

Vaccine Management

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Rationale and Topics

- ❑ **NVAC working group addressing immunization infrastructure needs**
- ❑ **Expanded routine childhood schedule, implications of health reform on immunization financing, and budget challenges suggest need for attention in several areas**
- ❑ **Today's topic: Vaccine management**
 - How we store and handle vaccines
 - How we pay for vaccines and vaccine administration

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.**

Storage and handling

Selected Recent US Immunization Policy Decisions (2005-2011)

New Vaccine/Indication

ACIP Vote

Meningococcal conjugate (adolescents)	February 2005
Tdap (adolescents)	June 2005
MMRV	October 2005
Universal hepatitis A	October 2005
Rotavirus (infants)	February 2006
Influenza (expanded 24 to 59 months*)	February 2006
Human papillomavirus (adolescent females)	June 2006
Second Dose Varicella	June 2006
Zoster (shingles)	October 2006
Influenza (expanded 5 to 18 years) *	February 2008
Influenza (universal >6 months)	February 2010
Second dose meningococcal conjugate (adol)	October 2010
Human Papilloma Virus (adolescent males)	October 2011

*Recommendation for 6 to 23 months in 2004

Childhood Immunization Schedule - 2012

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])

Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	9 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years	
Hepatitis B ¹		Hep B	HepB			HepB								Range of recommended ages for all children
Rotavirus ²				RV	RV	RV ²								
Diphtheria, tetanus, pertussis ³				DTaP	DTaP	DTaP	<i>see footnote³</i>		DTaP				DTaP	
<i>Haemophilus influenzae</i> type b ⁴				Hib	Hib	Hib ⁴		Hib						Range of recommended ages for certain high-risk groups
Pneumococcal ⁵				PCV	PCV	PCV		PCV				PPSV		
Inactivated poliovirus ⁶				IPV	IPV	IPV							IPV	
Influenza ⁷						Influenza (Yearly)								
Measles, mumps, rubella ⁸								MMR			<i>see footnote⁸</i>		MMR	Range of recommended ages for all children and certain high-risk groups
Varicella ⁹								Varicella			<i>see footnote⁹</i>		Varicella	
Hepatitis A ¹⁰								Dose 1 ¹⁰				HepA Series		
Meningococcal ¹¹						MCV4 — <i>see footnote¹¹</i>								

Vaccine Storage and Handling: 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

Report: Vaccines for Children Program: Vulnerabilities in Vaccine Management

- ❑ **As part of its annual work plan, HHS Office of the Inspector General (OIG) assessed the extent to which selected Vaccines for Children (VFC) program providers and grantees adhered to CDC vaccine management requirements**
 - Storage equipment
 - Vaccine management
 - VFC program eligibility screening
- ❑ **OIG selected 45 VFC providers from the five largest VFC Grantees for the sample**
- ❑ **Assessments conducted in April and May of 2011**

Report Findings

- ❑ **The report highlighted some areas for improvement and underscores the importance of maintaining a robust public health system**
- ❑ **Identified two types of findings:**
 - storage and handling of vaccine
 - program management issues
- ❑ **General recommendations from the report include:**
 - ensuring vaccine storage and handling in accordance with VFC requirements
 - enhancing processes for handling expired vaccines
 - improving management of vaccine inventories
 - ensuring oversight requirements
- ❑ **<http://oig.hhs.gov>**

Corrective Actions

CDC is undertaking a comprehensive review of all aspects of vaccine storage and handling in the provider setting:

- ❑ Reviewing and revising CDC's current temperature monitoring recommendations
- ❑ Developing recommendations for storage and handling equipment including temperature monitoring technology and refrigerator and freezer units
- ❑ Developing standardized tools and training for field staff conducting VFC provider visits
- ❑ Reviewing current VFC requirements and developing corrective action guidance for out of compliance providers
- ❑ Providing funding through new PPHF funding announcement to improve vaccine storage and handling
- ❑ Updating CDC's Storage and Handling Toolkit
- ❑ Considering development of a certification program for vaccine storage and handling

Key Messages

- ❑ **Vaccines administered through VFC providers are safe and effective**
 - CDC surveillance for disease suggests vaccines are performing as expected, and most diseases are at record low levels.
 - Phase IV and post-licensure studies support the safety and efficacy of vaccines stored under “routine use” conditions.
- ❑ **This is not just a public sector issue – this is a national vaccine management issue**
 - Most providers do not store and handle VFC vaccines differently than privately purchased vaccine.
 - Any changes based on the report will improve all vaccination efforts regardless of whether federally or privately funded.
 - Improving the VFC program is a shared responsibility among CDC, all Grantees, and VFC provider offices.

How we pay for vaccines and vaccine administration

Sources of payment for vaccines and vaccine administration

□ Private insurance

- Comprehensiveness of vaccine and administration coverage evolving
- Key Affordable Care Act measures effective for new plans since Sept 2010

□ Public sources

- VFC (Vaccines only), Medicaid (vaccine administration)
- Medicare (Parts B and D)
- S CHIP
- State government funds
- Section 317

□ Out of pocket

Section 317 Vaccine Funding: The Past

- ❑ Focus evolved over time but provided a safety net**
- ❑ Vaccines were fewer and not so expensive**
- ❑ If a family could not afford vaccines, the provider could refer them to the health department**

The Measles Epidemic

The Problems, Barriers, and Recommendations

The National Vaccine Advisory Committee

The nation has experienced a marked increase in measles cases during 1989 and 1990. Almost one half of all cases have occurred in unvaccinated preschool children, mostly minorities. The principal cause for the epidemic is failure to provide vaccine to vulnerable children on schedule. Major reasons for the low vaccine coverage exist within the health care system itself, which creates barriers to obtaining immunization and fails to take advantage of many opportunities to provide vaccines to children. Ideally, immunizations should be given as part of a comprehensive child health care program. However, immunization cannot await the development of such an ideal system. Essential changes can and should be made now. Specific recommendations include improved availability of immunization; improved management of immunization services; improved capacity to measure childhood immunization status; implementation of the two-dose measles vaccine strategy; and laboratory, epidemiologic, and operational studies to further define the determinants of decreased vaccine coverage and to develop new combinations of vaccines that can be administered earlier in life. The measles epidemic may be a warning flag of problems with our system of primary health care.

(*JAMA*. 1991;266:1547-1552)

school- and college-age students who had not been vaccinated or who had been vaccinated unsuccessfully. Because vaccine failure remains a problem, beginning in 1989, a second dose of vaccine was recommended to be administered at the time of enrollment in either primary school or middle or junior high school.^{2,3} Since this is a long-term solution requiring 7 to 13 years to reap the full benefits, aggressive revaccination during school-based outbreaks will be needed in the interim.

Studies reveal no change in the effectiveness of the vaccine during recent years (G. E. King, MD, unpublished data, 1991). The vaccine, licensed and in use since 1963, protects about 95% of those who receive it. About three fourths of those with measles during

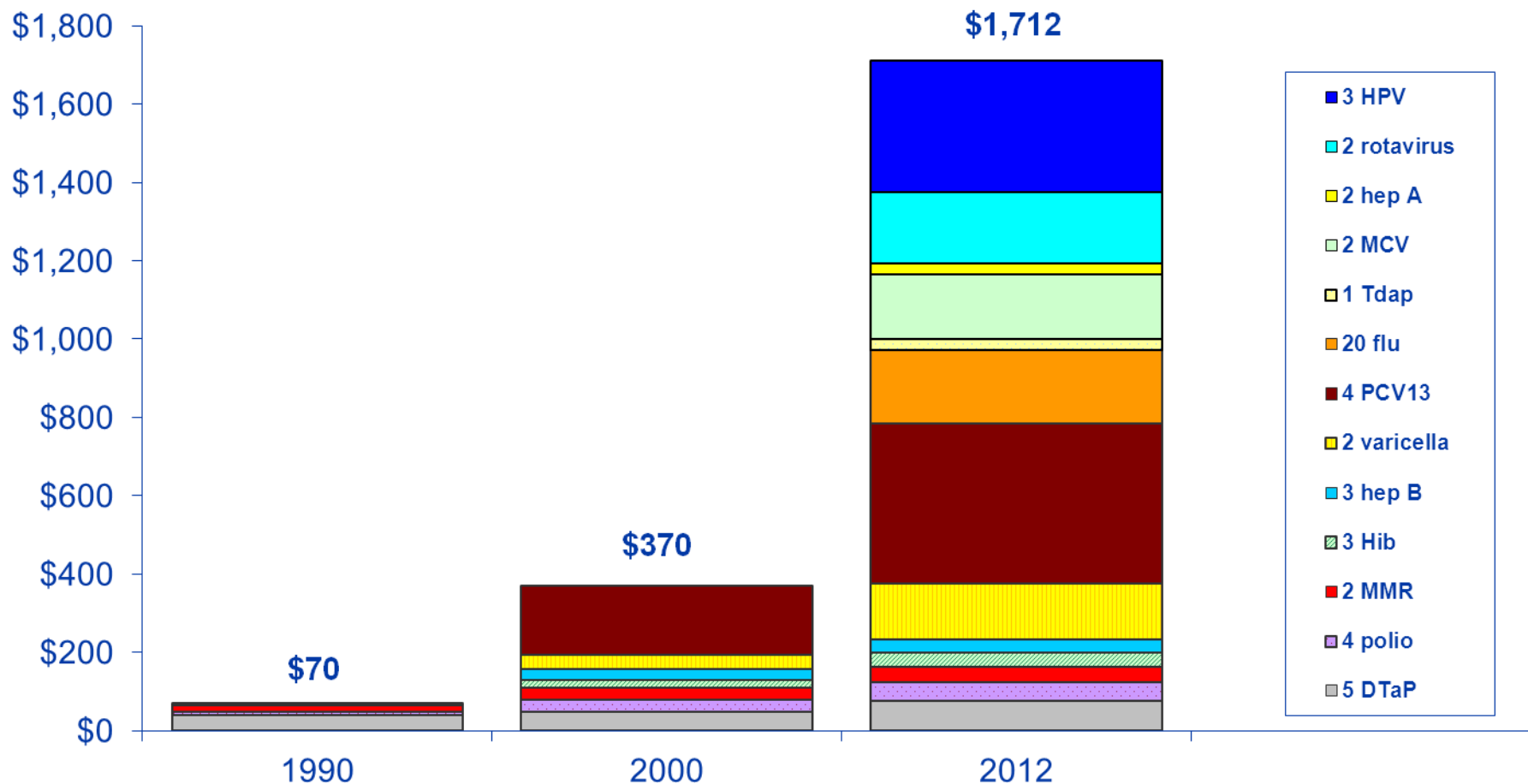
Vaccines for Children Program (VFC)

- ❑ 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-whatism.htm>

Cost to Vaccinate One Child with Vaccines Universally Recommended from Birth Through 18 Years of Age: 1990, 2000, and 2012



2012 represents minimum cost to vaccinate a child (birth through 18); exceptions are 1) no preservative influenza vaccine, which is included for children 6-47 months of age, and 2) HPV for males and females.

Federal contract prices as of February 1, 1990, September 27, 2000, and April 24, 2012.

Challenges for Private & Public Sectors

❑ Private immunization providers:

- Up front investment to stock more expensive vaccines
- Reimbursement uncertain or inadequate to cover costs

❑ Public sector:

- VFC grew as the need grew, but Section 317 funding did not
- More complex and more expensive program needed
 - New providers and new age groups
 - New surveillance systems
 - New coverage assessments
 - New professional education needs
 - New communication issues

The Problem of 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**
- ❑ **Some underinsured children can receive VFC vaccine at FQHCs and RHCs (~3000 clinics)**

***These children are not eligible for VFC vaccine at FQHCs or RHCs**

Section 317 Vaccine Funding: Recent Times

- ❑ Underinsured children
- ❑ Insured children
- ❑ Outbreak control
- ❑ Adults

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The Affordable Care Act (ACA)*

- 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 decreasing**
- 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**

*** Effective for plans drafted or updated after September 2010**

Federal Budget Realities

- ❑ **Great pressure to decrease Federal spending**
- ❑ **Expectation that the need for Section 317 vaccine purchase will decrease as health insurance coverage expands**

The Challenge of An In-Network Provider for Every Person with Insurance

- ❑ **Not all primary care providers provide all ACIP-recommended vaccines**
 - Investment needed to become a vaccinator
 - Small number of eligible patients in practice
 - Reimbursement rates inadequate
- ❑ **In some communities, health department immunization services are seen as convenient and more accessible than an in network provider**
- ❑ **Health departments that provide immunization services to insured persons need to identify funds other than 317 vaccine funding for vaccine purchase**

An In-Network Provider for Every Person with Insurance: A Shared Responsibility

- ❑ In-network providers need to be accessible in every community**
- ❑ In-network providers need to provide all recommended vaccines**
- ❑ Medical organizations need to help providers learn to become immunizers**
- ❑ Industry needs to help providers obtain initial vaccine stocks**
- ❑ Public health departments that serve insured people need to do so as in-network providers**
- ❑ Policymakers need to establish policies that facilitate these steps**

An In-Network Provider for Every Person with Insurance: NVAC and NVAC Stakeholders

- ❑ In-network providers need to be accessible in every community → **AHIP**
- ❑ In-network providers need to provide all recommended vaccines → **AHIP, Professional societies**
- ❑ Medical organizations need to help providers learn to become immunizers → **Professional societies**
- ❑ Industry needs to help providers obtain initial vaccine stocks → **Pharma**
- ❑ Public health departments that serve insured people need to do so as in-network providers → **AIM, ASTHO, NACCHO, CDC ARRA/PPHF Billing projects**
- ❑ Policymakers need to establish policies that facilitate these steps → **NVAC**

Section 317 Vaccine: Beginning FY 2013 Cannot be used for the Fully-Insured

- ❑ **Are we abandoning the childhood program?**
 - Section 317 infrastructure is critical to childhood immunization regardless of payer of vaccine
 - VFC Program remains unchanged
 - ACA insurance reforms expected to phase out underinsurance
- ❑ **Are we creating a public health crisis?**
 - Ensuring access is a shared responsibility
 - Many communities already preparing by working with insurers, providers, media
 - Opportunity to reinforce ACA provisions – not subsidize private insurance
- ❑ **What about the safety net?**
 - Directing vaccine to the greatest needs
 - Outbreak response

But Section 317 Remains Essential

Section 317 supports the public health systems and experts that contribute to:

- Science-base for making and evaluating vaccine recommendations
- Evidence of policy and program impact (coverage, effectiveness, safety)
- Science-based awareness campaigns and decision-tools
- Systems and tools for safe and effective program (Health IT, provider adherence)
- Efficient distribution and tracking of public sector vaccines
- Effective management of vaccine supply disruptions and shortages
- Timely and effective response to disease outbreaks
- A safety net for the non-VFC eligible uninsured

“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**

Where We Should End Up

- ❑ **Continued shared responsibility between public and private sectors**
- ❑ **For the insured, insurance should assure access to ACIP-recommended vaccines for both children and adults**
- ❑ **VFC will continue to provide vaccines for uninsured children, children eligible for Medicaid, and American Indian/Alaska Native children**
- ❑ **Section 317 vaccine funding should be able to help meet remaining needs**
 - Uninsured adults
 - Maintain or improve our ability to respond to outbreaks
 - Support preparedness

Where We Want to End Up

- Protecting our communities from vaccine-preventable diseases**
- Maintaining or improving our capacity to respond to public health threats**
- Protecting the most vulnerable in our communities**

Discussion on Vaccine Management

- ❑ Assuring appropriate vaccine storage and handling**
- ❑ Assuring appropriate payment for vaccines and vaccine administration**

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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