27 April 2010

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 #109

1. SCRIPPS RESEARCH TEAM FINDS STRUCTURE OF 'SWINE FLU' VIRUS: *"A team of scientists from The Scripps Research Institute and other institutions has solved the structure of a key protein from the virus that caused last year's "swine flu" influenza epidemic. The structure reveals that the virus shares many features with influenza viruses common in the early 20th century, helping to explain why, in general, older individuals have been less severely affected by the recent outbreak than younger ones."*

2. SAFETY AND IMMUNOGENICITY OF WHOLE-VIRUS, ALUM-ADJUVANTED WHOLE-VIRUS, VIROSOMAL, AND WHOLE-VIRUS INTRADERMAL INFLUENZA A/H9N2 VACCINE FORMULATIONS: *"Among subjects under 40 years, two doses (45. 15, and 5 mu g) of alum-adjuvanted vaccine achieved seroprotective HAI titres in 50%. 41%, and 39% respectively, and neutralization seroconversions in 83%. 82%, and 78% of recipients Among Subjects over 40 years, one dose (45, 15, and 5 mu g) of alum-adjuvanted vaccine achieved seroprotective HAI titres in 50%, 25% and 0% respectively, and neutralization seroconversions in 88%. 63% and 63% of recipients Among immunologically naive Subjects under 40 years."*

3. COMPARISON OF SINGLE, HOMOLOGOUS PRIME-BOOST AND HETEROLOGOUS PRIME-BOOST IMMUNIZATION STRATEGIES AGAINST H5N1 INFLUENZA VIRUS IN A MOUSE CHALLENGE MODEL: *"Moreover, the results indicate that heterologous prime-boost immunization regimes might broaden the specificity of the anti-H5N1 antibody response."*

4. PREVENTION OF NOSOCOMIAL TRANSMISSION OF SWINE-ORIGIN PANDEMIC INFLUENZA VIRUS A/H1N1 BY INFECTION CONTROL BUNDLE: *"Not wearing a surgical mask either by the exposed persons during contact with the index cases (4/4 vs 264/832, p=0.010) or vice versa (4/4 vs 300/832, p=0.017, Fisher's exact test) were found to be significant risk factors for nosocomial acquisition of S-OIV."*

5. RESEARCHERS FIND INFRARED THERMAL DETECTION SYSTEMS USEFUL FOR PATIENT SCREENING: *"According to the study, if fever was not detected by the ITDS, then there was a 97% chance that there was no fever present, making the ITDS a useful tool for quick fever screenings."*

6. UNIVERSAL INFLUENZA DNA VACCINE ENCODING CONSERVED CD4(+) T CELL EPITOPES PROTECTS AGAINST LETHAL VIRAL CHALLENGE IN HLA-DR TRANSGENIC MICE: *"Vaccination resulted in peptide-specific immune responses, augmented HA-specific antibody responses and protection of HLA-DR4 transgenic mice from lethal PR8 influenza virus challenge These studies demonstrate the utility of this vaccine format and the contribution of CD4(+) T cell responses to protection against influenza infection."*

7. PRIMING WITH AS03(A)-ADJUVANTED H5N1 INFLUENZA VACCINE IMPROVES THE KINETICS, MAGNITUDE AND DURABILITY OF THE IMMUNE RESPONSE AFTER A HETEROLOGOUS BOOSTER VACCINATION: *"An open non-randomised extension of a double-blind randomised primary study: "In individuals primed 14 months earlier with AS03(A)-adjuvanted A/Vietnam/1194/2004 vaccines, a single booster dose of AS03(A)-adjuvanted A/Indonesia/5/2005 induced rapid immune responses (licensure criteria met in 7-14 days) comparable to that observed in the un-primed control group following two doses of adjuvanted vaccine. In contrast, individuals primed with non-adjuvanted formulations exhibited minimal immune responses which, even after two doses, were unexpectedly much lower than that observed in un-primed subjects AS03(A) enhances the initial priming effect of pandemic influenza vaccination enabling a rapid humoral response to single dose boosting with a heterologous strain at 14 months In contrast, priming without adjuvant appears to inhibit the response to subsequent vaccination with a heterologous strain."*

8. HANOI DECLARATION SETS GLOBAL FRAMEWORK FOR AVIAN INFLUENZA, PANDEMIC READINESS, PROPOSES NATIONAL STEPS TO DETECT ANIMAL-HUMAN TRANSMISSION, CONTROL OUTBREAKS: *"It calls for focused action at the interface between human, animal and environmental health systems, as well as continued efforts to reduce the extent of H5N1 and H1N1."*

9. H1N1 LESSONS LEARNED - VACCINE PRODUCTION FOILED, CONFIRMED EXPERTS' PREDICTIONS: *"Researchers had predicted, for instance, that to be protected against a novel strain, most members of the population would require two doses of vaccine containing the new pandemic strain. And because that many doses of vaccine would stress the existing vaccine-manufacturing system, other researchers had predicted that the addition of dose-sparing adjuvants to the new vaccine would be crucial to stretch out scarce supplies of newly made antigen. Neither turned out to be true."*

10. 1976 'SWINE FLU' VACCINE MAY OFFER PANDEMIC H1N1 PROTECTION: *"Taken together, the authors say, those results suggest that vaccination with a closely related strain of flu may confer some protection when vaccines against a circulating strain do not exist—such as in the early months after a pandemic strain first emerges, before the vaccine-manufacturing system can respond."*

CB Daily Report

Chem-Bio News

SCRIPPS RESEARCH TEAM FINDS STRUCTURE OF 'SWINE FLU' VIRUS
NewsRx Health
April 11, 2010

"A team of scientists from The Scripps Research Institute and other institutions has solved the structure of a key protein from the virus that caused last year's "swine flu" influenza epidemic. The structure reveals that the virus shares many features with influenza viruses common in the early 20th century, helping to explain why, in general, older individuals have been less severely affected by the recent outbreak than younger ones.

The team's findings were published in the March 25, 2010, issue of Science Express, an advance, online publication of selected research papers from the prestigious journal Science.

In the study, the team describes the structure of the hemagglutinin (the influenza virus envelope protein) from the H1N1 swine flu virus that triggered the pandemic in 2009 and is still circulating in the human population. The team then compared the swine flu hemagglutinin protein with a range of different human H1N1 flu viruses in the past century.

"Parts of the 2009 virus are remarkably similar to human H1N1 viruses circulating in the early 20th century," said Scripps Research Professor Ian Wilson, who was the senior author of the study. "Our findings provide strong evidence that exposure to earlier viruses has helped to provide some people with immunity to the recent influenza pandemic."

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SAFETY AND IMMUNOGENICITY OF WHOLE-VIRUS, ALUM-ADJUVANTED WHOLE-VIRUS, VIROSOMAL, AND WHOLE-VIRUS INTRADERMAL INFLUENZA A/H9N2 VACCINE FORMULATIONS
Health & Medicine Week
April 19, 2010

"Avian influenza H9N2 viruses are considered as a pandemic threat We assessed the safety and immunogenicity Of fourteen H9N2 vaccine formulations A randomized, phase I trial was done in 353 adults. aged 18-82 years Subjects received two closes of A/Hong Kong/1073/99 (H9N2) whole-virus,

alum-adjuvanted whole-virus. virosomal, or intradermal whole-virus vaccine at four doses (1 7, 5. 15 or 45 mu g haemagglutinin)."

"Sera were obtained before and three weeks after each vaccination (days 0, 21, and 42) for haernagglutination-inhibition (HAI) and neutralization assays All formulations were well tolerated Prevaccination sera from subjects aged below or above 40 years had baseline antibody to H9N2 in 1% and 16% of samples Compared to intramuscular whole-virus vaccine, alum-adjuvanted vaccine was more immunogenic, intradermal vaccine was comparable, and virosomal vaccine less immunogenic."

"Among subjects under 40 years, two doses (45. 15, and 5 mu g) of alum-adjuvanted vaccine achieved seroprotective HAI titres in 50%. 41%, and 39% respectively, and neutralization seroconversions in 83%. 82%, and 78% of recipients Among Subjects over 40 years, one dose (45, 15, and 5 mu g) of alum-adjuvanted vaccine achieved seroprotective HAI titres in 50%, 25% and 0% respectively, and neutralization seroconversions in 88%. 63% and 63% of recipients Among immunologically naive Subjects under 40 years."

The full article can be found at: (K.G. Nicholson, et. al., "Safety and immunogenicity of whole-virus, alum-adjuvanted whole-virus, virosomal, and whole-virus intradermal influenza A/H9N2 vaccine formulations". Vaccine, 2009;28(1):171-178). Link not available.
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COMPARISON OF SINGLE, HOMOLOGOUS PRIME-BOOST AND HETEROLOGOUS PRIME-BOOST IMMUNIZATION STRATEGIES AGAINST H5N1 INFLUENZA VIRUS IN A MOUSE CHALLENGE MODEL
Biotech Week
April 21, 2010

"Preparation for an H5N1 influenza pandemic in humans may involve priming the population with a vaccine produced from an existing, available H5N1 strain We have used a mouse challenge model to compare the immunogenicity and efficacy of inactivated, Vero cell-derived, whole virus H5N1 vaccines in single immunization and homologous or heterologous prime-boost regimes A single immunization was sufficient to protect against a lethal challenge with strains from matched and unmatched H5N1 clades."

"Homologous and heterologous prime-boost regimes induced cross-neutralizing antibodies and cross-protection against representative viruses of H5N1 clade 1, clade 2.1, clade 2.2 and clade 2.3."

"Moreover, the results indicate that heterologous prime-boost immunization regimes might broaden the specificity of the anti-H5N1 antibody response."

The full article can be found at: (N. Sabarth, et. al., "Comparison of single, homologous prime-boost and heterologous prime-boost immunization strategies against H5N1 influenza virus in a mouse challenge model". Vaccine, 2010;28(3):650-656). Link not available.
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PREVENTION OF NOSOCOMIAL TRANSMISSION OF SWINE-ORIGIN PANDEMIC INFLUENZA VIRUS A/H1N1 BY INFECTION CONTROL BUNDLE
Medical Letter on the CDC & FDA
April 11, 2010

"During the containment and early mitigation phases of the swine-origin influenza virus (S-OIV) A H1N1 pandemic, an infection control bundle consisting of multiple coherent measures was organised by our infection control team to minimise nosocomial transmission."

"This included repeated open staff forum achieving high attendance; early recognition of index cases among inpatients by liberal testing; early relief of sick staff from work; directly observed hand hygiene practice during outbreaks; and monitoring of compliance with infection control practice. During the first

100 days (from 1 May to 8 August 2009) when the first 100 laboratory-confirmed patients with S-OIV and 12 infected healthcare workers (HCWs) were identified, a total of 836 asymptomatic exposed persons (184 patients and 652 HCWs) were required to undergo a seven-day medical surveillance. The infection control nurses monitored them for the onset of symptoms. Four (0.48%) exposed persons (one house officer, two non-clinical staff, and one patient) were virologically confirmed with S-OIV."

"Not wearing a surgical mask either by the exposed persons during contact with the index cases (4/4 vs 264/832, p=0.010) or vice versa (4/4 vs 300/832, p=0.017, Fisher's exact test) were found to be significant risk factors for nosocomial acquisition of S-OIV."

The full article can be found at: (V.C. Cheng, et. al., "Prevention of nosocomial transmission of swine-origin pandemic influenza virus A/H1N1 by infection control bundle". Journal of Hospital Infection, 2010;74(3):271-7). Link not available.
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RESEARCHERS FIND INFRARED THERMAL DETECTION SYSTEMS USEFUL FOR PATIENT SCREENING
NewsRx Health
April 11, 2010

"Researchers at the University of Nebraska Medical Center (UNMC) found an Infrared Thermal Detection System (ITDS) to be a fast and effective fever screening tool in clinical settings during the H1N1 influenza pandemic. The ITDS detected fever in patients through split-second, non-contact skin temperature measurements. Fever is a primary symptom of seasonal influenza, H1N1, avian influenza, SARS and other infectious diseases.

The results of the study were presented at the Fifth Decennial International Conference on Healthcare-Associated Infections in Atlanta.

Dr. Angela Hewlett and her colleagues evaluated the OptoTherm ThermoScreen in the Emergency Department of The Nebraska Medical Center, UNMC's hospital partner during the height of the H1N1 pandemic from November 18, 2009 to January 9, 2010 to test the tool's viability in a practical clinical setting. The ITDS employs a thermal imaging camera to measure skin temperature by detecting and quantifying the infrared energy being emitted from the face. The ITDS temperature measurements were compared with standard temperature measurements for 566 patients, ages 15 days to 89 years old."

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"During the study period, participating patients at the Emergency Department had their temperature measured by the ITDS and then by routine oral or rectal temperature measurements taken in the triage area of the Emergency Department. Patients who were identified with fever were managed with routine protocols, including separation or surgical masks.

The ITDS proved to be an effective screening tool for identifying patients with fever (>100.0°F) across all age ranges and genders. While the ITDS had a high negative predictive value-correctly excluding most patients without fever-the machine also generated a high percentage of false positive results, measuring higher temperatures than routine temperature measurements. According to the study, if fever was not detected by the ITDS, then there was a 97% chance that there was no fever present, making the ITDS a useful tool for quick fever screenings.

Dr. Hewlett cautioned that their study used mostly oral temperature measurements as the standard to measure the effectiveness of the ITDS. Oral measurements are not always an accurate measure of temperature, but represent the most widely used measurement of temperature in clinical settings. Further evaluation of the performance and utility of the device is needed."

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UNIVERSAL INFLUENZA DNA VACCINE ENCODING CONSERVED CD4(+) T CELL EPITOPES PROTECTS AGAINST LETHAL VIRAL CHALLENGE IN HLA-DR TRANSGENIC MICE
Vaccine Weekly
April 21, 2010

"The goal of the present study was to design a vaccine that would provide universal protection against infection of humans with diverse influenza A viruses. Accordingly, protein sequences from influenza A virus strains currently in circulation (H] NI, H3N2), agents of past pandemics (HI N1, H2N2, H3N2) and zoonotic infections of man (H1N1, H5N1, H7N2, H7N3, H7N7, H9N2) were evaluated for the presence of amino acid sequences, motifs, that are predicted to mediate peptide epitope binding with high affinity to the most frequent HLA-DR allelic products."

"Peptides conserved among diverse influenza strains were then synthesized, evaluated for binding to purified HLA-DR molecules and for their capacity to induce influenza-specific immune recall responses using human donor peripheral blood mononuclear cells (PBMC). Accordingly, 20 epitopes were selected for further investigation based on their conservancy among diverse influenza strains, predicted population coverage in diverse ethnic groups and capacity to recall influenza-specific responses. A DNA plasmid encoding the epitopes was constructed using amino acid spacers between epitopes to promote optimum processing and presentation. Immunogenicity of the DNA vaccine was measured using HLA-DR4 transgenic mice and the TriGrid (TM) in vivo electroporation device."

"Vaccination resulted in peptide-specific immune responses, augmented HA-specific antibody responses and protection of HLA-DR4 transgenic mice from lethal PR8 influenza virus challenge These studies demonstrate the utility of this vaccine format and the contribution of CD4(+) T cell responses to protection against influenza infection."

The full article can be found at: (J. Alexander, et. al., "Universal influenza DNA vaccine encoding conserved CD4(+) T cell epitopes protects against lethal viral challenge in HLA-DR transgenic mice". Vaccine, 2010;28(3):664-672). Link not available.
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PRIMING WITH AS03(A)-ADJUVANTED H5N1 INFLUENZA VACCINE IMPROVES THE KINETICS, MAGNITUDE AND DURABILITY OF THE IMMUNE RESPONSE AFTER A HETEROLOGOUS BOOSTER VACCINATION
Health Risk Factor Week
April 20, 2010

"Here we assess the role of AS03(A) (an oil-in-water emulsion based Adjuvant System containing tocopherol) in this prime-boost concept using H5N1 as a model shift influenza antigen."

In this open, non-randomised Study (NCT00506350: an extension of an earlier randomised study) we assessed immunogenicity in nine groups of 35-50 volunteers aged 19-61 years following administration of AS03(A)-adjuvanted split-virion H5N1 vaccine containing 3 75 mu g of haemagglutinin (HA) from the A/Indonesia/5/2005(IBCDC-RG2) clade 2.1 strain A single booster dose of vaccine was administered to four groups primed 14 months previously with different HA levels of AS03(A)-adjuvanted clade 1 A/Vietnam/1194/2004 H5N1 vaccine. Two booster doses (given 21 days apart) were administered to four groups primed 14 months previously with different HA levels of non-adjuvanted A/Vietnam/1194/2004 H5N1 vaccine and also to a control group of un-primed subjects."

"In individuals primed 14 months earlier with AS03(A)-adjuvanted A/Vietnam/1194/2004 vaccines, a single booster dose of AS03(A)-adjuvanted A/Indonesia/5/2005 induced rapid immune responses (licensure criteria met in 7-14 days) comparable to that observed in the un-primed control group following two doses of adjuvanted vaccine In contrast, individuals primed with non-adjuvanted formulations exhibited minimal immune responses which, even after two doses, were unexpectedly much lower than that observed in un-primed subjects AS03(A) enhances the initial priming effect of pandemic influenza vaccination enabling a rapid humoral response to single dose boosting with a heterologous strain at 14 months In contrast, priming without adjuvant appears to inhibit the response

to subsequent vaccination with a heterologous strain."

The full article can be found at: (I. Lerouxroels, et. al., “Priming with AS03(A)-adjuvanted H5N1 influenza vaccine improves the kinetics, magnitude and durability of the immune response after a heterologous booster vaccination: An open non-randomised extension of a double-blind randomised primary study”. Vaccine, 2010;28(3):849-857). Link not available.
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HANOI DECLARATION SETS GLOBAL FRAMEWORK FOR AVIAN INFLUENZA, PANDEMIC READINESS, PROPOSES NATIONAL STEPS TO DETECT ANIMAL-HUMAN TRANSMISSION, CONTROL OUTBREAKS
United Nations Press Release
April 21, 2010

“The Hanoi Declaration proposes a multisector array of national measures to keep a look out for new diseases that may cross from animals to humans and to deploy public health measures promptly against outbreaks. It calls for focused action at the interface between human, animal and environmental health systems, as well as continued efforts to reduce the extent of H5N1 and H1N1.

Countries and international agencies are urged to “remain vigilant with respect to emerging threats such as H5N1, pandemic H1N1, and other influenza viruses”.

The Declaration recognizes the necessity for continuing and strengthening international and regional cooperation against diseases for which there may be no human immunity and which can cross borders in a matter of days. It emphasizes the need for effective communication between professionals and public, community engagement, and for strengthened public health and veterinary systems.

The Declaration crystallizes results of discussions between delegates in Hanoi at the 20 to 21 April International Ministerial Conference on Animal and Pandemic Influenza, hosted by the Government of Viet Nam, and co-organized with the United States and the European Union, in partnership with the United Nations Food and Agriculture Organization (FAO), the World Health Organization (WHO), the World Organization for Animal Health, the Asian Development Bank, the World Bank and the United Nations Children’s Fund (UNICEF).

The conference took place despite the physical absence of one fifth of the expected delegates, whose travel had been blocked by clouds of volcanic ash over Europe. An earthquake in western China similarly limited the participation of the Chinese delegation. The severity of these natural occurrences, and the suddenness with which they struck, reminded delegates about the swift and unpredictable spread of new hazards that can emerge from the animal world.

Speaking at the closing ceremony of the conference, the Vice-Minister of Agriculture and Rural Development of the Government of Viet Nam, Bui Ba Bong, summarized the view of conference delegates: “We must continue to prevent and respond to bird flu (H5N1 Highly Pathogenic Avian Influenza), to tackle the ongoing H1N1 influenza pandemic and to prepare for other diseases that move from animals to humans. In Viet Nam’s experience, this calls for good human and animal health services, excellent communications, and whole of society responses.”

With an estimated 75 per cent of new infectious diseases in humans coming from animals, and two new animal diseases capable of affecting humans expected to emerge each year, delegates identified the capacities needed by Governments to cope with an ongoing state of uncertainty. There is a need for strong and predictable delivery systems for animal and human health, including emergency and contingency planning systems that reflect global standards and legal frameworks (e.g. the World Organization for Animal Health veterinary standards, WHO International Health Regulations) as well as new standards developed for pandemic readiness.

David Nabarro, United Nations System Influenza Coordinator, emphasized that “capacities for countries to work together in response to threats of avian and pandemic influenza have advanced in the last five years: the conference helped to identify areas on which we need to focus to ensure a secure future in

the face of emerging diseases".

To view the Hanoi Declaration, visit the IMCAPI website at www.imcapi-hanoi-2010.org/documents/en/."

The full article can be found at: http://www.un.org/News/Press/docs/2010/sag433.doc.htm
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H1N1 LESSONS LEARNED - VACCINE PRODUCTION FOILED, CONFIRMED EXPERTS' PREDICTIONS
By Maryn McKenna
CIDRAP News (Center for Infectious Disease Research & Policy – University of Minnesota)
April 26, 2010

"Researchers had predicted, for instance, that to be protected against a novel strain, most members of the population would require two doses of vaccine containing the new pandemic strain. And because that many doses of vaccine would stress the existing vaccine-manufacturing system, other researchers had predicted that the addition of dose-sparing adjuvants to the new vaccine would be crucial to stretch out scarce supplies of newly made antigen.

Neither turned out to be true.

To the great relief of health authorities, most members of the population turned out to need only one dose of the novel vaccine, though whether the youngest children needed two became a matter for international disagreement. And because that move freed up so many doses of antigen, the United States' long reluctance to test and license adjuvants used in flu vaccines in Europe did not become the bad bet that many flu experts had feared."

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"In a speech last week, Sebelius called the overpromising of vaccine one of the pandemic's "teachable moments" for her department. "We wanted to make sure the American people knew what we knew when we knew it, but we raised expectations too high," she said. Sebelius did not, however, specify how HHS would alter its approach in the future.

But additional millions of doses that remain in bulk form may last long enough to be combined into next fall's seasonal vaccine, giving manufacturers a head start on that always-unpredictable process—provided the circulating virus does not mutate over the summer to make the retained antigen unusable.

"It is theoretically possible that some of that antigen could be the H1N1 component of a trivalent vaccine," Dr. Anne Schuchat, director of the CDC's National Center for Immunizations and Respiratory Diseases, said in a briefing April 1. "Plans around that particular decision are under discussion between the Department of Health and Human Services and the individual manufacturers."

The full article can be found at:
http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/apr2610h1n1vax.html
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1976 'SWINE FLU' VACCINE MAY OFFER PANDEMIC H1N1 PROTECTION
By Maryn McKenna
CIDRAP News (Center for Infectious Disease Research & Policy – University of Minnesota)
April 26, 2010

"The long-derided "swine flu" vaccination campaign of 1976, infamous for its association with cases of paralyzing Guillain-Barre syndrome, may have had a benefit that went undetected for more than 30 years. According to work published Apr 23, it may have protected recipients against the 2009 pandemic

strain of flu.

Scientists from St Jude Children's Research Hospital in Memphis reported in the online edition of Clinical Infectious Diseases that people who received the 1976 vaccine produced a much more robust immune response against the novel 2009 strain than people of the same age who were not vaccinated back then. They also produced a stronger immune response against the seasonal H1N1 strain that circulated in 2008-09, which was replaced by the 2009 pandemic strain.

Taken together, the authors say, those results suggest that vaccination with a closely related strain of flu may confer some protection when vaccines against a circulating strain do not exist—such as in the early months after a pandemic strain first emerges, before the vaccine-manufacturing system can respond.

The study results arrive against a backdrop of observations and some laboratory reports from last winter that all describe older adults as less likely to have become infected with the novel 2009 flu."

The full article can be found at:
http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/apr2610sfvaccine.html
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