Future Federal Policy Directions: Influenza Vaccine and Vaccination

National Influenza Vaccine Summit
May 9, 2011

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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)

Early identification of areas with relatively low coverage. High correlation between early and late 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)

Early identification of areas with relatively high disparity. High correlation between early and late CMS data.

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

This Voucher Entitles You to Receive One Flu Shot at No Charge.*

Information below must be completed before receiving your shot. Please print clearly.

Patient Name: __________________________
Date of Birth: __________________________
Home Zip Code: ___________, Group#: S348ANWCH
Effective Date: 12/15/2010, Expiration Date: 1/31/2011

*Vouchers cannot be used in combination with any other Walgreens programs or discounts or benefits. This offer is not transferable. Walgreens is not responsible for lost or stolen vouchers. This offer is not 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.

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.
**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
• 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.
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.
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
Leading by example:

Flu vaccination and the federal workforce

Health Care Providers and Influenza Vaccine

HCP Seasonal Influenza Coverage

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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

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

WHO H1N1 Vaccine Deployment

Vaccine Deliveries, monthly

15 April 2010: Icelandic volcano disrupts shipment
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
Influenza Vaccine Technology Landscape (May 2011)

Building a Better Mousetrap
Diversification of Seasonal Influenza Vaccines

- High titer
- Intradermal
- Quadrivalent
- Adjuvants