

Latest Situation of US Vaccine Policies

Bruce G. Gellin, MD, MPH

Deputy Assistant Secretary for Health
Director, National Vaccine Program Office
Office of Public Health and Science
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services

Melinda Wharton, MD, MPH

Deputy Director, National Center for Immunization &
Respiratory Diseases

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America's National Vaccine Plan

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3rd Vaccine Policy Exchange
July 2012

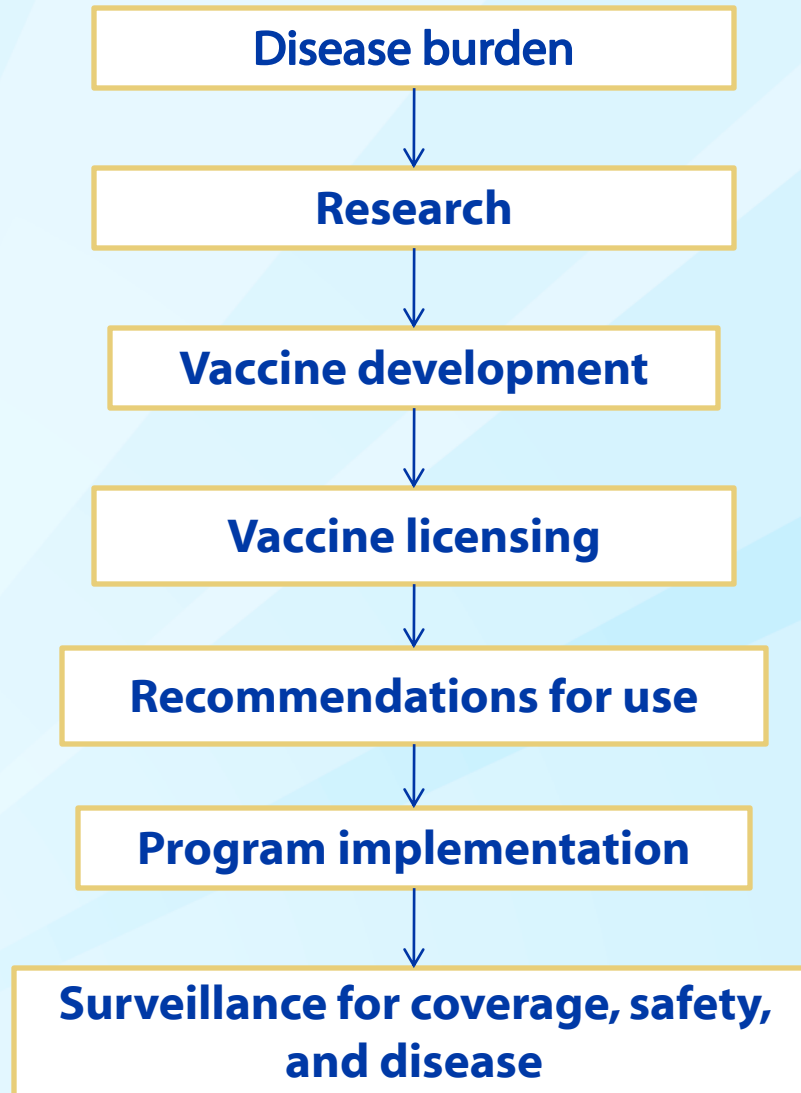
Immunization Financing and Policy in the United States

Melinda Wharton, MD, MPH

Deputy Director, National Center for Immunization &
Respiratory Diseases

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Vaccine and Immunization Framework



U.S. Department of Health and Human Services

U.S. Food and Drug Administration (FDA)

U.S. Centers for Disease Control and Prevention

Center for Biologics Evaluation and Research

National Center for Immunization and Respiratory Diseases

Vaccines and Related Biological Products Advisory Committee

Advisory Committee on Immunization Practices

Some Current Challenges

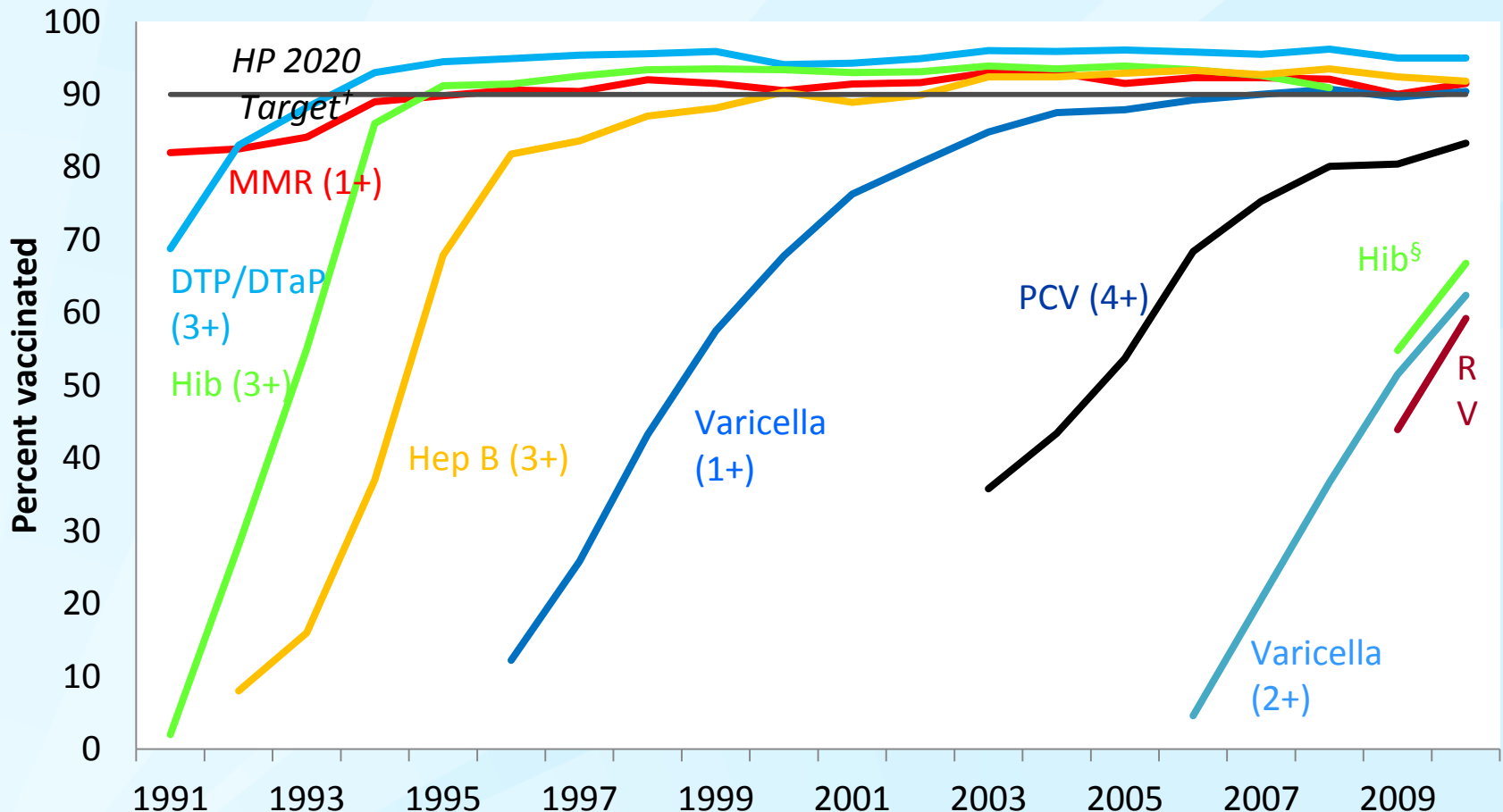
- ❑ Budget constraints, especially at the state and local level**
- ❑ Vaccine financing for newer, more expensive vaccines and changing health delivery landscape**
- ❑ Complexity of childhood recommendations**
- ❑ Vaccine hesitancy**
- ❑ Low coverage for recommended vaccines among adolescents**
- ❑ Low coverage for recommended vaccines among adults**
- ❑ Establishing and maintaining essential surveillance systems**

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	see footnote ⁴		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		see footnote ⁹			MMR	Range of recommended ages for all children and certain high-risk groups
Varicella ⁹								Varicella		see footnote ⁹			Varicella	
Hepatitis A ¹⁰								Dose 1 ¹⁰			HepA Series			
Meningococcal ¹¹						MCV4 — see footnote ¹¹								

This schedule includes recommendations in effect as of December 23, 2011. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.vaers.hhs.gov>) or by telephone (800-822-7967).

Estimated Vaccination Coverage, among Children 19-35 Months of Age, 1991-2010*



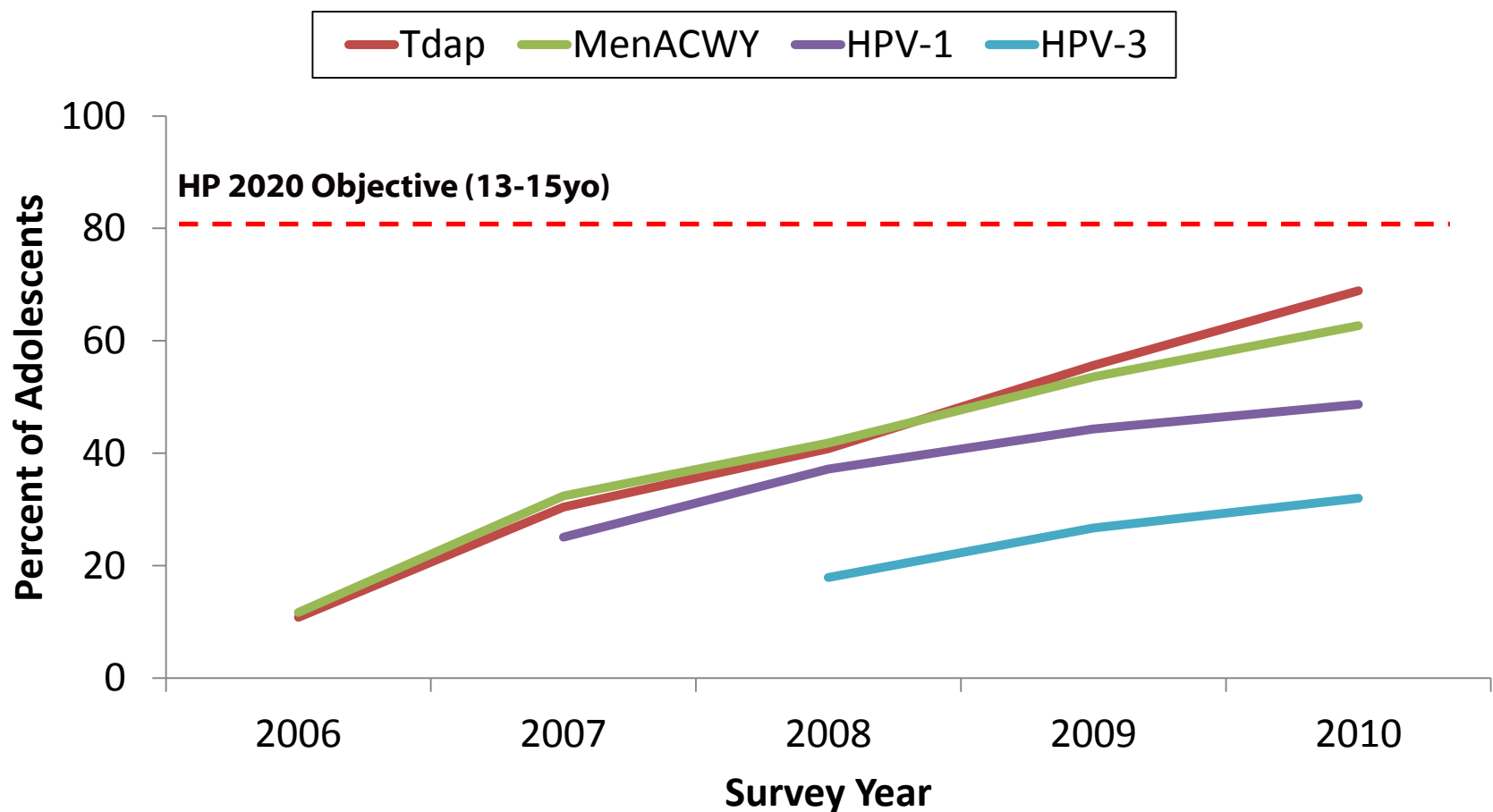
* Source: NHIS (1991-1993); NIS (1994-2010) children 19-35 months and NIS-Teen (2006-2010) teens 13-15 years

† 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

Estimated Vaccine Coverage Among Adults, 2010

- ❑ **Pneumococcal vaccine ≥65 years – 59.7%**
- ❑ **Tdap, past 5 years, 19-64 years – 8.2%**
- ❑ **Hepatitis B vaccine, 19-49 years, high risk – 42.0%**
- ❑ **Herpes zoster vaccine, ever, ≥60 years – 14.4%**
- ❑ **HPV vaccine, ≥1 dose females 19-26 years – 20.7%**
- ❑ **Influenza vaccine, ≥65 years, 2010-2011 season – 66.6%**
- ❑ **Healthcare personnel**
 - Tdap (<65 years, last 5 years) – 20.3%
 - Hepatitis B vaccine (≥19 years, ≥3 doses) – 63.2%
 - Influenza (2010-11 season) – 63.5%

National Health Interview Survey, 2010, MMWR 2012;61:66-72

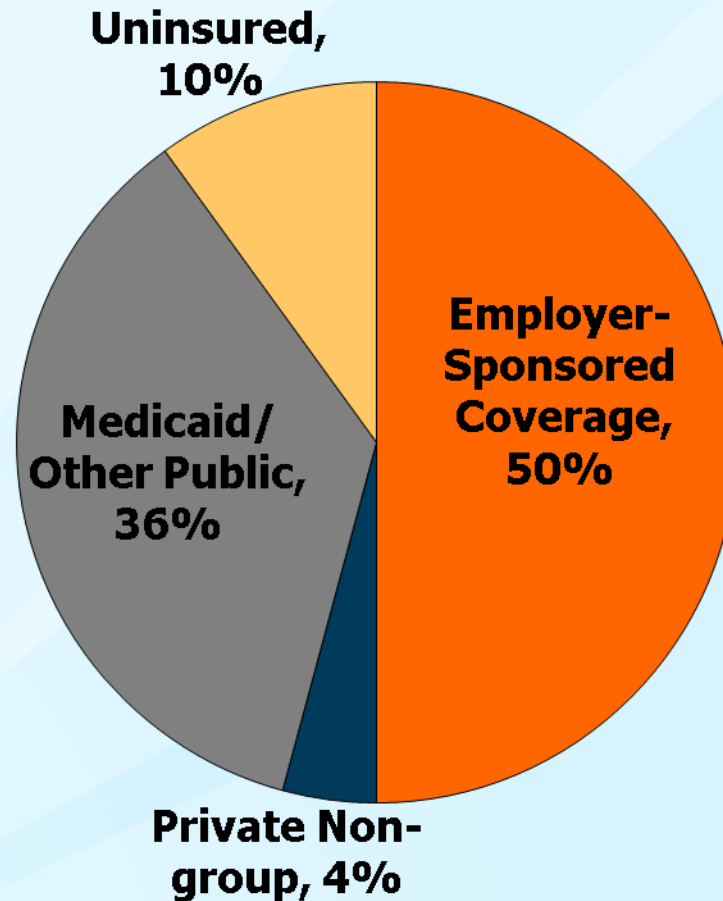
http://www.cdc.gov/flu/professionals/vaccination/coverage_1011estimates.htm

Lindley M et al, <http://www.cdc.gov/flu/professionals/vaccination/health-care-personnel.htm>

How Immunization is Funded in the United States

VACCINE FINANCING

Health Insurance Coverage of Children, 2010



79.3 Million Children

Data may not total 100% due to rounding. Children includes all individuals under age 19.
SOURCE: KCMU/Urban Institute analysis of 2011 ASEC Supplement to the CPS.

Federal Government Role in Purchasing Childhood Vaccines

- ❑ **Vaccines for Children program (VFC)**
 - Entitlement to certain vulnerable children
 - 45% of young children eligible for VFC
 - Mandatory funding
 - Inclusion of vaccines in VFC is determined by the U.S. ACIP
- ❑ **Section 317 vaccine funding**
 - Discretionary
 - No restrictions on vaccine or population

History of the 317 Immunization Program

- ❑ **1955: Polio Vaccination Assistance Act**
- ❑ **1962: Vaccination Assistance Act**
 - Allowed CDC to support mass immunization campaigns and support ongoing immunization activities
 - Provided vaccine and personnel to State and Local Health Departments
- ❑ **1963: First grants, authorized under Section 317 of the Public Health Service Act**
- ❑ **1992: Funding to support direct delivery of immunization services**

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**

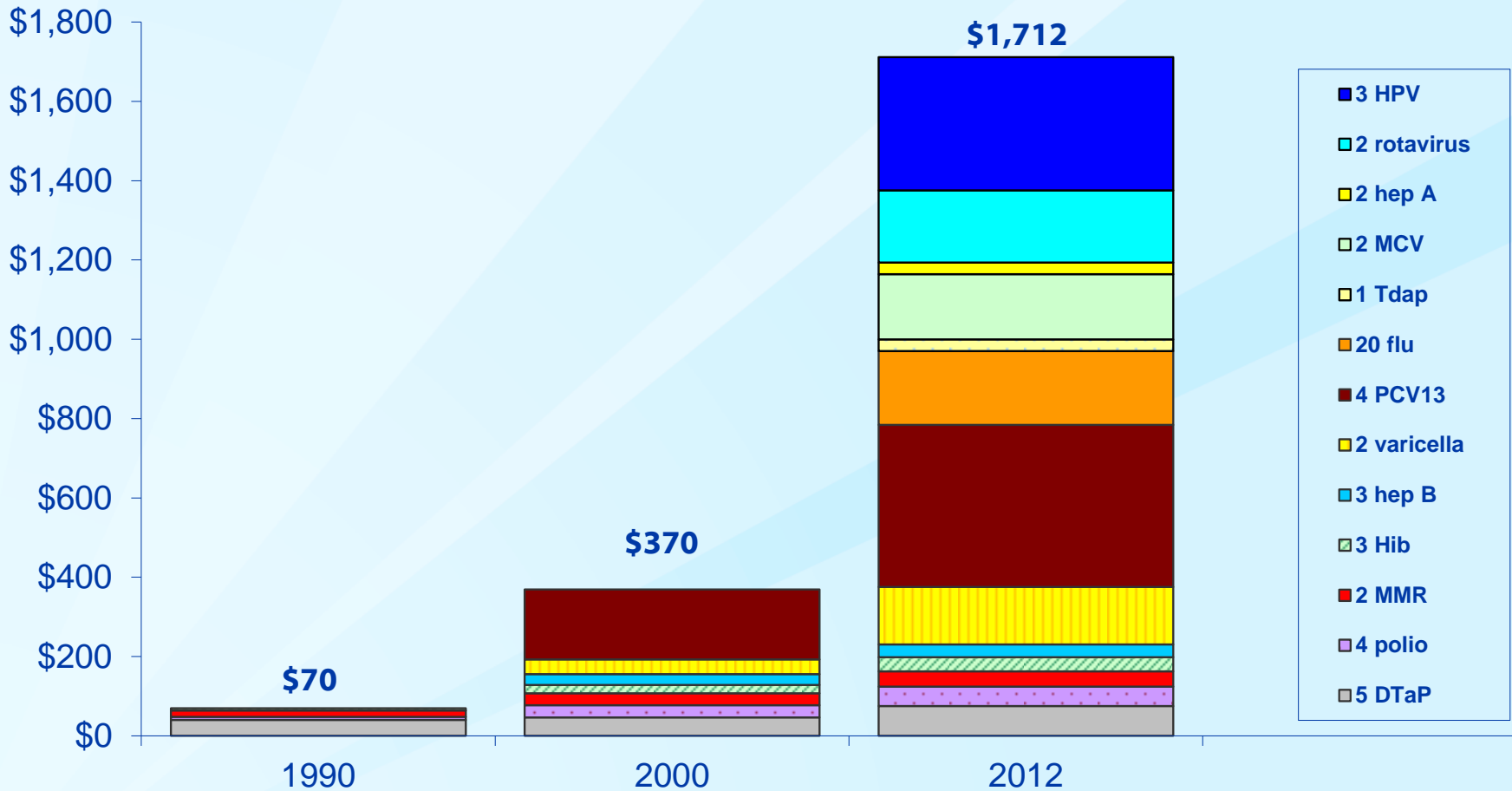
<http://www.cdc.gov/vaccines/programs/vfc/default.htm>

<http://www.cdc.gov/vaccines/programs/vfc/providers/acip-whatism.htm>

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
- ❑ **317 operations funding is critical for the implementation of the Vaccines for Children Program.**

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



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

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 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 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**

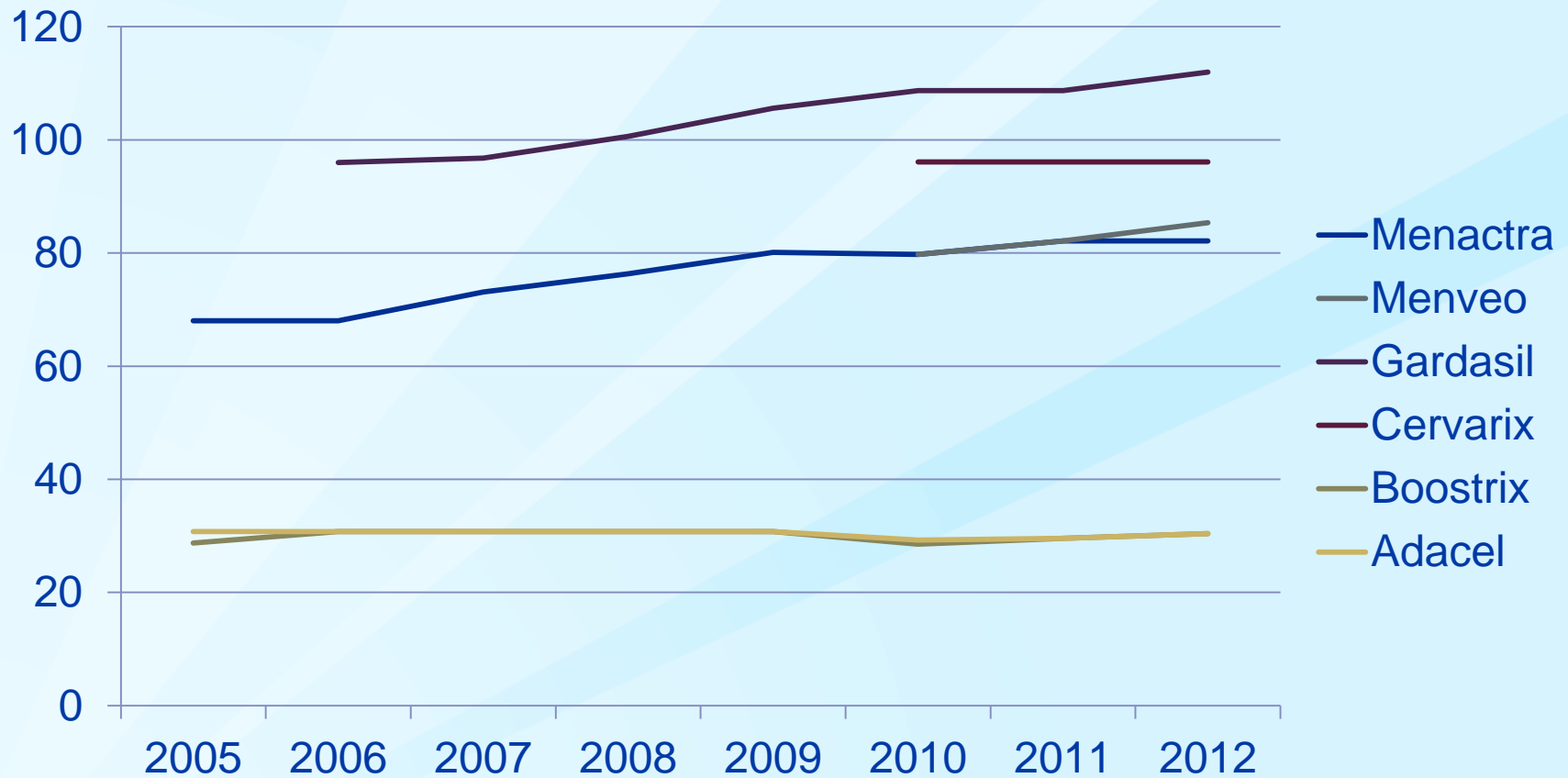
Public Sector Purchase of Vaccines in the U.S.

VACCINE PROCUREMENT AND DISTRIBUTION

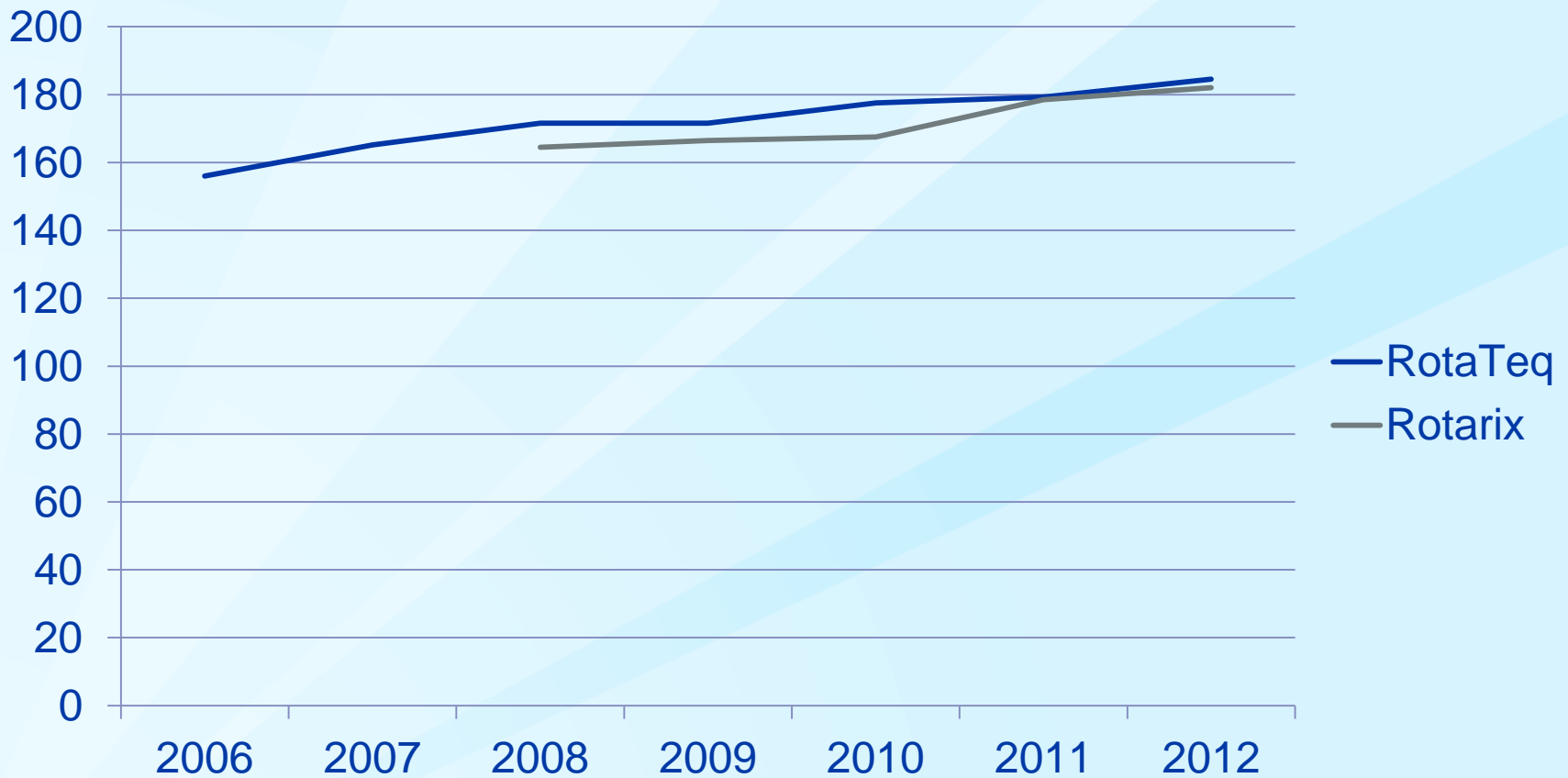
Vaccine Contracting

- ❑ **CDC attempts to negotiate a contract with each manufacturer of licensed vaccines recommended for routine use in children**
- ❑ **Procurements are made under U.S. Federal Acquisition Regulations and negotiated by CDC's Procurements and Grants Office**
- ❑ **Vaccine price data is publicly available at <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm>**
- ❑ **Newer, more expensive vaccines continue to command premium prices on Federal contracts even when a second product enters the market**

CDC/VFC Prices for Adolescent Vaccines, 2005-2012



CDC/VFC Prices for Rotavirus Vaccine Series, 2006-2012



Vaccine Ordering and Distribution

- ❑ **Since 2007, CDC has used a commercial distributor to store and distribute public sector vaccines directly to clinics and physician offices**
 - Improved visibility of vaccine stocks
 - Improved ability to address vaccine shortages/supply disruptions equitably
 - Product is insured against damage or loss
 - All VFC vaccines except for varicella vaccine (direct shipment from manufacturer)

- ❑ **A new vaccine order management system allows CDC to manage vaccine contracts and inventory as well as supporting on-line orders directly from end user providers**
 - Health departments can review/approve provider orders from their jurisdictions on line
 - System is currently being deployed in waves to include all US/territorial jurisdictions by mid 2013

The Role of the
Advisory Committee on Immunization Practices (ACIP)

VACCINE POLICY

U.S. Centers for Disease Control and Prevention

- ❑ **Performs surveillance, epidemiologic and laboratory research, and provides technical support to states for prevention and control of vaccine-preventable diseases**
- ❑ **Provides funding and technical support to state, some local, and territorial immunization programs**
- ❑ **Serves as Secretariat for the Advisory Committee on Immunization Practices**
 - Executive Secretary and committee management
 - Extensive support by CDC subject matter experts

Advisory Committee on Immunization Practices

- ❑ Provides expert external advice and guidance to the Director of CDC and the Secretary of the U.S. Department of Health and Human Services on use of vaccines in the civilian population**
- ❑ Policy recommendations for vaccines and related agents that are licensed by the FDA for prevention of diseases**
- ❑ Guidance for use of unlicensed vaccines can be developed if needed**
- ❑ Designates vaccines to be included in the Vaccines for Children Program**
- ❑ First dollar coverage for ACIP recommended vaccines in private health insurance plans**

ACIP Membership

- ❑ **15 voting members, with expertise in specific disciplines**
 - Vaccinology, immunology, pediatrics, internal medicine, infectious diseases, preventive medicine, public health
 - Consumer perspectives or social and community aspects of immunization programs
- ❑ **8 ex officio members from Federal agencies**
- ❑ **30 nonvoting representatives of liaison organizations representing a broad array of stakeholders**
 - Medical and public health organizations
 - Trade groups representing vaccine manufacturers

ACIP Meetings and Working Groups

- ❑ **Scheduled meetings 3 times a year**
 - Open to the public
 - Attended by stakeholders including vaccine manufacturers as well as media
- ❑ **Most of the actual ACIP work is done in working groups**
 - Review in depth data on specific vaccines or specific issues
 - Develop policy options and recommendations for presentation to the full Committee
 - Working group meetings are not open to the public
 - May review confidential information

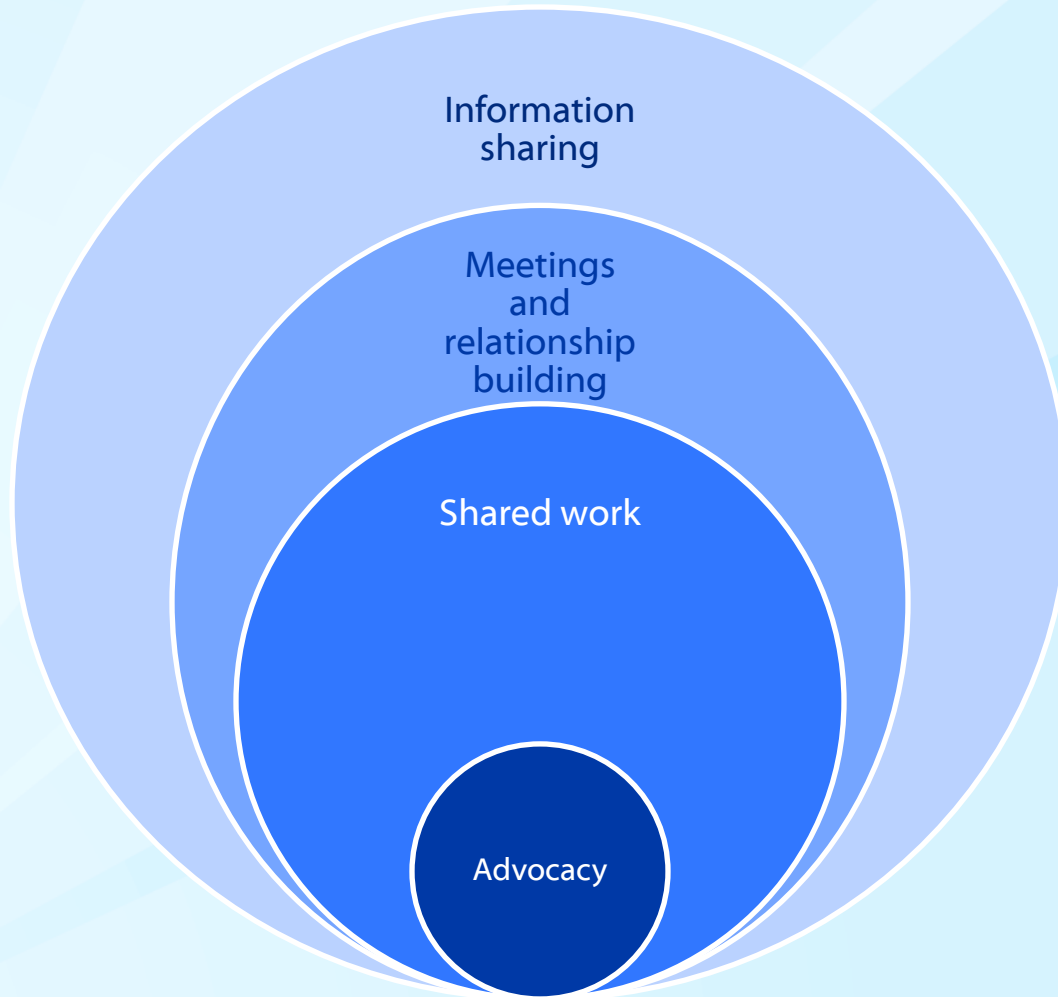
Working Together
to Achieve Common Goals

PARTNERSHIPS

Key Partners and Stakeholders Supporting the U.S. National Immunization Program

- ❑ **Governmental public health organizations**
 - Association of State and Territorial Health Officials
 - National Association of City and County Health Officials
- ❑ **Medical provider organizations**
 - American Academy of Pediatrics
 - American Academy of Family Physicians
 - American College of Physicians
 - American Medical Association
 - American Nurses Association
- ❑ **Advocacy groups**
 - Immunization Action Coalition
 - Every Child by Two
- ❑ **Health insurers and other payers**
- ❑ **Vaccine manufacturers and their trade groups**

Different Kinds of Partnerships



Communicating with Legislators

- ❑ **As a part of the Executive Branch of government, we support the Administration's goals, priorities, and budget proposals**
- ❑ **We cannot lobby the U.S. Congress or state legislatures for changes in law**
- ❑ **We can provide information that informs the legislative process**
- ❑ **Importance of**
 - A proactive approach to identifying and addressing Congressional interests
 - Partnerships

Thank you

www.cdc.gov/vaccines

www.cdc.gov/vaccines/recs/acip

www.cdc.gov/vaccines/conversations

www.cdc.gov/vaccinesafety

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: www.cdc.gov

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.

National Center for Immunization & Respiratory Diseases
Office of the Director

