APHL All Member Call:
Highly Pathogenic Avian Influenza A(H5N1)
May 13, 2024

Call Summary

Contact for Questions or Suggestions
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Slides presented during this call are available here.

Update on Federal Funding and CDC Activities (*Nirav Shah, MD, JD, CDC)*
On Friday, May 10, 2024 HHS announced new funding investments through CDC and FDA totaling $101 million to mitigate the risk of H5N1 and continue its work to test, prevent and treat H5N1. FDA's portion is roughly $8 million, largely for milk and dairy testing. CDC has six areas they are focusing on with their $93 million: 1) scale up monitoring of individuals who may have been exposed to infected animals or animal products, 2) characterization of additional clinical specimens through enhanced surveillance, 3) expanding wastewater testing, 4) assessing the circulating H5 viruses, 5) improving influenza diagnostic manufacturing, storage and distribution and 6) continued work assessing the viability of existing candidate vaccine viruses.

CDC would like to increase influenza surveillance and subtyping of circulating influenza over the summer months. Guidance will be forthcoming to both commercial clinical laboratories and public health laboratories.

Overview of USDA's National Animal Health Laboratory Network *(Christina Loiacono, USDA)*
The National Animal Health Laboratory Network (NAHLN) was established in 2002 as a partnership between two groups within USDA: the Animal and Plant Health Inspection Service (APHIS) and the National Institute for Food and Agriculture (NIFA) in partnership with the American Association of Veterinary Laboratory Diagnosticians. The partnership identified 12 laboratories around the country that already had infrastructure and expertise on hand to establish surveillance testing for some high consequence animal diseases. The network now has 63 laboratories in 42 states, primarily animal diagnostic laboratories, but one of the NAHLN laboratories in Pearl City, Hawaii is a public health laboratory.

There are five level designations for laboratories in the network. Level one is the highest performing and takes on the most responsibility and are fully accredited by a 3rd party auditor for their quality systems and have BLS-3 facilities.

Since the HPAI outbreak began in 2022, all laboratories activated to test are providing those test results in real time through electronic message in the HL7 format. NAHLN laboratories are providing high throughput screening tests for disease under our scope, including HPAI. Any non-negative results coming out of a NALHN laboratory must be sent to the national reference laboratory for that disease, either in Ames, Iowa or Plum Island, New York for confirmatory testing.

Fifty-six of our laboratories are activated for HPAI and have provided about 5,000 PCR results for cattle testing so far, with 42 cases across the country in 9 states that have been confirmed. A federal order came out on April 29th requiring that any dairy cattle that are lactating have a negative test for pre movement within 7 days of movement and that testing must be done at a NALHN laboratory. Laboratories must report positive influenza A, either nucleic acid, molecular detection or serologic detections.

NALHN is looking at testing cats as there have been a handful of cats on some of these affected dairies that present with neurologic signs. We have seen the mammalian species with neurologic signs associated with poultry outbreak, but we wanted to go back and look at some rabies negative cat samples and test them for HPAI. We did that in in Kansas and got a good number of rabies negative cats tested for influenza, all of which were negative. If PHLs have cat samples on hand and are willing to have them tested, you can send them to a NALHN laboratory where USDA will reimburse the laboratory for that testing.

Biosafety Risk Assessment Considerations for Raw Milk Testing (*Christopher Waggener, Ph.D., FDA)*
FDA laboratories across the country will soon stand-up testing for detecting HPAI in pasteurized milk using USDA's molecular screening method. To date, FDA analysis of USDA data has determined that the biosafety risk due to HPAI is very low for pasteurized milk samples. Viral particles have been found in such samples; however, none of those viral particles are virulent or could sustain growth in egg viability tests. FDA is recommending that any testing of pasteurized milk be done under BSL-2 conditions and out of an abundance of caution, that RNA extraction be done in a biosafety cabinet when possible. All laboratories are encouraged to do their own risk assessment to account for individual differences at each laboratory.

USDA studies on unpasteurized or raw milk have detected high viral titers of HPAI. FDA's risk assessment process determined that these samples would be best handled in BSL-2+ (BSL-2 laboratory that uses BSL-3 work practices) or BSL-3 laboratories. This is for the safety of analysts and for the biosecurity considerations of this virus. BSL-2+ includes using BSL-3 work practices, such as using proper BSL-3 PPE, appropriate airflow and mechanical considerations, using a biosafety cabinet, not bringing samples out of the testing area and ensuring the work area is isolated from other parts of the laboratory.

FDA advises medical surveillance for anyone who may feel ill after performing testing. FDA is also instructing field collection staff to don extra PPE and is providing risk assessments for field collections.

CDC Influenza Division Laboratory Updates (*John Barnes, Ph.D., and Todd Davis, MSPH, Ph.D., CDC)*
As seasonal influenza activity is declining, CDC would like to maintain the shoulder of the season surveillance goals. This means focusing on keeping specimens coming into public health and attempting to maintain the 1:200 Right Size goals that are targeted during the shoulders and edges of the season. PHLs are requested to continue influenza subtyping and CDC is reaching out to commercial entities and clinical laboratories to expand specimen sources for PHLs.

Instead of transitioning to one National Influenza Reference Center (NIRC) for the summer, all three NIRCs will remain operational. The Influenza Sequencing Centers (ISC) will also remain active through the summer.

A select agent exemption letter was disseminated to PHL Directors. APHL will send this out more broadly to the PHL community.

Questions and Answers (Q&A)

Q: Are there plans to expand testing capacity for influenza A/H5 beyond public health laboratories and CDC?

A: Some of the HHS funding may go toward working with commercial laboratories and FDA to build this capability and CDC is encouraging those laboratories to assess what would be necessary to achieve this.

Q: What are the plans for the $14 million HHS funding for genomic sequencing?
A: These funds will be focused on bioinformatics and data analysis at CDC for supporting surveillance and monitoring circulating influenza viruses and to support sequencing capacity at state laboratories through NIRC and ISC activities.

Q: What specific safety enhancements are recommended for BSL-2+ for handling raw milk samples?
A: BSL-2+ is a bit of a misnomer. FDA is recommending the work can be done safely in a BSL-2 laboratory while using BSL-3 work practices such as the proper BSL-3 level PPE, back closing gowns, Tyvek suits, respiratory protection, double gloves, etc. and keeping samples in BSCs. The testing room must be isolated physically from other laboratory space and waste must be autoclaved out.

Q: For PHLs that perform milk testing but are not doing the USDA molecular method for flu testing, is that USDA protocol available to assess whether it can be onboarded?
A: FDA is unsure about this as they are using a National Veterinary Services Laboratory method from USDA.

Q: What are the recommendations for screening staff who feel ill after testing raw milk samples?
A: FDA staff are included in the routine medical surveillance program and are always self-monitoring for illness after testing.

Q: Are there any recommendations for routine milk testing laboratories? Such as routine cultures, somatic cell counts, etc.?
A: FDA, along with our sister agencies have formed a workgroup to discuss these issues with a goal to hopefully provide some guidance in the coming weeks. Risk assessments should be completed at each facility for this type of testing based on where the samples are coming from and the work being performed.

Q: What type of outreach, concerning biosafety and biosecurity considerations, is being done with private milk testing laboratories?
A: There is no awareness of any from FDA. Other agencies might have provided guidance. Future information provided by federal agencies can be shared with private milk testing laboratories.