



Updated March 12, 2025

H5N1 Avian Influenza: The Human Health Response

Since early 2022, a U.S. H5N1 avian influenza ("bird flu") outbreak in poultry and wild birds has led to outbreaks in dairy herds. Increasing cases of transmission from animals to humans occurred in 2024. H5N1 influenza is a subtype of influenza A virus that causes highly pathogenic avian influenza, a form of influenza that is highly contagious and deadly to birds. The virus has adapted to spread among certain mammal species such as cattle and cats. Currently, H5N1 influenza is not known to spread easily among humans. To date, most human H5N1 influenza cases have been associated with animal exposures, with very few cases due to human-to-human transmission. Many uncertainties persist around if and when H5N1 influenza virus might adapt to spread more easily among humans, potentially resulting in a pandemic. In this case, most people would not have prior immunity to H5N1 influenza virus, which means the virus could spread quickly. The virus's growing spread among animals creates more opportunities for a strain with human pandemic potential to emerge.

Concerns about H5N1 influenza have long driven U.S. federal pandemic preparedness policy. Some of the first H5N1 influenza outbreaks in Asia in 2003-2004 led the George W. Bush Administration and Congress to pursue policy initiatives that inform preparedness for today's situation. Therefore, the United States is prepared for H5N1 influenza in some ways that it was not for the Coronavirus Disease 2019 (COVID-19) pandemic. Most notably, there are U.S. Food and Drug Administration (FDA)-licensed vaccines and vaccine components stockpiled for H5N1 influenza. Still, there are many unknowns about H5N1 influenza and the threat it may potentially pose to humans.

U.S. federal health agencies have been helping state, local, tribal, and territorial (SLTT) public health agencies respond to the current situation with a goal of preventing and containing spread among humans. Federal agencies are also preparing for the possibility of the virus adapting to spread more easily among humans. For information on dairy herd response, see CRS In Focus IF12837, *H5N1 HPAI Continues to Spread in Dairy Herds*.

Historical Cases and Outbreaks

Since the first H5N1 influenza human cases in 1997, the virus has caused periodic illness in humans as it has circulated globally. These human cases were mostly associated with animal exposures, with some limited close human-to-human spread in household and hospital settings. Historically, H5N1 influenza has generated concern because of its high severe illness and death rate among reported human cases. Between November 2003 and May 2019 there was a 53% mortality rate among reported human cases. It is widely understood that this reported mortality rate may not reflect the true historical mortality rate in humans. These data tend to capture more severe cases, as most H5N1 influenza patients were identified after hospital admission. Still, some experts think that even with a true

mortality rate of 5%, the virus would pose a major human health threat if it evolved to spread easily among humans.

Current Human Health Situation

The Centers for Disease Control and Prevention (CDC) states that the current public health risk to the general public is low, but is closely monitoring the situation for any changes. The risk is higher for those with regular exposure to infected animals. CDC has received reports of 70 confirmed cases in 13 states since 2024 (data as of March 10, 2025), most associated with agricultural animal exposure. There are also seven additional probable cases.

Four U.S. patients have been hospitalized and one has died from H5N1 influenza. The majority of other reported U.S. cases have involved mild illness with symptoms such as conjunctivitis (eye redness and discharge) and some mild respiratory symptoms It is unclear if the relatively mild illness cases are due to (1) a circulating strain that causes milder disease than prior strains, (2) the amount of virus the cases were exposed to, or (3) early detection and treatment of illness, or other possible reasons.

U.S. Public Health Response

In the U.S. federalist system of government, SLTT governments have primary legal authority and responsibility for responding to human infectious disease threats in their respective jurisdictions. Federal agencies may assist SLTT government agencies and may help coordinate across states. Federal agencies also have legal authority to prevent introduction of an infectious disease threat into the United States or transmission across state lines. Federal pandemic planning has long recognized that the general public may look to the federal government for leadership during a major infectious disease event.

SLTT governments have some infectious disease control laws, capabilities, and expertise, though the specifics vary among jurisdictions. Federal agencies assist SLTT public health agencies with infectious disease control through technical assistance, deployed staff and resources, and several ongoing grant programs focused on preparedness. For example, CDC's Public Health Emergency Preparedness cooperative agreement (a grant program) requires funded jurisdictions (all states, territories, and certain localities) to plan for a large-scale pandemic influenza response.

At the federal level, four U.S. Department of Health and Human Services (HHS) agencies have been involved in a response team for H5N1:

Administration for Strategic Preparedness and Response (ASPR): ASPR leads federal public health emergency responses. ASPR stockpiles emergency medical products and materials in its Strategic National Stockpile (SNS) and National Pre-pandemic Influenza Vaccine Stockpile. Under ASPR, the Biomedical Advanced

Research and Development Authority (BARDA) supports development and procurement of medical countermeasures. ASPR also assists SLTT health care delivery systems in preparing for and responding to public health emergencies, including pandemic influenza.

CDC: CDC assists SLTT health agencies and their partners in pandemic influenza prevention and control. CDC's scientists study circulating influenza viruses, cases, and outbreaks. CDC also leads public communication and guidance on disease prevention and control.

FDA: FDA regulates medical products that may diagnose, prevent, and treat H5N1 influenza. FDA may support advanced manufacturing for these products and monitor relevant supply chains, as needed. FDA also helps ensure the safety of the commercial milk supply, as unpasteurized milk may contain virus from infected cows.

National Institutes of Health (NIH): In June 2024, the National Institute of Allergy and Infectious Diseases released a research agenda on H5N1 influenza with four key objectives: understanding the biology of H5N1 viruses; developing and evaluating prevention strategies, such as vaccines; advancing existing and novel treatments; and supporting strategies for detecting H5N1 virus.

Prevention and Control Measures

The current U.S. human health response to H5N1 influenza focuses on prevention and control. For the general population, prevention involves avoiding contact with sick or dead animals and avoiding raw milk products. CDC has issued specific guidance for those at highest risk, including agricultural workers. CDC recommends that employers implement control measures such as requiring workers to wear personal protective equipment (PPE) and monitoring workers for infections. People exposed to infected animals should monitor for symptoms and may take antiviral treatments to prevent illness. PPE and antivirals in the SNS can be made available as needed.

CDC recommends testing for H5N1 infection based on symptoms and potential exposures. Tests for H5N1 influenza virus are currently carried out mostly in public health laboratories with the CDC test. CDC also encourages subtyping of all influenza A positive hospitalized patients (especially those in the ICU) within 24 hours of admission. Subtyping identifies the specific type of influenza virus that infected the patient. If the patient does not test positive for seasonal influenza A virus subtypes, providers are encouraged to submit clinical specimens to labs for testing that could identify if H5N1 virus is present. CDC's ongoing surveillance methods can help identify new cases and detect if and when the virus spreads more widely:

Active Monitoring: Some SLTT health agencies, in cooperation with affected farms, are actively monitoring persons with exposures to infected animals. As of March 10, 2025, at least 15,500 people have been monitored, and at least 850 people were tested for H5N1 influenza.

Passive Monitoring: CDC's influenza surveillance systems use several sources to monitor overall influenza activity among humans and circulating virus strains, including from laboratory testing, emergency departments, and wastewater testing—all in partnership with SLTT public health agencies and the health care sector. Both the public health

laboratory and wastewater testing can determine if H5 influenza strains are circulating. The wastewater data cannot distinguish whether virus in wastewater comes from human or animal sources; therefore, these data are intended to be viewed alongside other sources.

Medical Countermeasures (MCMs)

Medical countermeasures are medical products that may treat, prevent, or diagnose conditions associated with emerging infectious diseases. Selected H5N1 influenza MCMs that are either available or in development include:

Tests: Currently, the CDC's test is the only FDA-cleared test that can definitively identify H5N1 influenza virus. Clinical laboratories may relatively quickly design their own laboratory developed tests, which do not currently require FDA marketing authorization. CDC contracted with five companies to develop H5N1 tests, with three having been successfully launched. CDC also entered into an interagency agreement with the National Institute of Standards and Technology to develop synthetic genetic material that can safely be used to validate tests, a necessary component for rapid test development. As of 2023, CDC has an agreement with FDA, ASPR, and other partners for rapidly scaling up testing in an emergency.

Vaccines: There are currently three FDA-licensed vaccines for H5N1 influenza. As of January 14, 2025, stockpiles contained 5 million vaccine doses, with the expectation of 10 million doses by early 2025. There are also stockpiled components to make new vaccines. FDA has proposed a process for approving vaccine updates to match future strains. Two of the existing vaccines rely on lengthy eggbased manufacturing, inhibiting rapid scale-up during an emergency. BARDA has also announced contracts to develop mRNA-based H5N1 influenza vaccines with faster manufacturing capabilities. Future virus strains may not match stockpiled vaccines, which may delay availability in an emergency while updated vaccines are developed.

Therapeutics: Some currently available antiviral drugs are expected to work against H5N1 influenza. As of January 14, 2025, the SNS had 68 million antiviral courses on hand.

Funding

HHS agencies have announced several funding allocations for H5N1 influenza response, including \$101 million in May 2024 for epidemiology, surveillance, and commercial milk supply safety and \$306 million in January 2025 for preparedness programs, surveillance, and research, in addition to contracts mentioned above. As of March 2025, there is a reserve balance of over \$510 million in CDC's Infectious Diseases Rapid Response Reserve Fund, which could be made available in an emergency situation.

Considerations for Congress

Since 2022, the Government Accountability Office has identified HHS leadership and coordination of public health emergencies on its "high risk list" of priority areas for oversight and reform. Congress may monitor ongoing activities and determine if modifications to oversight, statute, or funding are needed.

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IF12895

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