News

Third Case of Newly Discovered Severe Acute Respiratory Syndrome–like Virus

5 November 2012 (Reuters Health [Maha El Dahan])—A Saudi citizen in the capital Riyadh is the world’s third confirmed case of a newly discovered severe acute respiratory syndrome (SARS)–related virus, but he has now recovered from his illness, the official Saudi Press Agency reported. The potentially deadly novel coronavirus is from the same family as SARS, but had only been confirmed in 2 previous cases: a 60-year-old Saudi man who died earlier this year, and a man from Qatar who was treated in a London hospital.

The World Health Organization (WHO) put out a global alert in September on the virus, but later added that it did not appear to spread easily from person to person.

Coronaviruses also include strains that cause the common cold, as well as SARS, which emerged in China in 2002 and killed around a tenth of the 8000 people it infected worldwide.

Saudi Arabia had taken precautions to prevent the disease from spreading among Muslim pilgrims during the annual Haj pilgrimage which took place at the end of October. Millions of Muslims from 160 countries flock to Mecca and Medina during the Haj season to perform the annual religious ritual, and Saudi Arabia had said at the time it was taking preventive measures to stop the virus from spreading.

Editorial comment. As of 10 December 2012, there have been a total of 9 confirmed cases, 5 from Saudi Arabia (3 deaths), 2 from Qatar and 2 from Jordan (2 deaths). There were 2 clusters: 1) 2 cases plus 2 unconfirmed cases in the same Saudi family, and 2) 2 cases and 9 unconfirmed cases, mainly among health care workers in a hospital in Jordan.

Genomic analysis of the coronavirus involved in the earlier cases indicates that the closest relative to this coronavirus was a bat virus identified in 2008 in the Netherlands. This was in turn closely related to bat coronaviruses detected in Hong Kong.

Hantavirus Pulmonary Syndrome in Visitors to a National Park—Yosemite Valley, California, 2012

(MMWR 61:952, 2012)—On 16 August 2012, the California Department of Public Health announced 2 confirmed cases of hantavirus pulmonary syndrome (HPS) in California residents who had stayed overnight in Yosemite National Park, launching an investigation by the National Park Service, California Department of Public Health, and the Centers for Disease Control and Prevention. On August 27, Yosemite National Park announced 2 additional cases, and by October 30, 10 cases had been confirmed.

The National Park Service notified by e-mail, telephone, or mail all registered overnight Yosemite National Park visitors (approximately 260,000 guests) who had stayed at the park during 1 June–17 September 2012.

The 10 confirmed patients came from 3 states: California (8), West Virginia (1), and Pennsylvania (1). Ages ranged from 12 years to 56 years; 4 were female. Nine patients had typical symptoms of HPS, and 1 lacked respiratory symptoms; 3 died.

Nine patients stayed in Curry Village “signature” cabins, which have insulation between the canvas exterior and interior hard walls. Rodent infestations were detected in the insulation, and all 91 signature cabins were closed indefinitely on August 28. In addition, educational interventions were enhanced for staff members and visitors parkwide, and multifaceted rodent control measures, including trapping throughout Curry Village, were implemented.

HPS is a nationally notifiable disease caused in the United States most commonly by Sin Nombre virus. The deer mouse (Peromyscus maniculatus) is the reservoir. Infected mice shed virus in urine, feces, and saliva. Humans become infected through the inhalation of aerosolized virus from rodent excreta and via direct contact from rodent bites. The incubation period ranges from 1 to 6 weeks. Early symptoms include fever, chills, myalgia, headache, and gastrointestinal symptoms for 1–7 days, progressing rapidly to respiratory distress and shock. Most patients require hospitalization, supplemental oxygen, and intubation. The case-fatality rate is approximately 36%. There is no specific treatment for HPS, but early supportive care can reduce mortality. Before this outbreak, 58 cases of HPS had been reported among California residents since 1994; 2 had been visitors to Yosemite National Park before 2012.

Clinicians are reminded to consider the diagnosis of hantavirus infection in all persons with febrile illness and sudden onset of respiratory symptoms with a history of rodent exposure. Because HPS is a reportable disease in the United States, clinicians suspecting HPS should notify and consult their state health department about confirmatory testing.
Park visitors and the public are advised to avoid contact with rodents and their urine, droppings, and nesting materials.

**Novartis Receives Food and Drug Administration Approval for Flucelvax, the First Cell-Culture Vaccine in United States to Help Protect Against Seasonal Influenza**

(Novartis news release)—Flucelvax utilizes full-scale cell-culture manufacturing technology, an alternative production method to traditional egg-based production. Cell-culture technology utilizes a well-characterized mammalian cell line rather than chicken eggs to grow virus strains.

The production occurs in a closed, sterile, controlled environment, which significantly reduces the risk of potential impurities. Flucelvax does not contain any preservatives, such as thimerosal, or antibiotics.

Cell-culture technology enables a rapid response to urgent public health needs such as a pandemic within weeks. Traditional influenza vaccine production depends on a large number of fertilized chicken eggs to grow virus strains and requires many months for the organization of egg supplies, virus incubation, and actual production before the vaccine is delivered to physicians or pharmacies. Cell-culture technology is successfully used to manufacture other vaccines, including those distributed during the H1N1 pandemic, as well as vaccines for polio, rubella, and hepatitis A.

“Modern cell-culture technology will likely become the new standard for influenza vaccine production and we are proud to lead the way,” said Andrin Oswald, Division Head, Novartis Vaccines and Diagnostics.

“The availability of a cell-culture vaccine is an important step to ensuring our Readiness for Seasonal influenza, as well as a potential pandemic,” said Dr William Schaffner, professor of medicine and chair of preventive medicine at Vanderbilt University, Nashville, Tennessee. “Annual influenza vaccination is an important public health measure that helps protect thousands of people from illness and death each year.”

**Editorial comment.** The development of facilities capable of using cell culture technology to produce influenza vaccines is important because of the elimination of the need for huge numbers of eggs and the ability to respond faster with vaccine production in a pandemic.

**Food and Drug Administration Panel Backs Dynavax’s Hepatitis B Vaccine Efficacy, Not Safety**

16 November 2012 (Reuters Health [Zeba Siddiqui])—A US Food and Drug Administration (FDA) panel voted unanimously to recommend the effectiveness of Dynavax Inc’s hepatitis B vaccine Heplisav, but raised concerns about its safety, asking for more data from studies on a wider population. The views of the panel of outside experts were based on data submitted by Dynavax that compared the safety and immunogenicity of its Heplisav with that of Engerix B, an older vaccine by GlaxoSmithKline PLC.

“The immunogenicity data that was provided by [Dynavax] was excellent, but I have concerns with the population. I think what we have here is really, really good but it is not representative of the United States,” a panel member said.

Dynavax conducted the studies on 5845 patients to support Heplisav’s marketing approval application. The patients, mainly from the United States, Canada and Germany, were 18 years and older.

“Prior to the vote, [the panel members] peppered [Dynavax] with questions about the adverse events and the lack of sufficient representation of cross-sections of the populations in the study pool, specifically Asian-Americans, African-Americans and Hispanics,” FDA spokeswoman Rita Chappelle said in an e-mail.

The panel members asserted that Dynavax should focus on a larger database of 10 000 or more ethnically diverse patients from a higher-risk population that would highlight the benefits of the vaccine more prominently.

All 13 panel members favored the efficacy profile of Heplisav. Eight panel members questioned the safety of the vaccine based on available data, while 5 favored it.

“I don’t think the safety database is sufficiently large to support the recommendation for use [of the vaccine] in a general adult population, given that it contains an adjuvant,” another member said.

“Products need to be both safe and effective for its intended use and in this case, the committee felt that Heplisav did not meet that threshold,” FDA’s Chappelle said.

In briefing documents, FDA staff had noted that while the incidence of autoimmune events in Heplisav-Engerix B studies were low, all autoimmune adverse events occurred in the Heplisav arm of the study.

The FDA will take the panel’s opinions into consideration when it decides whether to grant marketing approval to the vaccine.

**Editorial comment.** Heplisav is a 2-dose conjugate vaccine given a month apart and provides more reliable, and rapid, antibody responses than available hepatitis B vaccines. Available vaccines for adults require 3 doses given over 6 months to provide seroprotection of approximately 30%, 75%, and 90% after the first, second, and third doses, respectively. Furthermore, many do not finish the course of 3 injections.

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