Feds Spell Out Plan for Dealing With Flu Pandemic

Draft of federal plan calls for stockpiling vaccines and developing antiviral drugs and prophylaxis.

By DAVID STERNBERG
Contributing Writer

BALTIMORE — Acknowledging that “flu has a huge news factor,” Bruce Gellin, M.D., spelled out the federal influenza pandemic preparedness plan at a biode- fense research meeting sponsored by the American Society for Microbiology.

The Department of Health and Hu- man Services’ draft Pandemic Influenza Response and Preparedness Plan, devel- oped in August 2004, includes influenza control, stockpiling vaccines, developing antiviral drugs and prophylaxis, providing quality medical care, and maintaining community services, said Dr. Gellin, di- rector of the National Vaccine Program Office, a division of HHS. The Pandemic Influenza Vaccine Stockpile is a new federal influenza planning priority.

Influenza vaccine preparedness is a major focus of the HHS plan. To that end, Dr. Gellin said the United States must en- hance annual influenza vaccine use, ensure a year-round egg supply, increase and di- versify manufacturing capacity, and improve the ability to rapidly develop ref- erence strains.

As for antiviral drugs, the U.S. govern- ment currently stockpiles 2 million doses of Tamiflu (oseltamivir) and 4 million doses of Flumadine (rimantadine). He ac- knowledged the need for a greater stock- pile of these drugs, as well as a push for other therapies besides antivirals.

Even in the case of a mild pandemic, Dr. Gellin emphasized the heightened need for inpatient medical services and effective triaging of patients, noting that there would be an estimated 23% increase in de- mand for inpatient beds, ICU beds, and ventilators.

A few key issues remain unresolved, ac- cording to Dr. Gellin, including deter- mining priority groups for early vaccine and antiviral use in the event of a pan- demic; purchase and distribution of pub- lic- and private-sector vaccinations and related issues, including indemnification, liability protection, and compensation.

Two other significant issues addressed in the pandemic plan are development of new vaccines and therapeutics.

Richard J. Webby, Ph.D., of St. Jude Children’s Hospital in Memphis, pointed out the many considerations for creating a vaccine in response to an emerging in- fluenza pandemic.

“There is no way of accurately predict- ing what strain it might be; there is enor- mous diversity of viruses in animal reservoirs, and some viruses are highly pathogenic,” he said.

But a procedure called reverse genetics has been significant in Dr. Web- by’s work at St. Jude’s in accelerating the develop- ment of vaccines. Re- verse genetics begins with a cloned segment of DNA and introduces programmed mutations back into the genome to investigate gene and protein function.

Unresolved issues include determining priority groups for early vaccine and antiviral use in a pandemic, and purchasing public- and private-sector vaccinations.

HHS Hopes to Speed Production of Pandemic Vaccine With Contract

T he U.S. Department of Health and Human Ser- vices recently awarded $97 million to Sanofi Pasteur to speed development of a manufacturing technique that could cut the time it takes to get an influenza vacci- ne to market. But the technique, which involves growing flu strains in cell culture, initially will be used only to create a vaccine against a pandemic strain.

Traditionally, vaccine pro- duction takes at least 9 months, from the time strains are selected for in- clusion to when the shot is ready for distribution. The new technique might cut a few weeks off that process, even more savings coming in the beginning.

Under the current manu- facturing scenario, influenza strains must be adapted so they can be grown in chicken eggs. Eggs delay com- pletion of the strains either cannot be grown in eggs, or are difficult to grow. With the new technique, the strain would not need adaptation because it would be grown in a human cell line. The line—of retinal cells—was developed by a Sanofi part- ner, Crucell, a Dutch biotechnology company.

Even though many ex- perts think the cell culture line will be more reliable than eggs for growing influenza vaccine strains, there is no guarantee. And even if the manufacturing technique is successful, it will still have to be approved by the Food and Drug Administration.

Sanofi Pasteur said it an- ticipates beginning human tri- als late next year. The HHS contract provides funds only for phase I and II studies, but the company an- ticipates continuing through phase III and on to market.

As part of the HHS con- tract, the company is also re- quired to complete a feasibil- ity study for supplying up to 300 million doses a year. Cur- rently, the company has no plans for building a manufactur- ing facility that could ac- commodate that production.

By ALICIA AULT
Contributing Writer

WASHINGTON — Despite the severe shortage of influenza vac- cine this winter, the elderly, young children, and others at risk were able to find and receive shots, offi- cials said at the National Immu- nization Conference sponsored by the Centers for Disease Control and Prevention.

One it was known last October that Chiron Corp. would not be able to deliver its half of the na- tion’s vaccine supply, the CDC im- mediately set up a special surveil- lance team to find out where the vaccine was going and who re- ceived it, said Susan Chu, Ph.D., acting director of the agency’s Of- fice of Science Policy and Tech- nology Transfer.

Seventeen new questions on the flu vaccine were added to the monthly Behavioral Risk Factor Surveillance System survey. From November 2004 to February 2005, 105,473 adults and 35,106 children (of proxy) were interviewed, said Michael Link, Ph.D., of the CDC’s behavioral survey branch.

And, in a change of pace de- signed to keep state and federal agencies on top of the shortage, data were submitted to CDC week- ly, not monthly, and were analyzed within days, giving states new data every 12 days or so, Dr. Link said.

As of late March, the survey found that vaccines were received by 63.5% of respondents over aged 65 years, 26.8% of 18- to 64-year-olds at high risk, and 36% of health care workers, said Gary Euler, Dr.P.H., of the CDC’s National Immuniza- tion Program’s epidemiology and surveillance division. These figures were slightly higher than those gathered through January and re- ported in the CDC’s Morbidity and Mortality Weekly Report. Accord- ing to that data, 62.7% of those over aged 65 years, 25.3% of those with high-risk conditions aged 18- 64 years, and 31% of health care workers received vaccinations (MMWR 2005;54:304-7).

Through February, among healthy Americans, 7.2% of those aged 18-49 years, and 17.3% of those 50-64 years said they had been vaccinated, compared with 6.9% and 16.5%, respectively, through January.

Fifty-two percent of children aged 6-23 months received a vac- cine; up from 48.4% over the same period in January, a high uptake rate, given that 2004 was the first year the CDC’s Advisory Committee on Immu- nization Practices recommended adding the flu shot to routine im- munizations, said Carolyn Bridges, M.D., an epidemiologist with the agency’s influenza branch.

Dr. Euler said there was room for improvement, as the survey found that many parents said they did not get vaccines for their children because they did not think they needed them. The demand for vaccine among patients aged 65 years and older was mostly met, though there was some problem getting vaccine in early November, Dr. Euler said.

An audience member questioned whether some of the demand had been met in Canada. As part of the survey, patients were asked where they got a vaccine. So if they went to Canada, that data would be captured, through it has not been ana- lyzed yet, Dr. Euler said.

Vaccination rates also varied from state to state. Preliminary data indicate that states with low- er immunization coverage had a smaller vaccine supply. Further analysis of the variation and the entire flu database will be coming over the next 6 months, Dr. Link said.

The CDC researchers acknowled- ged that the survey was limited because it is self-reported information, and does not cover people who are institutionalized.

Dr. Bridges said the CDC cur- rently is researching whether faster analysis of flu data helped states with their shot distribution and management.

Many High-Risk Patients Got Flu Shots

By ALICIA AULT
Contributing Writer

The U.S. Department of Health and Hum- man Services recently awarded $97 million to Sanofi Pasteur to speed development of a manufacturing technique that could cut the time it takes to get an influenza vacci- ne to market. But the technique, which involves growing flu strains in cell culture, initially will be used only to create a vaccine against a pandemic strain.

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