Immunization Programs: More than Just Vaccine

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National Vaccine Advisory Committee
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Vaccines for Children Program (VFC)

- Created by the 1993 Omnibus Budget Reconciliation Act, operational since October 1994
- Eligible children (through age 18 yrs): Medicaid eligible, uninsured, American Indian/Alaska native, underinsured in Federally-Qualified Health Centers or Rural Health Centers
- Legislation gives the Advisory Committee on Immunization Practices the authority to determine the vaccines that will be provided in the VFC Program
- VFC is a federal entitlement program

http://www.cdc.gov/vaccines/programs/vfc/default.htm
http://www.cdc.gov/vaccines/programs/vfc/providers/acip-whatis.htm
The Underinsured

- Children who are covered by private insurance that does not cover all the costs of all recommended vaccines are considered underinsured
  - Some insurance plans do not cover ACIP-recommended vaccines
  - Parents or guardians may be responsible for some or all of the cost of vaccination because of high deductibles and/or co-payments

- Many families can and do pay these out-of-pocket costs, but for some they are a financial burden and an economic barrier to vaccination
The Affordable Care Act (ACA), 2010

- New health insurance plans must provide coverage for ACIP recommended vaccines without deductibles or co-pays, when delivered by an in-network provider.

- As the new plans are written and existing plans lose their grandfathered status, the number of underinsured children and adults should be starting to decrease.

- Although some uncertainties around the ACA remain, with full implementation over the next several years expect that the problem of the underinsured should largely be solved.
Section 317 Operations Funding

- These funds provide critical support for the people and systems that make immunization programs work
  - Recruiting immunization providers
  - Quality assurance and provider education
  - Surveillance of vaccine-preventable diseases
  - Response to outbreaks of vaccine-preventable diseases
  - Immunization information systems
  - Assessment of immunization coverage
  - Vaccine safety monitoring

- 317 operations funding is critical for the implementation of the Vaccines for Children Program.
Making Vaccination Available: Different Providers, Different Venues

- Public health role in helping medical offices and other venues to make immunization services available
- Different age groups receive medical care from different health care providers
- Other venues can supplement the medical care setting for immunization services
- Immunization program responsible for stewardship of public purchased vaccine administered in both public and private sectors
Medical Visits by Adolescents

Females

Males

Vaccination of Adults

- Wide range of settings and types of providers for medical care of adults
  - Medical primary care provider offices
  - Medical specialist offices
    - Obstetricians, nurse midwives, cardiologists, etc.
  - Hospital-based clinics
  - STD/HIV treatment clinics
  - Nursing homes/long-term care
  - Correctional facilities
  - Pharmacies
  - College health clinics

- Non-medical settings, especially workplaces
- Different strategies/resources needed to reach patients in different settings
School-located Vaccination Clinics
Surveillance of Vaccine-Preventable Diseases

- State-based systems for reporting by providers, hospitals, schools, and laboratories
- Critical importance of careful investigation
  - Dates of onset
  - Vaccination history
  - Exposure and travel history
- The essential role of the laboratory
  - Confirmation of the diagnosis
  - Tools for epidemiologic investigation
- Some outcomes require other systems for documenting disease burden and vaccine impact
- Local, state, national, and international responsibilities
Pertussis cases by age – 2006-2009

2006

2007

2008

2009
Incidence of Invasive Pneumococcal Disease Among Adults ≥65 Years by Serotype, 1998-2010

PCV7 vaccine introduced for children

Cases/100,000 population


Year

ABCs unpublished data, continuous sites
NVSN Rotavirus Hospitalization Rates by Age, 2006-2011

Note: surveillance was conducted only for children <3 years old from 2006-2008

Payne DC, unpublished 2012
Response to Outbreaks of Vaccine-Preventable Diseases

- **Epidemiologic investigation**
  - Case identification and investigation
  - Settings of exposure and transmission
  - Vaccine failure or failure to vaccinate

- **Control measures**
  - Isolation and quarantine
  - Vaccination
  - Antimicrobial prophylaxis

- **Resource-intensive efforts**, and most carried out by state and local public health
Measles Cases Reported to CDC, 2008 (N=140)

Grant County, WA
Outbreak N=19

Chaves Co, NM
N=1

Milwaukee County, WI
Outbreak, N=4

Missaukee County, MI
N=1

Portland, OR
N=1

San Francisco, CA
N=2

Santa Clara, CA
N=1

Los Angeles, CA
N=1

Orange County, CA
N=1

San Diego, CA
Outbreak N=12

Honolulu, HI
N=4

Vernon County, WI
N=1

Pima County, AZ
Outbreak N=14

Scott County, AR
N=2

Baton Rouge, LA
N=1

Franklin Co, IL
N=1

Du Page Co, IL
Outbreak N=30

Boone Co, IL
N=1

Fairfax, VA
N=1

D.C.
N=1

Boston, MA
N=2

Suffolk Co, NY
N=1

New York City, NY
N=28

Bergen, NJ
N=1

Fairfax, VA
N=1

Fulton Co, GA
N=1

Hillsborough Co, FL
N=1
Measles Outbreak San Diego, 2008

- Importation from Switzerland in an unvaccinated (PBE) 7 year old child exposed 839 persons
  - 11 additional cases in unvaccinated children including 3 infants too young to be vaccinated
  - Hospitalization in 10 month old infant
  - One exposed infant traveled by plane to Hawaii

- Total outbreak costs $176,980
  - Public sector cost $124,517 or $10,376 per case
  - Direct medical charges $16,163
  - Quarantine costs for families for 48 children $37,200
    - $775 per quarantined child

Mumps Age-specific Attack Rates, Orange County, NY
Vaccine Effectiveness Study
Pertussis, California, 2010

- 25 people reviewed charts from over 250 provider offices
- Abstraction forms completed for 1,039 cases & 3,194 controls
- Most prolific team member: reviewed 373 patient charts and completed data entry for 643 abstraction forms in 19 days
Immunization Policy

- Advisory Committee on Immunization Practices
  - Establishes the standard of practice for immunization in the United States
  - Long history of developing evidence-based recommendations
  - Disease burden, safety and efficacy are critical factors in ACIP deliberations

- State immunization advisory committees
- Other state immunization policies
- Interim recommendations for management of vaccine shortages
## FIGURE 1: Recommended Immunization schedule for persons aged 0 through 6 years—United States, 2012
(for those who fall behind or start late, see the catch-up schedule [Figure 3])

<table>
<thead>
<tr>
<th>Vaccine ▼</th>
<th>Age ►</th>
<th>Birth</th>
<th>1 month</th>
<th>2 months</th>
<th>4 months</th>
<th>6 months</th>
<th>9 months</th>
<th>12 months</th>
<th>15 months</th>
<th>18 months</th>
<th>19–23 months</th>
<th>2–3 years</th>
<th>4–6 years</th>
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<tr>
<td>Hepatitis B</td>
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<td>Diphtheria, tetanus, pertussis</td>
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<td>Haemophilus influenzae type b</td>
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<td>Measles, mumps, rubella</td>
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**Influenza (Yearly)**

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<tr>
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<th>MMR</th>
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**Dose 1**

**HepA Series**

**MCV4 — see footnote**

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Range of recommended ages for all children

Range of recommended ages for certain high-risk groups

Note: See footnotes for additional information.
Quality Assurance and Provider Education

- Vaccine recommendations and schedules are complex and frequently updated
- Safe and effective immunization requires
  - Appropriate vaccine storage and handling
  - Administration of the right vaccine to the right person by the right route of administration at the right time
Comprehensive Vaccine Management: Three Critical Components

- **Reliable and appropriate equipment**
  - Vaccine storage unit
  - Temperature monitoring equipment

- **Knowledgeable staff**
  - Designated person to handle storage and handling
  - Train all staff on vaccine storage and handling

- **Written storage and handling plans**
  - Routine storage and handling of vaccines
    - Ordering and accepting vaccine deliveries
    - Storing and handling vaccines
    - Managing inventory
    - Managing potentially compromised vaccines
  - Emergency vaccine retrieval and storage
4. Managing Potentially Compromised Vaccines

- Isolate the questionable vaccine
- Follow the immunization program policy and contact either the manufacturer or the immunization program for guidance
Management of Vaccine Shortages

- Work with industry to actively manage distribution of vaccine
- Interim recommendations for vaccine use during vaccine shortages
- Active communication efforts to immunization providers
Immunization Information Systems and Health Information Technology

- **Immunization information systems:**
  - Population-based systems that track the vaccination status of both vaccinated and unvaccinated populations
  - Record all vaccinations given to all age groups by all providers in a geopolitical catchment area
  - Provide functions needed by immunization programs (e.g., vaccine inventory management, adverse event reporting, etc.)
  - Have interoperability with other health information systems including electronic health records

- **“Meaningful use”**

- **Improving data quality through vaccine bar coding**
Potential Benefits of 2D Barcodes

- Improve accuracy of immunization information recorded in patient health records
- Improve consistency in availability of immunization information captured in IIS and VAERS reports
- Lot number information can help identify a safety concern with a specific lot and identify patients who may have been vaccinated with that lot in the case of a recall
- Reduce administration errors (incorrect, expired, or recalled vaccine)
Assessment of Immunization Coverage

- National Immunization Survey
  - Large telephone survey provides provider-verified immunization coverage for children 19-35 months of age

- NIS-Teen

- Behavioral Risk Factor Surveillance System

- National Health Interview Survey

- Innovative approaches
  - Alternative to telephone surveys
  - Internet panel surveys
Estimated Vaccination Coverage, among Children 19-35 Months of Age, 1991-2010*

† Target is 80 percent for Rotavirus, Tdap (1+), MCV4 (1+), HPV (3+) and 90% for varicella (2+)
§ Full series Hib (≥3 or ≥4 doses, depending on product type received). Brand of Hib vaccine received was not collected on the NIS prior to 2009.
‡ Among females
Estimated vaccination coverage among adolescents aged 13-17 years – NIS-Teen 2006-2010

*2006: HPV-1 was not reported; 2007: HPV-3 was not reported
Vaccine Safety

- **Surveillance**
  - Vaccine Adverse Event Reporting System

- **Rapid studies**
  - Rapid cycle analysis through the Vaccine Safety Datalink

- **Other special studies**
  - Guillain-Barré syndrome following H1N1 vaccine
  - Vaccines and autism
  - Vaccines and autoimmune diseases

- **Prevention**
  - Contraindications and precautions for use of vaccines
  - Withdrawal of recommendations for use of vaccines
Vaccine Adverse Event Reporting System

- National spontaneous reporting system for adverse events following immunization
- Jointly run by CDC and FDA
- VAERS has led to early identification of serious adverse events

Limitations
- Reporting is not complete
- Rarely able to establish a causal relationship to vaccine based on reports to VAERS

VAERS reports can be submitted online and data are publicly accessible:  [http://vaers.hhs.gov](http://vaers.hhs.gov)
A Faster Approach to Vaccine Safety Studies

- Alternative to traditional post-licensure vaccine safety study methods, which generally take years to complete

- The Rapid Cycle Analysis approach in the Vaccine Safety Datalink:
  - Tests specific hypotheses with well-defined outcomes
  - Each week, evaluate the number of events in vaccinated persons
  - Compare it to the expected number of events based on a comparison group
  - Weekly analyses with statistical adjustment for multiple looks

- Rapid Cycle Analyses have:
  - Provided reassuring data on safety of several newly introduced vaccines (e.g., Rotateq, 2009 H1N1 vaccine)
  - Identified increased risk of febrile seizures following MMRV vaccine

State Vaccine Safety Coordinators

- Established by CDC’s Immunization Safety Office in 2008 to promote effective pandemic influenza response planning

- Vaccine Safety Coordinators are public health officials at 62 Project Area* health departments who serve as vaccine safety liaisons
  - Serve as the state-level vaccine safety liaison to CDC and as a resource for local health departments and vaccine providers in the state

- Goal is to allow CDC and states to have a direct line of communication to prepare for and respond to vaccine safety issues and emergencies
  - Share updates
  - Alert CDC to vaccine safety concerns in their state, respond to vaccine safety emergencies (CDC assists with investigations as needed)
  - Optimize and coordinate risk communication activities

*The 62 CDC Public Health Emergency Preparedness Project Areas include the 50 US states, 4 major metropolitan areas (New York City, Chicago, Washington DC and Los Angeles County) and 8 US territories and freely associated island nations
Communication and Partnerships

- Provide information and communication resources to health care professionals who recommend and/or administer vaccines
- Apply communication science and best practices to deliver effective messages using appropriate formats, channels, and spokespeople
- Build and maintain immunization coalitions and partnerships
- Increase attention to issues and mobilize partners through events and observances
  - National Infant Immunization Week
  - National Influenza Vaccination Week
Provider Resources for Vaccine Conversations with Parents

- Developed with partners: AAP and AAFP
- Primary target audience: healthcare professionals
  - Provide information to help when talking to parents about vaccines, vaccine-preventable diseases, and vaccine safety
  - Dual purpose: resources healthcare providers can provide to parents
- Based on formative, mixed methods research
- Using risk communication principles
- Extensively reviewed by subject matter experts
National Infant Immunization Week (NIIW)

- Began in 1994
- Held in conjunction with Global Immunization Awareness Week
- Promotes immunization for children <2 years of age
- Celebrates immunization achievements
- Locally driven
- Revitalizes efforts
Social media groups meet up across US to get flu vaccine and promote flu vaccination through digital media.

HHS, CDC, local health departments, and community-based organizations work together to provide flu vaccinations clinics.
“Vaccines Don’t Give Themselves”

- Building and maintaining the public-private partnership of immunization providers
  - Quality assurance
  - Provider education
  - Immunization information systems

- Providing evidence-based immunization policy
  - Understanding disease burden
  - Vaccine risks and benefits

- Knowing how we are doing
  - Surveillance for disease and for safety
  - Surveillance for coverage

- Fostering multi-sector partnerships and coalitions to broaden access and awareness

- Responding to protect public health
Vaccine Storage & Handling Guide

Protect your vaccine ~ Protect your patients

December, 2011
Measles, United States, 2011

- 222 cases reported
- 72 importations from at least 20 countries
- 69 (31%) hospitalizations
  - 38% <5 years, 20% 5-19 years, 30% ≥20 years
  - 97% unvaccinated/unknown status, 3% 1 dose
- 17 outbreaks* (3-21 cases)
- U.S. resident cases (N=196)
  - 66% unvaccinated, 18% unknown vaccination status, 8% 1 dose, 7% ≥2 doses

*defined as ≥3 linked cases