

24 November 2009

This supplement has been prepared to present scientific and technical news items that may be of more interest to technical personnel at RDT&E activities and the labs, or the medics rather than the broader readership of the basic CB Daily. Due to the nature of the material, the articles, if available online, are usually only available through subscription services thus making specific links generally unavailable. Thus, usually only the bibliographic citation is available for use by an activity's technical library.

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Chem-Bio News – Pandemic Influenza Edition #88

1. CLUSTERS OF RESISTANT H1N1 CASES REPORTED IN UK, US: *“Health officials in Wales today announced the identification of a cluster of patients in a Cardiff hospital who are infected with oseltamivir-resistant pandemic H1N1 influenza. Also today, Duke University Medical Center in Durham, N.C., reported that oseltamivir-resistant H1N1 viruses were found in four very sick patients hospitalized there over the past 6 weeks.”*

2. POLK CORONER: H1N1 DEATHS UNDERSTATED: *“In the autopsy, what we're seeing is very heavy, wet hemorrhagic lungs, lungs with a lot of blood in them,” said Dr. Gregory Schmunk.”*

3. FDA EXPERT PANEL DECLINES TO ENDORSE NEW INFLUENZA VACCINE: *“The Food and Drug Administration's (FDA) Vaccines and Related Biologic Products Advisory Committee sent Protein Sciences Corporation back to the drawing board at a hearing yesterday, saying it needed more safety and efficacy data before it could wholeheartedly endorse the company's bid for licensure of its novel influenza vaccine.”*

4. DEPARTMENT - NOVARTIS INAUGURATES LARGE-SCALE US BASED CELL-CULTURE INFLUENZA VACCINE MANUFACTURING FACILITY: *“Today, Novartis officially inaugurated the US's first ever large-scale flu cell culture vaccine and adjuvant manufacturing facility in Holly Springs, North Carolina.”*

5. MUTATIONS IN H5N1 INFLUENZA VIRUS HEMAGGLUTININ THAT CONFER BINDING TO HUMAN TRACHEAL AIRWAY EPITHELIUM: *“We conclude that, although genetic changes that adapt H5 to human airways can be demonstrated, they may not readily arise during natural virus replication. This genetic barrier limits the likelihood that current H5 viruses will originate a human pandemic.”*

CB Daily Report

Chem-Bio News

CLUSTERS OF RESISTANT H1N1 CASES REPORTED IN UK, US

By Lisa Schnirring and Robert Roos

CIDRAP News (Center for Infectious Disease Research & Policy – University of Minnesota)

November 20, 2009

“Health officials in Wales today announced the identification of a cluster of patients in a Cardiff hospital who are infected with oseltamivir-resistant pandemic H1N1 influenza.

Also today, Duke University Medical Center in Durham, N.C., reported that oseltamivir-resistant H1N1 viruses were found in four very sick patients hospitalized there over the past 6 weeks. A Duke press release said all four patients had been in the same hospital unit, but it did not specify how many were there at the same time.

In Wales, the National Public Health Service (NPHS) said five patients in a unit at the University Hospital of Wales that treats people who have severe underlying health conditions have been diagnosed as having oseltamivir-resistant pandemic flu, and three of them appear to have been infected in the hospital.

Up to now, just one probable instance of person-to-person transmission of oseltamivir-resistant H1N1 flu has been reported. In September the US Centers for Disease Control and Prevention (CDC) reported oseltamivir-resistant pandemic H1N1 flu in two girls who stayed in the same cabin at a summer camp in western North Carolina.

Dr Roland Salmon, director of the NPHS's communicable disease surveillance center, said in the statement that the emergence of oseltamivir-resistant flu viruses isn't unexpected in patients who have serious underlying conditions and immune system compromise."

The full article can be found at:

<http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/nov2009resistance.html>

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POLK CORONER: H1N1 DEATHS UNDERSTATED

KCCI

November 20, 2009

"Iowa has officially recorded 21 H1N1 deaths, including seven in Polk County alone. But the county's medical examiner said he has performed autopsies on some residents who were never diagnosed with H1N1, but actually had it.

"In the autopsy, what we're seeing is very heavy, wet hemorrhagic lungs, lungs with a lot of blood in them," said Dr. Gregory Schmunk.

He said the official count of seven H1N1 deaths is inaccurate, but patient rights laws prohibit him from giving specific numbers.

He said there are two reasons for the discrepancy. First, not all sick patients get tests and second, the virus is difficult to detect. Some patients may be too sick to receive the most accurate H1N1 test.

"They're not always done and it can be hazardous to the patient if they're in a respiratory critical situation," Schmunk said."

The full article can be found at: <http://www.kcci.com/news/21670309/detail.html>

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FDA EXPERT PANEL DECLINES TO ENDORSE NEW INFLUENZA VACCINE

By Fran Lowry

Medscape Today

November 20, 2009

"The Food and Drug Administration's (FDA) Vaccines and Related Biologic Products Advisory Committee sent Protein Sciences Corporation back to the drawing board at a hearing yesterday, saying it needed more safety and efficacy data before it could wholeheartedly endorse the company's bid for licensure of its novel influenza vaccine.

The Meriden, Connecticut, company is seeking FDA approval of purified recombinant influenza hemagglutinin, which it plans to market as FluBlock, for active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B.

The vaccine consists of 3 recombinant influenza hemagglutinin antigens derived from H1, H3, and B strains which are inserted into insect cells. Its manufacture does not require the handling of live influenza viruses or eggs; it is formulated without adjuvant, antibiotics, or preservatives; and its production time is shorter than that required for currently licensed influenza vaccines.

Advisory committee members were impressed by this new technology and expressed the view that it represents the wave of the future for vaccine production.

However, they were less impressed by the efficacy and safety data that Protein Sciences Corporation presented.

The company submitted results from one phase 2 and three phase 3 trials in a total of 3231 adults aged 18 years and older. One phase 3 study, in young healthy adults aged 18 to 49 years, found that the protective efficacy of the recombinant vaccine was 44.8%. In the rest of the trials, the numbers were too small to draw meaningful conclusions regarding the relative risk for influenza among older adult recipients of the vaccine — those aged 50 years and older — in comparison with licensed vaccines.”

The full article can be found at: <http://www.medscape.com/viewarticle/712853>

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DEPARTMENT - NOVARTIS INAUGURATES LARGE-SCALE US BASED CELL-CULTURE INFLUENZA VACCINE MANUFACTURING FACILITY

Ad Hoc News

November 24, 2009

“Today, Novartis officially inaugurated the US's first ever large-scale flu cell culture vaccine and adjuvant manufacturing facility in Holly Springs, North Carolina. The facility is a result of a partnership between Novartis and the US Department of Health and Human Services (HHS). It is the first of its kind in the United States and highlights an important milestone in efforts to improve influenza vaccine manufacturing technology in the US and enhance domestic pandemic preparedness.”

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“The operations at this facility will use modern, cell culture-based manufacturing technology. Cell culture-based production operations are cleaner, can be scaled up more quickly to respond to a pandemic and do not rely on eggs for rapid response to a pandemic. Cell culture technology for influenza vaccines is not yet approved in the US, however part of the HHS contract support for Holly Springs includes funding for the development of a flu cell culture vaccine. If licensed in an emergency, the facility will be ready to respond to a pandemic as early as 2011. The plant is planned to be running at full scale commercial production in 2013.

Novartis already operates a cell culture-based manufacturing plant in Marburg, Germany. It is licensed to produce a seasonal cell culture-based influenza vaccine, Optaflu®, which is approved in all 27 member states of the European Union as well as in Iceland and Norway. It currently produces Celtura®, a H1N1 pandemic vaccine licensed in Germany and Switzerland.

The Novartis Holly Springs facility can also start producing MF59®, the Novartis proprietary adjuvant, as early as December 2009. Although not yet approved in the US, studies with adjuvants are currently underway in the US. Results of the most recent clinical trials conducted with the Novartis MF59 adjuvanted cell culture-based vaccine have shown that it is possible to induce protective antibody levels against A(H1N1) infection within two weeks of administration of a single low-dose adjuvanted vaccine. MF59 has also been shown to provide cross-protection across similar strains of a H5N1 virus, which is an additional important element for a pre-pandemic vaccine given that mutations are a common feature of emerging influenza strains.”

The full article can be found at: <http://www.ad-hoc-news.de/departement-novartis-inaugurates-large-scale-us-based--/de/Unternehmensnachrichten/20734753>

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MUTATIONS IN H5N1 INFLUENZA VIRUS HEMAGGLUTININ THAT CONFER BINDING TO HUMAN TRACHEAL AIRWAY EPITHELIUM

By Guadalupe Ayora-Talavera, Holly Shelton, Margaret A. Scull, Junyuan Ren, Ian M. Jones, Raymond J. Pickles, Wendy S. Barclay

PloS One

November 19, 2009

“Abstract

The emergence in 2009 of a swine-origin H1N1 influenza virus as the first pandemic of the 21st Century is a timely reminder of the international public health impact of influenza viruses, even those associated with mild disease. The widespread distribution of highly pathogenic H5N1 influenza virus in the avian population has spawned concern that it may give rise to a human influenza pandemic. The mortality rate associated with occasional human infection by H5N1 virus approximates 60%, suggesting that an H5N1 pandemic would be devastating to global health and economy. To date, the H5N1 virus has not acquired the propensity to transmit efficiently between humans. The reasons behind this are unclear, especially given the high mutation rate associated with influenza virus replication. Here we used a panel of recombinant H5 hemagglutinin (HA) variants to demonstrate the potential for H5 HA to bind human airway epithelium, the predominant target tissue for influenza virus infection and spread. While parental H5 HA exhibited limited binding to human tracheal epithelium, introduction of selected mutations converted the binding profile to that of a current human influenza strain HA. Strikingly, these amino-acid changes required multiple simultaneous mutations in the genomes of naturally occurring H5 isolates. Moreover, H5 HAs bearing intermediate sequences failed to bind airway tissues and likely represent mutations that are an evolutionary “dead end.” We conclude that, although genetic changes that adapt H5 to human airways can be demonstrated, they may not readily arise during natural virus replication. This genetic barrier limits the likelihood that current H5 viruses will originate a human pandemic.”

The full article can be found at: <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0007836>

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