Immunization Update: Looking Back at 2002, Looking Forward at the Coming Year

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Centers for Disease Control and Prevention

National Immunization Conference, 2003

CHICAGO

Hog Butcher for the World,
Tool Maker, Stacker of Wheat,
Player with Railroads
and the Nation's **Freight Handler;**
Stormy, **husky,** brawling,
City of the Big Shoulders.

Carl Sandberg

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Our Foundation

- Skilled, dedicated people
- Quality science and research
- Productive collaborations and partnerships
- Global, national, and local disease monitoring and surveillance systems
- Responsive information management systems
- Multi-faceted training/education programs
- Comprehensive communication efforts

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Our Most Recent Successful Application: Smallpox Readiness

- All states have pre-event smallpox vaccination plans in place
- All states have developed plans for rapid mass vaccination, if necessary
- Smallpox vaccine supplies are now adequate to vaccinate the entire population
- As of 03/07/03, 16,919 public health and health care responders have been vaccinated

2003 – A Milestone Year

- 10th anniversary of the creation of the National Immunization Program
- 40th year of federal grants for immunization programs
- And my 15th anniversary directing CDC's immunization programs

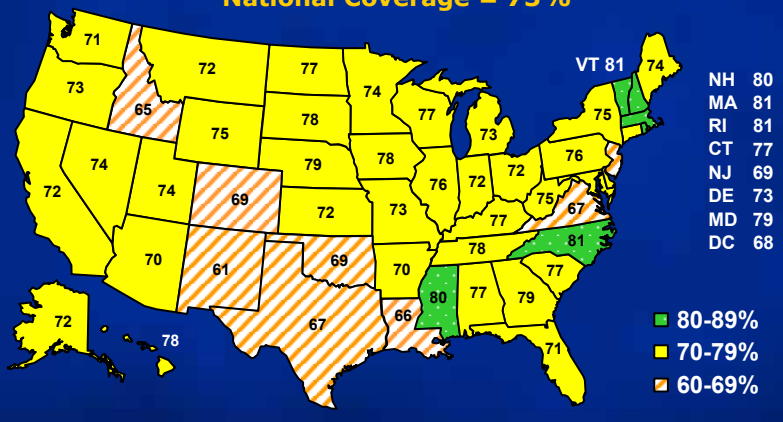
Comparison of 20th Century Annual Morbidity and Current Morbidity, Vaccine-Preventable Diseases

Disease	20th Century Annual Morbidity	2002*	Percent Decrease
Smallpox	48,164	0	100
Diphtheria	175,885	1	99.99
Measles	503,282	37	99.99
Mumps	152,209	238	99.84
Pertussis	147,271	8,296	94.37
Polio (paralytic)	16,316	0	100
Rubella	47,745	14	99.97
Congenital Rubella Syndrome	823	3	99.64
Tetanus	1,314	22	98.33
H. influenzae, type b and unknown (<5 yrs)	20,000	167	99.17

* Provisional Data

Estimated Vaccination Coverage with the 4:3:1:3:3* Series, by Coverage Level and State, July 2001 – June 2002

National Coverage = 73%



NH 80
MA 81
RI 81
CT 77
NJ 69
DE 73
MD 79
DC 68

*4+DTP, 3+Polio, 1MCV, 3+Hib, 3+HepB
Source: National Immunization Survey (NIS)
Children in the Third Quarter 2001 – Second Quarter 2002 NIS were born between August 1998 and November 2000

Another perspective on our success – outcomes achieved since 1988 and 1993

Childhood Immunization Coverage Rates Have Increased

Vaccine	1988	1993	July 2001-June 2002
DTP 3+	NO DATA AVAILABLE	88.2	93.9
DTP 4+		72.1	81.5
Polio 3+		78.9	89.8
MCV		84.1	91.0
Hib 3+		55	92.9
HepB 3+		16.3	88.3
4:3:1		67	78.0

Sources:
1993—National Health Interview Survey
July 2001-June 2002—National Immunization Survey

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Vaccine Preventable Disease Incidence Has (Generally) Gone in the Right Direction. . .

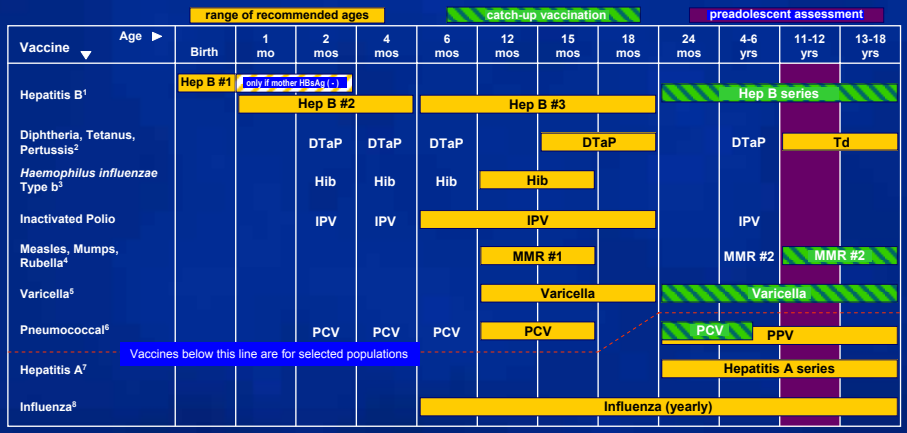
Disease	1988	1993	2002*
Measles	3396	312	37
Rubella	225	192	14
Mumps	4866	1692	238
Diphtheria	2	0	1
Tetanus	53	48	22
Pertussis	3450	6586	8296
Polio	9	3	0

*Provisional Data

And We've Expanded our Ability to Prevent Disease via Vaccination

1988	1993	2003
Measles	Measles	Measles
Rubella	Rubella	Rubella
Mumps	Mumps	Mumps
Diphtheria	Diphtheria	Diphtheria
Tetanus	Tetanus	Tetanus
Pertussis	Pertussis	Pertussis
Polio	Polio	Polio
Hib (toddler)	Hib (infant)	Invasive Hib
	HepB	HepB
		Varicella
		Pneumococcal Disease

Recommended Childhood and Adolescent Immunization Schedule United States, 2003



This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2002, for children through age 18 years. Any dose not given at the recommended age should be given at any subsequent visit when indicated and feasible. Indicates age groups that warrant special effort to administer those vaccines not previously given. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and the vaccine's other components are not contraindicated. Providers should consult the manufacturers' package inserts for detailed recommendations.

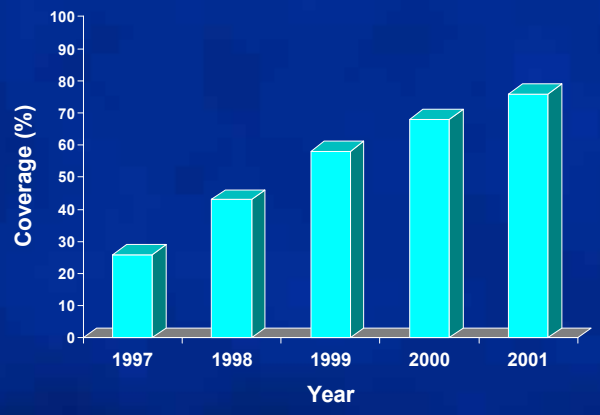
A Schedule which may be simplified by Combination Vaccines. . .

Number of injections	At 2 Month Visit	By 18 Months	By 18 Years
Without Pediarix*	4-5	16-20	20-24
With Pediarix*	3	13-14	17-21

*Combined DTaP, HepB, IPV

The Impact and Benefits of Vaccination: Our Most Recent Achievements

Varicella Vaccine Coverage, Children 19-35 Months, United States, 1997-2001*



*Source: National Immunization survey

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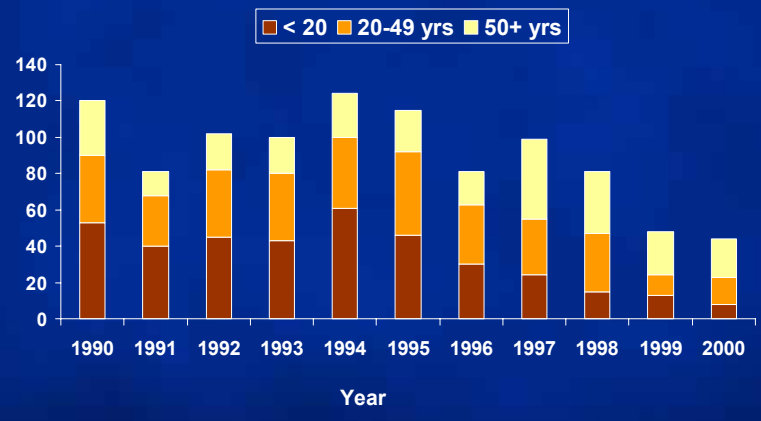
Varicella Deaths by Age
United States, 1990-2000



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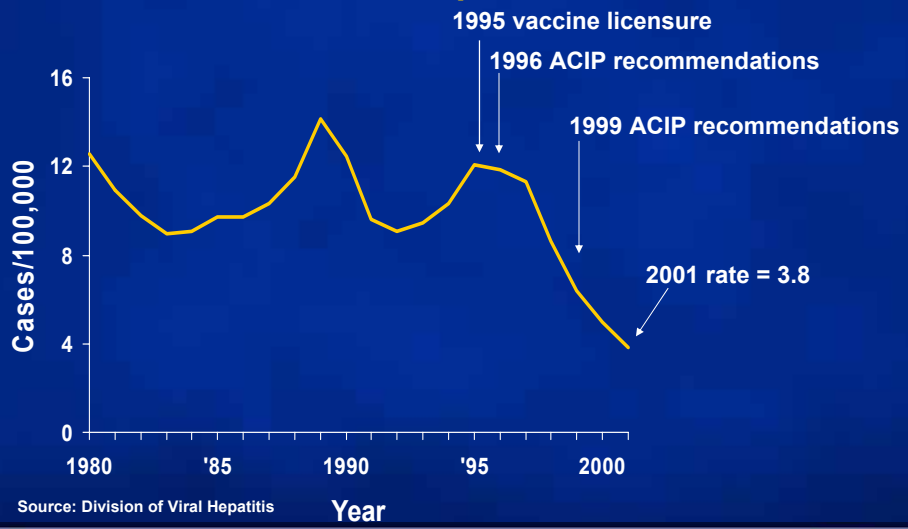
Hepatitis A Incidence,
United States, 1980-2001



Source: Division of Viral Hepatitis

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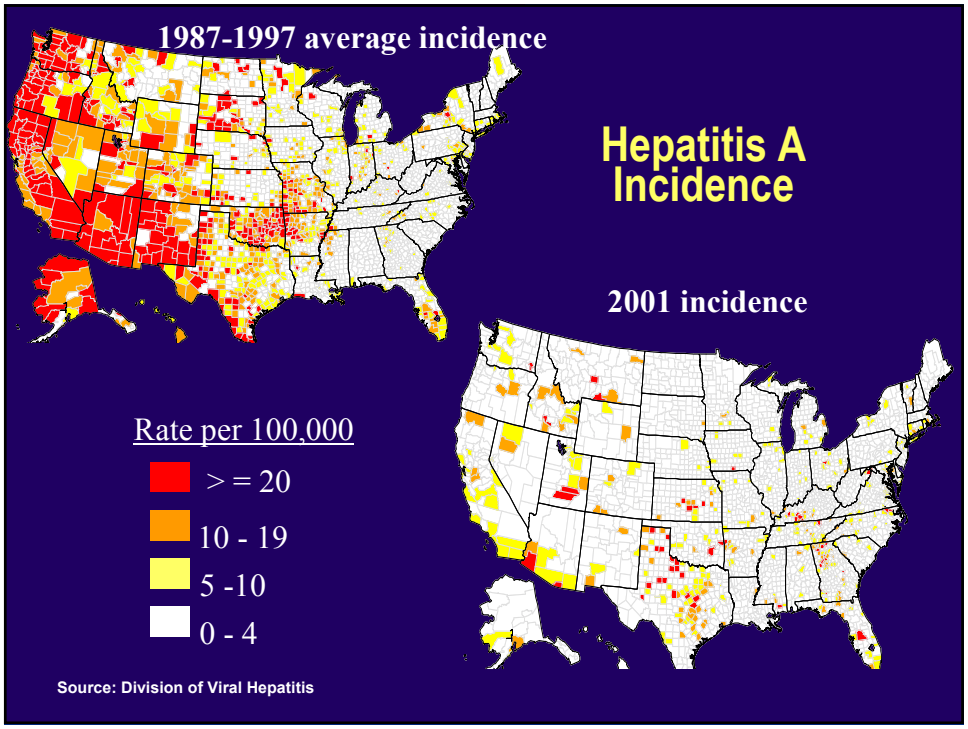
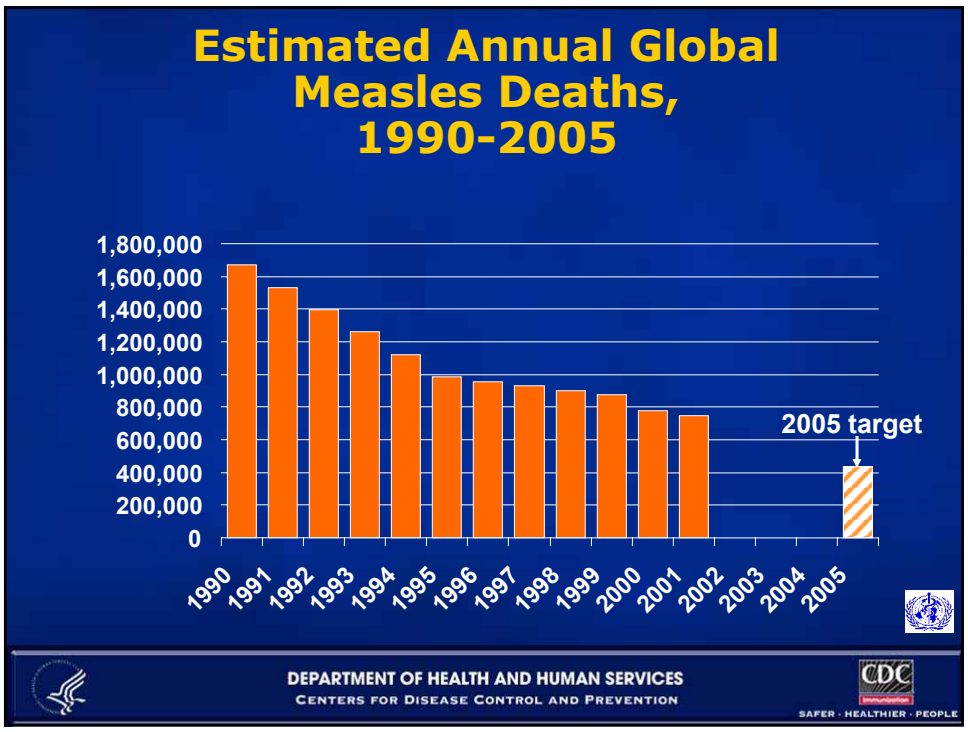

1987-1997 average incidence
Hepatitis A Incidence
2001 incidence
Rate per 100,000
> = 20
10 - 19
5 -10
0 - 4
Source: Division of Viral Hepatitis


Estimated Annual Global Measles Deaths, 1990-2005
1,800,000
1,600,000
1,400,000
1,200,000
1,000,000
800,000
600,000
400,000
200,000
0
2005 target
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
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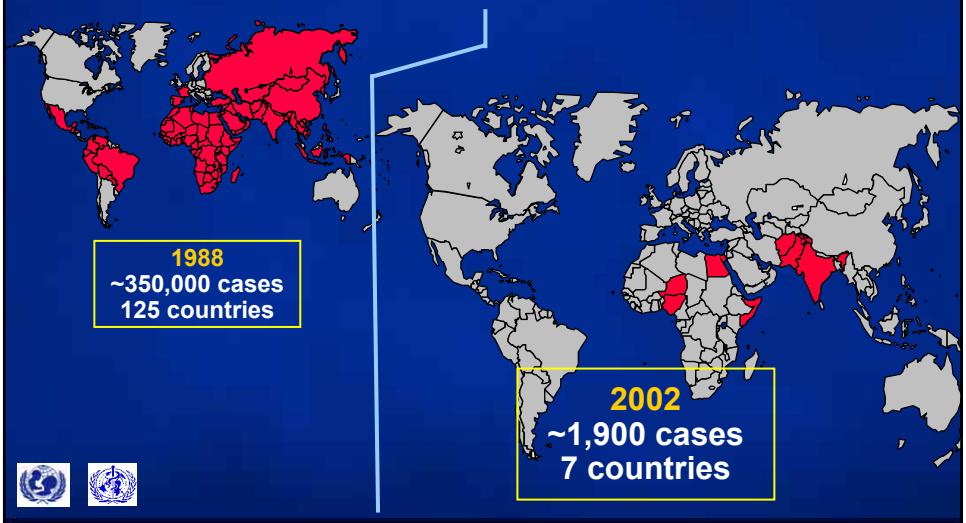
Global Polio Progress



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The Year Ahead (1)

- Three new immunization schedules to guide you:
  - A "Catch-up" Schedule for Children Age 4 Months through 6 Years
  - A "Catch-up" Schedule for Children Age 7 through 18 Years
  - An Adult Immunization Schedule

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Recommended immunization Schedule for Children and Adolescents Who Start Late or Who are >1 Month Behind, United States, 2003

Table 1

TABLE 1. Catch-up Schedule for Children Age 4 Months Through 6 Years

Dose One (Minimum Age)	Minimum Interval Between Doses			
	Dose One to Dose Two	Dose Two to Dose Three	Dose Three to Dose Four	Dose Four to Dose Five
DTaP (6 Wks)	**4 weeks**	**4 weeks**	**6 months**	**6 months**[1]
IPV (6 Wks)	**4 weeks**	**4 weeks**	**4 weeks**[2]	
HepB[3] (Birth)	**4 weeks**	**8 weeks** (and 16 weeks after 1st dose)		
MMR (12 Mos)	**4 weeks**[4]			
Varicella (12 Mos)				
Hib[5] (6 Wks)	**4 weeks:** if 1st dose given at age <12 mos **8 weeks (as final dose):** if 1st dose given at age 12-14 mos **No further doses needed:** if 1st dose given at age ≥15 mos	**4 weeks**[6]: if current age <12 mos **8 weeks (as final dose)**[6]: if current age ≥12 mos and 2nd dose given at age <15 mos **No further doses needed:** if previous dose given at age ≥15 mos	**8 weeks (as final dose):** this dose only necessary for children age 12 mos - 5 yrs who received 3 doses before age 12 mos	
PCV[7] (6 Wks)	**4 weeks:** if 1st dose given at age <12 mos and current age <24 mos **8 weeks (as final dose):** if 1st dose given at age ≥12 mos or current age 24-59 mos **No further doses needed:** for healthy children if 1st dose given at age ≥24 mos	**4 weeks:** if current age <12 mos **8 weeks (as final dose):** if current age ≥12 mos **No further doses needed:** for healthy children if previous dose given at age ≥24 mos	**8 weeks (as final dose):** this dose only necessary for children age 12 mos - 5 yrs who received 3 doses before age 12 mos	

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Recommended immunization Schedule for Children and Adolescents Who Start Late or Who are >1 Month Behind, United States, 2003

Table 2

TABLE 2. Catch-up Schedule for Children Age 7 Through 18 Years

Vaccine	Minimum Interval Between Doses		
	Dose One to Dose Two	Dose Two to Dose Three	Dose Three to Booster Dose
Td[8]	**4 weeks**	**6 months**	**6 months:** if 1st dose given at age <12 mos and current age <11 yrs **5 years:** if 1st dose given at age ≥12 mos and 3rd dose given at age <7 yrs and current age ≥11 yrs **10 years:** if 3rd dose given at age ≥7 yrs
IPV[9]	**4 weeks**	**4 weeks**	**4 weeks**[2]
HepB	**4 weeks**	**8 weeks** (and 16 weeks after 1st dose)	
MMR	**4 weeks**		
Varicella[10]	**4 weeks**		

Report adverse reactions to vaccines through the federal Vaccine Adverse Event Reporting System. For information on reporting reactions following vaccines, please visit www.vaers.org or call the 24-hour national toll-free information line at 800-822-7967. Report suspected cases of vaccine-preventable diseases to your state or local health department.

For additional information about vaccines, including precautions and contraindications for immunization and vaccine shortages, please visit the National Immunization Program Website at www.cdc.gov/nip or call the National Immunization Information Hotline at 800-232-2522 (English) or 800-232-0233 (Spanish).

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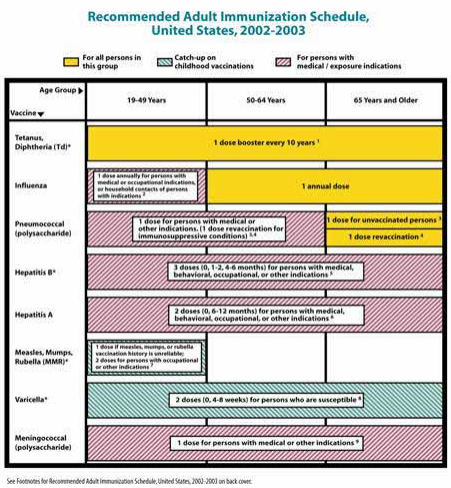
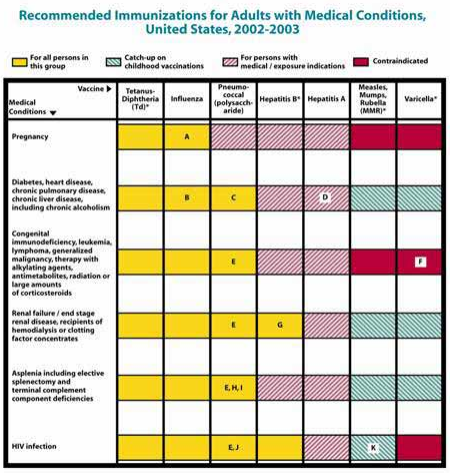
Adult Immunization Schedule





The Year Ahead (2)

- New tools and resources to assist you, including:
  - An interactive childhood immunization "scheduler" on the NIP website (let's you or parents create a immunization schedule for individual children) www.cdc.gov/nip
  - The "ABC's of Childhood Immunization" video and Powerpoint presentations from NIP
  - 2nd Edition of the National Partnership for Immunization Reference Guide on Vaccines and Vaccine Safety

The Year Ahead (3)

- And challenges that will test us:
  - —Securing stable and sufficient vaccine financing
  - —Avoiding delays and shortages in vaccine supplies
  - —Ensuring and maintaining vaccine safety
  - —Fostering and achieving adult immunization
  - —Managing smallpox-related demands and building our preparedness

Securing stable and sufficient vaccine financing

- A growing concern – higher new vaccine costs require more discretionary funds
- Without increased funding, we're seeing:
  - Two-tiered PCV7 implementation
  - Universal states becoming non-universal
- IOM Vaccine Financing Study
  - Report expected Summer 2003
- Proposed improvements to the Vaccines for Children program

Proposed Improvements to the VFC Program

Three Initiatives:

1. Improve vaccine access for underinsured children by expanding the number of clinics that can provide VFC vaccines
2. Restore Td and DT to VFC Program
3. Build 6- month national stockpile of childhood vaccines by 2006

Initiative #1 – A Closer Look

- Improves the access of underinsured children to VFC vaccines– e.g., allows state and local public health clinics to provide VFC at no cost.
- Designed to take pressure off 317 vaccine purchases and state funds to cover immunizations.
- This proposal should not result in any changes in the public/private market share.

Avoiding delays and shortages in vaccine supplies – NVAC Report

- Consider financial incentives for manufacturers
- Streamline regulatory processes
- Build complete stockpiles
- Strengthen Vaccine Injury Compensation Program (VICP)
- Enhance communication
- Use government owned production only for limited use vaccines

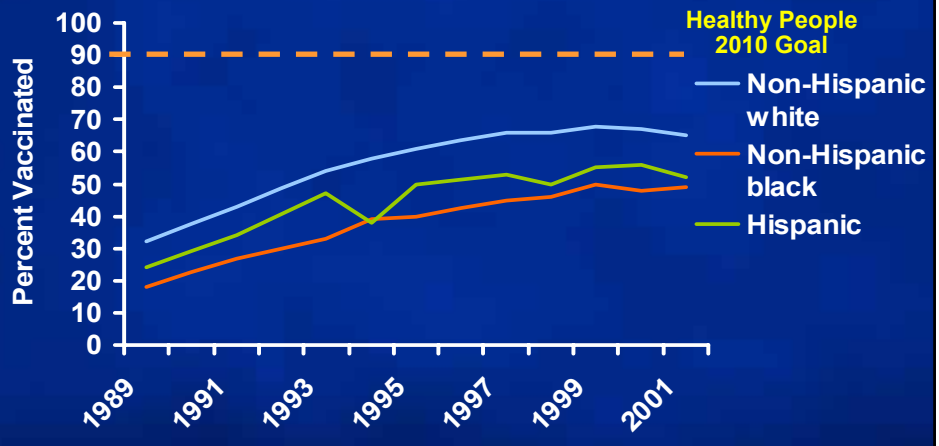
Ensuring and maintaining vaccine safety

- Our commitment to vaccine safety is critical to maintaining parent and public trust and confidence.
- We need to continue to build upon our strong vaccine safety foundation:
  - Vaccine Safety Datalink
  - Clinical Immunization Safety Assessment Network
  - Vaccine Adverse Event Reporting System
  - Institute of Medicine
  - Communication and Education

Fostering and achieving adult immunization

- Disease impact is great – for example:
  - About 36,000 people (up from 20,000 in previous estimates) die from influenza-related complications each year in the United States
  - About one-third of the estimated 60,000 cases of invasive pneumococcal disease are in people 65 and older. Over half of the estimated 6000-7,000 annual deaths occur in the elderly.
- Need to continue our efforts to increase influenza and pneumococcal vaccination coverage

Influenza Vaccination Levels of Persons Aged ≥65 Years, by Race/Ethnicity*



*National Health Interview Survey, United States, 1989, 1991, 1993-95, 1997-2001

The Foundation for Fostering and Achieving Adult Immunization Has Been Strengthened

- **Standing orders** - For vaccination of Medicare enrollees in hospitals, long-term care facilities, home health care settings
- **Medicare reimbursement** – 2003 fee schedule increases vaccine administration from $3.98 in 2002 to $7.72
- **Influenza Summit** – 60 different groups, institutions and organizations

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Managing smallpox-related demands and building our preparedness

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Smallpox

The Federal Plan
(announced 12/13/03)

- Establish and vaccinate civilian smallpox response teams – 1) public health response teams and 2) hospital response teams
- Vaccinate military personnel
- Vaccinate selected staff in overseas assignments (Department of State)
- Vaccination not recommended for the general public at present – However, work to accommodate those who insist. . .

Managing Smallpox-Related Demands: Challenges Ahead of Us

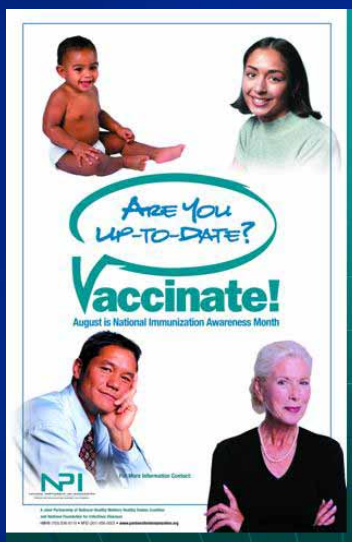
- Establishing plans and activities that:
  - Enable rapid and effective outbreak (or post-event) responses
  - Foster effective pre-event vaccination
  - Create infrastructure and resources for expanding to a wide range of emergencies
- Balancing smallpox-related activities with our ongoing, routine immunization needs
- Developing a better, more complete definition of "smallpox preparedness"

Defining Smallpox Preparedness: Important Elements

- Enhanced community awareness and clinician expertise
- Expanded disease surveillance and laboratory capabilities
- Ability to quickly and effectively implement public health interventions (e.g., surveillance and containment)
- Ability to rapidly provide large –scale vaccination (i.e., entire population)
- Establish and vaccinate smallpox response teams

Finally,

- Remember, we have faced enormous challenges in the past.
- Those challenges have strengthened our foundation and prepared us for the challenges we face today.
- And it's important that along the way, we identify and recognize achievements and successful efforts.



NPI
NATIONAL PARTNERSHIP FOR IMMUNIZATION
PROMOTING IMMUNIZATION ACROSS THE LIFESPAN

August is National Immunization Awareness Month

Go to: www.partnersforimmunization.org

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Thank you
&
Enjoy the conference!!

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[extra slides]

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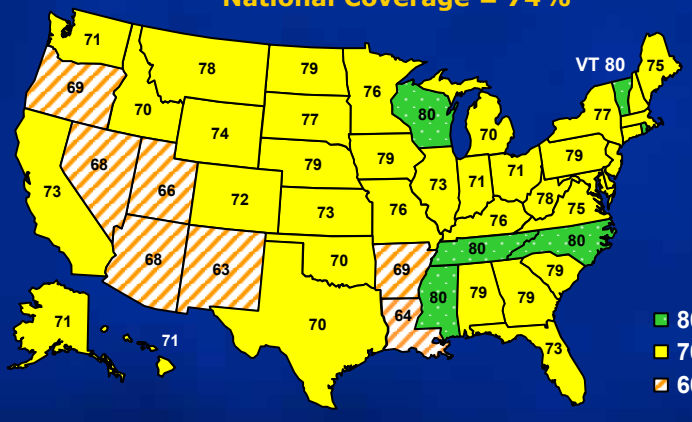
Estimated Vaccination Coverage with the 4:3:1:3:3* Series, by Coverage Level and State, 2001

National Coverage = 74%



*4+DTP, 3+Polio, 1MCV, 3+Hib, 3+HepB
Source: National Immunization Survey (NIS)
Children in the 2001 NIS were born between February 1998 and May 2000

Strategies

1. Surveillance and containment
2. Mass Vaccination
3. Cadre of workers to facilitate 1 and 2

If an Influenza Pandemic Occurred Today…

- Up to 200 million people infected
- Up to 50 million people requiring care
- Up to 2 million hospitalizations
- Between 100,000 and 500,000 deaths
- Up to $166 billion (excluding commerce & social disruption)

…in the U.S.

Autism and Vaccines

- MMR Vaccine
- Mercury
- Rubella vaccine
- Autoimmunity
- Antigen overload

"MMR and Autism"

- "A population-based study of measles, mumps, and rubella vaccination and autism"
  Madsen et al. *New England Journal of Medicine* 2002, Nov 7:347 (10): 1477-82
  - Conducted a cohort study of all children born in Denmark from January 1991 to December 1998
  - Concluded that there was no association between the age at the time of vaccination, the time since vaccination, or the date of vaccination, and the development of autistic disorder

Mercury, Vaccines and Autism*

- Increasing ethyl Hg in 1990s
- Exceeds some Federal guidelines
- Hg is neurotoxin
- Some features of Hg poisoning similar to autism
- Anecdotal reports of improvement with chelation
- Detectable levels in biologic specimens

*Bernard S. et al, ARC Research, Cranford, NJ, 2000

Vaccine Safety

- IOM Reports on Vaccine Safety
  - SV40 contamination of polio vaccine and cancer
  - Hepatitis B vaccine and neurological disorders
- CISA—Clinical Immunization Safety Assessment Network

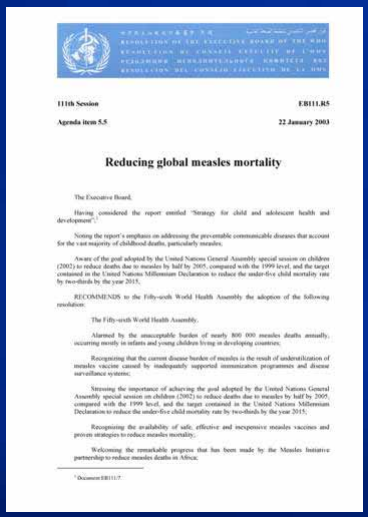
Indications for Pediarix

- 3 doses at 2, 4 and 6 months of age
- Not approved for booster doses
- Not indicated for birth dose of Hepatitis B
- Minimum intervals between doses determined by hepatitis B schedule
- Dose 1-2 — 4 weeks
- Dose 2-3 — 8 weeks and at least 16 weeks after dose 1

Smallpox Vaccination Participation
as of February 21, 2003

- 7,354 vaccinated:
  - 3,287 public health
  - 3,472 health care
  - 595 other
- 488 hospitals with at least one worker vaccinated
- 272,500 doses released (2/28)

Global Measles Control



111th Session — EB111.R5

Agenda item 5.5 — 22 January 2003

Reducing global measles mortality

The Executive Board,

Having considered the report entitled "Strategy for child and adolescent health and development" [1];

Noting the report's emphasis on addressing the preventable communicable diseases that account for the vast majority of childhood deaths, particularly measles;

Aware of the goal adopted by the United Nations General Assembly special session on children (2002) to reduce deaths due to measles by half by 2005, compared with the 1999 level, and the target contained in the United Nations Millennium Declaration to reduce the under-five child mortality rate by two-thirds by the year 2015;

RECOMMENDS to the Fifty-sixth World Health Assembly the adoption of the following resolution:

The Fifty-sixth World Health Assembly,

Alarmed by the unacceptable burden of nearly 800 000 measles deaths annually, occurring mostly in infants and young children living in developing countries;

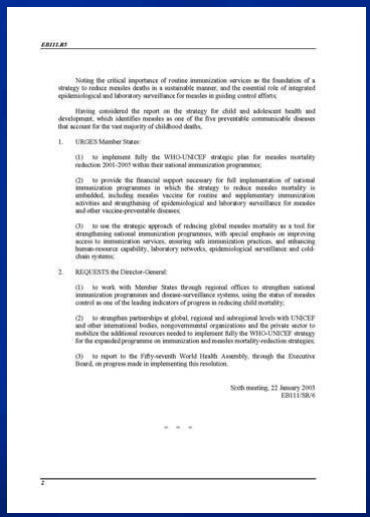
Recognizing that the current disease burden of measles is the result of underutilization of measles vaccine caused by inadequately supported immunization programmes and disease surveillance systems;

Stressing the importance of achieving the goal adopted by the United Nations General Assembly special session on children (2002) to reduce deaths due to measles by half by 2005, compared with the 1999 level, and the target contained in the United Nations Millennium Declaration to reduce the under-five child mortality rate by two-thirds by the year 2015;

Recognizing the availability of safe, effective and inexpensive measles vaccines and proven strategies to reduce measles mortality;

Welcoming the remarkable progress that has been made by the Measles Initiative partnership to reduce measles deaths in Africa;

[1] Document EB111/7



EB111.R5

Noting the critical importance of routine immunization services as the foundation of a strategy to reduce measles deaths in a sustainable manner, and the essential role of integrated epidemiological and laboratory surveillance for measles in guiding control efforts;

Having considered the report on the strategy for child and adolescent health and development, which identifies measles as one of the five preventable communicable diseases that account for the vast majority of childhood deaths;

1. URGES Member States:

(1) to implement fully the WHO-UNICEF strategic plan for measles mortality reduction 2001-2005 within their national immunization programmes;

(2) to provide the financial support necessary for full implementation of national immunization programmes in which the strategy to reduce measles mortality is embedded, including measles vaccine for routine and supplementary immunization activities and strengthening of epidemiological and laboratory surveillance for measles and other vaccine-preventable diseases;

(3) to use the strategic approach of reducing global measles mortality as a tool for strengthening national immunization programmes, with special emphasis on improving access to immunization services, ensuring safe immunization practices, and enhancing human-resource capability, laboratory networks, epidemiological surveillance and cold-chain systems;

2. REQUESTS the Director-General:

(1) to work with Member States through regional offices to strengthen national immunization programmes and disease-surveillance systems, using the status of measles control as one of the leading indicators of progress in reducing child mortality;

(2) to strengthen partnerships at global, regional and subregional levels with UNICEF and other international bodies, nongovernmental organizations and the private sector to mobilize the additional resources needed to implement fully the WHO-UNICEF strategy for the expanded programme on immunization and measles mortality-reduction strategies;

(3) to report to the Fifty-seventh World Health Assembly, through the Executive Board, on progress made in implementing this resolution.

Sixth meeting, 22 January 2003
EB111/SR/6

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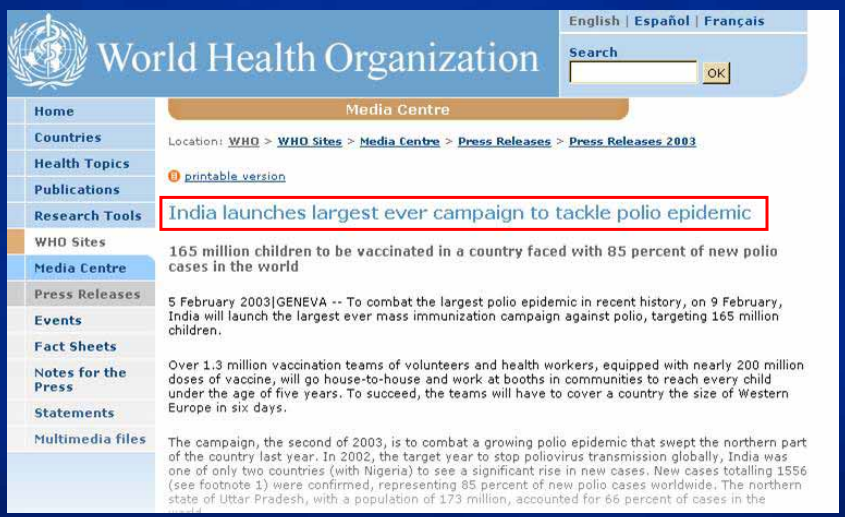
Polio Eradication



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India launches largest ever campaign to tackle polio epidemic

165 million children to be vaccinated in a country faced with 85 percent of new polio cases in the world

5 February 2003|GENEVA -- To combat the largest polio epidemic in recent history, on 9 February, India will launch the largest ever mass immunization campaign against polio, targeting 165 million children.

Over 1.3 million vaccination teams of volunteers and health workers, equipped with nearly 200 million doses of vaccine, will go house-to-house and work at booths in communities to reach every child under the age of five years. To succeed, the teams will have to cover a country the size of Western Europe in six days.

The campaign, the second of 2003, is to combat a growing polio epidemic that swept the northern part of the country last year. In 2002, the target year to stop poliovirus transmission globally, India was one of only two countries (with Nigeria) to see a significant rise in new cases. New cases totalling 1556 (see footnote 1) were confirmed, representing 85 percent of new polio cases worldwide. The northern state of Uttar Pradesh, with a population of 173 million, accounted for 66 percent of cases in the

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

CDC Immunization
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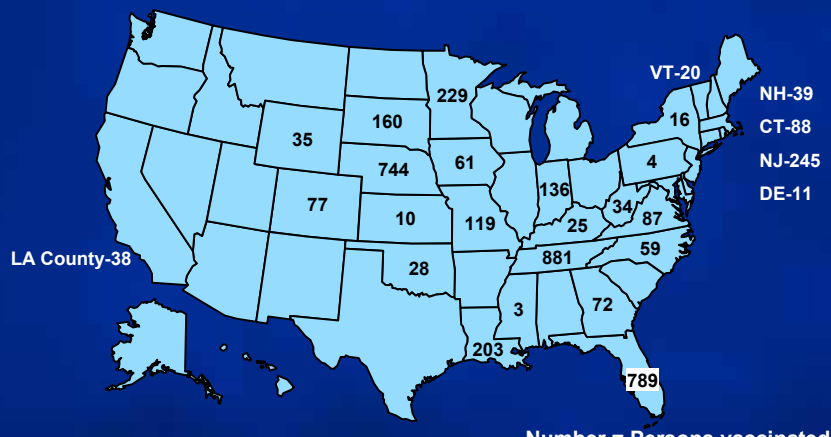
Smallpox Vaccination Program Status, United States*



*As of February 19, 2003

Number = Persons vaccinated
Total persons vaccinated—4,213

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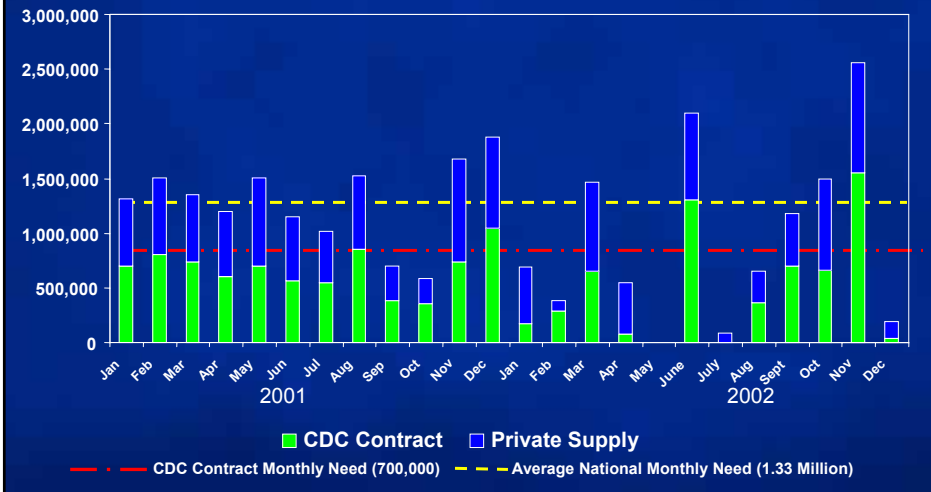
Pneumococcal Conjugate Vaccine Supply, U.S. Market

January 2001 – December 2002



Source: Biologic Surveillance/Wyeth-Vaccines

Pneumococcal Disease High Risk Conditions

- Sickle cell disease
- Functional or anatomic asplenia
- HIV infection
- Immunocompromise
- Chronic illness
- Cochlear implants

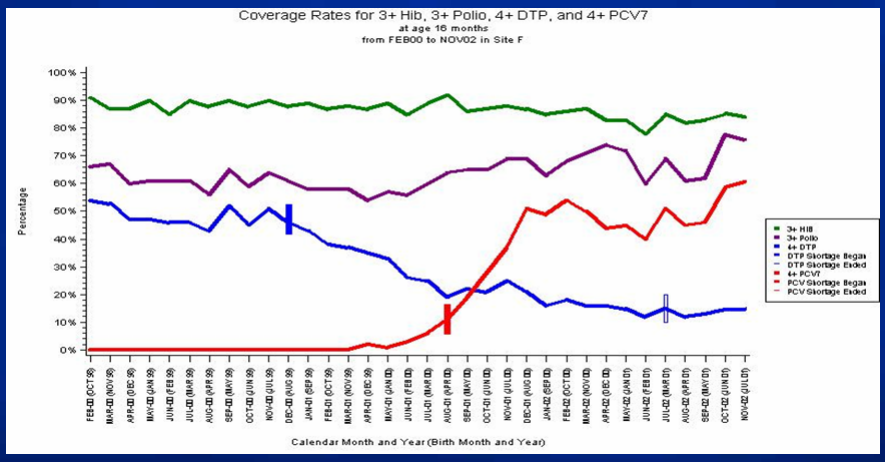
Pediarix is Licensed

- DTaP—Infanrix
- Hep B—Engerix B
- IPV
- Notice to readers pending

Tangible Benefits of Registry Data

- Registries can help quickly identify how immunization recommendations are being implemented
- Registries can quickly identify impact of vaccine delays and shortages
- Registries greatly foster the identification and notification of children with deferred vaccinations (e.g., due to a vaccine shortage)
- Registries are an effective way to identify children who do not meet school vaccination requirements

Impact of Vaccine Shortages on Coverage



Vaccine Financing

- Presidential Initiative
- IOM study on financing—pending

Pre-exposure Smallpox Vaccination Policy: ACIP Recommendations

- Vaccinate laboratory workers who handle smallpox and related viruses (was being done)
- Vaccinate smallpox response teams: persons designated to evaluate and investigate initial smallpox cases (with patient contact)
  - —At least one team per state and territory
  - —Include medical team leader, public health advisor, medical epidemiologists, disease investigators, diagnostic laboratory scientist, nurses, other personnel

Pre-exposure Smallpox Vaccination Policy: ACIP Recommendations

- Vaccinate selected personnel in hospital and medical facilities that agree to participate in the program and provide care for the initial cases of smallpox
  - Facilities identified by state / local health officials responsible for terrorism preparedness
  - Includes clinical and non-clinical personnel at high risk for exposure to initial cases
  - Does not substitute for isolation and proper infection control strategies