

*10th journées annuelles de santé publique:
Applying Science to Immunization Programs
The Role of Expert Committees*

Advisory Committee on Immunization Practices

Dixie E. Snider, MD, MPH
Centers for Disease Control and Prevention
October 26, 2006
Montreal, Quebec



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

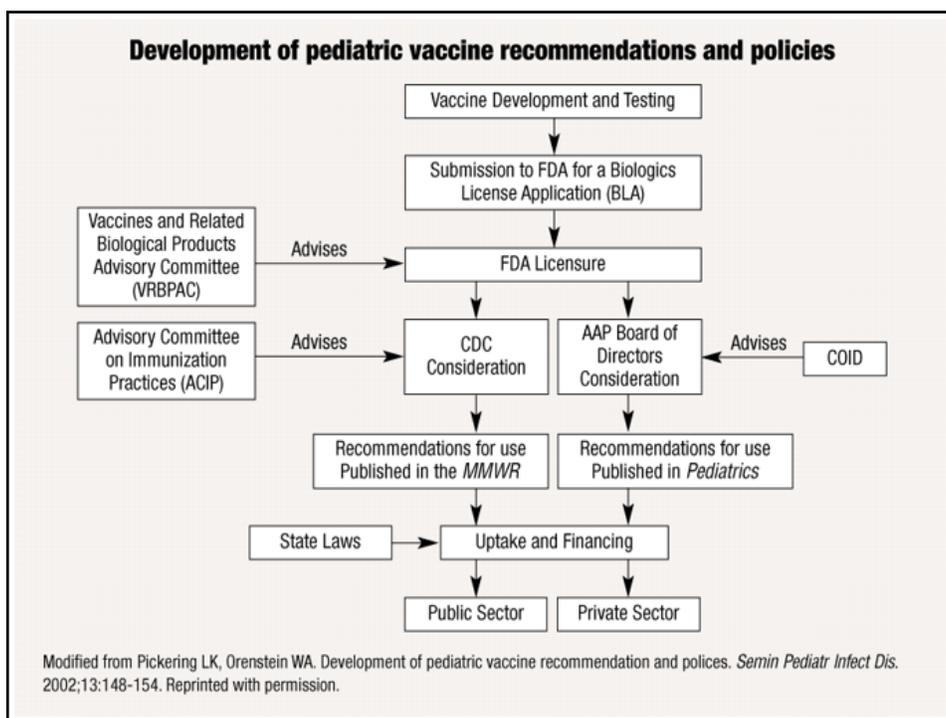


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Objectives

- **To review the process of immunization policy development in the U.S.**
- **To discuss the responsibilities, structure, and function of the ACIP**
- **To review the interaction of ACIP with organizations and societies in the public and private sectors**
- **To summarize key issues facing the ACIP**

Cette présentation a été effectuée le 26 octobre 2006, au cours du Symposium "Mettre la science au service des programmes d'immunisation, le rôle des comités d'experts" dans le cadre des Journées annuelles de santé publique (JASP) 2006. L'ensemble des présentations est disponible sur le site Web des JASP, à l'adresse <http://www.inspq.qc.ca/jasp>.



Advisory Committee on Immunization Practices

ACIP Responsibilities

- Since 1964: Provides advice and guidance to Office of Secretary, DHHS and Director, CDC on most effective means to prevent vaccine-preventable diseases in the civilian population
 - Antigens and related agents (e.g. vaccines, antisera, immune globulins, antiviral agents, chemotherapy and chemoprophylaxis)
 - Licensed vaccines and unlicensed vaccines if warranted

Advisory Committee on Immunization Practices

ACIP Responsibilities

- Since 1993: Vaccines for Children (VFC) Program
 - Unique statutory authority established by Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. § 1396s) gives ACIP authority to determine the vaccines, number of doses, schedule and contraindications for the VFC
 - **VFC is a \$1.5 billion annual entitlement program**

Advisory Committee on Immunization Practices

Structure

- **15 voting members including the chair**
 - 4 year terms
 - CDC nominates, OS DHHS selects
 - Chairman selected from current members
- **8 *ex officio* members** – representing CMS, DOD, DVA, FDA, HRSA, IHS, NIH, NVPO,
- **22 liaison members** – representatives of professional societies and organizations responsible for vaccine development and immunization programs

ACIP Liaison Organizations

- American Academy of Family Physicians
- American Academy of Pediatrics
- America's Health Insurance Plans
- American College Health Association
- American College of Obstetricians and Gynecologists
- American College of Physicians
- American Medical Association
- American Osteopathic Association
- American Pharmacists Association
- Association of Teachers of Preventive Medicine
- Biotechnology Industry Organization
- Canadian National Advisory Committee on Immunization
- Healthcare Infection Control Practices Advisory Committee
- Infectious Diseases Society of America
- London Department of Health
- National Association of County and City Health Officials
- National Foundation for Infectious Diseases
- National Immunization Council & Child Health Program
- National Medical Association
- National Vaccine Advisory Committee
- Pharmaceutical Research & Manufacturers of America
- Society for Adolescent Medicine

Advisory Committee on Immunization Practices

Function

- **3 meetings annually – February, June, and October**
- **Agenda items**
 - Solicited from ACIP members, liaisons, CDC staff and others using standard format
 - Finalized by ACIP Chair, Executive Secretary, ACIP Steering Committee
- **Follow FACA* rules and procedures**
- **Recommendations published in MMWR**

* Federal Advisory Committee Act

Expertise of ACIP Members

- Infectious diseases
- Immunology
- Pediatrics
- Internal medicine
- Public health, preventive medicine
- Vaccine research and policy
- Cost-effectiveness
- Consumer concerns

Advisory Committee on Immunization Practices

- Working Group (WG) Function
 - Develop draft policies/options for review/vote by full ACIP
 - Work by teleconference throughout the year, and before/during ACIP meetings
 - WG guidelines regularly updated
 - WG is chaired by ACIP member; must include at least 1 other ACIP member
 - Other members: lead CDC staff member, other CDC staff, *ex officio* representatives, liaisons and consultants
 - WG may be disbanded when work complete; new WGs formed as required

ACIP Working Groups

- **Permanent (4)**
 - Adult Immunization Schedule
 - General Recommendations
 - Childhood/Adolescent (“Harmonized”) Schedule
 - Influenza Vaccine

ACIP Working Groups

- **Task Oriented WGs (*as of Oct 2006*)**
 - Evidenced Based Recommendations
 - Human Papillomavirus Vaccine
 - Herpes Zoster (Shingles) Vaccine
 - Meningococcal Vaccine
 - Rabies
- **New WGs – being established**
 - Pneumococcal Vaccines
 - Vaccines During Pregnancy
 - Japanese Encephalitis (JE) Vaccine

Advisory Committee on Immunization Practices

Key Documents

- ACIP Charter –amended July 2006
- ACIP Policies and Procedures –Oct 2002
- Guidelines for Working Groups
 - Describe WG purpose, composition, approach to potential conflicts of interest, etc – updated Sept 2006
 - Membership list of WGs
 - Calendar of ACIP activities
- New member orientation booklet - 2006

Advisory Committee on Immunization Practices

CDC Management

- Executive Secretary
 - Leads CDC management of ACIP
 - Assures meetings follow guidelines, approves meeting agendas, guides development/revision of procedures, charter, and other documents
 - Provides briefing to the CDC Director
- National Center for Immunization & Respiratory Diseases (NCIRD/CDC)
 - Provides management support services
 - 2 full-time staff members
 - Assistant to the Director for Immunization Policy (Medical Officer)
 - ACIP Program Operations Assistant

Advisory Committee on Immunization Practices

CDC Management

- ACIP Steering Committee
- CDC Federal Advisory Committee Management
 - Provides FACA support and liaison with DHHS
- CDC Office of General Counsel
 - Advice on legal questions (e.g., potential conflicts of interest)
- Funding for ACIP Operations

Advisory Committee on Immunization Practices

Steering Committee

- Coordinates ACIP Activities across the Coordinating Center for Infectious Diseases (CCID)
- Develops consensus CDC position on: ACIP issues, policies and procedures, ACIP meeting agendas, nominees for ACIP
- Convened by Executive Secretary with ACIP Chair
- Composition
 - Director, NCIRD
 - Representatives from CCID Centers
 - AD for Immunization Policy
 - ACIP Program Operations Assistant
 - *Ex officio* member representing FDA

Implementation of Civilian Immunization Programs in the U.S.

- **Government: federal, state, and local**
- **Private industry**
- **Academic institutions**
- **Private providers**
- **Insurers**

Childhood Immunization Policy Recommending Bodies

- **U.S. Advisory Committee on
Immunization Practices**
- **American Academy of Pediatrics
Committee on Infectious Diseases**
- **American Academy of Family
Physicians**

Immunization Policy Product: Two Immunization Schedules

- **ACIP, AAP, and AAFP produce a “harmonized” childhood and adolescent immunization schedule**
 - First harmonized in 1994
 - Before 1994, differing schedules existed
- **ACIP, AAFP produce a harmonized adult immunization schedule**
- **Schedules are updated once annually**
- **Look at the complete schedule, with each vaccine in the context of the other vaccines**

Evidence Considered in Immunization Policy Development

- **Preventable burden of disease**
- **Efficacy and effectiveness in various age groups and population**
- **Safety of the vaccine**
- **Interactions with other vaccines**
- **Economic analysis**

Types of ACIP Recommendations

- **Universal use**
 - Age-based recommendation
 - Least confusing and easiest to implement
 - Vaccine must benefit all

- **Risk-based**
 - Medical, occupational, behavioral risk
 - Difficult for providers to identify those who should be vaccinated
 - Much less well implemented than universal

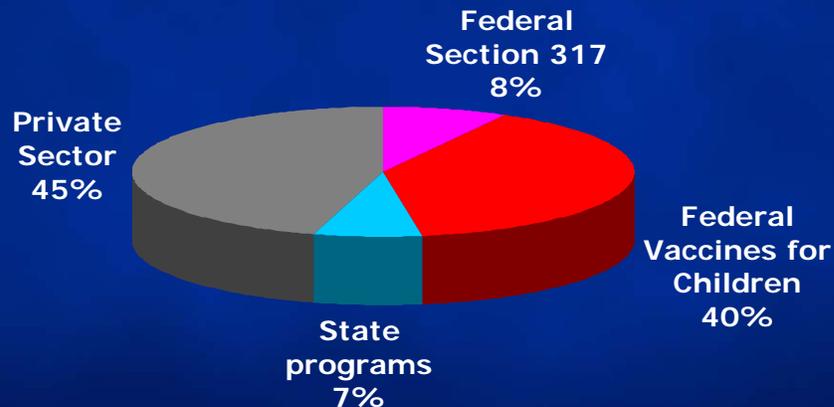
Assuring Purchase of Recommended Vaccines

- **Shared public sector and private sector responsibility**

- **Cost of vaccines to parents is a significant barrier to vaccination**

- **Adequate financing of vaccines is critical to successful implementation**

Who Paid for Childhood Vaccines in FY 2004?



Source: Biologics Surveillance Data 2004 from vaccine manufacturers

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

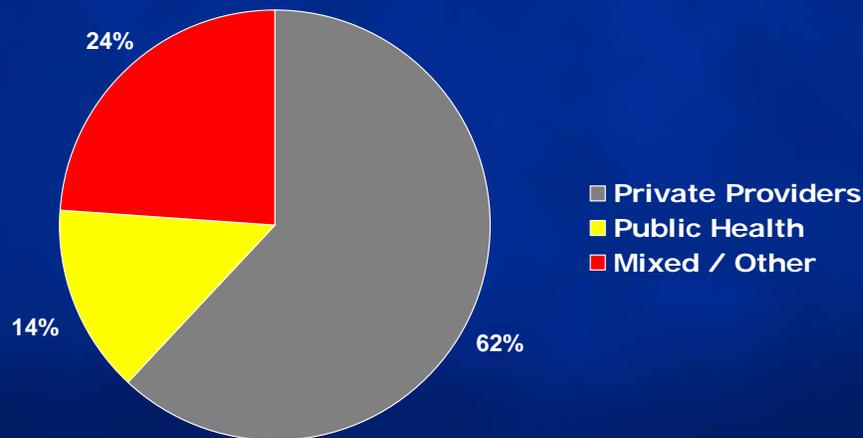
Private Sector Role in Vaccine Financing

- **Private health insurance usually includes immunization benefit**
- **Some children have insurance that does not cover vaccines**
 - In general, their parents must pay for the vaccines
 - Only about 2% of the U.S. childhood population

State Government Role in Purchasing Vaccine

- **Varies substantially by state**
 - Most states contribute some funding
- **Some states have purchase policies in which they guarantee purchase of all vaccines**
- **States regulate most insurance companies and can mandate inclusion of vaccines into insurance packages**

Who Vaccinated Children in the U.S. in 2003 and 2004?



How Does Public Health Reach Children

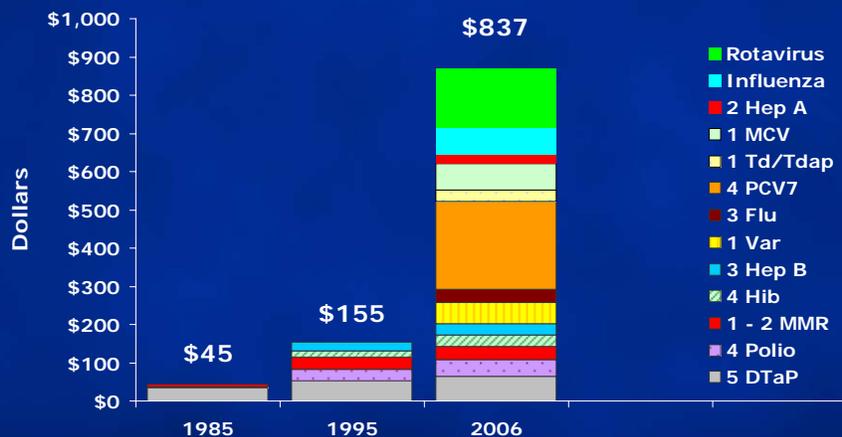
- VFC program has 45,000 provider sites
 - 75% of sites are private providers
 - 25% are public sector sites
- Collectively, VFC providers vaccinate 90% of children
 - VFC vaccine for VFC-eligible children
 - Private purchase vaccine for other children
- Improving VFC providers' practices improves vaccinations for almost all children

Number of Vaccines in the Routine Childhood Immunization Schedule

1985 (7)	1995 (10)	2005 (13)
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	HepB
	Varicella	Varicella
		Pneumococcal Disease
		Influenza
		Meningococcal

2006: ACIP added Rotavirus, HPV (15)

Federal Contract Prices for Vaccines Recommended Universally for Children and Adolescents 1985 – 2006



Federal contract price shown for 1985 and 1995 are averages that account for price changes within that year.
 Analysis accounts for market share of specific products.
 Analysis current as of May 1, 2006.

Conclusions

- Routine immunizations provide a tremendous benefit to infants, children, adolescents, adults and to society
- Immunization is a shared public / private responsibility
- The ACIP is a well functioning, well respected FACA committee
- Many challenges face the ACIP & implementation of immunization programs in the US, including vaccine financing, vaccine supply and vaccine acceptance issues

