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# Lab-created bird flu virus accident shows lax oversight of risky 'gain of function' research

*How the H5N1 viruses came to be created – and the response to a 2019 safety breach – raise table questions about the tremendous trust the world is placing in research labs.*

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*This exclusive article is adapted from former USA TODAY investigative reporter Alison Young's forthcoming book "Pandora's Gamble: Lab Leaks, Pandemics, and a World at Risk," which will be released April 25. In this excerpt, Young reveals for the first time details of a December 2019 lab safety breach involving one of the world's most infamous lab-created "gain of function" viruses – and the efforts that were made to downplay the event, avoid notifying health authorities and oversight bodies, and keep the public and policymakers in the dark.*

Inside the high-security Influenza Research Institute at the University of Wisconsin-Madison, two experienced scientists were pulling ferrets out of their HEPA-filtered cages on a Monday in December 2019. Another researcher, still in training, was also in the room to watch and learn.

One by one, the animals were put into a biosafety cabinet, where a solution was washed into their nostrils. It's a procedure used to collect evidence of infection, and this particular experiment involved exposing the animals to a highly controversial lab-engineered strain of H5N1 avian influenza virus.

The virus they were working with that day was far from ordinary, and there should have been no room for the safety breach that was about to happen and the oversight failures that followed.

The experiment underway involved one of two infamous lab-made bird flu viruses that had alarmed scientists around the world when their creation became widely known nearly a decade earlier. In each case, scientists had taken an avian influenza virus that was mostly dangerous to birds and manipulated it in ways that potentially increased its threat to humans.

In nature, the H5N1 virus has rarely infected humans. But when people have been sickened, usually through close contact with infected birds, more than half died. So it is fortunate that the H5N1 virus isn't capable of spreading easily from person to person. If the virus were ever to evolve in ways that gave it that ability, it could cause a devastating pandemic.

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## **'Gain of function' research created controversial flu viruses**

And yet in late 2011 the world learned that two scientific teams – one in Wisconsin, led by virologist Yoshihiro Kawaoka, and another in the Netherlands, led by virologist Ron Fouchier – had potentially pushed the virus in that direction. Each of these labs had created H5N1 viruses that had gained the ability to spread through the air between ferrets, the animal model used to study how flu viruses might behave in humans.

The ultimate goal of this work was to help protect the world from future pandemics, and the research was supported with words and funding by two of the most prominent scientists in the United States: Dr. Francis S. Collins, director of the National Institutes of Health, and Dr. Anthony Fauci, director of the NIH's National Institute of Allergy and Infectious Diseases.

Kawaoka contended it would be “irresponsible not to study” how the virus might evolve in nature. “Some people have argued that the risks of such studies – misuse and accidental release, for example – outweigh the benefits. I counter that H5N1 viruses circulating in nature already pose a threat,” he said at the time.

Yet these groundbreaking scientific feats set off a heated international debate over the ethics and safety of “gain of function” research. The controversy continues to this day.

Concerns about the safety of biological research have taken on heightened urgency in the wake of the COVID-19 pandemic and growing acceptance of the possibility that it was caused by a lab accident in China. In February, it was revealed that analysts at the U.S. Department

of Energy had joined the FBI in leaning toward a lab accident as the most likely source of the pandemic, though other U.S. intelligence agencies lean toward a natural origin or are undecided.

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The story of how the H5N1 viruses came to be created – and how the University of Wisconsin and the Kawaoka lab would later respond to the 2019 safety breach during the ferret experiment – raises uncomfortable questions about the tremendous trust the world places in these kinds of labs.

We are trusting that every hour of every day their layers of laboratory containment equipment are working properly, that all of their employees are sufficiently trained, qualified and attentive, and that their written safety and incident response protocols are followed in real-life practice.

When something goes wrong, we are trusting that the labs will immediately notify local public health officials who are responsible for preventing outbreaks and the federal authorities who oversee the safety of experiments with genetically engineered organisms.

Given that so much about this work is shrouded in secrecy, what happened in Wisconsin raises the question: Should the public give this trust blindly?

## **'Miscommunication' over quarantine alarmed NIH a decade ago**

In 2013, six years before the 2019 safety incident with the ferret experiment at Kawaoka's lab in Wisconsin, another member of his research team accidentally pierced their finger with a needle that had an engineered H5N1 virus on it.

It was a moment of poor judgment, human error around 6:30 p.m. Nov. 16, 2013, that set off a series of emergency calls that would eventually raise concerns in the nation's capital.

An expert at the Centers for Disease Control and Prevention told officials at Wisconsin's state health department that while the likelihood the scientist would develop symptoms of H5N1

was “low,” the needlestick “should be considered a serious exposure” and treated aggressively. The chief medical officer at the Wisconsin Department of Health Services told the university that the researcher would need to quarantine for seven days and take a treatment-level dose of Tamiflu twice a day for 10 days.

Six months earlier, while seeking funding and approval for the controversial experiments, Kawaoka had assured officials at the National Institutes of Health that the university had a designated quarantine apartment.

But it turned out that wasn’t the case.

So lab officials told the researcher’s family to pack up their belongings and go to a hotel. And the injured researcher was sent to quarantine at home.

Officials in the NIH office responsible for overseeing research with engineered organisms were alarmed to learn that the university didn’t have a dedicated quarantine facility for such emergencies.

“This policy is not what was communicated to us in Dr. Kawaoka’s application to perform research with mammalian transmissible strains of H5N1,” wrote Dr. Jacqueline Corrigan-Curay, acting director of the NIH Office of Biotechnology Activities, in a letter to the university.

A researcher’s home, the NIH told the university, was not an appropriate quarantine site for Kawaoka’s high-risk studies because influenza viruses can be transmissible through the air, and many residences are in high-occupancy buildings, like apartments, that share air exchange and other infrastructure.

Trying to provide an explanation, university officials told NIH there had been a “miscommunication” between Kawaoka and the university’s administration. Wisconsin officials noted that the needlestick was not expected to put the researcher at high risk of infection, and that this engineered virus “was determined not to be a mammalian-transmissible strain.”

The scientist with the needlestick completed quarantine without showing symptoms or becoming ill.

But even if a high-risk incident occurred with a more dangerous strain, UW officials told the

NIH, the lab worker would still be quarantined at home.

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It was a stunning change by the university to a critical safeguard that federal officials thought was in place for the Kawaoka lab's research. The NIH demanded the university find a dedicated quarantine facility outside of workers' residences, such as a hospital isolation room, or face the suspension or termination of its grant funding, correspondence shows.

The university didn't want to use the UW Hospital as a quarantine site.

Their concerns included that researchers might be unwilling to come forward about potential exposures if they faced being confined in hospital isolation rooms. The university and its medical team also worried about the increased potential for the public to learn about its lab accidents, noting in correspondence that "it would be much harder to control the spread of information and as a result there would be a higher probability of incorrect information being told to (the) general public and potentially members of the media."

The university eventually agreed to NIH's demands. And on Dec. 24, 2013, the NIH gave its approval for Kawaoka's lab to resume its research manipulating H5N1 virus strains that were transmissible to mammals.

## **Safety concerns led to US pause on 'gain of function' studies**

By 2014, there was a growing discomfort at the highest levels of the U.S. government about the risk of an accident with an engineered virus.

Wisconsin's needlestick incident, which drew questions within NIH but wasn't publicly known, was soon followed by a series of high-profile accidents at federal labs in 2014 – from safety breaches with anthrax and avian influenza at the CDC to the discovery of forgotten vials of smallpox that had been kept for decades in a storage room on the NIH campus.

In October 2014, citing these federal lab incidents, the White House Office of Science and Technology Policy announced a moratorium on new federal funding for certain gain-of-

function research while the risks and benefits of the controversial experiments were studied.

The funding pause remained in place for three years until it was finally lifted in December 2017. But it was only in 2019 that some of the halted experiments were quietly allowed to begin again under a revised federal oversight process, which was criticized for keeping secret the details of the new experiments and the basis for the government approvals.

The Kawaoka lab was one of the first to receive approval and NIH funding.

Not long after the Kawaoka lab was greenlighted in 2019 to resume work with its infamous lab-created H5N1 influenza virus – the one that had helped spark the worldwide debate over gain-of-function research – there was an accident.

And in the days and weeks that followed, efforts were made to downplay the significance of the event, avoid notifying public health officials and oversight bodies, and keep the public and policymakers in the dark.

A lot was at stake.

Not only would the incident draw attention to safety issues at the UW lab, but it also would raise larger questions about the rigor and effectiveness of how the U.S. government was overseeing the riskiest experiments in which scientists are creating enhanced pathogens with pandemic potential.

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## **Scientist's air hose detached in lab while working with engineered virus**

When the accident happened on Dec. 9, 2019, Kawaoka's three scientists were working in an enhanced biosafety level 3 agriculture lab suite at the University of Wisconsin's Influenza Research Institute.

This facility had been built specifically for Kawaoka's research and featured labs with negative air pressure, watertight and airtight seals, double HEPA-filtered exhaust air and redundant air handling systems.

The experiment they were performing involved a virus whose name describes the components of its engineering: VN1203HA(N158D/N224K/ Q226L/T318I)/CA04. It was the virus described in Kawaoka's controversial H5N1 gain-of-function experiments that had been published nearly eight years earlier, the NIH would later confirm in written responses to my questions.

It was the virus that had gained the concerning ability to spread between ferrets and had raised fears it could do this among humans.

On that December day, two experienced researchers from Kawaoka's team were helping train a colleague as they collected samples from ferrets. The animals were part of a transmission experiment and had been in contact with other ferrets infected with this engineered H5N1 virus or another wild-type flu strain.

The three scientists wore several layers of personal protection equipment. One of their most important pieces of personal protective equipment was the air-purifying respirator that each wore to ensure they didn't breathe any air from inside the laboratory. Even though they were using a biosafety cabinet, there was always the potential for virus to be present in the room's air.

These kinds of high-tech respirators encase workers' heads in a protective hood with a clear face-plate. A blower attached to a belt delivers purified air through what looks like a vacuum cleaner hose that runs up the scientist's back and attaches to the hood behind their head.

Labs are responsible for training workers how to properly assemble and use this kind of equipment.

As one of the senior researchers prepared to start collecting samples from the next round of ferrets, the trainee realized there was a problem with their respirator.

The powered air-purifying respirator (PAPR) hose had somehow disconnected from the unit that supplied safe, filtered air. Instead, the detached hose dangled loose in the lab's potentially contaminated air.

The hose was "immediately" reconnected, Wisconsin officials later said, and one of the experienced researchers radioed out to the lab's operations manager as the trainee began the process of exiting the lab, incident records show.

The trainee was initially told to follow the lab's quarantine procedure to keep them from spreading the virus if they were infected. The university would later say this was done "out of an abundance of caution." But at some point, a lab compliance official released the worker from quarantine.

It is unclear whether this quarantine release happened within minutes, hours or days of the incident. Nor is it clear whether university officials first consulted with any public health and oversight agencies.

Kawaoka and university officials wouldn't agree to be interviewed and provided little information in response to my questions.

## **State and local health officials weren't notified about lab accident**

If there were ever a virus requiring that everyone follow safety and incident reporting rules, this was it. The system of oversight in place that day had been created in response to the international furor over this very virus.

Yet, after the trainee's respirator hose disconnected in December 2019, the university didn't notify local or state public health officials about the incident or consult with them before discontinuing the trainee's quarantine, despite representations going back years indicating this would occur following "any potential exposure."

The university says it didn't need to notify them. That's because UW officials, in consultation with the university's health experts, made their own determination that no potential exposure had occurred.

Officials at Public Health Madison & Dane County, the local health department, told me they defer to the university's judgment and expertise when it comes to lab safety issues. The department said it "does not need to be notified of something that was determined to not be a significant exposure. It is also not incumbent on us to further evaluate whether there was a significant exposure, if UW reports that there was not."

The university also didn't immediately alert other key oversight entities that the public relies upon to ensure the safety of this kind of particularly risky research.

UW officials waited two months – until Feb. 10, 2020 – to file a report that should have been made immediately to the NIH Office of Science Policy, which oversees U.S. research with



genetically manipulated organisms like the engineered H5N1 influenza virus involved in the experiment.

Records show the university's internal biosafety committee, which had approved the Kawaoka lab's research, wasn't "apprised" of the Dec. 9, 2019, incident until Feb. 5, 2020.

The university was less slow in reporting the incident to the federal funding officials at NIH's National Institute of Allergy and Infectious Diseases, which provided the grant for the controversial experiments. But UW still waited 10 days – until Dec. 19, 2019 – to report the incident to NIAID program staff, according to information provided to me in writing by NIH officials.

The grant's terms required immediate notification in the event of an "illness or exposure." It was UW's contention, however, that "neither of the two criteria were met" because there was "no reasonable risk of virus exposure," NIH officials told me. When the university eventually notified grant officials, it said it was doing so "in the spirit of transparency and responsible conduct of research," the NIH said.

UW officials, who for months wouldn't answer many of my questions about the incident, eventually said that Kawaoka "informed his program officer at NIH in early December," before following up with an incident summary on Dec. 19.

As I pressed NIH to reconcile the agency's statement with UW's account, a few more details emerged. NIH said that the first time UW contacted anyone at the agency was on Dec. 12, 2019 – three days after the incident. That's when UW first requested a phone call from an NIAID program officer. A first discussion about the incident happened on Dec. 13, and on Dec. 16, during a follow-up discussion, NIAID staff asked UW to send in a written description of the incident.

Both NIAID Director Anthony Fauci and NIAID Principal Deputy Director Hugh Auchincloss "were briefed about the incident," the NIH said in a written response to my questions. But NIH would not tell me when Fauci and Auchincloss were briefed or whether they provided guidance on how the UW incident should be handled.

UW officials said Kawaoka's lab immediately reported the incident to the CDC's select agent lab regulators. But the university didn't answer my questions about why the incident was immediately reported to the CDC – and not NIH – given UW's stated position that there

wasn't any potential exposure.

It is unclear whether Kawaoka's team consulted the CDC in advance of the university's decision to release the researcher from quarantine. CDC officials – including Dr. Samuel Edwin, who heads the select agent program – didn't answer my questions about this.

## **University notified federal oversight team 2 months after lab accident**

When the university finally notified the NIH Office of Science Policy about the ferret incident – two months after it happened – UW officials unsuccessfully tried to justify their significant delay by saying the incident was “not reportable ” because even though the trainee's PAPR tube had detached, in their view there was “no potential exposure.”

The university's justifications, records show, included that the ferrets had been handled inside a biosafety cabinet and that the contact ferrets had been exposed to infected ferrets for only about 24 hours “and were not shedding virus yet.”

The university also told NIH officials that “the air the observer would have breathed during the few seconds the hose was disconnected would have come from inside the PAPR hood, which would have been HEPA- filtered before the hose disconnected.”

The lab's report to the NIH doesn't say how they determined this.

The reason UW finally told the NIH oversight office about the incident was because lab regulators at the Federal Select Agent Program – as well as the NIH office that funded the research – “recommended” it be reported.

The report UW finally submitted to the NIH Office of Science Policy includes the following notation: “\*Confidential – do not release this information without written authorization of the University of Wisconsin-Madison.”

What were the consequences of UW's delayed reporting of the incident? The NIH Office of Science Policy told me it “reminded the institution about its reporting responsibilities,” and “noted that it should have been immediately reported to OSP.”

If NIH delivered that message, UW officials say they never heard it. “This is certainly the kind of information we would have remembered or recorded in notes taken at the time,” a UW

spokesperson said by email.

UW repeatedly pointed to a short email from an NIH analyst thanking the university for its Feb. 10, 2020, report and adding that “the actions taken in response to this incident appear appropriate.” NIH says this email referred only to UW’s “biosafety actions,” not to the university’s failure to file an immediate report.

In the end, the trainee apparently didn’t become infected. But how the university and the lab oversight system handled the incident should be cause for concern.

“It is all too easy to sensationalize this research, to misconstrue events, and misrepresent the nature of incidents rightfully reported by institutions to regulatory agencies,” said Kelly Tyrrell, UW’s director of media relations, in a email that spoke in broad brushstrokes about the importance of research, the humanity of researchers, and how sometimes there can be differences in interpretations of incident reporting requirements and about regulations.

Tyrrell said that UW takes safety seriously, and that the Kawaoka lab has never had an incident where public health or safety have been put at risk.

“There are few people in the world trained to understand the nature of the pathogens involved, the biosafety and biosecurity measures in place and the protocols developed and followed,” Tyrrell continued. “Most people are also not equipped to appropriately evaluate the risk. It is unfortunate that some seek to capitalize on this knowledge gap.”

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