

28 July 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.

Should you wish to be removed from this Pandemic Influenza Supplement address group, just send an email to one of the people listed at the bottom of this message. This will not affect your continued receipt of the CB Daily.

Chem-Bio News– Pandemic Influenza Edition #71

1. TAMIFLU BEING GIVEN OUT UNNECESSARILY CLAIMS BMA [BRITISH MEDICAL ASSOCIATION] LEADER: *“Dr Peter Holden, the BMA's lead GP on pandemic flu, said the Department of Health was encouraging GPs to dish out 'a pill for every ill' and were in danger of becoming over reliant on Tamiflu.”*

2. FDA AUTHORIZES EMERGENCY USE OF ANOTHER TEST FOR 2009 H1N1 INFLUENZA VIRUS: *“The EUA for the Focus Diagnostics Influenza H1N1 (2009) Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) diagnostic test is the third diagnostic test authorized under an EUA by the FDA since the public health emergency involving the 2009 H1N1 influenza virus was declared on April 26, 2009.”*

3. FDA MAY USE STRAIN CHANGE MODEL FOR EVALUATING H1N1 VACCINES: *“The Food and Drug Administration (FDA) may review vaccines for the novel H1N1 influenza virus the same way it evaluates the annual updates of seasonal flu vaccines, which would probably lead to faster FDA approval than occurs with brand-new products, an FDA official said in the wake of an FDA advisory committee meeting today.”*

4. HEALTH AGENCY TO TEST LINK BETWEEN FLU, VITAMIN D: *“Epidemiological evidence suggests a role for vitamin D in seasonal influenza,” the agency said, adding that the low amounts of the nutrient in the winter “appear to correlate with the occurrence of seasonal influenza.”*

5. EMEA [EUROPEAN MEDICINES AGENCY] FAST TRACKING H1N1 VACCINE DATA: *“The EMEA is fast tracking the review of data on H1N1 pandemic vaccines to ensure it has checked submissions before the northern hemisphere flu season, which starts in September.”*

6. AN IMPROVISED OXYGEN SUPPLY SYSTEM FOR PANDEMIC AND DISASTER USE: *“The study consisted of a laboratory design, assembly, and testing of an improvised oxygen system. A liquid oxygen (LOX) Dewar container was used to supply oxygen systems built from inexpensive commercially available plastic tubing and fittings.”*

7. CITIES SLAM OTTAWA FOR POOR PANDEMIC PLANNING: *“Currently, there is neither a national plan, nor guidelines in place, to help cities and communities protect critical*

front-line workers such as police, firefighters, public transit operators, water and wastewater workers and municipal public-health professionals.”

8. DIAGNOSIS AND STRAIN DIFFERENTIATION OF AVIAN INFLUENZA VIRUSES BY RESTRICTION FRAGMENT MASS ANALYSIS: “The procedure described is rapid, inexpensive and compatible with automation.”

CB Daily Report

Chem-Bio News

TAMIFLU BEING GIVEN OUT UNNECESSARILY CLAIMS BMA [BRITISH MEDICAL ASSOCIATION] LEADER

By Lilian Anekwe
PulseToday.co.uk
July 28, 2009

“Dr Peter Holden, the BMA’s lead GP on pandemic flu, said the Department of Health was encouraging GPs to dish out ‘a pill for every ill’ and were in danger of becoming over reliant on Tamiflu.”

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“Dr Holden, a GP in Matlock, Derbyshire, who helped draft the clinical algorithm used by operators on the National Pandemic Flu Service telephone line, said he feared the thresholds for issuing Tamiflu had been set too low – a policy which would come back to haunt the DH if the H1N1 virus becomes resistant to Tamiflu.”

The full article can be found at: <http://www.pulsetoday.co.uk/story.asp?sectioncode=35&storycode=4123346&c=1>

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FDA AUTHORIZES EMERGENCY USE OF ANOTHER TEST FOR 2009 H1N1 INFLUENZA VIRUS

US Food and Drug Administration News Release
July 24, 2009

“The U.S. Food and Drug Administration today announced it has issued an Emergency Use Authorization (EUA) for a another diagnostic test for the 2009 H1N1 influenza virus, whose spread has caused the virus to be characterized as a pandemic by the World Health Organization.

The EUA for the Focus Diagnostics Influenza H1N1 (2009) Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) diagnostic test is the third diagnostic test authorized

under an EUA by the FDA since the public health emergency involving the 2009 H1N1 influenza virus was declared on April 26, 2009.

The EUA allows Focus Diagnostics to distribute the test to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests. This test is not typically utilized in a doctor's office—it is a complex laboratory test performed in an environment that has the necessary equipment. These tests are intended for use in the detection of the 2009 H1N1 influenza virus in patients with symptoms of respiratory infection.

"This authorization will contribute to the nation's capacity for accurate testing for the 2009 H1N1 influenza virus," said Daniel G. Schultz, M.D., director of the FDA's Center for Devices and Radiological Health.

The Focus Diagnostics test amplifies the viral genetic material obtained from swabs of the nose or throat, or from nasal discharges. A positive result indicates that the patient is infected with the 2009 H1N1 influenza virus. However, the test does not indicate the stage of infection. A negative result does not preclude influenza virus infection.

The EUA authority allows the FDA, based on the evaluation of available data and other things, to authorize the use of unapproved medical products or unapproved uses of approved medical products following a determination and declaration of emergency. The Focus Diagnostics test is an unapproved device whose use is authorized by the EUA. The authorization ends when the declaration of emergency is terminated or when the FDA revokes the authorization.

Emergency Use Authorization is part of Project BioShield, which became law in July 2004.

Focus Diagnostics is based in Cypress, Calif.

For more information:

FDA's Guidance on Emergency Use Authorization of Medical Products: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>."

The full article can be found at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173543.htm>

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FDA MAY USE STRAIN CHANGE MODEL FOR EVALUATING H1N1 VACCINES

By Robert Roos

CIDRAP News (Center for Infectious Disease Research & Policy – University of Minnesota)
July 23, 2009

"The Food and Drug Administration (FDA) may review vaccines for the novel H1N1 influenza virus the same way it evaluates the annual updates of seasonal flu vaccines, which would

probably lead to faster FDA approval than occurs with brand-new products, an FDA official said in the wake of an FDA advisory committee meeting today.

FDA spokeswoman Peper Long said the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) expressed support for an FDA staff recommendation to handle the H1N1 vaccines the way seasonal flu vaccines are handled. The committee met today to publicly air H1N1 vaccine issues.

Five companies—Sanofi Pasteur, Novartis, CSL Ltd., GlaxoSmithKline (GSK), and MedImmune—are rushing to make H1N1 influenza vaccines for the US government and are launching or preparing to launch clinical trials. US officials want trial data as soon as possible so they can approve vaccines in time for a potential renewed surge of the virus this fall after children return to school.

The committee didn't make a formal recommendation about how to regulate the new vaccines, but a consensus in favor of using the seasonal vaccine approach emerged, Long told CIDRAP News."

The full article can be found at: <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/jul2309vaccines.html>

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HEALTH AGENCY TO TEST LINK BETWEEN FLU, VITAMIN D

By Martin Mittelstaedt
The Globe and Mail (CA)
July 28, 2009

"In an effort to discover new ways to fight the swine flu, the Public Health Agency of Canada intends to test the blood of people contracting the ailment to check their vitamin D levels.

The agency is taking the unconventional action to try to find out whether those with mild cases of the flu have more of the sunshine vitamin circulating in their bodies than those who develop severe or even deadly reactions to the H1N1 virus."

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"Scientists have long been wondering about a possible connection between vitamin D and influenza because of the striking observations in both the northern and southern hemispheres that flu is mostly a wintertime ailment. This is the period each year when sunshine isn't intense enough to allow people to make the vitamin the natural way – in naked skin exposed to ultraviolet light – causing levels of the nutrient to plunge among those not taking supplements."

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"Epidemiological evidence suggests a role for vitamin D in seasonal influenza," the agency

said, adding that the low amounts of the nutrient in the winter “appear to correlate with the occurrence of seasonal influenza.”

The annual pattern of influenza – bad in winter and rare in summer – is the reason many health experts are worried that the swine flu epidemic, now running at relatively modest infection rates, will go into overdrive starting in the fall.”

The full article can be found at: <http://www.theglobeandmail.com/news/national/agency-to-test-link-between-flu-vitamin-d/article1231852/>

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EMEA [EUROPEAN MEDICINES AGENCY] FAST TRACKING H1N1 VACCINE DATA

By Nick Taylor

In-Pharma Technologist.com

July 27, 2009

“The EMEA is fast tracking the review of data on H1N1 pandemic vaccines to ensure it has checked submissions before the northern hemisphere flu season, which starts in September.

Manufacturers have begun submitting data to the European Medicines Agency (EMA) and a review of submissions started this month. The agency has prioritised this process to prepare for the feared spike in cases when the flu season starts.

Mock-up vaccines, those based on data from the H5N1 virus strain, from Baxter, GlaxoSmithKline (GSK) and Novartis have already been approved in Europe. These have already been tested on 8,000 people so substantial, relevant data is already available.

To make the vaccine effective against swine flu manufacturers are replacing the H5N1 virus strain with H1N1.

According to the EMA this change “should not substantially affect the safety or level of protection offered” but post-marketing monitoring programmes will be implemented by manufactures and the agency.

Clinical trials for the mock-ups are being initiated or currently ongoing and initial data is expected to be available from September onwards. Data on the H1N1 variants will be reviewed by the Committee for Medicinal Products for Human Use (CHMP) as it becomes available.”

The full article can be found at: <http://www.in-pharmatechnologist.com/Industry-Drivers/EMEA-fast-tracking-H1N1-vaccine-data>

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AN IMPROVISED OXYGEN SUPPLY SYSTEM FOR PANDEMIC AND DISASTER USE

Hospital Business Week

July 26, 2009

"In a pandemic of respiratory illness, supplemental oxygen will be a life-saving intervention. There are currently few options to provide these proposed surge beds with the necessary oxygen. A method of providing an improvised oxygen delivery system for use in a disaster was developed and tested. This system was designed to use readily available commercial materials to assemble an oxygen delivery system. The study consisted of a laboratory design, assembly, and testing of an improvised oxygen system. A liquid oxygen (LOX) Dewar container was used to supply oxygen systems built from inexpensive commercially available plastic tubing and fittings. The system will drive ventilators without significant pressure drop or ventilator malfunction. The final developed system will supply 30 patients with up to 6 L/min (l pm) oxygen each by nasal cannula from a single oxygen Dewar. An improvised system to deliver oxygen for patient beds or ventilator use can be easily assembled in the event of a disaster."

The full article can be found at: (C.M. Little, et. al., "An Improved Oxygen Supply System for Pandemic and Disaster Use". Academic Emergency Medicine, 2009;16(6):558-563). Link not available.

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CITIES SLAM OTTAWA FOR POOR PANDEMIC PLANNING

By Gloria Galloway and Caroline Alphonso

Globe and Mail (CA)

July 28, 2009

"A lapse in federal leadership has left the country with no plan to keep essential services going if pandemic influenza becomes more deadly this fall, the Federation of Canadian Municipalities warns.

"The global outbreak of the H1N1 virus has exposed a serious gap in the federal government's overall pandemic preparedness strategy," Basil Stewart, the president of the federation, writes in an open letter sent Monday to federal Health Minister Leona Aglukkaq.

"Currently, there is neither a national plan, nor guidelines in place, to help cities and communities protect critical front-line workers such as police, firefighters, public transit operators, water and wastewater workers and municipal public-health professionals. This puts at risk the critical services that provide the foundation for effective pandemic response measures."

The full article can be found at: <http://www.theglobeandmail.com/news/national/cities-slam-ottawa-for-poor-pandemic-planning/article1233027/>

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DIAGNOSIS AND STRAIN DIFFERENTIATION OF AVIAN INFLUENZA VIRUSES BY RESTRICTION FRAGMENT MASS ANALYSIS

TB & Outbreaks Week

July 28, 2009

"In a pandemic, however, the analysis of very large numbers of samples may become necessary within a short period. A method is described for the characterisation of avian influenza virus (AIV) subtypes by restriction fragment mass fingerprint (RFMF) analysis. Amplified genomic fragments encoding the pathogenicity-determining region of the hemagglutinin gene were digested with a cocktail of restriction enzymes, and the restriction fragments were assayed by mass spectrometry. Characteristic spectra with sequence coverage ranging from 75 to 100% were obtained for a panel of 27 isolates representing 18 relevant serotypes. Three marker masses were identified that are highly specific for strains of the H5N1 virus. Within the H5N1 serotype, discrimination of individual strains was possible by detailed evaluation of the spectra."

"The procedure described is rapid, inexpensive and compatible with automation."

The full article can be found at: (K. Michael, et. al., "Diagnosis and strain differentiation of avian influenza viruses by restriction fragment mass analysis". Journal of Virological Methods, 2009; 158(1-2):63-69). Link not available.

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