

Future Federal Policy Directions: Influenza Vaccine and Vaccination

National Influenza Vaccine Summit

May 9, 2011

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



Howard Koh, MD, Assistant Secretary for Health,
receiving his influenza vaccination



HHS Interagency Task Force on Seasonal Influenza Vaccination

Goal: Bolster and extend HHS' efforts on universal flu coverage by coordination and synergy of the entire Department

- Led by Assistant Secretary for Health
- Seasonal influenza as an annual exercise in pandemic preparedness
- Opportunity to address short-term and long-term policies and programs to related to seasonal influenza vaccine use
- Representation from across HHS: CDC, CMS, FDA, NIH, HRSA, OMH, Partnership Center, AoA, ACF, OWH, IHS, FOH, and Regional Health Administrators
- Leveraged department resources in key areas

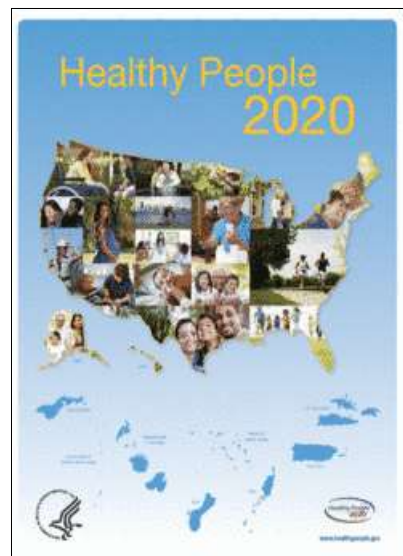
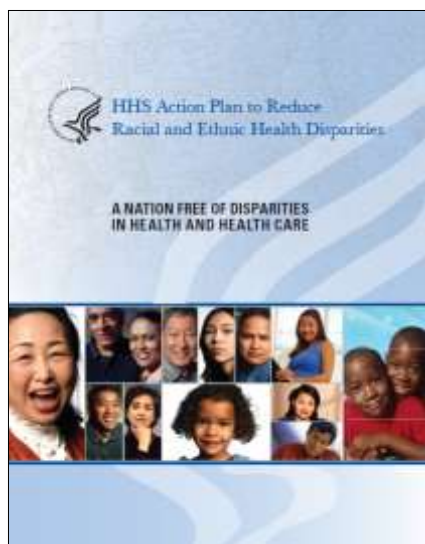
HHS Interagency Task Force on Seasonal Influenza Vaccination

- Health Disparities
- Pregnant women
- Employers
- Health Care Providers
- Communications

HHS Interagency Task Force on Seasonal Influenza Vaccination

- Outreach/Partners
 - Pharmacies
 - CMS
 - Office of the National Coordinator for Health Information Technology
 - HHS Regions and Community Organizations
 - Medical societies
- Billing
- Vaccine coverage
- Vaccine effectiveness
- Vaccine safety

“A Nation Free of Disparities in Health and Health Care”



Reducing Health Disparities: Protecting All From Flu

- Demonstration Project to address health disparities and influenza vaccination in cities around the country.
- Significant involvement from local and state public health
- Provider outreach
- Vaccine voucher distribution program
- Project evaluation in process



Using CMS Data to Estimate Vaccination Coverage

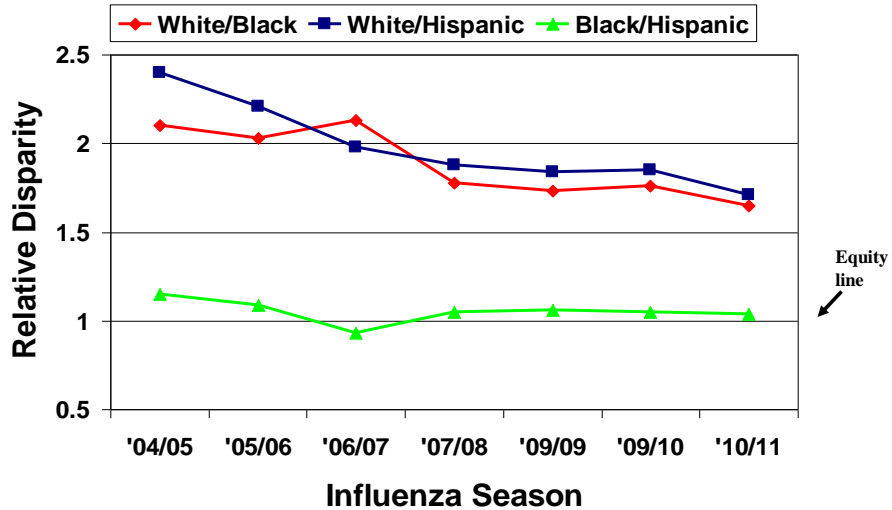
Potential Advantages

- Only two week delay
- Coverage for all areas and over time
- Large numbers allows for sub-analyses (e.g., by race)
- Internally consistent
- Linked to morbidity data

Many Caveats:

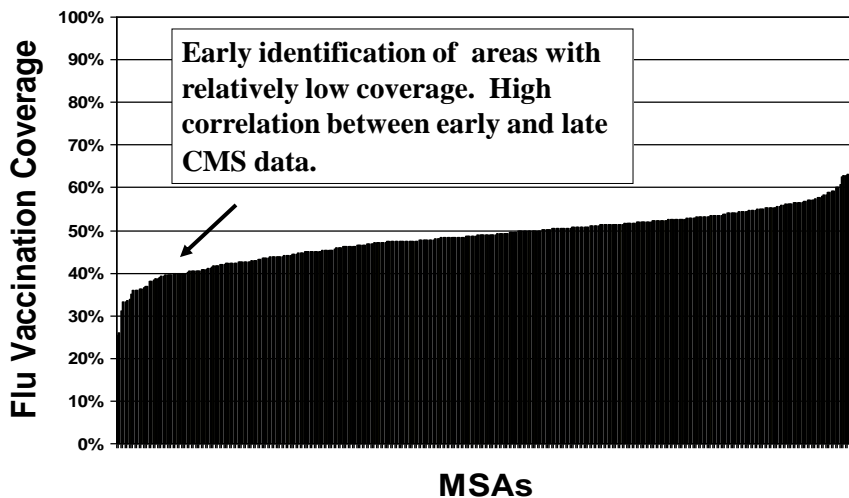
- Only Medicare fee for service patients
- Adjusted for reporting delays
- Coverage levels poorly correlated with CDC survey data:

Relative Disparity of Influenza Vaccination, Medicare Population, by Flu Season (CMS data)



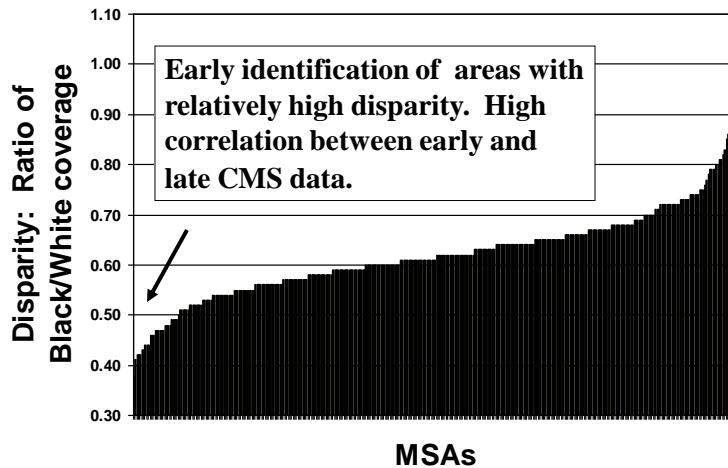
Source: CMS, Medicare Parts A and B Nationwide, approximately 30 million enrollees in 2011

Influenza vaccination coverage for 2010/11, by 366 MSAs, April 8, 2010 (CMS data)



Source: CMS, Medicare Parts A and B Nationwide, approximately 30 million enrollees in 2011

Relative Disparity of Influenza Vaccination by 366 MSAs, 2010/2011, (CMS data)



Source: CMS, Medicare Parts A and B Nationwide, approximately 30 million enrollees in 2011

U.S. Department of Health & Human Services
HHS.gov

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News Release

FOR IMMEDIATE RELEASE
 Friday, December 17, 2010

CONTACT: HHS Press Office
 (202) 696-6342

HHS and Walgreens Announce New Effort Aimed at Addressing Health Disparities in Flu Vaccination

New effort will provide \$10 million worth - approximately 350,000 free flu vaccines to underserved and underserved U.S. Department of Health and Human Services Secretary Kathleen Sebelius today announced that Walgreens has agreed to donate \$10 million in vouchers for free flu shots for 200,000 eligible underserved and underserved people in 13 markets across the country.

Secretary Sebelius made the announcement earlier today in a conference call with Assistant Secretary for Health Dr. Howard Koh, the Centers for Disease Control and Prevention's Dr. Dan Berigan, and Walgreens President of Pharmacy Services, Robert Crawford. The announcement is part of a larger demonstration project being undertaken by HHS and its partners to address continuing health disparities in flu vaccination rates.

"Thanks to the new health care law, many people can get their flu vaccination without paying a co-pay or deductible, but there are still more Americans who cannot afford to get vaccinated for the flu," said Secretary Sebelius. "With this generous donation, Walgreens is helping individuals and families who otherwise might be unprotected from the flu this season. We are also troubled by recent data showing disparities among people when it comes to flu vaccination. This donation will help us remove barriers that have prevented some from getting vaccinated."


Vouchers are good for one flu shot at any Walgreens pharmacy, Duane Reade pharmacy in New York or Take Care Clinic, and will be available beginning early next week in the following metropolitan areas:

- Atlanta, GA
- Kansas City, MO
- Bronx, NY
- Newark, NJ
- Chicago, IL
- Oakland, CA
- Houston, TX
- Philadelphia, PA

Vouchers will also soon be distributed and available through local health agencies in:

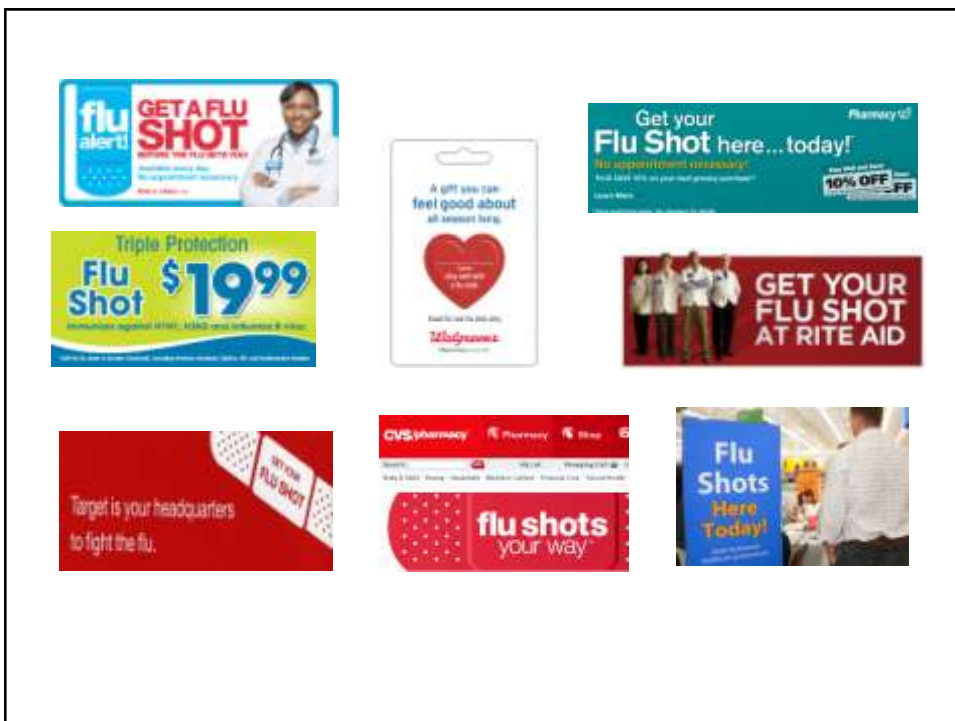
- Fort Lauderdale, FL
- Waco, TX
- Miami-Dade County, FL
- Washington, D.C.
- Palm Beach, FL
- Northern New Hampshire
- Seattle, WA
- Brooklyn, Queens, Staten Island, NY

Vouchers

 <p>This Voucher Entitles You to Receive One Flu Shot at No Charge.*</p> <p>Information below must be completed before receiving your shot. Please print clearly.</p> <p>Patient Name: _____</p> <p>Date of Birth: _____</p> <p>Home Zip Code: _____ Group#: 534SANWVCH</p> <p>Effective Date: 12/15/2010 Expiration Date: 4/15/2011</p> <p>I certify that I do not have insurance of any kind, including any medical coverage through any public health system care program such as Medicare or Medicaid.</p> <p>Signed: _____</p>	<p>Walgreens Instructions</p> <ul style="list-style-type: none"> • Ensure member information on voucher is completed • Locate the patient within IC+ • Select "Patient Information" • Select "Third Party Plans" • Enter the voucher information listed below into the plan information. • Plan ID: FLU <p>Request #: form up code, 5 digit patient D.O.B. and 5 digit store number</p> <p>Group# 534SANWVCH</p> <ul style="list-style-type: none"> • Select "Start Scanning Card" button • Scan the voucher into IC+ 	<p>Take Care Clinic Instructions</p> <ul style="list-style-type: none"> • Ensure member information on voucher is completed • Evolve Flu Vaccination encounter in EMR • Scan voucher in EMR • At checkout screen, enter the following information: • Choose Promotion: WAG Flu Voucher <p>Request #: form up code, 5 digit patient D.O.B. and 5 digit store number</p> <p>Group# 534SANWVCH</p> <ul style="list-style-type: none"> • When completed with encounter, please attach voucher
<p>To find a location near you, call 800-WALGREENS (800-925-4733) or visit Walgreens.com/flu.</p>		
<p><small>*Expires 04/15/2011. Entitles bearer to one flu shot during 2010-2011 season. Vaccines subject to availability. State, age and health condition-related restrictions may apply. See pharmacy or Take Care Health Clinic for details. Employees of Walgreen Co. (the "Sponsor"), their immediate family members, and any person domiciled with any such employees are not eligible to participate. The term "immediate family members" includes spouses, parents, grandparents, siblings, children and grandchildren. This voucher is intended for use by the uninsured person whose name appears on the voucher. This voucher is non-transferable. It may not be copied or duplicated and may be used only once. If the bearer of the voucher has medical insurance or prescription coverage of any kind, this voucher is void. Voucher is not valid in ND or Puerto Rico. Patient care services provided by Take Care Health ServicesSM, an independently owned professional corporation whose licensed healthcare professionals are not employed by or agents of Walgreen Co. or Take Care Health SystemsSM, LLC.</small></p>		

The Fine Print*

*Expires 04/15/2011. Entitles bearer to one flu shot during 2010-2011 season. Vaccines subject to availability. State, age and health condition-related restrictions may apply. See pharmacy or Take Care Health Clinic for details. Employees of Walgreen Co. (the "Sponsor"), their immediate family members, and any person domiciled with any such employees are not eligible to participate. The term "immediate family members" includes spouses, parents, grandparents, siblings, children and grandchildren. This voucher is intended for use by the uninsured person whose name appears on the voucher. This voucher is non-transferable. It may not be copied or duplicated and may be used only once. If the bearer of the voucher has medical insurance or prescription coverage of any kind, this voucher is void. Voucher is not valid in ND or Puerto Rico. Patient care services provided by Take Care Health ServicesSM, an independently owned professional corporation whose licensed healthcare professionals are not employed by or agents of Walgreen Co. or Take Care Health SystemsSM, LLC.



Influenza Vaccination in Pharmacy Settings: A Case Study for Adult Immunizations?

Pharmacies provide access:

- ~60,000 retail pharmacies: most large ones offered seasonal flu
- 93% of Americans currently live within 5 miles of a retail pharmacy
- All states approve pharmacists as influenza immunizers for adults
- 20% of adults (> 18 years old) received their influenza vaccine at a retail pharmacy this past season

Partnering with Pharmacies

- Early messaging for (August?) to support pharmacies
- State approvals for pharmacists to immunize children?
 - Role of vaccine donation/voucher program?
 - 21 states only allow pharmacists to vaccinate adults ≥ 18 years?
 - Timely and reliable information to primary provider?
 - Timely and reliable information to public health?



Achieving high vaccination coverage among pregnant women

- ACOG
 - Partnership strengthened during pH1N1
 - ACOG policy statement
- Communications materials targeted pregnant women
- Continued partnership development, communications efforts, and coverage assessment is needed to support this level of immunization

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For Release: September 23, 2010

All Pregnant Women Should Get the Flu Vaccine
 Flu Prevention is Essential Prenatal Care

Washington, DC – All pregnant women, regardless of trimester, should get the influenza vaccination during the flu season, according to new recommendations issued today by The American College of Obstetricians and Gynecologists and published in the October issue of *Obstetrics & Gynecology*. The College emphasizes that preventing the flu during pregnancy is an essential element of prenatal care and that it is imperative that physicians, healthcare organizations, and public health officials improve their efforts to increase immunization rates among pregnant women.

Last week, the CDC, along with The College and other medical organizations, encouraged all physicians and health care providers to urge their pregnant and postpartum patients to get vaccinated against the seasonal flu.

Annual flu vaccination is crucial for pregnant women because the immune system changes during pregnancy, which results in women being at increased risk of serious complications if they get the flu. Flu vaccination performs double duty by protecting both pregnant women and their babies. Babies cannot be vaccinated against the flu until they are six months old, but they receive antibodies from their mother which help protect them until they can be vaccinated.

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- All pregnant women, regardless of trimester, should get influenza vaccination during the flu season.
- ACOG emphasizes that preventing flu during pregnancy is an essential element of prenatal care and that it is imperative that physicians, health care organizations, and public health officials improve their efforts to increase immunization rates among pregnant women.

Medicare.gov
The Official U.S. Government Site for Medicare

Home • Manage Your Health • Medicare Basics • Resource Locator • Help & Support

Home • Manage Your Health • Preventive Services • Flu Information

Flu Information

How often is it covered?
Medicare covers the flu shot once per flu season. Flu shots are available starting in the fall for flu season.

Who's eligible?
All people with Medicare.

Your costs in Original Medicare
You pay nothing for the flu shot if the doctor or other health care provider accepts assignment for giving the shot.

Note: Medicare Part B also covers administration of the H1N1 flu shot. You pay nothing if the doctor accepts assignment for giving the shot.

Flu Resources
• Centers for Disease Control and Prevention (CDC): [Influenza](#)

Related Links
• [Your Guide to Medicare's Preventive Services](#)

[Medicare & You Handbook](#)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 309-D
200 Independence Avenue, SW
Washington, DC 20201

Public Affairs Office

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

MEDICARE NEWS

For Immediate Release
April 29, 2011

Contact: CMS Office of Media Affairs
(202) 690-6145

CMS PROPOSES TO EXPAND ACCESS TO SEASONAL INFLUENZA IMMUNIZATION
Proposed Requirement Would Make Flu Shots Available to Patients at Most Commonly Visited Medicare-certified Health Care Facilities

- This proposed rule would require certain Medicare and Medicaid providers to offer all patients an annual influenza vaccination.
- This proposed rule would also require certain providers and suppliers to develop policies and procedures that would allow them to offer vaccinations for pandemic influenza, in case of a future pandemic influenza event for which a vaccine may be developed.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 302-D
200 Independence Avenue, SW
Washington, DC 20201



Public Affairs Office

MEDICARE NEWS

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- Hospitals, including Short-term Acute Care, Psychiatric, Rehabilitation, Long-Term Care, Children's, and Cancer;
- Critical Access Hospitals (CAHs);
- Rural Health Clinics (RHCs);
- Federally Qualified Health Centers (FQHCs) and;
- End-Stage Renal Disease (ESRD) Facilities that offer dialysis services.

Employers are a significant source for flu vaccination

- 15% of adults received influenza vaccination at worksite this past season (*National Flu Survey, March, 2010*)
- The CDC Employer Toolkit (posted October, 2010) has received over 57,000 page views
- Update the CDC Employer Toolkit
- Outreach to employer groups (National Business Group on Health, National Safety Council) to assist with messaging
- Promote the workplace as a place to get flu vaccine
- Explore how pharmacies can help small and mid-sized employers promote influenza immunization to employees





MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: KATHLEEN SENSEBUELL, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

TO: JOHN BERRY, DIRECTOR, U.S. OFFICE OF PERSONNEL MANAGEMENT

Subject: Immunization of Federal Workers with Seasonal Influenza Vaccines

I am sure the Bureau and the Federal workforce came together to fight the H1N1 influenza pandemic. Thanks to your hard work, we were able to help keep millions of Americans healthy and help those who were afflicted with the disease. We learned many important lessons and were reminded of the importance of following basic but critical advice when it comes to fighting the flu – like washing our hands, coughing into our sleeves or a tissue, staying home if we are sick, and getting our flu vaccine.

This year, the President has made fighting flu a priority, again, and we need your help. It is not enough, and flu strains seasonal influenza is just around the corner. Flu can be very serious, and even healthy people can get and spread the flu, significantly contributing to illness, hospitalizations, and reduced productivity. Every year, thousands of Americans die from flu-related complications. Getting vaccinated is the best way to be protected from influenza and its complications, and there is plenty of vaccine available. We are also aware that more flu vaccine is available as

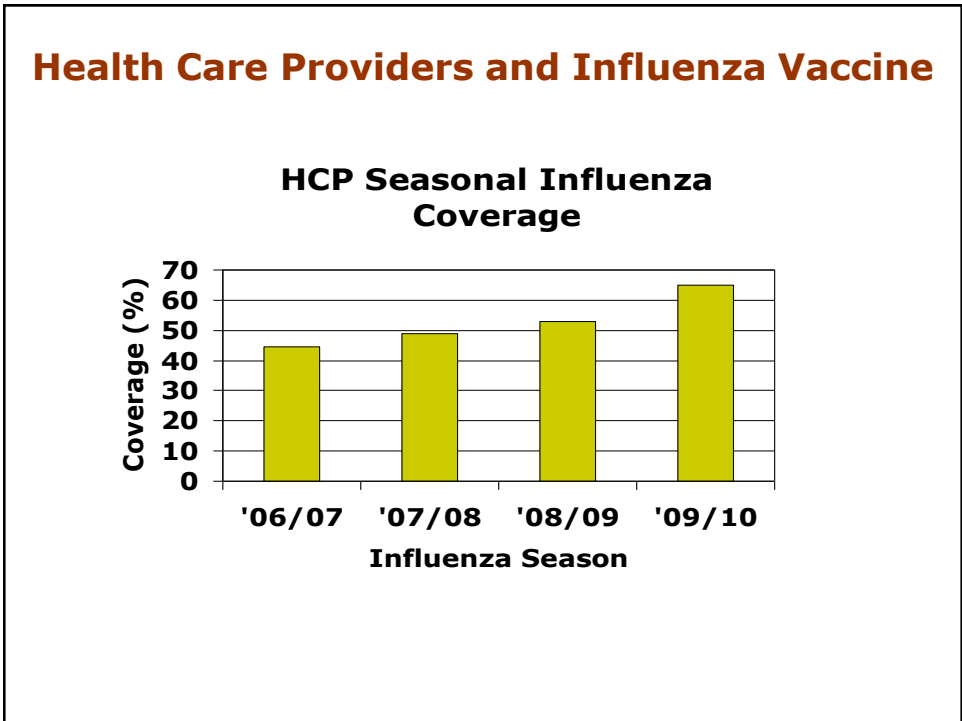
As the agencies responsible for both all Americans, the U.S. Office of Personnel Management and the entire Federal workforce and its contractors.

Please help to maintain a healthy and vaccinated against the flu. Flu can be very serious, and even healthy people can get and spread the flu, significantly contributing to illness, hospitalizations, and reduced productivity. Every year, thousands of Americans die from flu-related complications. Getting vaccinated is the best way to be protected from influenza and its complications, and there is plenty of vaccine available. We are also aware that more flu vaccine is available as

Leading by example:

Flu vaccination and the federal workforce

Please help to maintain a healthy workforce by encouraging your employees to get vaccinated against the flu. Vaccine is provided at no cost to Federal employees in Federal health clinics across the country. To further protect our entire workforce, we also recommend that all departments and agencies consult with their Offices of General Counsel to determine whether funds are legally available to purchase vaccine for contractors working in close proximity to Federal staff. Attached is a memo from the Department of Health and Human Services' Office of the General Counsel to the General Counsel Exchange with the rationale for providing flu vaccine to contractors. For information, please contact Mogbeyi Omatete (202-619-0153) in the HHS Office of the General Counsel.





Influenza Vaccination of Staff and Licensed Independent Practitioners

Start Date: April 5, 2011

End Date: May 17, 2011

The Joint Commission is seeking input from the field on proposed requirements addressing influenza vaccination of staff and licensed independent practitioners. Revisions to current requirements are being proposed for Hospital, Critical Access Hospital, and Long Term Care accreditation programs. New requirements are being proposed for Ambulatory Care, Behavioral Health Care, Home Care, Laboratory, Medicare Based Long Term Care, and Office-Based Surgery accreditation programs.

National Vaccine Advisory Committee: Health Care Personnel Influenza Vaccination

- The Adult Immunization Working Group (AIWG) of the National Vaccine Advisory Committee established the Health Care Personnel Influenza Vaccination Subgroup in November 2010
- Develop recommendations on strategies to achieve the Healthy People 2020 annual goal of 90% influenza vaccine coverage for health care personnel.

http://www.hhs.gov/nvpo/nvac/subgroups/healthcare_personnel_influenza_vacc_subgroup.html



Communications Lessons

•Partnerships

- Pharmacies
- Faith-based organizations
- Professional medical organizations
- Community outreach
- Other parts of government

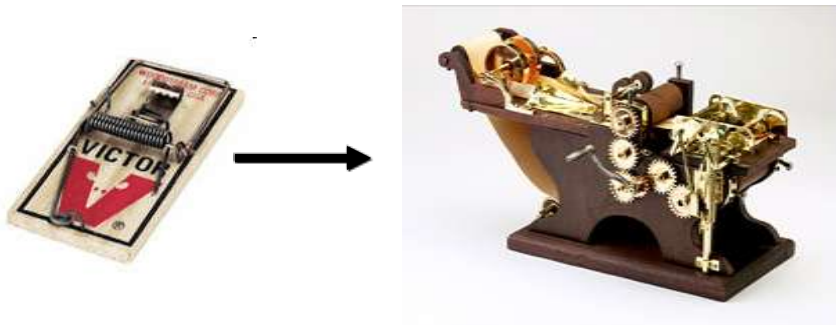
Strategy and Tactics:

- Earlier kickoff? Earlier NIVW?
- How to best use HHS resources and universal materials?
- How to get more provider organizations engaged?
- Flu-fatigue with media post-pandemic
- Ongoing challenges of vaccine hesitancy and misinformation

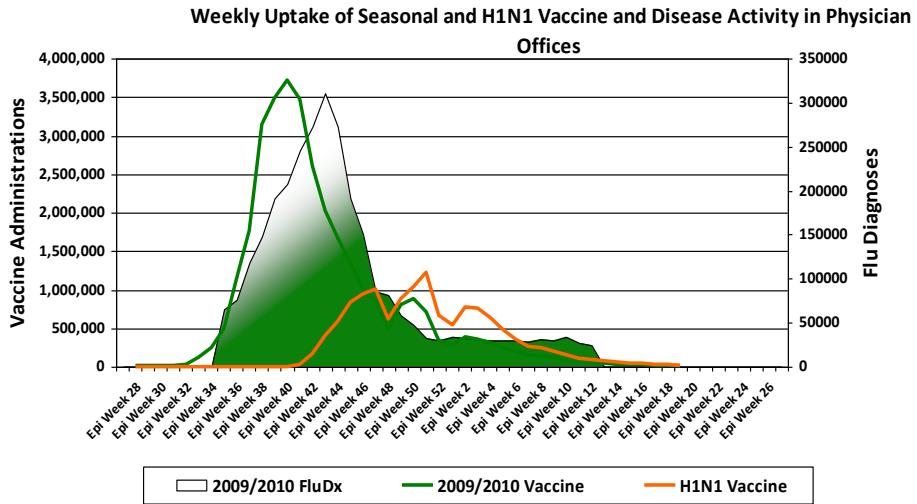
The Important Role of Clear Communications



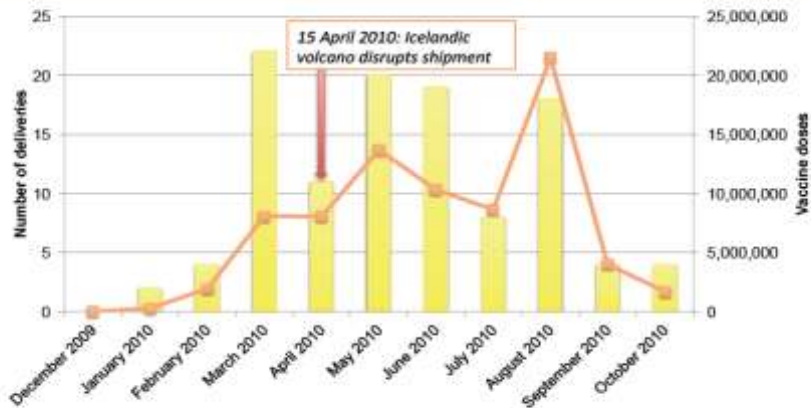
Building a Better Mousetrap



The H1N1 Pandemic: A race between the virus and the vaccine



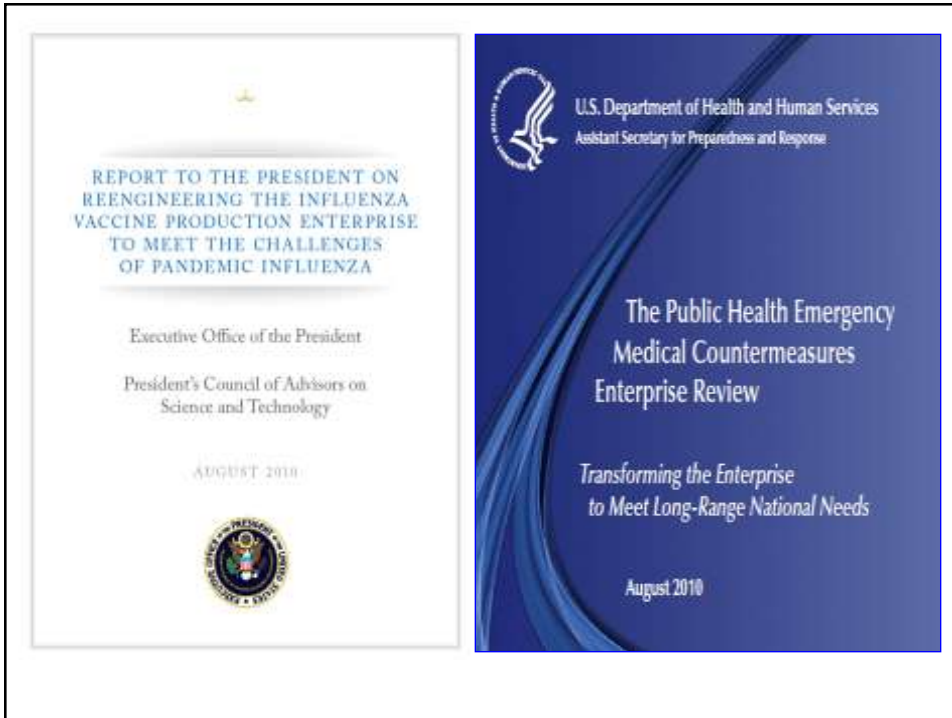
WHO H1N1 Vaccine Deployment Vaccine Deliveries, monthly



■ Deliveries
— Volume delivered

WHO H1N1 Pandemic Vaccine Deployment and Vaccination update

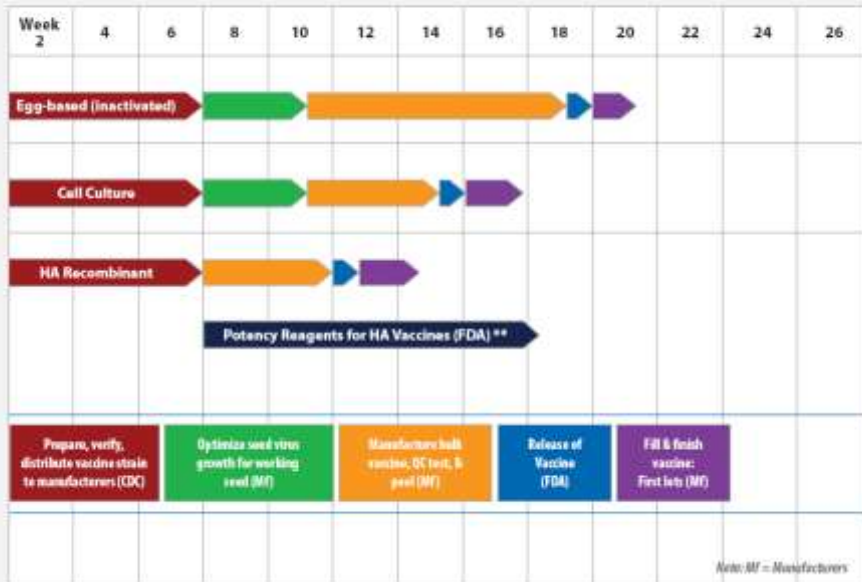




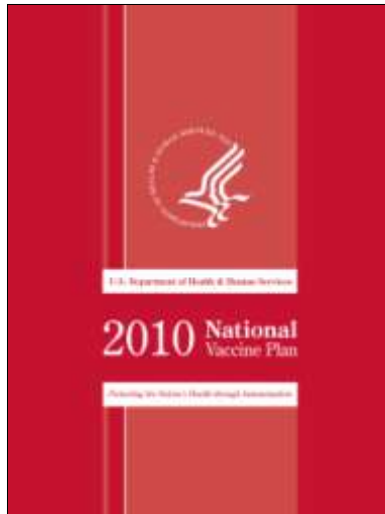
Overview of PCAST Recommendations

- Actions with Short-term Impact (1-3 years)
 - Accelerating the identification of new pandemic threats
 - Shortening time for availability of virus strains, potency and sterility testing
 - Establishing a fill-finish manufacturing network
- Actions with Longer-term Impact (2-10 years)
 - Advancing cell culture and recombinant vaccine technologies
 - Accelerating clinical research on live attenuated vaccines
 - Supporting adjuvant development and licensure
 - Supporting basic immunology research on influenza
 - Expanding domestic vaccine manufacturing infrastructure
 - Developing flexible investment strategies
 - Implementing a new management structure for enterprise oversight

Influenza Vaccine Production Timelines



2010 National Vaccine Plan



2010 National Vaccine Plan Goals:

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*

Setting Priorities for Vaccine Development



IOM Committee on Identifying and Prioritizing New Preventive Vaccines

- Charge: Develop an evidence-based approach and methodology for identifying and prioritizing the needs for developing new preventive vaccines of domestic and global importance.
- Considerations:
 - International and domestic priorities
 - Burden of illness and costs
 - Scientific opportunities and platform technologies
 - Stakeholder perspectives

The screenshot shows the HHS.gov website interface. At the top, there is a navigation bar with the HHS logo and a search box. Below the navigation bar, there is a menu with various categories like Home, About HHS, HHS Secretary, News, Jobs, Grants/Funding, Families, Prevention, Diseases, Regulations, and Preparedness. The main content area displays a news release titled "HHS awards contracts to develop new flu vaccine technology". The release is dated Monday, February 28, 2011, and is for immediate release. The text of the release describes two contracts awarded to Novavax, Inc. and Valinone, Inc. to develop next-generation recombinant influenza vaccines. The total value of the contracts is \$215 million. The release also mentions that the 2009 H1N1 pandemic demonstrated the need for technologies that can provide vaccines more rapidly.

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HHS.gov

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FOR IMMEDIATE RELEASE **NEWS RELEASE** Contact: HHS Press Office
Monday, February 28, 2011 (202) 690-6343

HHS awards contracts to develop new flu vaccine technology

Two contracts support advanced development of next-generation recombinant vaccine

The U.S. Department of Health and Human Services (HHS) awarded two contracts today to help make vaccine available more quickly for seasonal flu outbreaks and pandemics. The contracts for advanced development of new types of vaccine and new ways to make flu vaccine known as next-generation recombinant influenza vaccine total \$215 million.

"The 2009 H1N1 pandemic demonstrated the need for technologies that can provide vaccines more rapidly," HHS Secretary Kathleen Sebelius said. "These next-generation flu vaccines hold the potential to be even more effective and to make the first and last doses of vaccine available sooner than existing flu vaccines by weeks and months which can save more lives during a pandemic as well as during seasonal flu outbreaks."

HHS awarded one contract to Novavax, Inc., of Rockville, Md., for \$97 million over the first three years, which can be extended for an additional two years, for a total contract value of \$179.1 million. HHS awarded a separate contract to Valinone, Inc. of Cranbury, N.J., for \$117.9 million over the first three years, which can be extended for two additional years, for a total contract value of \$196.6 million.

Diversification of Seasonal Influenza Vaccines

- High titer
- Intradermal
- Quadrivalent
- Adjuvants

