Chelan-Douglas December 2009

IMMUNIZATION NEWS

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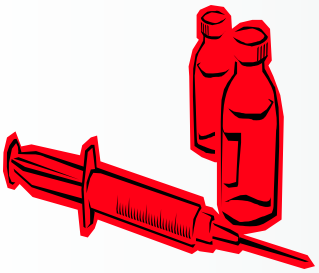


SEPARATE MEASLES, MUMPS, RUBELLA VACCINE FORMULATIONS DISCONTINUED

A representative from Merck announced that the company plans to discontinue production of monovalent measles, mumps, rubella vaccine formulations during the Advisory Committee on Immunization Practice's meeting. "We greatly value the role the CDC and the ACIP have taken in putting forth recommendations and policies about the optimal use of vaccines for infectious diseases. Similarly, we take our role very seriously in terms of developing and supplying vaccines that are optimally suited to meet these needs," said Mark Feinberg, MD, PhD, vice president of medical affairs in Merck's division of vaccines and infectious diseases. "Based on discussions that took place at the last ACIP meeting among scientific leaders we have decided that Merck will not resume production of our monovalent measles, mumps and rubella vaccines." Feinberg added that the company will focus attention to meet current prevention needs on production of the combination M-M-R II vaccine. "When we receive questions from parents or other interested parties we will refer them to the useful information provided by the CDC, the ACIP, the AAP and other professional organizations." Merck's decision is based on the ACIP's stated general preference for combination vaccines and follows controversial debates concerning the increased risk for febrile seizures among measles, mumps, rubella and varicella virus live vaccine (ProQuad, Merck) recipients at the past several meetings. Health care providers continue to experience push back from vaccine-hesitant parents, despite no evidence to support long term adverse events among patients who experienced the seizures and amid additional unfounded concerns that vaccines cause autism. These parents either decline vaccination or request to space out recommended vaccines, contrary to evidence that indicates delaying vaccines poses a greater risk to children than the theoretical threat from vaccines.

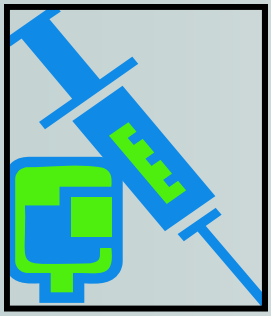
ANOTHER VACCINE FOR MENINGOCOCCAL DISEASE MAY BE MOVING TOWARD LICENSURE

An investigational vaccine for meningococcal disease was well-tolerated and yielded a stronger immune response in adolescents than the currently-licensed meningococcal vaccine, and these results may lead to another vaccine approval, according to findings presented by **Carol Baker, MD,** professor of pediatric molecular biology and microbiology at Baylor College of Medicine. The researchers compared the safety and immunogenicity of the investigational quadrivalent meningococcal CRM (197) conjugate vaccine MenACWY-CRM (Novartis) with the licensed meningococcal conjugate vaccine, Menactra (Sanofi Pasteur). The human complement geometric mean titers in participants receiving the MenACWY-CRM vaccine were higher than those in the Menactra group. Superiority criteria for this endpoint were met for all serogroups. Mild and/or moderate adverse reactions were reported by 64% of the participants in the MenACWY-CRM group and 70% of the participants in the Menactra group. "These results very likely could lead to another license," Baker said. "We are not yet certain about the duration of protection for the investigative drug, and questions remain about herd immunity. But for now, these results look promising."

Newborn vaccination with pneumococcal conjugate vaccine promising

Vaccinating children at birth with the seven-valent pneumococcal conjugate vaccine may be a viable way of providing early protection in countries who have a high disease burden, according to a speaker at the American Society for Microbiology's 49th Interscience Conference on Antimicrobial Agents and Chemotherapy. **David Goldblatt, PhD,** of the Immunobiology Unit at the UCL Institute of Child Health in London presented the results of the first trial to ever examine vaccine safety and immunogenicity in infants administered a first dose of seven-valent pneumococcal conjugate vaccine (PCV7, Wyeth) at birth compared with newborns administered a first dose at six weeks in accordance with WHO's Expanded Program on Immunization (EPI). The study was conducted at the Kenya Medical Research Institute in Kilifi. The following results were reported: Eighty-five percent or more of children in both groups achieved protective antibody titers greater than 0.35 mg/mL by 18 weeks. Patients vaccinated at six weeks had significantly higher immunoglobulin G geometric mean titers for serotypes 4, 6B, 18C and 19F at 18 weeks, and for serotype 4 at 36 weeks. Despite lower titers at 18 weeks of age, the avidity of the antibody specific for serotype 4 was of higher avidity in the newborn group when measured at 18 weeks of age. This indicates the antibody might be more functional, and this was confirmed by the observation that the newborn group had lower nasopharyngeal carriage of vaccine type pneumococci and higher carriage of nonvaccine types at both 18 and 36 weeks of age. "Functionally, despite the absence of demonstrable antibody responses in the first six weeks, when given at birth the vaccine clearly primed the infants in a way that they had more functional antibody that protect them from acquisition of pneumococci over the first 36 weeks of life. In resource-poor settings with high transmission of pneumococci, that could translate into clinical protection," Goldblatt said. – *by Nicole Blazek*

FDA Approves Agriflu Seasonal Influenza Vaccine
Another option to prevent illnesses caused by subtypes A and B influenza



The U.S. Food and Drug Administration approved Agriflu for people ages 18 years and older to prevent disease caused by influenza virus subtypes A and B. Agriflu, manufactured by Novartis Vaccines and Diagnostics in Siena, Italy, was approved using the FDA's accelerated approval pathway, which helps safe and effective medical products for serious or life-threatening diseases become available sooner. In this case, Novartis demonstrated that the vaccine induced levels of antibodies in the blood likely to be effective in preventing seasonal influenza. Common side effects in clinical studies included pain, swelling and redness at the injection site, headache, muscle aches and malaise. People with severe or life-threatening allergies to chicken eggs, or to any other substance in the vaccine, should not be vaccinated. As part of the accelerated approval process, Novartis is required to conduct further studies to verify that the vaccine induces levels of antibodies in the blood that are effective in preventing seasonal influenza.

Current Outbreaks
Providing Guidance to Travelers

Rabies in Bali, Indonesia

As of October 2009, the Indonesia Ministry of Health has reported 15 deaths caused by rabies on Bali. Most human and animal rabies cases have been confirmed near popular tourist destinations on the southern tip of Bali. However, because the situation is evolving, CDC advises travelers to take precaution on the *entire island*.

Israel in Midst of Mumps Outbreak

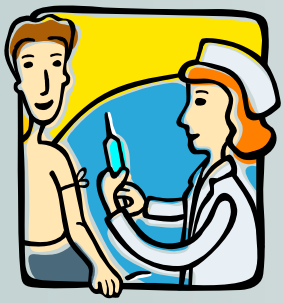
Since the beginning of September, 105 people in Israel have been diagnosed with mumps, the Health Ministry announced. Most of the cases have occurred in people between ages 10 and 24 years. In the same period of 2008, only four people were diagnosed, and only 13 cases were reported for the entire year. Most of the cases are believed to be in unvaccinated communities.

Yellow Fever in Brazil

Since the beginning of 2009, there has been an expansion in areas of yellow fever virus transmission in Brazil. Two states, Rio Grande do Sul and Sao Paolo, have recently designated expanded areas of risk following confirmation of new human cases of yellow fever within their boundaries. This demonstrates the particular intensity of yellow fever virus activity in the southern part of the country. Since February 2009, the state of Sao Paolo in Southern Brazil has reported 26 confirmed human cases of yellow fever, including 9 deaths. These cases have occurred in the municipalities of Itatinga, Sarutaia, Buri, and Piraju, which lie outside the previously reported risk area. These cases represent an expansion of yellow fever transmission in Sao Paolo.

Current Measles Activity

Since the beginning of 2009, there has been a growing number of cases of measles in the United Kingdom, specifically England and Wales. As of July 10, 2009, health authorities stated that England and Wales had reported 4,141 cases of measles, with 107 of those cases reported in the week ending July 10 alone. As of July 16, 2009, the Public Health Service of Wales had reported 355 cases of measles in Wales. Counties greatly affected are Carmarthenshire, Conwy, and Swansea. As of June 30, 2009, the United Nations Office for the Coordination of Humanitarian Affairs (UNOCHA) has reported over 51,000 cases and 300 deaths of measles in Burkina Faso so far this year. This is the largest measles outbreak in Burkina Faso in 10 years.



We're on the web!
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QUESTION AND ANSWER SECTION

Frequently asked questions on use of influenza A (H1N1) 2009 monovalent vaccines:

Q: The interval between doses stated in the 2009 H1N1 monovalent influenza vaccine prescribing information is "approximately 1 month". What does "approximately 1 month" mean?

A: CDC recommends that the two doses of 2009 H1N1 monovalent vaccines be separated by 28 days (4 weeks).

Q: Can the seasonal inactivated vaccine (trivalent inactivated vaccine or TIV) and the 2009 H1N1 monovalent inactivated vaccine be given at the same visit?

A: Yes

Q: If seasonal LAIV and 2009 H1N1 monovalent LAIV are inadvertently given at the same visit, do either or both doses need to be repeated, and if so, when?

A: Seasonal LAIV and 2009 H1N1 monovalent LAIV should not be administered at the same visit. While use of the 2 types of LAIV at the same visit could result in reduced immunogenicity for one vaccine, according to some experts, there are no data describing what happens with the vaccine response following simultaneous administration of LAIV vaccines. However, if both types of LAIV are inadvertently administered at the same visit neither vaccine needs to be repeated.

Q: What is the minimum interval between doses of seasonal LAIV and 2009 H1N1 monovalent LAIV?

A: There are no data on sequential administration of seasonal and 2009 H1N1 monovalent LAIV. The ACIP recommends a minimum interval of 28 days (4 weeks) between use of a seasonal LAIV and a 2009 H1N1 monovalent LAIV because these are considered to be 2 different vaccines. The ACIP recommendations were developed based on data from studies using attenuated injectable live virus vaccines such as the measles, mumps and rubella vaccine. Trials of 2009 H1N1 live attenuated vaccines have used a 28 day interval between doses and therefore, 28 days is the recommended interval between 2 doses of LAIV (seasonal and H1N1 monovalent LAIV). However, based on previous studies of LAIV replication and immune response, as little as 14 days (2 weeks) might be sufficient to allow for an appropriate immune response to both vaccines. Therefore, an interval between the two types of LAIV of 2 weeks or more may be acceptable, although an interval of 28 days is preferred.

Q. Can a live attenuated vaccine be given at the same visit as an inactivated influenza vaccine (e.g., seasonal LAIV and 2009 H1N1 monovalent inactivated vaccine, or 2009 H1N1 monovalent LAIV and seasonal trivalent inactivated influenza vaccine [TIV])?

A: Yes, based upon ACIP's recommendations, these two types of vaccines can be given at the same visit.

Immunization Action Coalition and the Centers for Disease Control and Prevention. Information about proper citations can be found at http://www.immunize.org/citeiac. You can access more "Ask the Experts" Q&A's in the online archive at http://www.immunize.org/askexperts.

With credit to the Immunization Action Coalition and the Centers for Disease Control and Prevention.