, more than 700 participants, representing 45 States and numerous Federal agencies, participated in the exercise program. The date of the exercise, participating laboratories, and total number of participants are shown below in Table 1. A breakdown of participating agencies is shown in Table 2.

Table 1. Dates and participating laboratories for the NAHLN exercise program

| Exercise date (2008) | Participating NAHLN laboratories | Number of participants |
|---|---|---|
| February 11 | Iowa State University Veterinary Diagnostic Laboratory | 19 |
| February 14 | Ohio Department of Agriculture Animal Disease Diagnostic Laboratory | 22 |
| April 28 | University of Missouri Veterinary Medical Diagnostic Laboratory | 10 |
| April 29 | Illinois Department of Agriculture Centralia Animal Disease Laboratory and Galesburg Animal Disease Laboratory | 16 |
| May 5 | Arizona Veterinary Diagnostic Laboratory | 16 |
| May 9 | University of Georgia Veterinary Diagnostic Laboratory,<br>Athens Veterinary Diagnostic Laboratory,<br>Tifton Veterinary Diagnostic Laboratory, and<br>Georgia Poultry Laboratory | 19 |
| May 13 | Thompson Bishop Sparks State Diagnostic Laboratory (Alabama) | 22 |
| May 14 | Mississippi Veterinary Research and Diagnostic Laboratory | 10 |
| May 15 | Louisiana Veterinary Medical Diagnostic Laboratory | 19 |
| May 16 | Purdue University Animal Disease Diagnostic Laboratory (Indiana) | 18 |
| May 19 | Harrisonburg Regional Animal Health Laboratory (Virginia) | 18 |
| May 28 | Nebraska Veterinary Diagnostic Center | 11 |
| May 29 | Kansas State Veterinary Diagnostic Laboratory | 35 |
| May 29 | Washington Animal Disease Diagnostic Laboratory,<br>Avian Health and Food Safety Laboratory (Washington), and<br>Idaho Department of Agriculture Animal Health Laboratory | 23 |
| June 3 | Hawaii Department of Health State Laboratory Division | 12 |
| June 10 | Oregon State Veterinary Diagnostic Laboratory | 14 |

Table 1. Dates and participating laboratories for the NAHLN exercise program

| Exercise date (2008) | Participating NAHLN laboratories | Number of participants |
|---|---|---|
| June 13 | South Dakota Animal Disease Research and Diagnostic Laboratory and North Dakota Veterinary Diagnostic Laboratory | 11 |
| June 16 | Moorefield Animal Health Diagnostic Laboratory (West Virginia) | 19 |
| June 26 | Animal Health Diagnostic Center at the Cornell University (New York), New Jersey Department of Agriculture Animal Diagnostic Laboratory, Pennsylvania Veterinary Laboratory, and Pennsylvania State University Animal Diagnostic Laboratory | 20 |
| June 30 | Michigan State University Diagnostic Center for Population and Animal Health | 26 |
| July 22 | Rollins Diagnostic Laboratory (North Carolina) | 24 |
| July 25 | Wyoming State Veterinary Laboratory, Colorado State University Veterinary Diagnostic Laboratory, and Montana Veterinary Diagnostic Laboratory | 23 |
| July 29 | California Animal Health and Food Safety Laboratory and Nevada Animal Disease and Food Safety Laboratory | 16 |
| August 1 | Wisconsin Veterinary Diagnostic Laboratory and USGS National Wildlife Health Center | 34 |
| August 7 | Kissimmee Diagnostic Laboratory (Florida) | 12 |
| August 12 | Murray State University Breathitt Veterinary Center (Kentucky) | 23 |
| August 13 | New Mexico Veterinary Diagnostic Services | 18 |
| August 14 | CE Kord Diagnostic Laboratory (Tennessee) | 25 |
| August 18 | Arkansas Livestock and Poultry Commission Laboratory | 21 |
| August 25 | Environmental Health Laboratory (Alaska) | 9 |
| Sept 11 | Connecticut Veterinary Medicine Diagnostic Laboratory | 14 |
| Sept 17 | University of Illinois College of Veterinary Medicine Veterinary Diagnostic Laboratory | 11 |
| Sept 18 | Utah Veterinary Diagnostic Laboratory | 15 |
| October 1 | University of Minnesota Veterinary Diagnostic Laboratory | 15 |
| October 2 | Clemson Veterinary Diagnostic Center (South Carolina) | 12 |
| October 7 | Oklahoma Animal Disease Diagnostic Laboratory | 9 |
| October 14 | University of Delaware Poultry Laboratory, Charles C. Allen Biotechnology Laboratory, and Maryland Department of Agriculture and Animal Health Laboratory | 43 |
| October 17 | Texas Veterinary Medical Diagnostic Laboratory (College Station) | 23 |
| TOTALS | | |
| 38 exercises | 54 laboratories | 707 participants |

Table 2. Interagency participation in the NAHLN exercise program

| | Participating agencies | | | | | |
|---|---|---|---|---|---|---|
| Exercise location | USDA APHIS | State animal health agency | State (or local) public health agency | State (or Federal) wildlife agency | State emergency management agency | Industry organization |
| Alabama | X | X | | | | X |
| Alaska | X | X | | X | X | |
| Arizona | X | X | X | X | | |
| Arkansas | X | X | X | X | X | X |
| California and Nevada | X | X | X | | | |
| Colorado and Wyoming | X | X | X | | | X |
| Connecticut | X | X | | X | | |
| Delaware and Maryland | X | X | | X | | X |
| Florida | X | X | | | | |
| Georgia | X | X | X | | | X |
| Hawaii | X | X | X | X | | |
| Illinois | X | X | X | | X | |
| Illinois - UIUC | X | | | X | | |
| Indiana | X | X | X | X | | X |
| Iowa | X | X | | | | |
| Kansas | X | X | X | X | X | |
| Kentucky | X | X | X | | | X |
| Louisiana | X | X | X | | | |
| Michigan | X | X | X | X | | X |
| Minnesota | X | X | | | | X |
| Mississippi | X | X | | | | |
| Missouri | X | X | X | | | |
| Nebraska | X | X | X | | | X |
| New Mexico | X | X | X | X | | |
| New York, New Jersey, Pennsylvania | X | X | X | | | |
| North Carolina | X | X | X | | X | X |
| Ohio | X | X | X | | | X |
| Oklahoma | | X | X | X | | |
| Oregon | X | X | | | | |
| South Carolina | X | X | X | X | | |

Table 2. Interagency participation in the NAHLN exercise program

| | Participating agencies | | | | | |
|---|---|---|---|---|---|---|
| Exercise location | USDA APHIS | State animal health agency | State (or local) public health agency | State (or Federal) wildlife agency | State emergency management agency | Industry organization |
| South Dakota | X | X | | X | | |
| Tennessee | X | X | X | X | X | X |
| Texas | X | X | | | | |
| Utah | X | X | X | X | | |
| Virginia | X | X | X | | | X |
| Washington | X | X | | X | | |
| West Virginia | X | X | X | X | | X |
| Wisconsin | X | X | X | X | X | X |

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