It takes a (vaccination) village:
Influenza Vaccine Manufacturing in Context:

Bruce Gellin, MD, MPH
Deputy Assistant Secretary for Health
Director, National Vaccine Program Office
Department of Health and Human Services
Vaccine and Immunization Framework

Surveillance
Research
Testing and Development
Licensing
Recommendations and Use
Measuring Impact
Vaccine and Vaccination Framework: Elements of the System

- Vaccine Research
- Vaccine Development
- Safety and efficacy testing of vaccines
- Licensing of vaccine manufacturers and vaccines
- Production and procurement of vaccines
- Distribution and use of vaccines
- Evaluating the need, effectiveness, and adverse effects of vaccines and immunization activities
- Coordinating governmental and non-governmental activities
- Funding
US National Vaccine Program Responsibilities
Title XXI Public Health Service Act

- Vaccine Research
- Vaccine Development
- Safety and efficacy testing of vaccines
- Licensing of vaccine manufacturers and vaccines
- Production and procurement of vaccines
- Distribution and use of vaccines
- Evaluating the need, effectiveness, and adverse effects of vaccines and immunization activities
- Coordinating governmental and non-governmental activities
- Funding of federal agencies

http://www.hhs.gov/nvpo/
Vaccine and Immunization Enterprise: A system perspective

- Vaccine Research
- Vaccine Development
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Communication and Education Strategies
- Develop vaccine recommendations
- Access/Payment for Vaccination / Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- 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

- Recognition of public health priorities
- Disease Surveillance
- Translational research for diffusion of innovation

- Attitudes about vaccination
- Vaccine Coverage Surveillance
- Vaccine Injury Compensation
1. Develop new and improved vaccines

2. Enhance the vaccine safety system

3. Support communications to enhance informed vaccine decision-making

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

http://www.hhs.gov/nvpo/vacc_plan/
Vaccine and Immunization Enterprise: A system perspective

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

- Disease Surveillance
- Recognition of public health priorities

- Vaccine Research
- Vaccine Development

- Vaccine Licensure
- Vaccine Injury Compensation

- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution

- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Vaccine Coverage Surveillance

- Communication and Education Strategies
- Access/Payment for Vaccination/Reimbursement

- Attitudes about vaccination
- Adverse Event Monitoring
- Vaccination (Adult, Adolescent and Childhood)

- Develop vaccine recommendations

- 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

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

- Vaccine Injury Compensation
Vaccine and Immunization Enterprise:
A system perspective

- Vaccine Research
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Communication and Education Strategies
- Develop vaccine recommendations
- Access/Payment for Vaccination/Reimbursement
- Vaccine Coverage Surveillance

- Recognition of public health priorities
- Disease Surveillance
- Translational research for diffusion of innovation

- 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

- Vaccine Injury Compensation

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
What questions should you anticipate?

• From the medical community?
• From the public?
• From the media?
• From the skeptics?
What You Should Know for the 2012-2013 Influenza Season
Questions & Answers

On this Page

- What should I do to prepare for flu season?
- Are there new recommendations for the 2012-2013 influenza season?
- Who should get vaccinated?
- When should I get vaccinated?
- Where can I get a flu vaccine?
- Why do I need a flu vaccine every year?
- Is there treatment if I get sick with the flu?
- What sort of flu season is expected this year?
- When will flu activity begin and when will it peak?
- Will new flu viruses circulate this season?
- What kind of vaccines will be available in the United States for 2012-2013?
- How much vaccine will be available during 2012-2013?
- Who produces influenza vaccine for the United States?
- What flu viruses does the vaccine protect against?
- How long does a flu vaccine protect me from getting the flu?
- Should people wait until later in the influenza season to be vaccinated?
- How effective is the flu vaccine?
- Will this season's vaccine be a good match for circulating viruses?
- How do we know if there is a good match between the vaccine viruses and those causing illness?
- Has CDC received reports of people who have gotten a flu vaccine and then tested positive for influenza?
- Can the vaccine provide protection even if the vaccine is not a good match?
- In what years was there a good match between the vaccine and the circulating viruses?
- Has CDC always recommended vaccination each year, regardless of vaccine virus strain changes?
- What is antiviral resistance?
- What will CDC do to monitor antiviral resistance in the United States during the 2012-13 season?
Negative beliefs and perceptions about the flu shot were common reasons for not getting one:

- Shot could have side effects or cause disease: 20.4%
- Didn’t think it would prevent the flu/could get the flu anyway: 16.9%
- Didn’t know it was needed: 16.4%
- Getting flu isn’t serious/not at risk of getting the flu: 12.9%
- Shot could cause flu: 12.8%
- Forgot/missed it: 10.8%
- Don’t like shots or needles/concerned about reaction: 8%
- Doctor recommended against getting shot for medical reasons: 5.3%
- Doctor did not recommend getting a flu shot: 4.7%
- Vaccine unavailable: 2.1%
- Inconvenient to get a shot/couldn’t get to a location: 2.1%
- Too expensive/not worth the money: 0.6%
- Already had a flu shot and didn’t need it again: 0.5%
Vaccine and Immunization Enterprise: A system perspective

- Vaccine Research
- Vaccine Development
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Injury Compensation
- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Attitudes about vaccination
- Communication and Education Strategies
- Develop vaccine recommendations
- Recognition of public health priorities
- Disease Surveillance
- Translational research for diffusion of innovation
- 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

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
- High Vaccination Rates
- Vaccine Effectiveness
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Attitudes about vaccination
- Communication and Education Strategies
- Develop vaccine recommendations
- Recognition of public health priorities
- Disease Surveillance
- Translational research for diffusion of innovation
- Vaccine Injury Compensation
Who should get it?

Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) — United States, 2012–13 Influenza Season

In 2010, the Advisory Committee on Immunization Practices (ACIP) first recommended annual influenza vaccination for all persons aged ≥6 months in the United States (1). Annual influenza vaccination of all persons aged ≥6 months continues to be recommended. This document 1) describes Influenza Work Group meets every 2–4 weeks throughout the year. Work Group membership includes several voting members of ACIP and representatives of ACIP Liaison Organizations. Meetings are held by teleconference and include discussion of influenza-related issues, such as influenza surveillance, vaccine
Seasonal Influenza Vaccine Production, Distribution: United States 1979-2010
(millions of doses)
Estimated Size of ACIP-Recommended Groups

2010: Flu vaccine recommended for all > 6 months of age
Vaccine and Immunization Enterprise: A system perspective

- Recognition of public health priorities
- Vaccine Research
- Vaccine Development
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Attitudes about vaccination
- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Access/Payment for Vaccination/Reimbursement
- Develop vaccine recommendations
- Communication and Education Strategies
- 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
How much should you make?
(How much can you make?)
Will people want it?
US Influenza Vaccine Supply

Cumulative doses of influenza vaccines distributed in US by month, by season
2004/05-2012/13*

Cumulative number of doses distributed, in millions

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>July wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>August wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>September wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>October wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>November wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>December wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>January wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>February wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>March wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>April wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>May wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>June wk 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wk 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Vaccine and Immunization Enterprise: A system perspective

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

- Attitudes about vaccination
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent, and Childhood)
- Adverse Event Monitoring

- Communication and Education Strategies
- Develop vaccine recommendations

- Disease Surveillance
- Recognition of public health priorities

- Translational research for diffusion of innovation

- 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

- Vaccine Coverage Surveillance
- Vaccine Effectiveness

- Vaccine Injury Compensation
Will it be there when it’s needed?
U.S. Will Miss Half Its Supply Of Flu Vaccine

British Suspend License of Factory Making It

By ANDREW POLLACK

Nearly half of the nation's expected supply of flu vaccine will not be available this winter because the British government has suspended the manufacturing license at the factory in Liverpool that makes it.
The H1N1 Pandemic:
A race between the virus and the vaccine

Weekly Uptake of Seasonal and H1N1 Vaccine and Disease Activity in Physician Offices
Where will you get it?

Figure 2. Place of vaccination for children and adults, early 2012-13 flu season, National Immunization Survey and National Internet Flu Survey

- Doctor's Office: 64.8% (Children), 34.5% (Adults)
- Other Medically-Related Place: 25.3% (Children), 21.5% (Adults)
- Pharmacy or Store: 18.4% (Children), 2.9% (Adults)
- Workplace: 17% (Children), 0.4% (Adults)
- School: 5.5% (Children), 2.4% (Adults)
- Other Non-Medical Place: 6.3% (Children), 1% (Adults)

HealthMap Flu Vaccine Finder

**Flu Vaccine Options**
- Flu Shot
- Intradermal Flu Shot
- High-Dose Flu Shot
- Flu Nasal Spray

Read about the flu vaccine here. You can also learn more about the different flu vaccines by clicking on the vaccine names above.
Walgreens
DRIVE-THRU PHARMACY

COME IN AND SCHEDULE YOUR FLU SHOT TODAY!
WONDER BREAD 2 FOR $3
Vaccine and Immunization Enterprise: A system perspective
Does it work?
Does it work?
USA needs more effective flu shots

Liz Szabo and Elizabeth Weise
January 12, 2013

While flu shots aren't perfect, doctors still urge people to get vaccinated.

Analysts say the USA needs to speed up research on 'game-changing' vaccines.

'Next-generation' vaccines would protect against many viral strains for a decade or more.
Vaccine and Immunization Enterprise: A system perspective

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

**Recognition of public health priorities**

- **Disease Surveillance**
- **Translational research for diffusion of innovation**

- **Communication and Education Strategies**
- **Develop vaccine recommendations**

- **Attitudes about vaccination**
- **Access/Payment for Vaccination/Reimbursement**

- **Vaccination (Adult, Adolescent and Childhood)**
- **Vaccine Effectiveness**
- **Vaccine Coverage Surveillance**

- **Adverse Event Monitoring**

- **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**

- **Vaccine Injury Compensation**
How do you know it’s safe?

Institute of Medicine: August 2011
1976

The Swine Flu Affair
Decision-Making on a Slippery Disease

Richard E. Neustadt
Harvey V. Fineberg

2009
Importance of background rates of disease in assessment of vaccine safety during mass immunisation with pandemic H1N1 influenza vaccines

Steven Black, Juhani Eskola, Claire-Anne Siegrist, Neal Halsey, Noni MacDonald, Barbara Law, Elizabeth Miller, Nick Andrews, Julia Stowe, Daniel Salmon, Kirsten Vannice, Hector S Izurieta, Aysha Akhtar, Mike Gold, Gabriel Oselka, Patrick Zuber, Dina Pfeifer, and Claudia Vellozzi

<table>
<thead>
<tr>
<th>Coincident events</th>
<th>Number of coincident events since a vaccine dose:</th>
<th>Baseline incidence rate used for estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Within 1 day</td>
<td>Within 7 days</td>
</tr>
<tr>
<td>Guillain-Barré Syndrome (per 10 million vaccinated people)</td>
<td>0.51</td>
<td>3.58</td>
</tr>
<tr>
<td>Optic Neuritis (per 10 million female vaccinees)</td>
<td>2.05</td>
<td>14.40</td>
</tr>
<tr>
<td>Spontaneous abortions (per 10 million vaccinated pregnant women)</td>
<td>3,970</td>
<td>27,800</td>
</tr>
<tr>
<td>Sudden death within 1 hour of onset of any symptoms (per 10 million vaccinated people)</td>
<td>0.14</td>
<td>0.98</td>
</tr>
</tbody>
</table>
Effectiveness of Maternal Influenza Immunization in Mothers and Infants

K. Zaman, M.B., B.S., Ph.D., Eliza Roy, M.B., B.S., D.C.H.,
Shams E. Arifeen, M.B., B.S., Dr.P.H., Mahbubur Rahman, M.B., B.S., Ph.D.,
Rubhana Raqib, Ph.D., Emily Wilson, M.H.S., Saad B. Omer, M.B., B.S., Ph.D.,
Nigar S. Shahid, M.B., B.S., M.P.H., Robert F. Breiman, M.D.,
and Mark C. Steinhoff, M.D.

CONCLUSIONS
Inactivated influenza vaccine reduced proven influenza illness by 63% in infants up to 6 months of age and averted approximately a third of all febrile respiratory illnesses in mothers and young infants. Maternal influenza immunization is a strategy with substantial benefits for both mothers and infants. (ClinicalTrials.gov number, NCT00142389.)
Example: Background Rates in Subpopulations

Pregnant women prioritized to receive H1N1 vaccine

– 6 million clinically recognized pregnancies in the US each year
– 15% terminate in a clinically recognized spontaneous abortion
– 900,000 clinically recognized spontaneous abortions each year
– 2,466 clinically recognized spontaneous abortions each day
Example: Background Rates in Subpopulations

Pregnant women prioritized to receive H1N1 vaccine

– 6 million clinically recognized pregnancies in the US each year
– 15% terminate in a clinically recognized spontaneous abortion
– 900,000 clinically recognized spontaneous abortions each year
– 2,466 clinically recognized spontaneous abortions each day
– With 50% vaccine coverage, @1,200 spontaneous abortions within 24 hours of vaccination
Vaccine and Immunization Enterprise: A system perspective

- Vaccine Research
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Vaccine Licensure
- Disease Surveillance
- Translational research for diffusion of innovation

- Recognition of public health priorities
- Communication and Education Strategies
- Develop vaccine recommendations
- Vaccine Coverage Surveillance
- Vaccine Effectiveness

- Attitudes about vaccination
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring

- 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

- Disease Surveillance
- Translational research for diffusion of innovation

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

- Recognition of public health priorities
- Communication and Education Strategies
- Develop vaccine recommendations
- Vaccine Coverage Surveillance
- Vaccine Effectiveness

- Attitudes about vaccination
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring

- 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
Will you be able to track vaccine use?

Figure 1. Flu vaccination coverage estimates, National Immunization Survey, National Internet Flu Survey, and National Flu Survey

FIGHTING FLU

PHARMACIES RATIONING VACCINE

#ABCWorldNews
Vaccine and Immunization Enterprise: A system perspective

- Vaccine Research
- Vaccine Development
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Communication and Education Strategies
- Develop vaccine recommendations
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Vaccine Effectiveness
- Vaccine Coverage Surveillance
- Adverse Event Monitoring
- Recognition of public health priorities
- Disease Surveillance
- 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
- Vaccine Injury Compensation
- Translational research for diffusion of innovation
Vaccine and Immunization Enterprise: A system perspective

- Vaccine Research
- Vaccine Development
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Vaccine Injury Compensation
- Communication and Education Strategies
- Develop vaccine recommendations
- Disease Surveillance
- Translational research for diffusion of innovation
- Recognition of public health priorities
- Attitudes about vaccination
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Reduced Morbidity and Mortality from infectious disease in the U.S. and Globally
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Recognition of public health priorities
- Attitudes about vaccination
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Vaccine Research
- Vaccine Development
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Vaccine Injury Compensation
- Communication and Education Strategies
- Develop vaccine recommendations
- Disease Surveillance
- Translational research for diffusion of innovation
- Recognition of public health priorities
- Attitudes about vaccination
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Reduced Morbidity and Mortality from infectious disease in the U.S. and Globally
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Vaccine Research
- Vaccine Development
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Vaccine Injury Compensation
- Communication and Education Strategies
- Develop vaccine recommendations
- Disease Surveillance
- Translational research for diffusion of innovation
- Recognition of public health priorities
- Attitudes about vaccination
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Reduced Morbidity and Mortality from infectious disease in the U.S. and Globally
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Vaccine Research
- Vaccine Development
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Vaccine Injury Compensation
- Communication and Education Strategies
- Develop vaccine recommendations
- Disease Surveillance
- Translational research for diffusion of innovation
- Recognition of public health priorities
- Attitudes about vaccination
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Reduced Morbidity and Mortality from infectious disease in the U.S. and Globally
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Vaccine Research
- Vaccine Development
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Vaccine Injury Compensation
- Communication and Education Strategies
- Develop vaccine recommendations
- Disease Surveillance
- Translational research for diffusion of innovation
- Recognition of public health priorities
- Attitudes about vaccination
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Reduced Morbidity and Mortality from infectious disease in the U.S. and Globally
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Vaccine Research
- Vaccine Development
- Vaccine Manufacture
- Vaccine Sales/Purchase
- Vaccine Distribution
- Vaccine Coverage Surveillance
- Vaccine Effectiveness
- Vaccine Injury Compensation
- Communication and Education Strategies
- Develop vaccine recommendations
- Disease Surveillance
- Translational research for diffusion of innovation
- Recognition of public health priorities
- Attitudes about vaccination
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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

- Reduced Morbidity and Mortality from infectious disease in the U.S. and Globally
- Access/Payment for Vaccination/Reimbursement
- Vaccination (Adult, Adolescent and Childhood)
- Adverse Event Monitoring
- Vaccine Coverage Surveillance
- 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
Sustainable Influenza Vaccine Production Capacity in Context

It takes a (vaccination) village