United States Immunizations: A Bright Spot in Child Health

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Thank You

- Lance Rodewald, MD
  - Immunization Services Division
  - CDC
- Archana Chatterjee, MD
  - Creighton University

Topics

- Vaccination-The Success
- The Challenge-The System
- The Cost-Financing challenges
- Opportunities-The Future

MEASLES

HAEMOPHILUS INFLUENZAE

RUBELLA

MENINGOCOCCEMIA

POLIO

MUMPS

VARICELLA

DIPHTHERIA

Fundamental Concepts of the US Policies Concerning Vaccines

- Benefit (protection from disease) must outweigh risk (adverse reaction)
- Accept that adverse reactions will occur – minimize risk
- There is no 100% safe vaccine
  - All vaccines have adverse reactions
  - Most reactions are minor
  - Rarely are reactions fatal

Impact of Cervical Cancer

- United States:
  - Annual incidence: ~10,000
  - ~10 women die each day of cervical cancer
- Worldwide:
  - Annual incidence: ~500,000
  - Second most common cause of cancer death in women
  - ~240,000 deaths each year

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2009

For those who fall behind or start late, see the catch-up schedule

Vaccine ▼ Age ▶	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	HepB	HepB		see footnote 1	HepB						
Rotavirus[2]			RV	RV	RV[2]						
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP	see footnote 3	DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	Hib[4]	Hib					
Pneumococcal[5]			PCV	PCV	PCV	PCV				PPSV	
Inactivated Poliovirus			IPV	IPV	IPV						IPV
Influenza[6]					Influenza (Yearly)						
Measles, Mumps, Rubella[7]						MMR	see footnote 7				MMR
Varicella[8]						Varicella	see footnote 8				Varicella
Hepatitis A[9]						HepA (2 doses)				HepA Series	
Meningococcal[10]										MCV	

Range of recommended ages

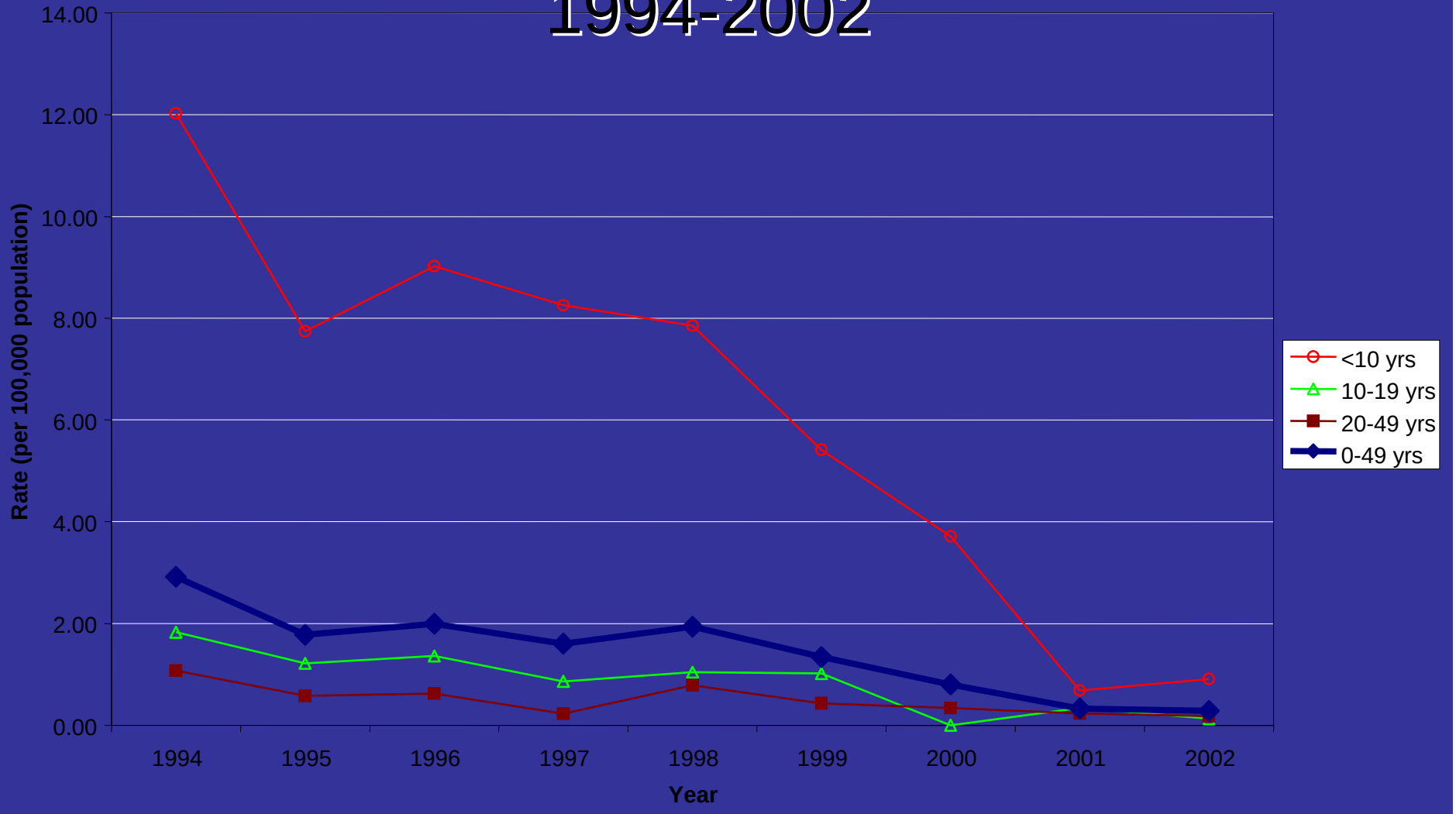
Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed vaccines, as of December 1, 2008, for children aged 0 through 6 years. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. Licensed combination vaccines may be used whenever any component of the combination is indicated and other components are not contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations, including high-risk conditions: http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at http://www.vaers.hhs.gov or by telephone, 800-822-7967.

Number of Diseases Prevented Through Routine Vaccination of Children

1985 (7)	1995 (10)	2006 (16)
Measles	Measles	Measles
Rubella	Rubella	Rubella
Mumps	Mumps	Mumps
Diphtheria	Diphtheria	Diphtheria
Tetanus	Tetanus	Tetanus
Pertussis	Pertussis	Pertussis
Polio	Polio	Polio
	Hib (infant)	Hib (infant)
	HepB	Hepatitis B
	Varicella	Hepatitis A
		Varicella
		Pneumococcal Disease
		Influenza
		Meningococcal
		Rotavirus
		Human papillomavirus

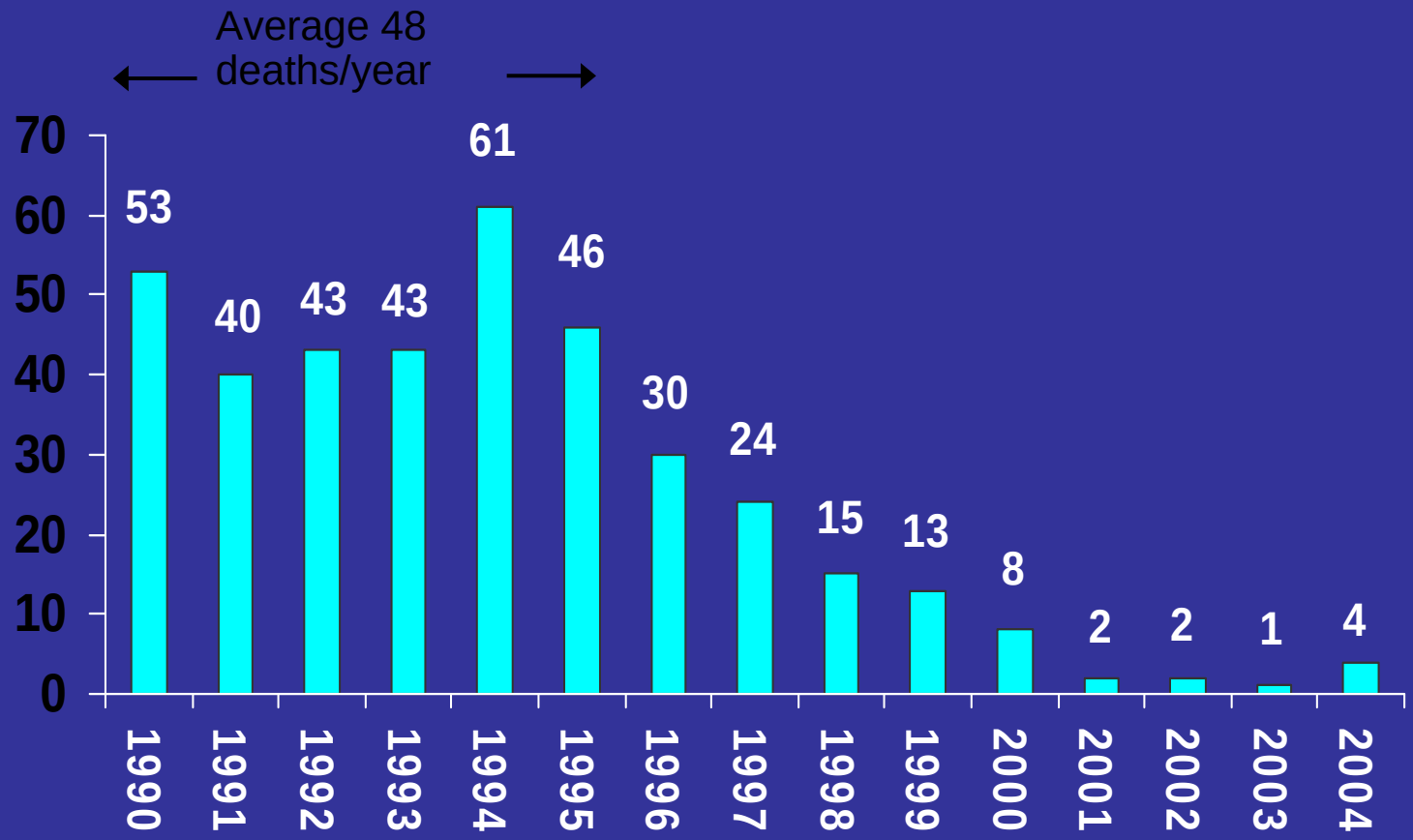
Varicella-related Hospitalization Rates*, 1994-2002



*Varicella as the primary diagnosis code

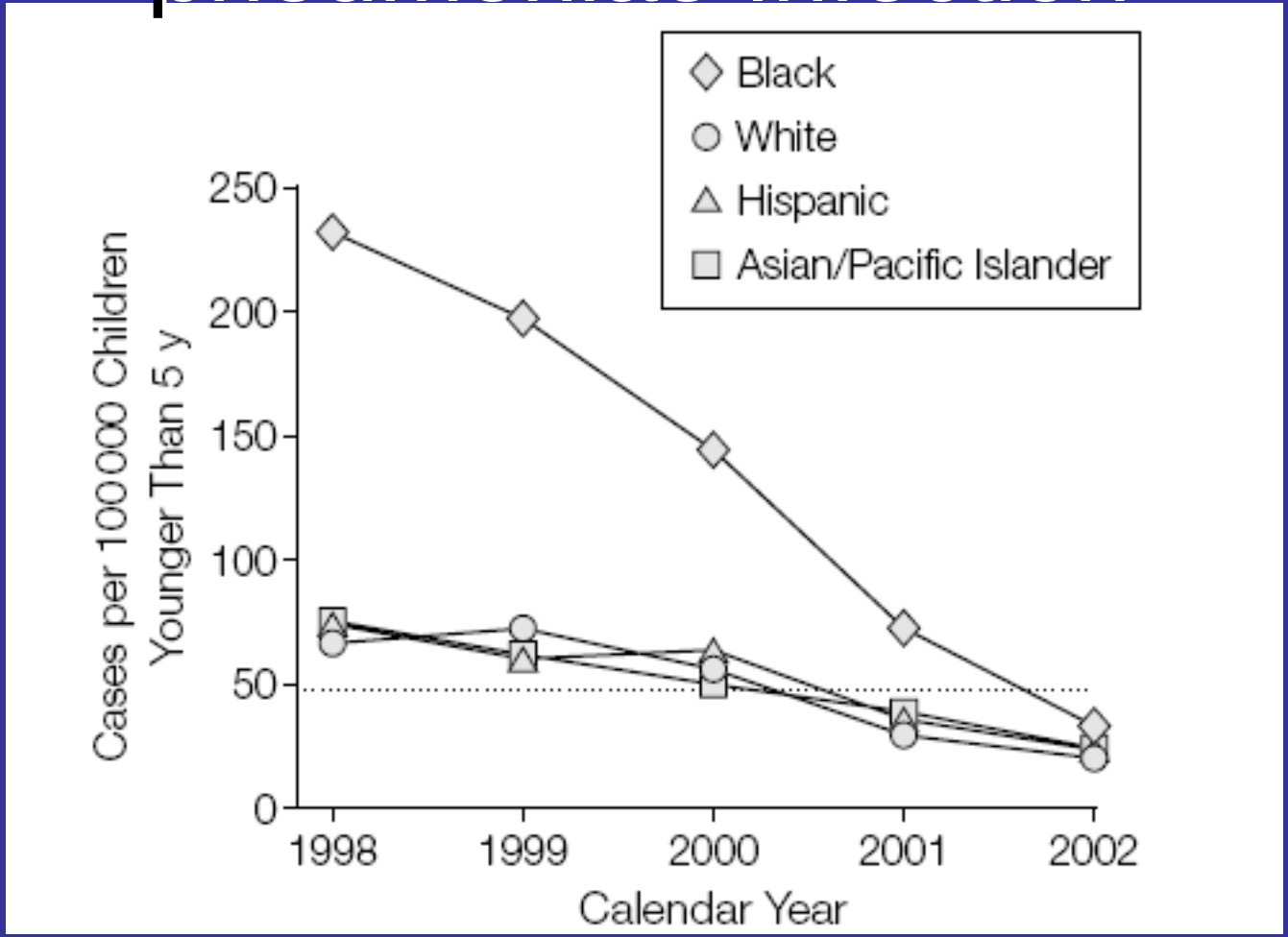
Zhou F, et al. JAMA 2005

Varicella Deaths* among Children and Adolescents < 20 years, U.S., 1990-2004



* NCHS, varicella as underlying cause of death

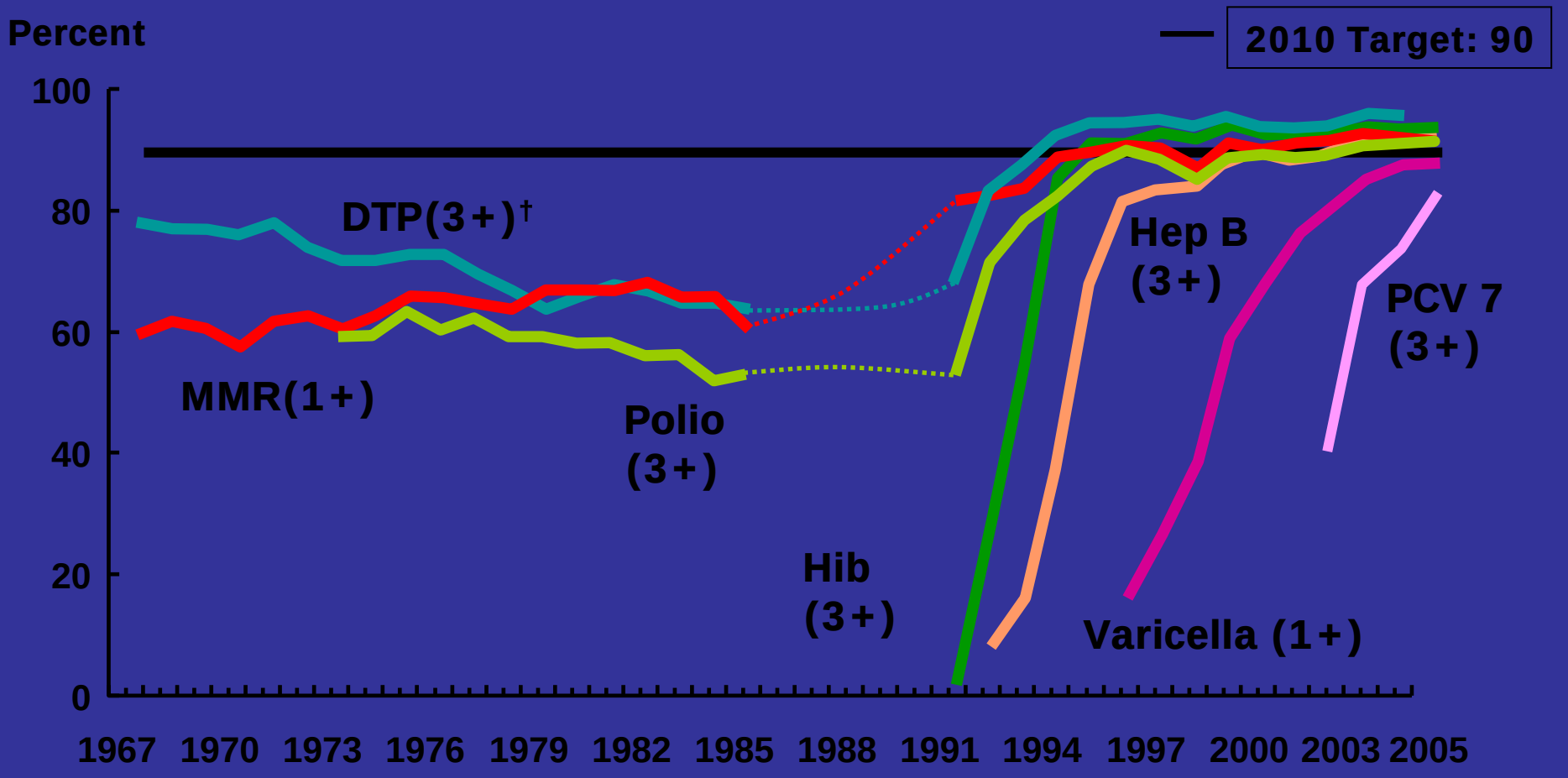
Impact of PCV7 Vaccine on Racial Disparities in Invasive Strep pneumoniae Infection



Flannery et al. *JAMA* 2004; 291: 2197 - 2203

Vaccine-Specific Coverage: Preschool-Aged Children

Note: † DTP(3+) is not a Healthy People 2010 objective. DTP(4) is used to assess Healthy People 2010 objective 14-22a.
Source: USIS (1967-1985), NHIS (1991-1993) CDC, NCHS, and NIS (1994-2005), CDC, NCIRD and NCHS;



U.S. Average Vaccination Coverage Levels Among Children 19-35 Months of Age: NIS – 2006/07

Vaccine or Series	U.S. Average	Healthy People Objective Met?
4 DTaP	**85**	**No (Objective: 90)**
3 IPV	**93**	**Yes**
1 MMR	**92**	**Yes**
3 Hib	**93**	**Yes**
3 Hepatitis B	**93**	**Yes**
1 Varicella	**90**	**Yes**
3 PCV7	**90**	**N/A**
4 PCV7	**79**	**N/A**
4:3:1:3:3:1	**77**	**No (Objective:**

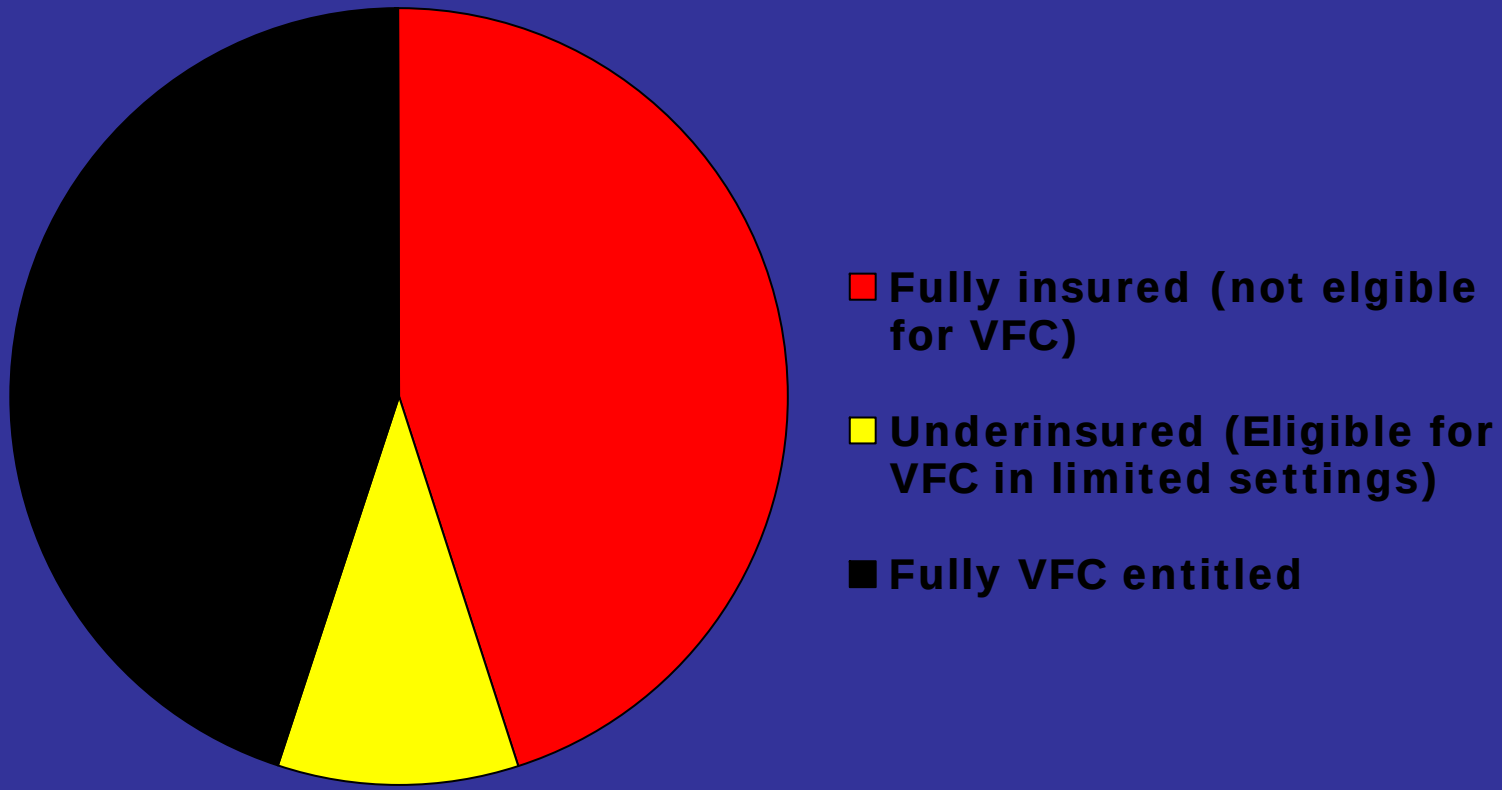
The U.S. Childhood Immunization System is Two Separate Systems: Private Sector and Public Sector

The two systems are bound together through *harmonized recommendations* and an *entitlement* to children and adolescents: The Vaccines for Children Program (VFC)

Major Components of and Participant Groups in the US Vaccine System

Role	Primary Responsibility
Health Burden Determination	Government – CDC, NIH
Basic Research	Government – NIH, FDA, CDC Private Industry Academic Institutions
Vaccine Development including Clinical Trials	Private Industry Government
Vaccine Production and Distribution	Private Industry
Regulation	Government - FDA

Approximate Childhood Insurance Category Populations



Vaccines For Children is an Entitlement

- VFC belongs to children in the U.S.
- VFC vaccine list is controlled by Advisory Committee on Immunization Practices(ACIP)
  - Control by advisory committee rather then federal officials is highly unusual
  - Only the HHS Secretary can overrule ACIP
- VFC is a mandatory program
  - Federal government must fund VFC vaccines
  - States must implement VFC vaccines
  - Participating providers must implement VFC vaccines, with rare exceptions

It All Comes Together At The Providers' Offices

- In Universal-purchase states, providers
  - Receive vaccine at no cost
  - Do not have to screen for program eligibility

- In all other states, providers
  - Receive some vaccine at no cost for program-eligible children
  - Purchase vaccine for their private sector children
  - Providers must screen patients for program eligibility
  - For fully insured children
    - Providers vaccinate using their privately purchased vaccine
    - Insurance company is billed for vaccine and vaccination
  - For VFC children, providers can vaccinate with VFC vaccine
  - For underinsured children, providers charge parents or use state vaccine, depending on the state policy

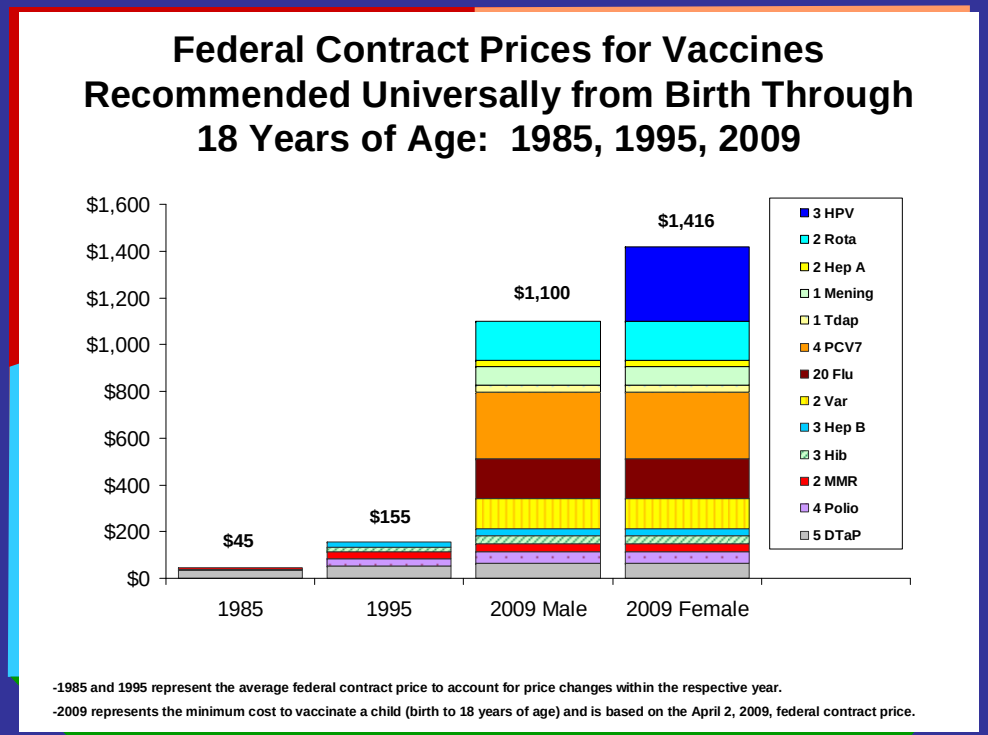
Providers Determine Eligibility for the VFC Program

- Providers ask parents up to 3 questions to determine if a child can receive VFC vaccine
  - Is your child enrolled in Medicaid?
  - Does your child have commercial health insurance?
  - Is your child an American Indian or Alaska Native
- No independent test for eligibility is needed, which is highly unusual for a means-tested program

Summary of Current U.S. Vaccine Delivery System

- 45,000 VFC providers vaccinate 90% of U.S. children using VFC vaccine, private purchase vaccine, or Section 317 and state purchase vaccine
  - A “public health army” in the words of Walt Orenstein
- Program gaps tend to be closed over time through adoption of new vaccines by insurers and through increased federal and state funding
- To date, new vaccine introduction has led to relatively rapid rises in coverage levels

Six Roles of Immunization Programs



Immunization Finance Policies and Practices

Institute of Medicine, 2000, “Calling the Shots”

HPV (HUMAN PAPILLOMAVIRUS) VACCII

WHAT YOU NEED TO KN

LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2007-08

1 Why get vaccinated?

3 Who can get LAIV?

Live, intranasal influenza vaccine is approved for healthy people from 5 through 49 years of age, who are not pregnant. This includes people who can spread influenza to others at high risk, such as:

- Household contacts and out-of-home caregivers of children from birth up to 5 years of age.
- Physicians and nurses, and family members or any

MENINGOCOCCAL VACCINES

WHAT YOU NEED TO KNOW

1 What is meningococcal disease?

Meningococcal disease is a serious illness, caused by a bacteria. It is a leading cause of bacterial meningitis in children 2-18 years old in the United States.

Meningitis is an infection of fluid surrounding the brain and the spinal cord. Meningococcal disease also causes blood infections.

About 2,600 people get meningococcal disease each year in the U.S. 10-15% of these people die, in spite of treatment with antibiotics. Of those who live, another 11-19% lose their arms or legs, become deaf, have problems with their nervous systems, become mentally retarded, or suffer seizures or strokes.

Anyone can get meningococcal disease. But it is most common in infants less than one year of age and people with certain medical conditions, such as lack of a spleen. College freshmen who live in dormitories have an increased risk of getting meningococcal disease.

Meningococcal infections can be treated with drugs such as penicillin. Still, about 1 out of every ten people who get the disease dies from it, and many others are affected for life. This is why *preventing* the disease through use of meningococcal vaccine is important for people at highest risk.

2 Meningococcal vaccine

Two meningococcal vaccines are available in the U.S.:

people who might b
vaccine.

Both vaccines work
those who get it. M
longer-lasting protec

MCV4 should also b
from spreading from

3 Who shou vaccine a

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Meningococcal vacc
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- Microbiologists wl
meningococcal bac
- U.S. military recru
- Anyone traveling
world where meni
such as parts of Af
- Anyone who has a
spleen has been re

POLIO VACCINE

WHAT YOU NEED TO KNOW

1 What is polio?

Polio is a disease caused by a virus. It enters a child's (or adult's) body through the mouth. Sometimes it does not cause serious illness. But sometimes it causes *paralysis* (can't move arm or leg). It can kill people who get it, usually by paralyzing the muscles that help them breathe.

Polio used to be very common in the United States. It paralyzed and killed thousands of people a year before we had a vaccine for it.

2 Why get vaccinated?

Inactivated Polio Vaccine (IPV) can prevent polio.

History: A 1916 polio epidemic in the United States killed 6,000 people and paralyzed 27,000 more. In the early 1950's there were more than 20,000 cases of polio each year. **Polio vaccination was begun in 1955.** By 1960 the number of cases had dropped to about 3,000, and by 1979 there were only about 10. The success of polio vaccination in the U.S. and other countries sparked a world-wide effort to eliminate polio.

Today: No wild polio has been reported in the United States for over 20 years. But the disease is still common

3 Who should get polio vaccine and when?

IPV is a shot, given in the leg or arm, depending on age. Polio vaccine may be given at the same time as other vaccines.

Children

Most people should get polio vaccine when they are children. Children get 4 doses of IPV, at these ages:

✓ A dose at 2 months
✓ A dose at 4 months
✓ A dose at 6-18 months
✓ A booster dose at 4-6 years

Adults

Most adults do not need polio vaccine because they were already vaccinated as children. But three groups of adults are at higher risk and *should* consider polio vaccination:

(1) people traveling to areas of the world where polio is common,
(2) laboratory workers who might handle polio virus, and
(3) health care workers treating patients who could have polio.

Adults in these three groups who **have never been vaccinated against polio** should get 3 doses of IPV:

✓ The first dose at any time,
✓ The second dose 1 to 2 months later,
✓ The third dose 6 to 12 months after the second.

Vaccine Injury Compensation Program

- In 1986, the federal government initiated the Vaccine Injury Compensation Program (VICP) because liability was threatening vaccine supply

- Key features
  - No-fault program
  - Table of injuries and compensation
  - Avoids courts, but courts remain an option for individuals after VICP
  - New, universally-recommended vaccines are added to the program by Congress
  - New vaccines have 8 years of retroactivity

Importance of Vaccine Safety

- Decreases in disease risks and increased attention on vaccine risks
- Public confidence in vaccine safety is critical
  - higher standard of safety is expected of vaccines
  - vaccinees generally healthy
  - lower risk tolerance = need to search for rare reactions
  - vaccination universally recommended /mandated
  - ongoing safety monitoring needed for the development of sound policies and recommendations

Vaccine Adverse Event Reporting System (VAERS)

- National reporting system
- Inception in 1990
- Jointly administered by CDC and FDA
- Monitored Continuously
- Passive (depends on healthcare providers and others to report)
- Receives ~15,000 reports per year
- Report of ANY medical condition occurring after vaccine (no time limit)
- Anyone can report

Vaccine Adverse Event Reporting System (VAERS)

- Detects
  - new or rare events
  - increases in rates of known side effects
  - patient risk factors
- Additional studies required to confirm VAERS signals
- Not all reports of adverse events are causally related to vaccine
- Cannot be used to prove a hypothesis, but to generate one

Vaccine Safety Datalink (VSD)

- Large-linked database estd. 1990
- Links vaccination and health records
- “Active surveillance”
  - 8 HMOs
  - ~2.5% of the U.S. population
- Powerful tool for monitoring vaccine safety concerns and hypotheses

Brighton Collaboration

- International, voluntary collaboration
- Facilitate Development, Evaluation and Dissemination about Vaccine Safety

The Brighton™ Collaboration

Vaccine Injury Compensation Program (VICP)

- Established by National Childhood Vaccine Injury Act (1986)
- “No fault” program
- Covers all routinely recommended childhood vaccines
- Vaccine Injury Table

Kids Are Getting ‘Too Many’ Shots

- Advantages of simultaneous/combination vaccination:
  - Protection vs. several dz at once ASAP
  - Delays in vaccination less likely
  - Decreased discomfort and costs
- Children are exposed to foreign antigens daily
- Viral URI - 4-10 antigens
- Strep. Pharayngitis - 25-50 antigens
- Immune system capable of responding to thousands of antigens simultaneously
- 1994 IOM report - number of separate antigens in childhood vaccines unlikely to be burden on immune system
- No evidence multiple vaccines at same time are harmful

What to Say and Do When Vaccine Refusal Occurs

- Introduce Yourself
- Be Welcoming, Warm, Compassionate, Non-judgmental
- Express Interest in the Caregiver
- Listen, Avoid Interrupting
- Maintain Eye Contact
- Spend Time, Discuss Risks vs. Benefits, Scientific Evidence, Websites
- Use Understandable Terms
- Be Non-Paternalistic
- Elicit Caregivers' Agenda, Validate Importance of Concerns
- Ask Open-Ended Questions, Assess Caregiver's Knowledge of Vaccines
- Encourage Questions from Caregiver
- Offer to Delay Some Vaccines
- Check for Understanding
- Summarize

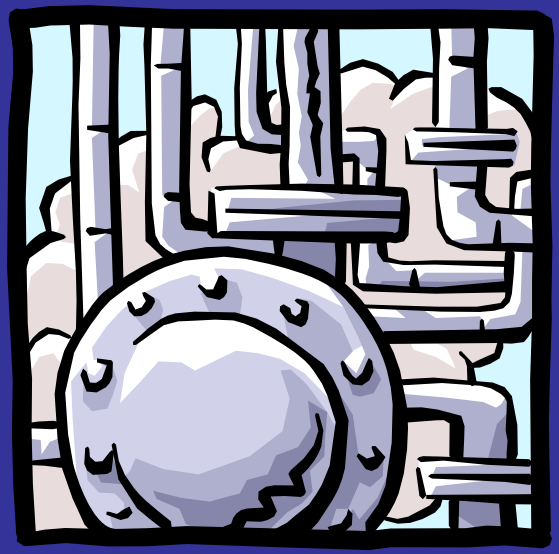
Omer SB, et al. N Engl J Med 2009;360

Diekema DS. Pediatrics 2005;115

Offit PA, Moser CA. Pediatrics 2009; 123

Vaccines in Development/Licensing

- H1N1
- HPV
- PCV-13
- Meningococcal
- RSV, Parainfluenza
- HSV
- CMV, EBV
- Group A and B Strep
- Parvo
- Cholera, Malaria, TB, HIV



http://aapredbook.aappublications.org/news/vaccstatus.shtml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UK should expect swine flu cases, says HPA chief
Britain should expect cases of the swine flu that has killed over 100 peo in Mexico, the head of the Health Protection Agency has said.
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Are Mexico's young most at risk?
The question of who ultimately dies from the swine flu virus is a matter of great concern. And the answers that are emerging have been ominous.
NFL draft report card
Race on to contain

Conclusions

- The U.S. immunization system is a private / public collaboration that is held together by ACIP, VFC, states, and private provider organizations

- Program gaps include
  - Financing vaccines for underinsured children
  - Delays in coverage of new vaccines in private health insurance

Conclusions

- Program challenges include
  - Vaccinating pre-teens and teenagers
  - Conducting surveillance for newly vaccine preventable diseases
- Although complicated and diverse, the U.S. system works
  - Robust set of new vaccines
  - Rapid uptake of new vaccines