

24 March 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 #53

- 1. [INDONESIAN] MINISTER WARY OF FOREIGN 'ATTACK':** *"Health Minister Siti Fadillah Supari on Friday called the country's medical institutions to carry out their own virus and DNA research free of foreign funding so as to avoid exploitation from developed countries and the possibility of a future biological attack against the nation."*
- 2. EUROPEAN LAB ACCIDENTS RAISE BIOSECURITY CONCERNS:** *"Lab accidents involving bird flu and Ebola viruses have increased biosecurity fears in Europe, where public health experts say research on dangerous pathogens needs to be more strictly monitored."*
- 3. TYPE B VIRUSES RISE AS OVERALL FLU ACTIVITY DECLINES:** *"The second week of March brought a slight decline in influenza activity across the country, with 30 states still reporting widespread cases, down from 35 states a week earlier, according to the Centers for Disease Control and Prevention (CDC)."*
- 4. USE OF OSELTAMIVIR AFTER INFLUENZA INFECTION IS ASSOCIATED WITH REDUCED INCIDENCE OF RECURRENT ADVERSE CARDIOVASCULAR OUTCOMES AMONG MILITARY HEALTH SYSTEM BENEFICIARIES WITH PRIOR CARDIOVASCULAR DISEASES:** *"Meanwhile, in patients with CV disease, strict adherence with current practice guidelines for prevention and treatment of influenza is recommended."*
- 5. INTERIM GUIDANCE FOR CARGO TRUCKING CREWS FOR THE PREVENTION OF PANDEMIC INFLUENZA:** *"This draft interim guidance is meant to inform and educate cargo trucking management and crew personnel about precautions and appropriate work practices to minimize exposure and prevent workplace-related transmission of flu in the event of a pandemic."*
- 6. GUIDANCE FOR INDUSTRY - INFLUENZA: DEVELOPING DRUGS FOR TREATMENT AND/OR PROPHYLAXIS:** *"Specifically, this guidance addresses the Food and Drug Administration's (FDA's) current thinking regarding the overall development program and designs of clinical and nonclinical studies to support the development of influenza drug products."*

CB Daily Report

Chem-Bio News

[INDONESIAN] MINISTER WARY OF FOREIGN 'ATTACK'

By Dessy Sagita

Jakarta Globe

March 21, 2009

"Health Minister Siti Fadillah Supari on Friday called the country's medical institutions to carry out their own virus and DNA research free of foreign funding so as to avoid exploitation from developed countries and the possibility of a future biological attack against the nation.

"I'm truly afraid the world will use our viruses or DNAs to create a mass biological weapon that may be used to attack us," she said."

The full article can be found at: <http://www.thejakartaglobe.com/home/article/13817.html>

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EUROPEAN LAB ACCIDENTS RAISE BIOSECURITY CONCERNS

By Laura MacInnis and Debra Sherman

Reuters

March 19, 2009

"Lab accidents involving bird flu and Ebola viruses have increased biosecurity fears in Europe, where public health experts say research on dangerous pathogens needs to be more strictly monitored.

A scientist in Germany last week pricked herself with a needle that was believed to be contaminated with a strain of the Ebola haemorrhagic virus with a mortality rate of around 90 percent. She is still under observation in hospital.

That accident added to public health concerns following the recent disclosure that deadly H5N1 bird flu virus samples were mixed with seasonal flu samples at a Baxter International contracted laboratory in Austria."

The full article can be found at: <http://www.reuters.com/article/rbssHealthcareNews/idUSLJ55693920090319>

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TYPE B VIRUSES RISE AS OVERALL FLU ACTIVITY DECLINES

By Robert Roos

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

March 23, 2009

“The second week of March brought a slight decline in influenza activity across the country, with 30 states still reporting widespread cases, down from 35 states a week earlier, according to the Centers for Disease Control and Prevention (CDC).

As overall activity has decreased, however, the season has seen an increase in the proportion of influenza B viruses, the one type of flu that is not very well-matched by this year's vaccine, the CDC reported. The spread of B viruses also poses a challenge for decisions about antiviral treatment, the agency said.

Eighteen states reported regional flu activity, and two—Utah and West Virginia—reported only local activity. Seven percent of all deaths reported through the CDC's mortality reporting system were attributed to pneumonia and influenza, which is below the epidemic threshold of 8%.

However, the proportion of medical visits attributed to flu-like illness in the CDC's flu surveillance network was 2.9%, still above the national baseline of 2.4%.”

The full article can be found at: <http://www.cidrap.umn.edu/cidrap/content/influenza/general/news/mar2309flu.html>

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USE OF OSELTAMIVIR AFTER INFLUENZA INFECTION IS ASSOCIATED WITH REDUCED INCIDENCE OF RECURRENT ADVERSE CARDIOVASCULAR OUTCOMES AMONG MILITARY HEALTH SYSTEM BENEFICIARIES WITH PRIOR CARDIOVASCULAR DISEASES

By S. Ward Casscells, MD; Elder Granger, MD, FACP, FACPE; Amii M. Kress, MPH; Andrea Linton, MS; Mohammad Madjid, MD, MSc and Linda Cottrell, BS

Circulation: Cardiovascular Quality and Outcomes (American Heart Assn.)

March 5, 2009

“Background— Influenza infection has been associated with increased risk of adverse cardiac and cerebral vascular outcomes. Oseltamivir, a treatment for influenza, has been shown to decrease the severity of an influenza episode, but few data exist regarding its potentially protective effect against recurrent vascular outcomes among influenza patients with a history of vascular disease.

Methods and Results— Electronic healthcare service and pharmacy records for 37 482 TRICARE beneficiaries, aged 18 and older, with a coded history of cardiovascular (CV) disease and a subsequent diagnosis of influenza from October 1, 2003, through September 30, 2007, were examined. Subjects were grouped according to whether they had filled a prescription for oseltamivir within 2 days of their influenza diagnosis. The incidence of

recurrent CV events within 30 days after the influenza diagnosis among oseltamivir-treated and untreated subjects was 8.5% and 21.2%, respectively ($P < 0.005$). Subject age was a persistent and significant contributor to the likelihood of recurrent CV outcomes. After controlling for the differences in demographics among treated and untreated cohorts using a propensity-scored logistic regression model, a statistically significant protective effect was associated with oseltamivir treatment (odds ratio, 0.417; 95% CI, 0.349 to 0.498).

Conclusions— Our findings suggests that oseltamivir treatment for influenza is associated with significant decrease in the risk of recurrent CV events in subjects with a history of CV disease. These findings merit confirmation in further prospective and controlled studies. Meanwhile, in patients with CV disease, strict adherence with current practice guidelines for prevention and treatment of influenza is recommended.”

The full article can be found at: <http://circoutcomes.ahajournals.org/cgi/reprint/2/2/108>

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INTERIM GUIDANCE FOR CARGO TRUCKING CREWS FOR THE PREVENTION OF PANDEMIC INFLUENZA

PandemicFlu.gov

March 24, 2009

“Cargo trucking is part of the critical infrastructure essential to maintaining the Nation’s continuity of operations in the event of an influenza (flu) pandemic (a worldwide outbreak of a novel flu virus). This draft interim guidance is meant to inform and educate cargo trucking management and crew personnel about precautions and appropriate work practices to minimize exposure and prevent workplace-related transmission of flu in the event of a pandemic. These recommendations are primarily based on standard infection control practices and information about preventing seasonal flu and specific concerns associated with the potential for an outbreak of pandemic flu.

These guidelines were developed for the three main segments of the U.S. trucking industry: government entities, private cargo carriers, and for-hire motor carriers, but are also applicable for couriers, local delivery enterprises, and other trucking operations such as refuse haulers. These guidelines and recommendations may change as more becomes known about the specifics of a particular flu pandemic, the virus believed to be responsible, and the efficacy of public health control measures.”

The full article can be found at: http://pandemicflu.gov/health/cargo_trucking.html

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GUIDANCE FOR INDUSTRY - INFLUENZA: DEVELOPING DRUGS FOR TREATMENT AND/OR PROPHYLAXIS

US Food and Drug Administration

February 2009

"The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment and/or prophylaxis of illness caused by influenza viruses A and B, including both seasonal and pandemic varieties.² Specifically, this guidance addresses the Food and Drug Administration's (FDA's) current thinking regarding the overall development program and designs of clinical and nonclinical studies to support the development of influenza drug products.³ This guidance is intended to serve as a focus for continued discussions among the Division of Antiviral Products (DAVP), pharmaceutical sponsors, the academic community, and the public.⁴ As the science of influenza treatment and prophylaxis evolves, this guidance may be revised.

Sponsors considering development of antiviral drugs for the treatment or prophylaxis of disease with novel influenza strains, or in a pandemic influenza setting, are encouraged to consult this guidance and to communicate with the FDA through the pre-investigational new drug application (pre-IND) consultation program and frequently throughout drug development. Proposals for fast track designation can be considered at any time during development, depending on appropriate fulfillment of the designated criteria.

This guidance does not address drug development for the treatment and/or prophylaxis of influenza C. This guidance also does not address development of influenza vaccines or vaccine adjuvants. Inquiries regarding vaccines should be addressed to the Center for Biologics Evaluation and Research (CBER).

This guidance does not contain discussion of the general issues of clinical trial design or statistical analysis. Those topics are addressed in the ICH guidances for industry E9 Statistical Principles for Clinical Trials and E10 Choice of Control Group and Related Issues in Clinical Trials.⁵ This guidance focuses on specific drug development and trial design issues that are unique to the study of influenza.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required."

The full article can be found at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2009-D-0044-gdl.pdf>

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