Immunization Programs: More than Just Vaccine

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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

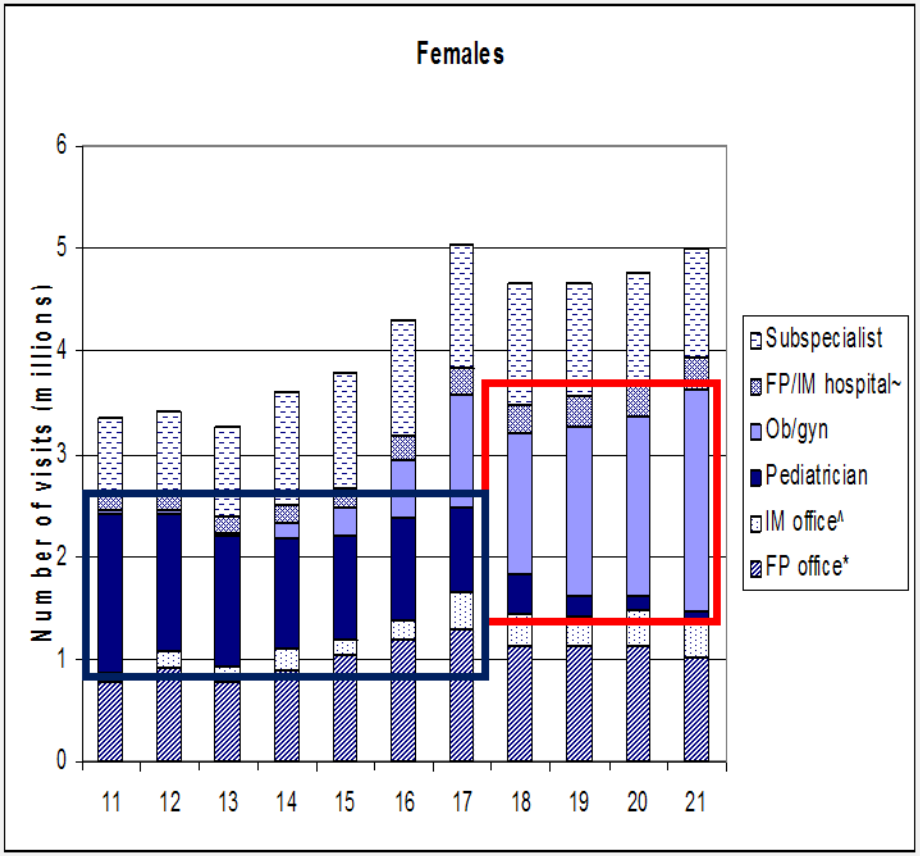
- **These funds provide critical support for the people and systems that make immunization programs work**
  - Recruiting immunization providers
  - Quality assurance and provider education
  - Surveillance of vaccine-preventable diseases
  - Response to outbreaks of vaccine-preventable diseases
  - 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

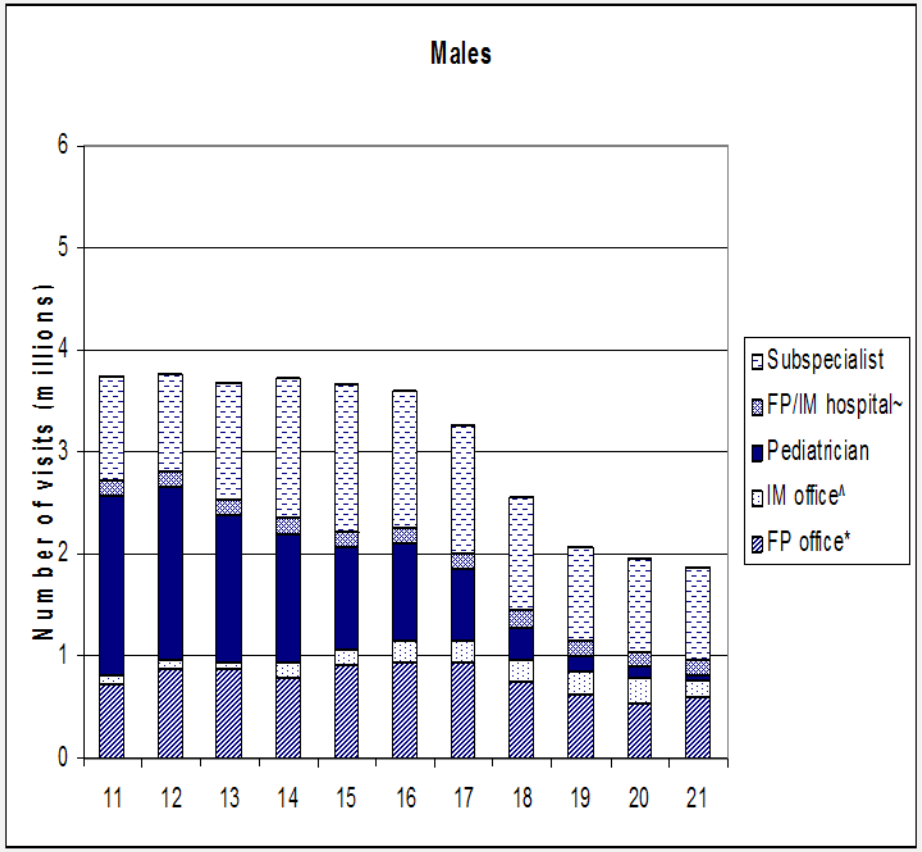
- Public health role in helping medical offices and other venues to make immunization services available
- Different age groups receive medical care from different health care providers
- Other venues can supplement the medical care setting for immunization services
- Immunization program responsible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

Medical Visits by Adolescents

Females



Males



Rand CM, et al. Arch Pediatr Adolesc Med. 2007;161:252-259.

Vaccination of Adults

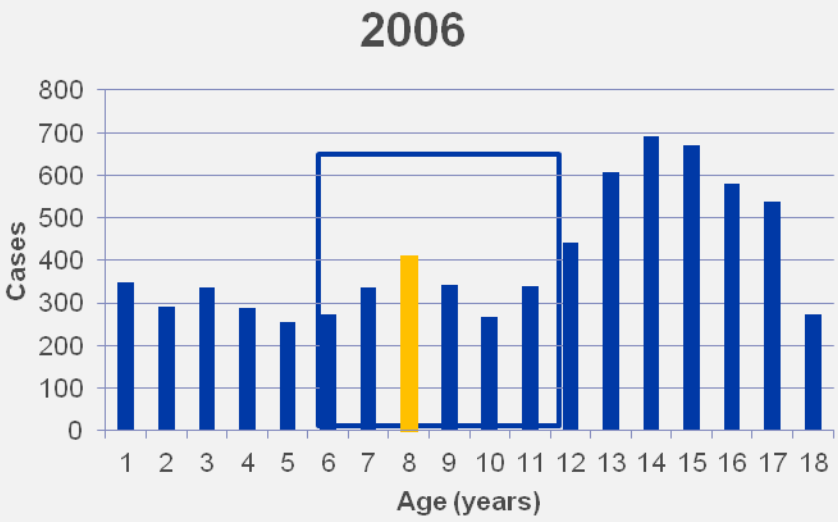
- **Wide range of settings and types of providers for medical care of adults**
  - Medical primary care provider offices
  - Medical specialist offices
    - Obstetricians, nurse midwives, cardiologists, etc.
  - Hospital-based clinics
  - STD/HIV treatment clinics
  - Nursing homes/long-term care
  - Correctional facilities
  - Pharmacies
  - College health clinics
- **Non-medical settings, especially workplaces**
- **Different strategies/resources needed to reach patients in different settings**

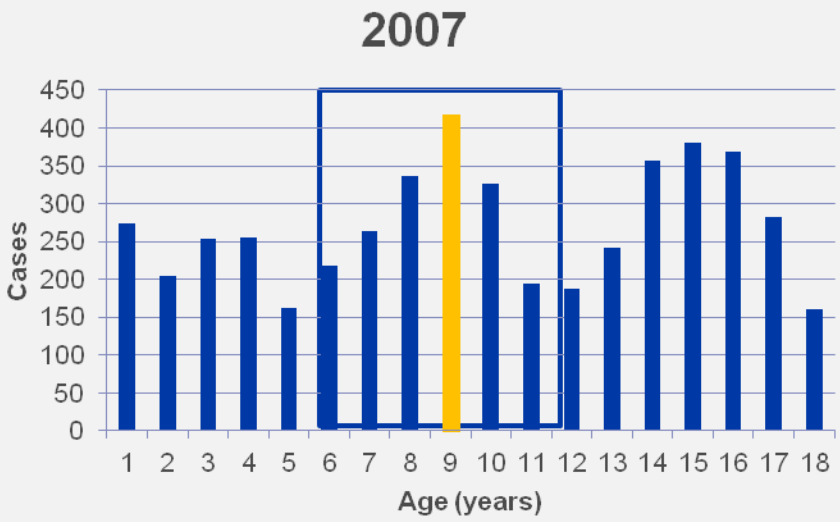
School-located Vaccination Clinics

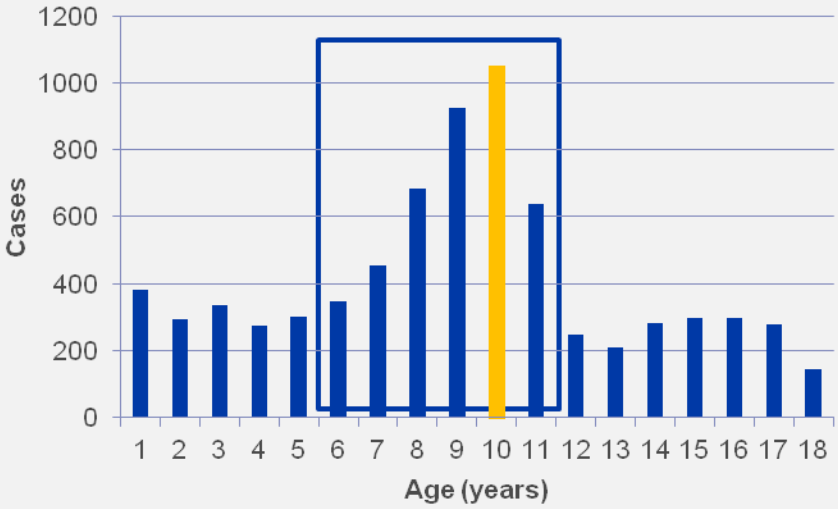
Surveillance of Vaccine-Preventable Diseases

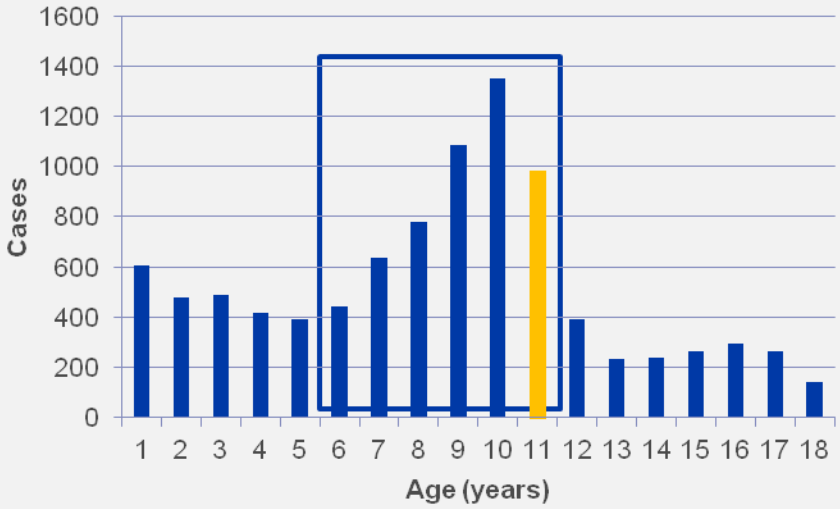
- **State-based systems for reporting by providers, hospitals, schools, and laboratories**
- **Critical importance of careful investigation**
  - Dates of onset
  - Vaccination history
  - Exposure and travel history
- **The essential role of the laboratory**
  - Confirmation of the diagnosis
  - Tools 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

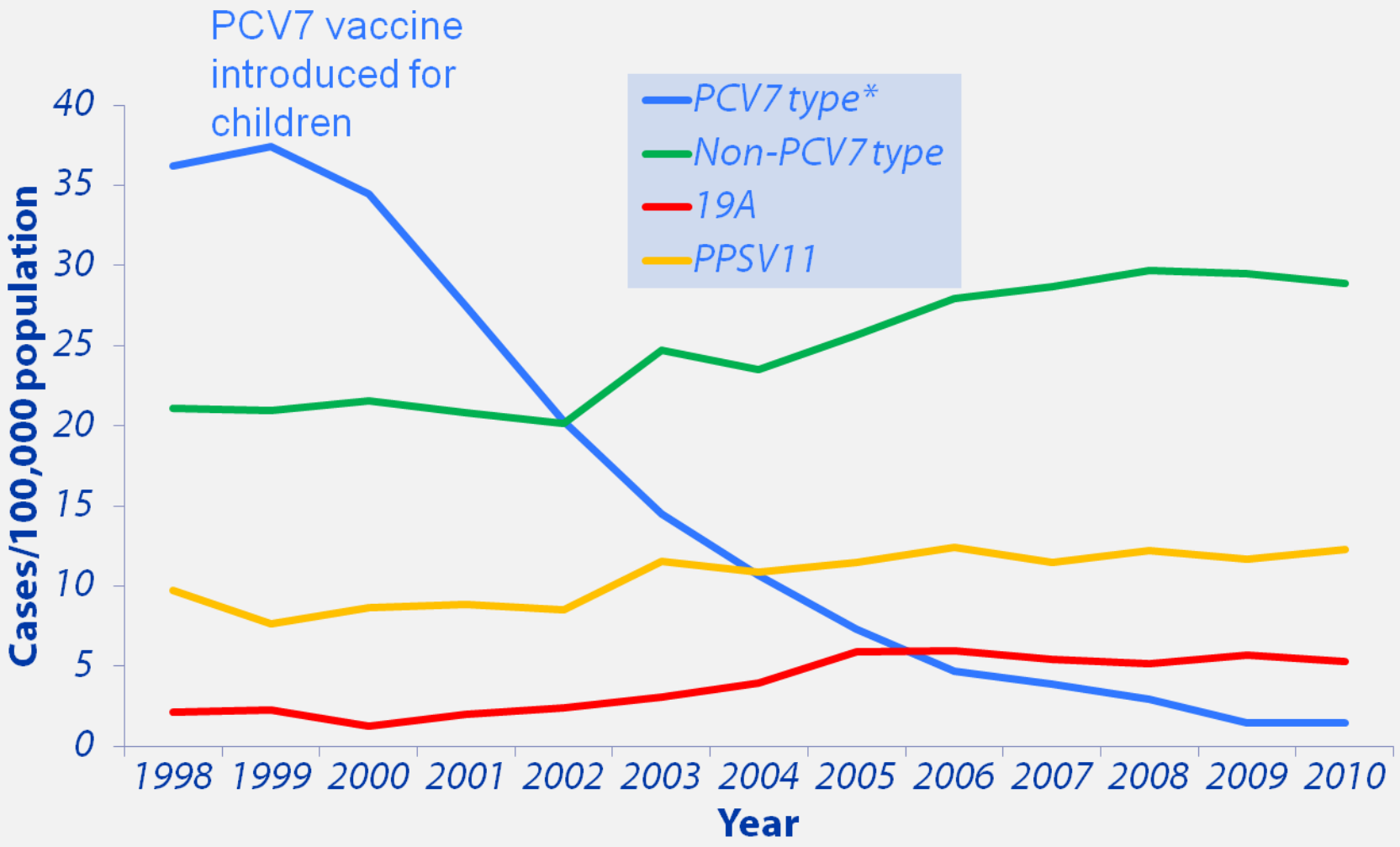






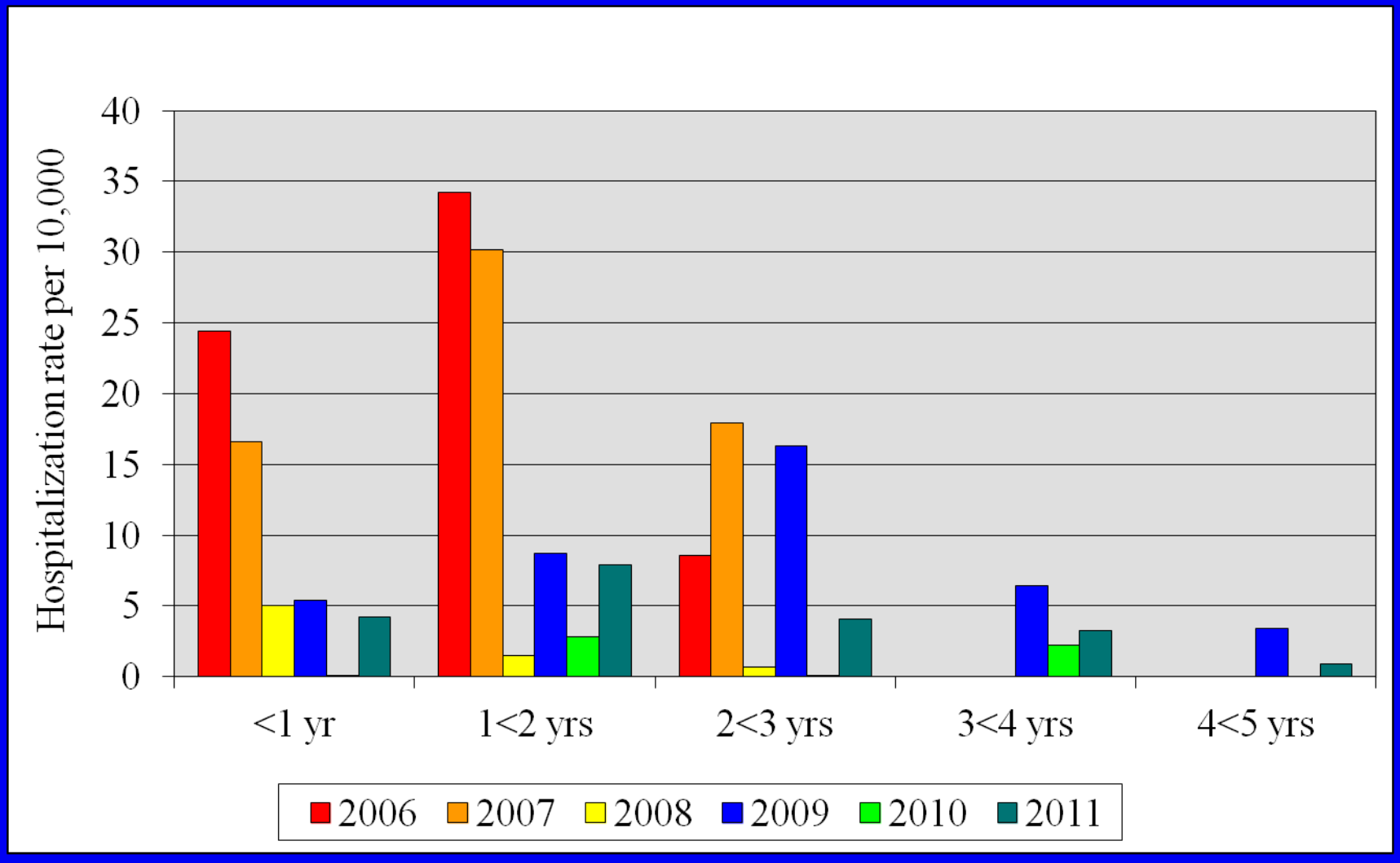


Incidence of Invasive Pneumococcal Disease Among Adults ≥65 Years by Serotype, 1998-2010



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**

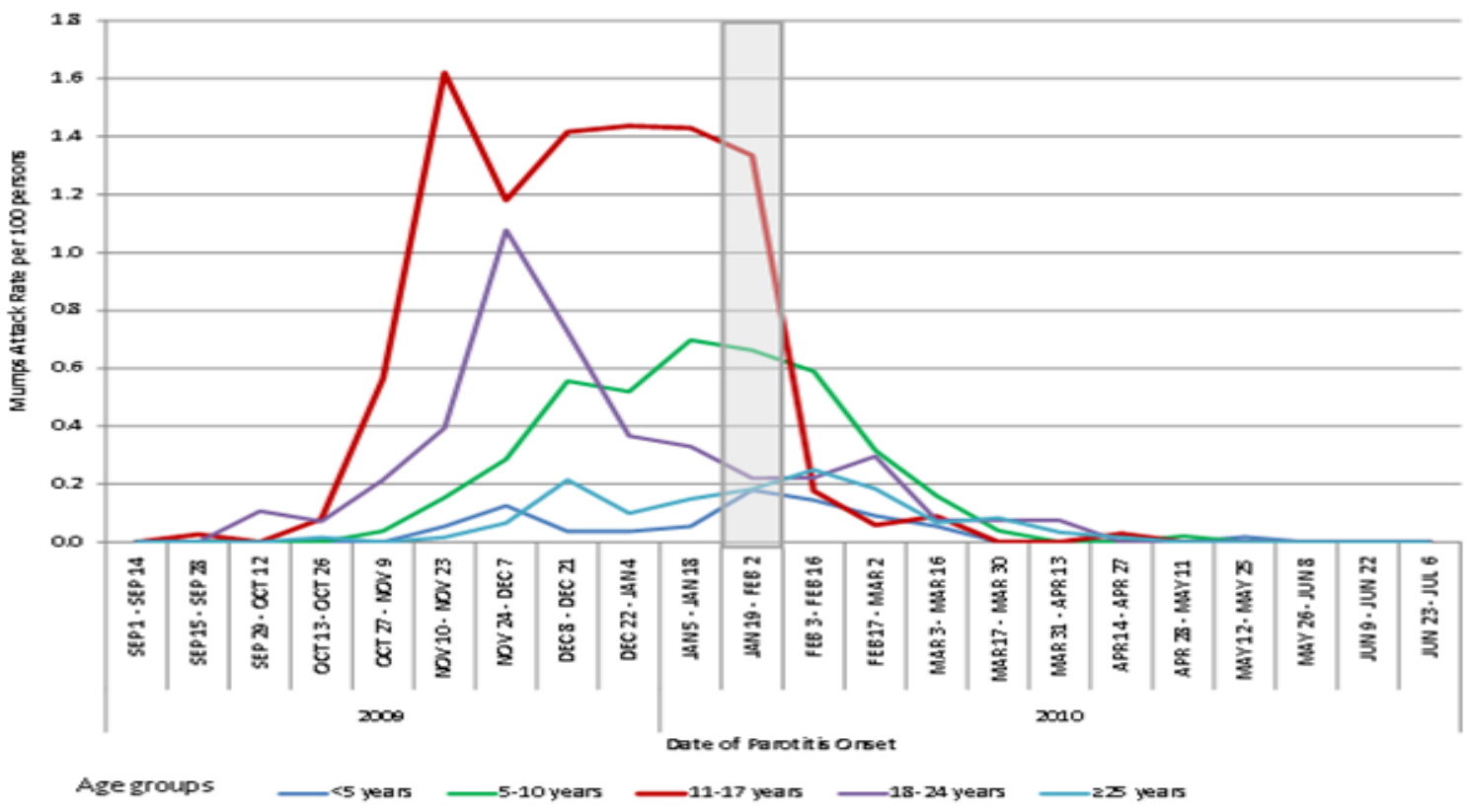
Measles Cases Reported to CDC, 2008 (N= 140)

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

Sugerman DE et al Pediatrics 2010;125: 747-755

Mumps Age-specific Attack Rates, Orange County, NY



Vaccine Effectiveness Study
Pertussis, California, 2010

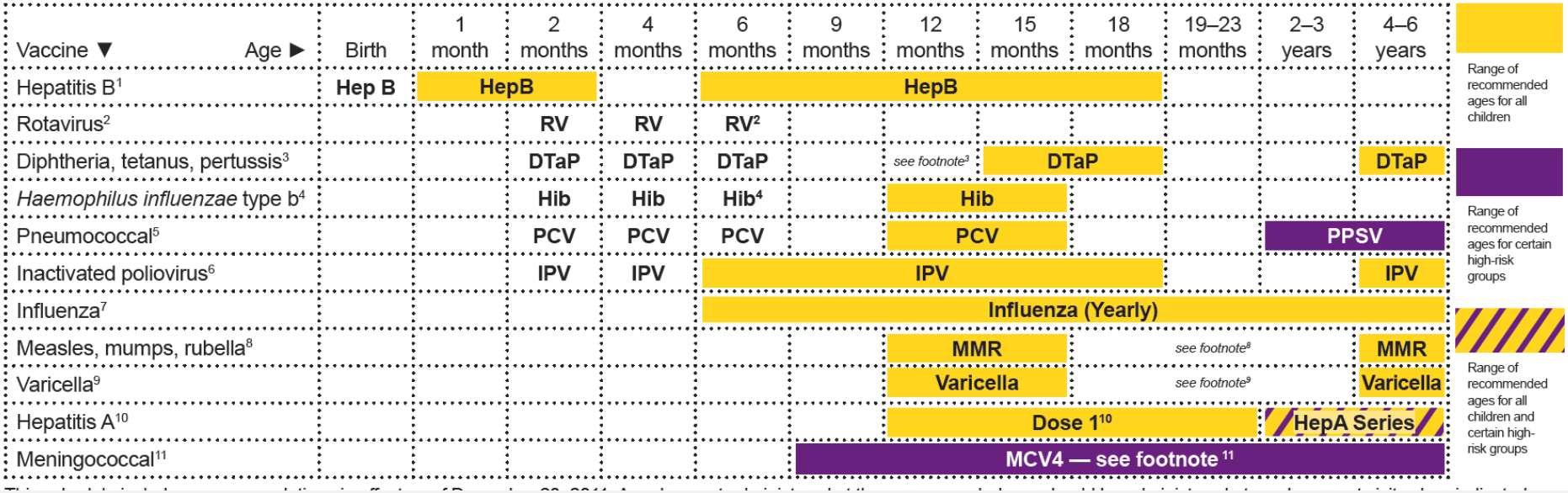
- 25 people reviewed charts from over 250 provider offices
- Abstraction forms completed for 1,039 cases & 3,194 controls
- Most prolific team member: reviewed 373 patient charts and completed data entry for 643 abstraction forms in 19 days


09.05.2010

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])



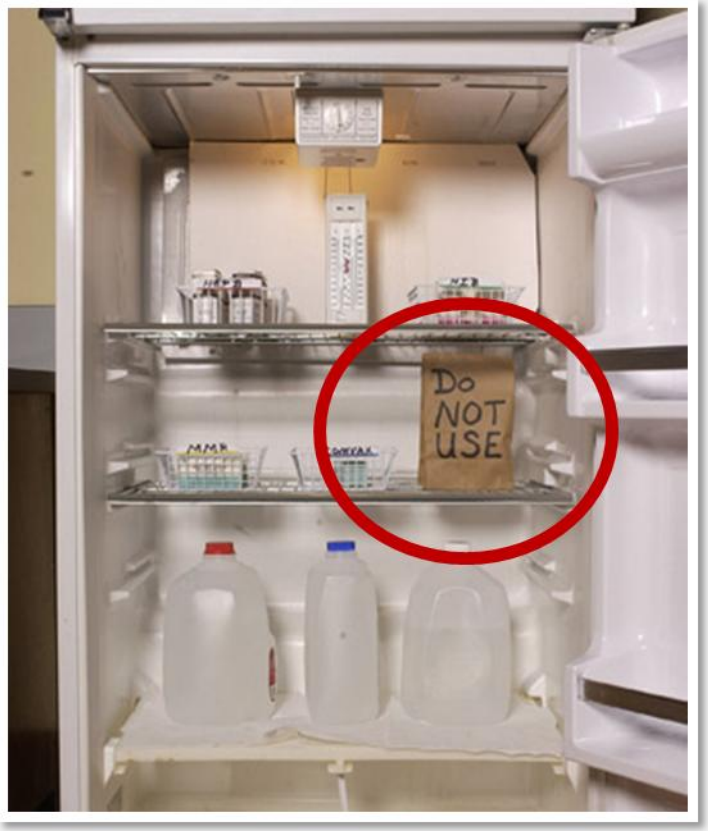
Quality Assurance and Provider Education

- **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**

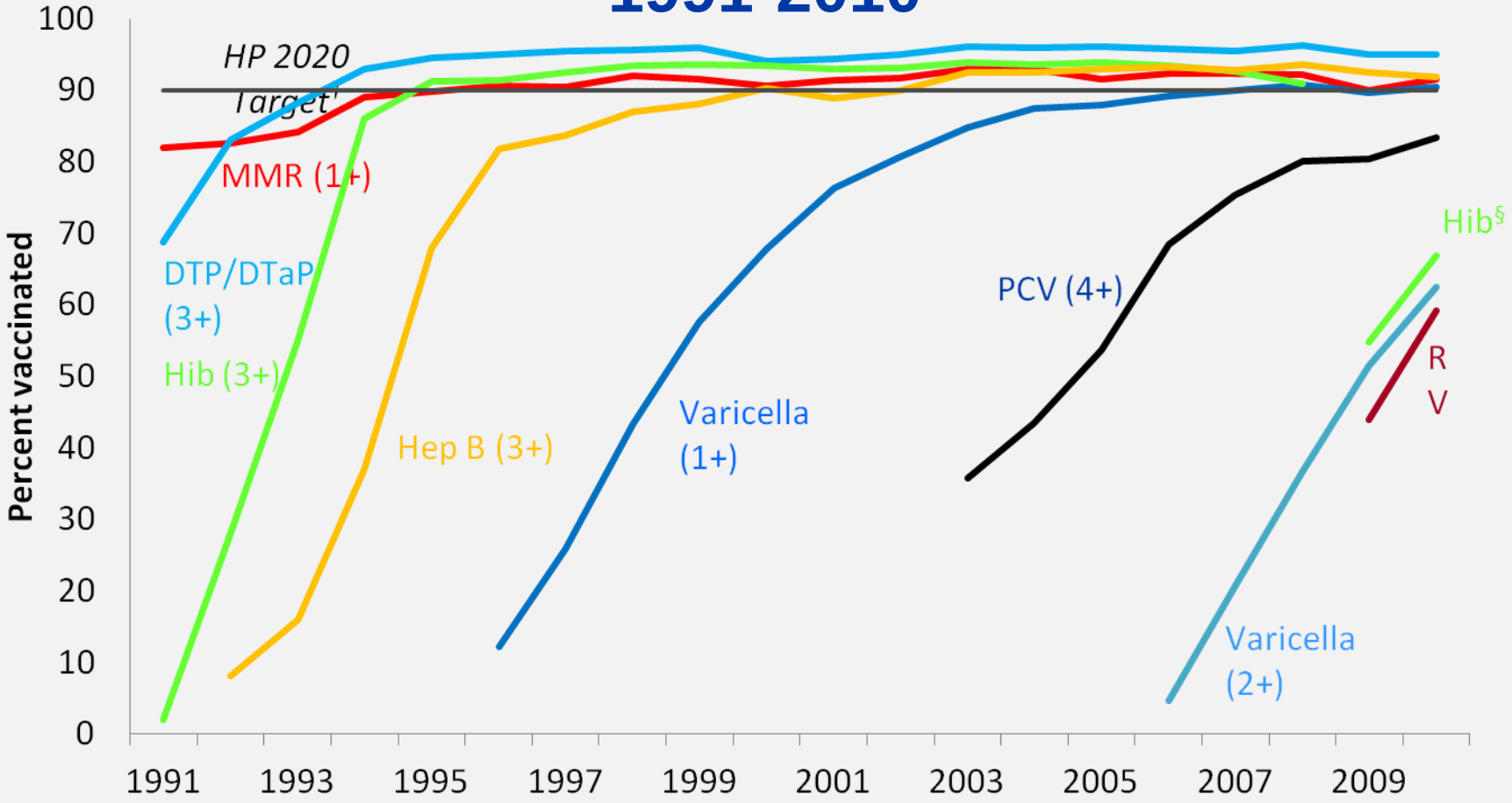
Potential Benefits of 2D Barcodes

- 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*



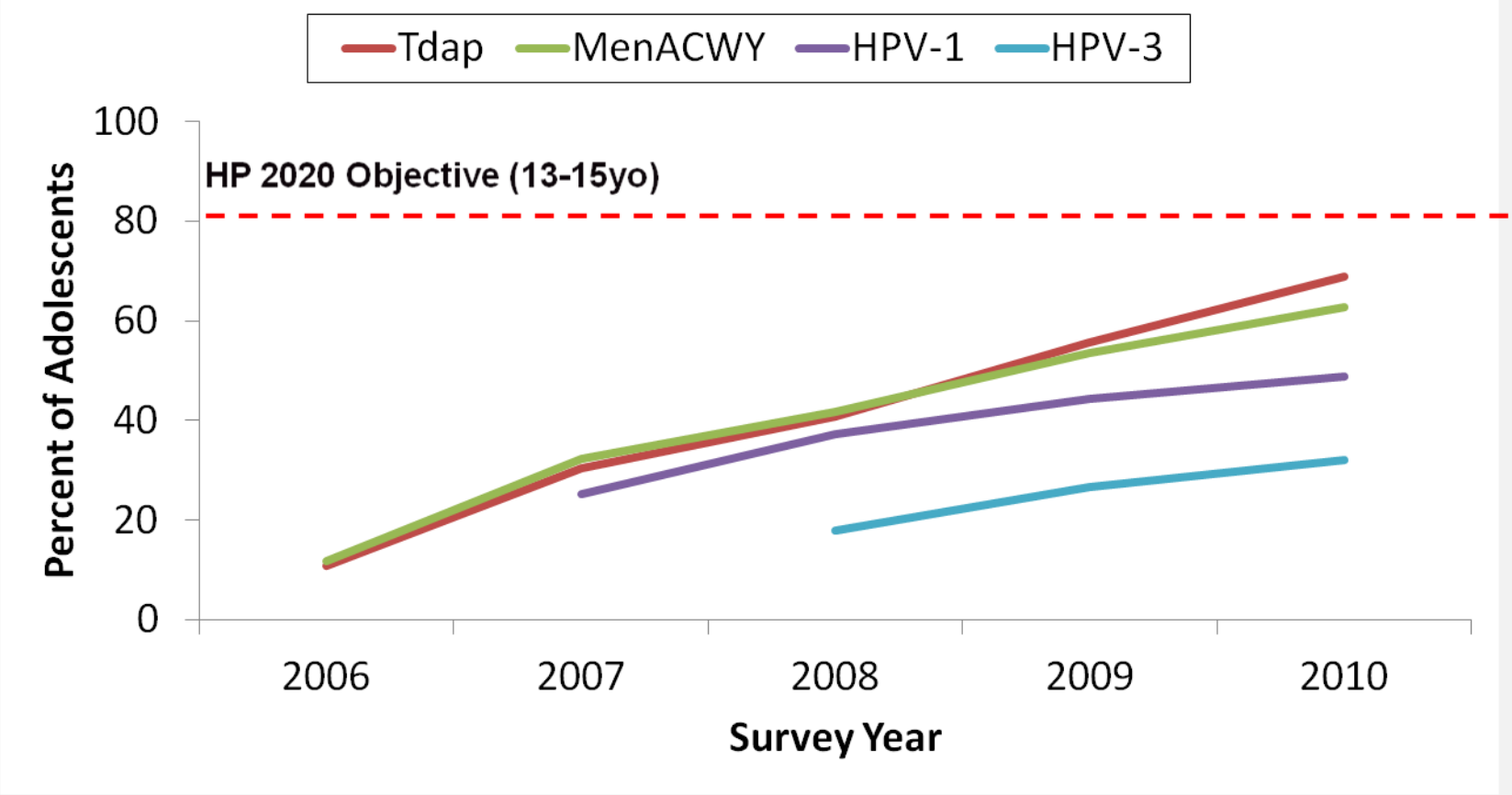
* Source: NHIS (1991-1993); NIS (1994-2010) children 19-35 months and NIS-Teen (2006-2010) teens 13-15 years

† 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**

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

Lieu TA, et al. Real-time vaccine safety surveillance for the early detection of adverse events. Med Care. 2007 Oct;45:S89-95.

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

NIVW FLU ACTIVITIES: GENERAL PUBLIC AND ETHNIC POPULATIONS

"This was always on the list of things to do, it was just a matter of remembering to go down and do it. There are just so many health issue to focus on when you are pregnant that you tend to forget the 'routine' ones but I could not imagine how I would cope with being pregnant and sick at the same time. Thanks for the reminder."

The SF Bay Area Expectant Mothers Group

Social media groups meet up across US to get flu vaccine and promote flu vaccination through digital media

South Dakota Native American children promote vaccination

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**

For more information please contact Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: http://www.cdc.gov

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