

PCAST Recommendations and Administration Progress

VACCINES

Recommendation: We recommend that DHHS accelerate the availability of a portion of the vaccine supply to mid-September by having manufacturers begin to “fill and finish” a subset of the bulk vaccine product at 15 micrograms. Such a decision would need to be taken almost immediately.

Progress: All five manufacturers with orders to make H1N1 vaccine for USG have been asked to put their initially available vaccine in vials as soon as they are ready . This will move forward, even while awaiting results of clinical studies to confirm expected dosing, to assure the earliest possible availability of initial doses of vaccine. Once ready, it takes approximately a month for vaccine to both be placed in vials and then for the needed testing to be completed before the vaccine is ready to use.

TRACKING THE VIRUS

Recommendation: *We recommend that DHHS take rapid advantage of available opportunities to upgrade national surveillance systems to improve decision making during the fall resurgence. The critical surveillance information for decision making includes data on influenza-like symptoms in the population, emergency room admissions, health system utilization, hospitalized patients, and adverse events.*

Progress: HHS and CDC, with assistance and guidance from OSTP and the office of the Chief Technology Officer, in partnership with hospitals throughout the country, are expanding a system to track emergency department visits and admissions for influenza-like illness, which will help monitor the spread of the disease. HHS and CDC are expanding the capability to track the influenza virus by providing test kits and devices to over 140 public health laboratories to detect 2009 -H1N1 flu and other influenza subtypes. Viruses detected through this network are characterized to determine if they are resistant to antiviral drugs and if they continue to be similar to the viruses used in the vaccines. CDC is adding approximately 900 additional sentinel clinic providers to improve tracking of influenza-like illness. Public health surveillance is being enhanced through addition of aggregate data from existing emergency department and hospital information systems to help determine when influenza activity is increasing in communities across the U.S. In addition, CDC is expanding the number of large metropolitan areas participating in hospitalization surveillance to detect increased severity of influenza in the U.S. CDC has enhanced and expanded existing tracking systems and will be collaborating with public and private partners to better understand the spread and impact of the virus.

HHS, CDC, and FDA, in collaboration with states and health insurers, have been enhancing their surveillance for vaccine adverse events.

DHS, in conjunction with Federal departments and agencies, State, local, and territorial governments, and tribal and private sector partners, are adding to our situational awareness by tracking flu-related socio-economic indicators. This will facilitate timely, intelligent decision-making as we navigate the fall flu season.

SCHOOLS AND EDUCATION

Recommendation: We recommend that the Department of Education, working with the Department of Health and Human Services and the Department of Labor, meet with representatives from state and local school districts in August 2009 to identify the financial needs and regulatory barriers that would discourage decisions to close schools when public health conditions warrant such closures and to consider actions that Federal, state, and local authorities could take to reduce those disincentives. We also recommend that the Department of Education develop clear and effective 2009-H1N1 contingency plans by October 1, 2009, and designate a health professional who is familiar with public schools to provide guidance to schools.

Progress: A legal team at the Department of Education has fast-tracked the task of exploring what would be involved in waiving certain federal education requirements that could inadvertently hurt schools with high rates of flu-related absenteeism. The Department is also investigating various options that could help provide breakfast and lunches to children who count on the federal school lunch program to meet their basic nutritional requirements. In addition, the Department of Agriculture (USDA) has recently issued guidance on how schools or other community organizations can receive authorization from their States to use the Summer Food Service Program or the Seamless Summer Option to reimburse for meal service to low-income children during H1N1-related school dismissals. In addition, Education Secretary Arne Duncan, in collaboration with CDC, has issued guidance for K-12 school administrators and separate guidance to institutions of higher education. CDC is also developing guidance for early childhood education and child care centers.

ANTIVIRALS

Recommendation: We recommend that CDC clarify and strengthen its guidelines for use of antiviral drugs, including for treatment, pre-exposure, and post-exposure prophylaxis, and contingency plans for the development of drug resistance. These guidelines and plans, and their rationales (including preservation of limited supply for those in greatest need), should be clearly communicated to state and local health departments, health care practitioners, and the public. State and Federal supplies of antiviral drugs should be monitored on a frequent basis.

Progress: CDC is currently revising interim guidance for use of influenza antiviral medications, including recommendations for appropriate use for treatment, pre/post-exposure prophylaxis, and prioritization of early treatment of persons at increased risk for influenza-related complications, and expects to have these revisions finalized by the end of August. CDC is currently working in conjunction with influenza antiviral medication manufacturers, distributors, and national retail pharmacy stakeholders to develop a 'dashboard' for medication inventory within the commercial supply chain system.

INTRAVENOUS ANTIVIRALS

Recommendation: We recommend that FDA accelerate a decision about the availability of antiviral drugs (peramivir, zanamivir, or oseltamivir) for intravenous antivirals.

Progress: The FDA is actively engaged with manufacturers, along with other relevant Federal agencies, to promote the manufacture and sound evaluation of these products and to develop the data that could potentially allow such products, if found safe and effective, to be approved. Preparatory work is also being done to facilitate their availability under an Emergency Use Authorization if needed and appropriate, based on the scientific data. HHS is moving forward with the purchase of intravenous antivirals for use under EUA for individuals who may require them.

HEALTH COMMUNICATIONS

Recommendation: We recommend that CDC engage not only traditional media, with which CDC has deep experience, but also new media and social networking channels, especially given the propensity of the 2009-H1N1 virus to infect young people.

Progress: CDC emergency twitter already has over 300,000 followers (in comparison to 30,000 at the start of the spring outbreak). CDC plans to expand those strategies throughout the fall and winter flu seasons (e.g., pushing information to social networking sites like Facebook and MySpace, reaching out to select bloggers, utilizing mobile communication technology, Twitter feeds, widgets and content syndication).

Recommendation: We recommend that CDC work to harmonize its recommendations with those of relevant professional societies prior to their public release. As discussed in Chapter 5, relevant societies include the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), and, where recommendations concern children, the American Academy of Pediatrics (AAP).

Progress: CDC has been holding frequent consultations with clinical professional associations related to the development and release of health recommendations. In addition, CDC holds twice-monthly calls and outreach activities involving more than 150 clinician professional organizations and 40,000 individual clinicians for updates and discussion of 2009-H1N1 and related health issues.