Future Federal Policy Directions: Influenza Vaccine and Vaccination

National Influenza Vaccine Summit
May 18, 2010

Bruce Gellin, MD, MPH
Director, National Vaccine Program Office
Deputy Assistant Secretary for Health

Seasonal-Pandemic-Seasonal-Pandemic-Seasonal-Pandemic-Seasonal

Look ahead but remember where you’ve been

Pandemic-Seasonal-Pandemic-Seasonal-Pandemic-Seasonal-Pandemic-Seasonal
Updating the National Vaccine Plan:
A roadmap for the next decade
A National, not Federal, Plan

2008 Draft Strategic National Vaccine Plan

**Goals**

1. Develop new and improved vaccines
2. Enhance the safety of vaccines and vaccination practices
3. Support informed vaccine decision-making by the public, providers, and policy-makers
4. Ensure a stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability and death in the United States
5. Increase global prevention of death and disease through safe and effective vaccination
The Vaccine and Immunization Enterprise

The race between the virus and the vaccine
The race between the virus and the vaccine

National Weekly uptake of vaccine and Disease Activity 2009/2010 season

Weekly Uptake of Seasonal and H1N1 Vaccine and Disease Activity in Physician Offices

Source: SDI
Improving Influenza Vaccine Manufacturing

- Surge capacity
- Vaccine platforms that can shorten production timelines
- Dose optimization strategies
  - Adjuvants
  - Delivery systems
- A “universal” vaccine
Advances in influenza and influenza vaccine: Science and Opportunity

New Strategies for Influenza Vaccines
- DNA-based vaccines
- Recombinant subunit vaccines
- Microbial vector vaccines
- Virus-like particles
- Synthetic peptide vaccines
• Coordination
• Scenarios
• Surveillance
• Response
• Barriers
• Communications
• Future Preparedness
• Future Preparedness
  – Accelerate speed and increase yield and effectiveness of vaccine production
  – Facilitate development of additional antiviral drugs
  – Improve medical surveillance
  – Enhance animal surveillance measures

We have gone from a bystander to a leader in the fight against climate change. We’re helping developing countries to feed themselves, and continuing the fight against HIV/AIDS. And we are launching a new initiative that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease — a plan that will counter threats at home and strengthen public health abroad.
Prospects for and barriers to improved production of influenza vaccines
Next generation influenza vaccines in development
Financial and regulatory incentives/disincentives
Implications for other biological threats

Translation of early phase investments in basic science towards potential public health interventions.
Partnerships: federal programs, the innovator and the commercial marketplace
Market forces: incentives and disincentives
Regulatory issues and regulatory science
Application of innovative approaches being used to advance drug development for orphan products (e.g., rare, neglected, tropical diseases) or any other area of difficult commercial market development (e.g. oncology therapeutics)
The Vaccine and Immunization Enterprise

The Critical Role of Communications
Public Understanding of Science

Figure 7-6
Public understanding of scientific terms and concepts: 2001

<table>
<thead>
<tr>
<th>Term</th>
<th>Europe</th>
<th>United States</th>
</tr>
</thead>
<tbody>
<tr>
<td>How long does it take for the Earth to go around the Sun? (4 years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the Earth go around the Sun, or does the Sun go around the Earth? (Earth around the Sun)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radioactive waste can be made safe by boiling it. (False)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The earliest humans lived at the same time as the dinosaurs. (False)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human beings, as we know them today, developed from earlier species of animals. (True)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The continents on which we live have been moving their location for millions of years and will continue to move in the future. (True)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibiotics kill viruses as well as bacteria. (False)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrons are smaller than atoms. (True)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lasers work by focusing sound waves. (False)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is the father’s gene which decides whether the baby is a boy or a girl. (True)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The oxygen we breathe comes from plants. (True)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All radioactivity is man-made. (False)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The center of the Earth is very hot. (True)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SOURCES: National Science Foundation, Division of Science Resources Statistics, Survey of Public Attitudes Toward and Understanding of Science and Technology, 2001; and European Commission, Eurosibometer 55.2 survey and standard report, Europeans, Science and Technology, December 2001.
How long does it take the Earth to go around the Sun?

The earliest humans lived at the same time as the dinosaurs.
Public Understanding of Science

Antibiotics kill viruses as well as bacteria

ACIP Recommendations for H1N1 Vaccine: Implications for Implementation of Universal Recommendations

When supply adequate:
- Pregnant women,
- People who live with or care for children younger than 6 months of age,
- Health care and emergency services personnel,
- Persons between the ages of 6 months through 24 years of age, and
- People from ages 25 through 64 years who are at higher risk for novel H1N1 because of chronic health disorders or compromised immune systems.

When supply limited:
- Pregnant women,
- People who live with or care for children younger than 6 months of age,
- Health care and emergency services personnel with direct patient contact,
- Children 6 months through 4 years of age, and
- Children 5 through 18 years of age who have chronic medical conditions.
The Vaccine and Immunization Enterprise

- Vaccine Research
- Vaccine Development
- Vaccine Licensure
- Vaccine Manufacture
- Vaccine Distribution
- Vaccine Sales/Purchase

Communication and Education Strategies
- Develop vaccine recommendations
- Attitudes about vaccination

Access/Reimbursement
- Vaccination (Adult, Adolescent, and Childhood)
- Adverse Event Monitoring

Vaccine Coverage Surveillance
- Vaccine Injury Compensation

High Vaccination Rates
- Population health protection against infectious disease in the U.S. and globally
- Reduced Morbidity and Mortality from infectious disease in the U.S. and globally

Translational research for diffusion of innovation

Recognition of public health priorities

The Swine Flu Affair
Decision-Making on a Slippery Disease
Richard E. Neustadt
Harvey V. Fineberg

1976 and 2009

Another H1N1 Victim - Teen Athlete Crippled With...
National Vaccine Advisory Committee

H1N1 Vaccine Safety Risk Assessment Working Group

• Conduct rapid reviews of 2009 H1N1 vaccine safety data
• Provide ongoing updates of their findings to the National Vaccine Advisory Committee (NVAC).
• They will meet regularly to review and assess data for six months after the conclusion of the 2009 H1N1 influenza vaccination program.
• The VSRAWG will make monthly reports to the NVAC on public conference calls.

The working group’s primary objectives are to:

• Serve as a sounding board for the federal government to independently assess possible adverse events of interest
• Objectively and rapidly review potential vaccine-associated adverse events
• Identify and establish priorities for additional studies that will inform their assessment of an association between a vaccine and a health event
• Assess the likelihood of a causal relationship between a vaccination and a health event
• Identify any special populations who may be at increased risk
• Provide information needed for action by the health officials through the National Vaccine Advisory Committee in a timely manner

http://www.hhs.gov/nvpo/nvac/subgroups/h1n1risk.html
The Vaccine and Immunization Enterprise

- Vaccine Research
- Vaccine Development
- Vaccine Licensure
- Vaccine Manufacture
- Vaccine Distribution
- Vaccine Sales/Purchase
- Vaccination (Adult, Adolescent, and Childhood)
- Adverse Event Monitoring
- Access/Payment for Vaccination/Reimbursement
- Development of Vaccine Recommendations
- Communication and Education Strategies
- Recognition of Public Health Priorities

- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Adverse Event Monitoring
- Access/Payment for Vaccination/Reimbursement
- Development of Vaccine Recommendations
- Communication and Education Strategies
- Recognition of Public Health Priorities

- Vaccine Injury Compensation
- Vaccine Injury Compensation

- High Vaccination Rates
- Reduced Morbidity and Mortality from Infectious Disease in the U.S. and Globally
- Population Health Protection against Infectious Disease in the U.S. and Globally

- Cumulative Number of Provider Agreements, H1N1 Vaccine Program, Sept 2009-Jan 2010

- Tripled number of providers receiving vaccine through public health system

- Cumulative Number of Provider Agreements, H1N1 Vaccine Program, Sept 2009-Jan 2010
Patient Protection and Affordable Care Act and Immunization: Selected Highlights

- Expands health insurance access

- All ACIP-recommended vaccines shall be included/paid for in new private insurance plans without cost-sharing
  - Medicaid: Incentive eligible for 1% Federal Medical Assistance Percentage (FMAP) for states that cover United States Preventive Services Task Force A and B and ACIP services with no cost sharing for adults (Effective 2013)

- Comptroller General to study Medicare part D regarding any barriers to vaccines; report to Congress by 06/01/2011

- HHS may develop contracts for states to purchase (additional) vaccines for adults

The Vaccine and Immunization Enterprise
The Council of Europe has alleged that pharmaceutical companies have forced the World Health Organization to declare swine flu as a pandemic, seeking more profits.

It is of the view that they have misled governments to stockpile vaccines…and have bought billions of dollars worth of medicines.

Some of the agreements do not allow governments to get out of buying vaccines.

Now, the governments are saddled with excess vaccines, and they are planning to sell them to other countries. Excess supply over demand will push down the prices as well.

The Council is likely to probe the pharmaceutical companies based on some evidence. It is in the process of gathering arguments along with the legal standards organization.

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release  September 17, 2009

President Announces Plan to Expand Fight Against Global H1N1 Pandemic

Today, President Obama announced the United States will continue to act aggressively to stop the global spread of the pandemic 2009-H1N1 influenza virus and is prepared to make 10 percent of its H1N1 vaccine supply available to other countries through the World Health Organization (WHO).

In recognition that diseases know no borders and that the health of the American people is inseparable from the health of people around the world, the United States is taking this action in concert with Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland, and the United Kingdom.

The United States will make the H1N1 vaccine available to the WHO on a rolling basis as vaccine supplies become available, in order to assist countries that will not otherwise have direct access to the vaccine.
For Immediate Release

September 17, 2009

President Announces Plan to Expand Fight Against Global H1N1 Pandemic

Today, President Obama announced the United States will continue to act aggressively to stop the global spread of the pandemic 2009-H1N1 influenza virus and is prepared to make 10 percent of its H1N1 vaccine supply available to other countries through the World Health Organization (WHO).

In recognition that diseases know no borders and that the health of the American people is inseparable from the health of people around the world, the United States is taking this action in concert with Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland, and the United Kingdom.

The United States will make the H1N1 vaccine available to the WHO on a rolling basis as vaccine supplies become available, in order to assist countries that will not otherwise have direct access to the vaccine.

WHO Pandemic Vaccine Deployment
May 3, 2010

<table>
<thead>
<tr>
<th>Country</th>
<th># of Doses</th>
<th>Arrival</th>
<th>Country</th>
<th># of Doses</th>
<th>Arrival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
<td>500,000</td>
<td>22 Feb</td>
<td>Angola</td>
<td>370,000</td>
<td>29 Mar</td>
</tr>
<tr>
<td>Lao</td>
<td>400,000</td>
<td>25 Feb</td>
<td>Guyana</td>
<td>75,000</td>
<td>29 Mar</td>
</tr>
<tr>
<td>PHL Government</td>
<td>700,000</td>
<td>26 Feb</td>
<td>Guatemala</td>
<td>260,000</td>
<td>30 Mar</td>
</tr>
<tr>
<td>Togo</td>
<td>132,000</td>
<td>27 Feb</td>
<td>Philippines</td>
<td>1,900,000</td>
<td>30 Mar</td>
</tr>
<tr>
<td>Nuvar</td>
<td>1,000</td>
<td>27 Feb</td>
<td>Toalista</td>
<td>1,000</td>
<td>30 Mar</td>
</tr>
<tr>
<td>Maldives</td>
<td>31,200</td>
<td>02 Mar</td>
<td>Azerbaijan</td>
<td>341,000</td>
<td>01 Apr</td>
</tr>
<tr>
<td>Fiji</td>
<td>88,200</td>
<td>03 Mar</td>
<td>Bolivia</td>
<td>900,000</td>
<td>02 Apr</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>110,000</td>
<td>00 Mar</td>
<td>Myanmar</td>
<td>972,000</td>
<td>04 Apr</td>
</tr>
<tr>
<td>Tonga</td>
<td>10,000</td>
<td>00 Mar</td>
<td>Suriname</td>
<td>50,000</td>
<td>15 Apr</td>
</tr>
<tr>
<td>Vanuatu</td>
<td>25,000</td>
<td>00 Mar</td>
<td>Seychelles</td>
<td>9,000</td>
<td>21 Apr</td>
</tr>
<tr>
<td>Kiribati</td>
<td>10,000</td>
<td>04 Mar</td>
<td>Timor-Leste</td>
<td>117,000</td>
<td>21 Apr</td>
</tr>
<tr>
<td>Solomon Is.</td>
<td>55,000</td>
<td>04 Mar</td>
<td>Liberia</td>
<td>78,000</td>
<td>23 Apr</td>
</tr>
<tr>
<td>Kosovo</td>
<td>100,000</td>
<td>09 Mar</td>
<td>Niue</td>
<td>1,700</td>
<td>23 Apr</td>
</tr>
<tr>
<td>Cuba</td>
<td>1,124,000</td>
<td>17 Mar</td>
<td>Bangladesh</td>
<td>3,000,000</td>
<td>27 Apr</td>
</tr>
<tr>
<td>Honduras</td>
<td>140,000</td>
<td>18 Mar</td>
<td>Sudan</td>
<td>700,000</td>
<td>29 Apr</td>
</tr>
<tr>
<td>Kenya</td>
<td>730,000</td>
<td>24 Mar</td>
<td>El Salvador</td>
<td>2,276,000</td>
<td>30 Apr</td>
</tr>
<tr>
<td>Cook Is.</td>
<td>2,000</td>
<td>24 Mar</td>
<td>Georgia</td>
<td>100,000</td>
<td>01 May</td>
</tr>
<tr>
<td>Samoa</td>
<td>10,000</td>
<td>24 Mar</td>
<td>Paraguay</td>
<td>600,000</td>
<td>02 May</td>
</tr>
<tr>
<td>Tokelau</td>
<td>200</td>
<td>24 Mar</td>
<td>Cambodia</td>
<td>1,800,000</td>
<td>03 May</td>
</tr>
<tr>
<td>Pakistan</td>
<td>3,100,000</td>
<td>29 Mar</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total: 39 Countries / 20,930,900 doses
Map of current and new influenza vaccine manufacturers

CDC’s 2010 National Immunization Conference

- Adolescent Immunization
- Adult Immunization
- Assessment
- Barriers to Vaccination
- Community Partnerships
- Childhood Immunization
- Cultural Diversity
- Global Immunization
- Health Communications
- Health Education
- Policy and Legislation
- New Vaccines and Vaccine Development
- Vaccine-Preventable Diseases
- Vaccine Safety
- Vaccine Supply
- Immunization Registries
- Surveillance
• Adolescent Immunization
• Adult Immunization
• Assessment
• Barriers to Vaccination
• Community Partnerships
• Childhood Immunization
• Cultural Diversity
• Global Immunization
• Health Communications
• Health Education
• Policy and Legislation
• New Vaccines and Vaccine Development
• Vaccine-Preventable Diseases
• Vaccine Safety
• Vaccine Supply
• Immunization Registries
• Surveillance

Seasonal Influenza Preparedness  Pandemic Influenza Preparedness
Seasonal Influenza Preparedness

Pandemic Influenza Preparedness

Preparedness for emerging infectious disease threats and other hazards