POLICY

Progress on the Childhood Immunization Initiative

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Synopsis

President Clinton submitted the Comprehensive Childhood Immunization Initiative Act to Congress in April 1993. The objective of the legislation is to protect all children in the United States by their second birthday against nine vaccine-preventable infectious diseases. As originally introduced in the Congress the initiative called for (a) Federal purchase and distribution of recommended childhood vaccines for all children, (b) improving the public health capacity to deliver vaccine, (c) establishing a State-based national immunization information and tracking system, and (d) expanding immunization education and mobilization efforts directed to health care providers and parents.

The authors review the progress and current status of the initiative, updating a previous progress report. The President's legislative proposal, modified by Congress, was enacted August 10, 1993. Several key provisions of the original legislation, deferred by Congress, may be incorporated in subsequent legislation or implemented through existing authorities. Therefore, the evolving framework for the initiative derives not from a single legislative mandate, but expands current immunization program activities and adds important new and complementary activities. As mentioned in the original title of the legislation, this is a "comprehensive" effort to address the problem of under-immunization in U.S. preschool children.

THE HEALTH CARE SYSTEM in the United States is working toward the as yet unattained goal of immunizing all children at the appropriate ages. An additional concern is reaching the children of the poor, medically underserved, and otherwise disadvantaged.

These shortfalls in immunization leave many of the youngest children vulnerable to diseases that are entirely preventable through vaccination. There are nine childhood diseases that can be prevented by immunization—poliomyelitis, measles, pertussis (whooping cough), mumps, rubella (German measles), tetanus, diphtheria, hepatitis B, and *Haemophilus influenza* type b (Hib). Except for tetanus, these diseases are contagious. They can spread from child to child and from community to community. And when children are not protected against them, serious outbreaks of disease can occur.

The Public Health Service's Advisory Committee on Immunization Practices (ACIP) has recommended that, by 15 months of age, children have a basic series of four doses of diphtheria-tetanus-pertussis (DTP) vaccine, three doses of oral poliovirus vaccine (OPV), one dose of measles-mumps-rubella (MMR) vaccine, three doses of hepatitis B vaccine, and three or four doses of Hib, depending on the type of vaccine used. The vaccines and the optimum recommended schedule for administration are shown in table 1.

Interim 1993 data from the Centers for Disease Control and Prevention (CDC), shown in table 2, indicate that the percentage of children who had obtained the recommended immunization coverage for the three vaccines (described in table 2 as DTP-4, polio-3, MMR-1) by their second birthday was 71.6 percent; the median was 85.9 percent for one dose of MMR vaccine; 74.8 percent for four doses of DTP vaccine; and 80.4 percent for three doses of OPV.

The Public Health Service's National Vaccine Advisory Committee has identified factors most

Table 1. Public Health Service's Advisory Committee on Immunization Practices (ACIP) recommended schedule for routine active immunization of normal infants and children, as of November 1993 [1]

Age [4]	Hepatitis B [2] Schedule A	Hepatitis B [2] Schedule B	Oral polio	Diphtheria-tetanus-pertussis	Haemophilus influenzae type b [3] Schedule A	Haemophilus influenzae type b [3] Schedule B	Measles-mumps-rubella
Newborn	X	...	...	...	...	...	...
2 months	X	X	X	[5] X	[5] X	X	...
4 months	...	X	X	X	X	X	
6 months	X	X	X	X	X	...	...
12–15 months	...	...	...	...	X	X	X
15 months	...	...	...	[6]DTP/DTaP	...	...	...
4–6 years, before school entry	...	...	X	[6]DTP/DTaP	...	...	X
14–16 years	...	...	...	[7]Td	...	...	...

[1] Recommended vaccines for a given age may be administered in a single physician visit.

[2] Hepatitis B vaccine may be given in either of 2 schedules: schedule A, at birth, 1–2 months, and 6–18 months; schedule B, at 1–2 months, 4 months, and 6–18 months. Optional schedules shown are for infants born of HBsAg-**negative** mothers. Premature infants born of HBsAg-**negative** mothers should receive the first dose of the hepatitis B vaccine series at the time of hospital discharge, or when the other routine childhood vaccines are initiated. Infants born of HBsAg-**positive** mothers should receive immunoprophylaxis for hepatitis B as soon as possible after birth.

[3] Hib conjugate vaccines may be given in either of 2 schedules: schedule A, HbOC (HibTITER (TM)), PRP-T (ActHIB (TM)), or DTP/HbOC (TETRAMUNE (TM), at 2, 4, 6, and 12–15 months; schedule B, PRP-OMP (PedvaxHIB (R)), at 2, 4, and 12–15 months.

[4] The recommended ages for vaccine administration are not absolute. For example, the recommended age of 2 months may be 6–10 weeks. Physician consultation is advised.

[5] Combination DTP/Hib conjugate vaccine may be used when both injections are scheduled.

[6] DTP preparation containing acellular pertussis vaccine (DTaP) is recommended for the 4th and 5th doses, but whole-cell DTP may be used if DTaP is not available.

[7] At 14–16 years and every 10 years thereafter.

NOTES: For details on specific vaccines, consult the latest edition of "Recommendations of the Advisory Committee on Immunization Practices (ACIP)," published in Morbidity and Mortality Weekly Report, Recommendations and Reports series, by the Centers for Disease Control and Prevention.

DTP = diphtheria-tetanus-pertussis vaccine. A combined DTP and Hib vaccine is available. DTaP = diphtheria-tetanus-acellular pertussis vaccine. Td = tetanus-diphtheria toxoid.

frequently associated with low immunization coverage levels. These are missed opportunities for administering vaccine, resource shortfalls in the health care delivery system, inadequate access to health care services, and a lack of public awareness of the benefits of immunization (*1*).

The Childhood Immunization Initiative calls for major steps to address those barriers and to improve the delivery of childhood immunizations (*2*). The objectives of the immunization initiative are to

1. Improve the quality and quantity of vaccination delivery services.
2. Reduce the cost of vaccine for parents.
3. Increase awareness of infant immunization, enhance community participation, and expand private-public partnerships.
4. Improve the systems for measuring vaccination coverage and disease surveillance.
5. Increase the emphasis on the development of new, safer, and more effective vaccines.

The goal is to eliminate or control vaccine-preventable diseases through a system that initially vaccinates at least 90 percent of 2-year-olds by 1996. The initiative recognizes that preventing disease through immunizations has far-reaching benefits in relation to a reduction in mortality and morbidity of children and the prevention of disability. Ongoing efforts to reform the nation's health care system are expected to strengthen this goal by providing full insurance coverage of all recommended childhood immunizations, with no copayment. Proper immunization would also be a desirable standard to assess the adequacy of health care plans under the new system.

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Improved Immunization Services

CDC has awarded grants to immunization programs in 87 areas in the United States and territories. In announcing the awards, Donna E. Shalala, Secretary of Health and Human Services, said, "These Federal funds represent an unprecedented increase in funding for these childhood immunization programs made possible, at the urging of President Clinton, when Congress increased the immunization budget for CDC to $528 million in fiscal year 1994, more than $187 million over 1993 (*3*)."

State and local governments developed and submit-

Table 2. Vaccination levels of children ages 19-35 months for selected diseases, United States, 1992 and 1993

Vaccine	1992		January-June 1993 [1]		July-September 1993 [2]	
	Percent	95 percent confidence levels	Percent	95 percent confidence levels	Percent	95 percent confidence levels
DTP/DT:						
3 or more doses	83.0	80.8, 85.2	87.2	84.3, 90.4	89.9	86.9, 93.0
4 or more doses	59.0	56.1, 61.9	71.1	67.1, 75.1	74.8	69.9, 79.7
Polio: 3 or more doses	72.4	70.1, 74.7	78.4	74.8, 82.0	80.4	75.8, 84.9
Hib: 3 or more doses	28.2	25.6, 30.9	49.6	45.4, 53.8	60.3	55.0, 65.7
Measles containing[3]	82.5	80.2, 84.8	80.8	77.2, 84.4	85.9	82.0, 89.8
Hep B: 3 or more doses	. . .	. . .	12.7	9.4, 16.0	15.7	12.1, 19.2
DTP-3, polio-3, MMR-1	68.7	66.2, 71.2	72.0	68.1, 75.9	78.7	74.2, 83.2
DTP-4, polio-3, MMR-1	55.3	52.5, 58.1	64.8	60.6, 68.9	71.6	66.7, 76.4

[1] Provisional data based on quarters 1 and 2.
[2] Provisional data based on quarter 3.
[3] Refers to a vaccine with a measles component, such as MMR (measles, mumps, rubella).
NOTES: In 1993, increases were seen in all vaccinations. The only statistically significant increase was in Hib vaccinations between the first 2 quarters of 1993 and the third quarter of 1993.
DTP/DT = diphtheria-tetanus-pertussis vaccine / diphtheria tetanus.
Hib = *Haemophilus influenzae* type b conjugate vaccine.
Hep B = hepatitis B vaccine.
MMR = measles-mumps-rubella vaccine.

ted immunization action plans (IAP) to CDC for grant funding. IAPs are community-based planning efforts designed to overcome barriers associated with low preschool immunization levels. IAP awards are used to supplement ongoing activities and establish new initiatives that focus on improved immunization coverage. A total of $86 million was awarded in January 1994, representing 67 percent of the IAP funds available for award this fiscal year. An additional $33 million in grant funds is to be awarded as incentive payments to grantee organizations that best demonstrate progress toward achieving performance standards incorporated in the IAPs.

The framework for the Childhood Immunization Initiative expands current immunization activities and adds important new and complementary activities (*4*).

Increased Public Awareness of Immunization

A key to reversing low immunization rates among preschool-aged children is strengthening community coalitions that promote immunization. To accomplish this objective, the Department of Health and Human Services (DHHS) will conduct a national outreach campaign to reach each State and community. "Our challenge is to increase awareness among parents, health care providers, and others about the importance of childhood immunizations, and reduce any barriers that might limit access to immunizations," Secretary Shalala said in announcing the campaign (*5*).

The campaign is based on a two-part integrated strategy for increasing immunization rates and helping to create a social norm concerning the need for proper immunization. The two parts of the campaign include a national immunization promotion and awareness effort and State and community mobilization activities.

The national immunization promotion effort concerns the means by which people receive information promoting proper childhood immunization. Immunization messages are being provided through public service announcements, speeches, and special events. Messages are communicated in traditional ways through television, radio, and in print, as well as through nontraditional mechanisms, such as on baby food jars and diaper boxes and in storefront windows (*6*). After identifying and defining the intended audiences, a uniform immunization message will be disseminated in a broad information effort involving both the public and private sectors.

The State and community mobilization activities are designed to stimulate community education and involvement related to the benefits of immunization. The activities will involve religious and civic leaders, elected officials, corporate executives, teachers, parents, and health care professionals. Outreach coordinators will be placed in 10 regions to encourage coalition building and mobilization activities at the grassroots level and to tie State and local efforts to the national campaign.

The immunization promotion activities are focused nationally and the mobilization activities are focused locally. The planning phase of the campaign began in early 1993 and implementation began during National Infant Immunization Week, April 23–29, 1994. The campaign strategy will be reassessed at the end of each phase and integrated into ongoing immunization program efforts.

Improve Availability of Vaccines

On August 10, 1993, the President signed the Omnibus Budget Reconciliation Act of 1993, now Public Law 103-66. The legislation made significant

changes in the Federal system for the purchase and delivery of vaccines for children. The Vaccines for Children Program created by the legislation establishes a distribution program to provide free vaccine to an estimated 10.6 million children (*7*). The program will enable States to build on their experiences under the current vaccine purchase program to develop the most effective delivery systems to meet the needs of their residents. The legislation includes clarifications of provisions for Medicaid coverage of immunization, provisions prohibiting the repeal of State laws mandating insurance coverage for vaccines, and the extension of the National Vaccine Injury Compensation Program.

Under the Vaccines for Children Program, which will begin on October 1, 1994, the Federal Government will purchase vaccines from manufacturers and provide them, without cost, to a variety of health care providers directly or through a State vaccine distribution system. Among children 18 years of age or younger, those who will be eligible for free vaccine under the program are those eligible for Medicaid, those with no health insurance, all American Indians and Alaskan Natives, and those with health insurance that does not cover vaccines as a benefit.

Those who are in one of the first three categories may go to any qualified health care provider who chooses to participate in the program. Those in the last category may receive services through such facilities as Federally Qualified Health Centers and Rural Health Clinics. The vaccine program will provide the pediatric vaccines recommended by ACIP.

States may purchase additional quantities of the vaccines, at the Federal contract price, for any other categories of children. Eleven States currently have universal purchase programs that provide vaccines for all children (Alaska, Connecticut, Idaho, Maine, Massachusetts, New Hampshire, Rhode Island, South Dakota, Vermont, Washington, and Wyoming). They provide some or all of the recommended childhood vaccines to health care providers for delivery to any child in their jurisdiction. Other States have expressed interest in establishing similar systems.

Any health care providers licensed by a State to administer vaccines can participate in the program and receive free vaccine, if they agree to

- administer vaccines according to the schedule and contraindications established by the ACIP,
- not charge for the vaccines,
- not charge fees for administering vaccines that exceed regional fee schedules developed by DHHS, and
- not refuse to vaccinate a child because of a family's inability to pay the administration fee.

Table 3. Immunization levels by percentage of coverage for children 2 years of age in 1992 and immunization goals for 2-year-olds during 1994—96 [1]

Vaccine	*1992*	*1994*	*1995*	*1996*	*1998*
DTP-3	83	85	87	90	. . .
OPV-3	72	75	85	90	. . .
MMR-1	83	85	90	90	. . .
Hib-3	. . .	75	85	90	. . .
HEP B-3	. . .	30	50	70	90

[1] Surveys are to assess those 19–35 months of age.
NOTES: DTP-3 = 3 doses of diphtheria-tetanus-pertussis vaccine.
OPV-3 = 3 doses of live oral polio vaccine.
MMR = measles-mumps-rubella vaccine.
Hib-3 = 3 doses of *Haemophilus influenzae* type b conjugate vaccine.
HEP B-3 = 3 doses of hepatitis B vaccine.

To establish a stable funding source, the Vaccines for Children Program was included as part of the Medicaid statute, making immunization benefits an entitlement not requiring annual appropriations by the Congress. Additionally, the fiscal 1994 DHHS appropriation provides continued funding of the CDC Immunization Grant Program. Grant funds are used partly to improve the hours and staffing of public clinics, to support local immunization outreach and public education efforts, for program administration, and to purchase vaccine for additional groups. The Vaccines for Children Program contains a sunset provision to end the program when a pattern of regular preventive immunization services for all children is established as part of a broad-based reform of the national health care system.

Goals for Disease Prevention

The success of the initiative ultimately will be determined by achieving specified immunization coverage and disease prevention goals. A major goal has been established to eliminate or control vaccine-preventable diseases by vaccinating at least 90 percent of all 2-year-olds. That goal originally was established in 1990 to be achieved by the year 2000 as one of the "Healthy People 2000" health objectives for the nation (*8*). The Childhood Immunization Initiative accelerates those efforts with the 1996 goal.

Goals for immunization coverage of children who will be 2 years old during the period from 1994—96 are shown in table 3. Base year estimates are provided for 1992. Specifically, coverage goals for each antigen in the basic immunization series are 90 percent coverage among 2-year-olds in 1996. The

Some Federal Agency Activities Related to Childhood Immunization

Interagency Committee on Immunization
Coordinates Federal support for immunization by 4 Federal departments, including the Departments of Health and Human Services, Agriculture, Housing and Urban Development, and Education, as well as 10 separate offices and agencies within Health and Human Services.

Department of Health and Human Services
The National Vaccine Program Office (NVPO) is part of the Office of the Assistant Secretary for Health, Department of Health and Human Services. The Office formulates and coordinates policies regarding Federal immunization activities.

Administration for Children and Families administers the Head Start Program, which serves infants, toddlers, and pregnant women. Requires providing or arranging for completion of all recommended childhood immunizations.

Public Health Service, Centers for Disease Control and Prevention (CDC), National Immunization Program, provides grant support, technical assistance, national surveillance, and epidemic aid, and conducts research to assist State and local health agencies in planning and implementing immunization programs. CDC has developed and distributed "Standards for Pediatric Immunization Practices," recommended national standards for vaccine administration by health professionals in public and private settings.

Public Health Service, Health Resources and Services Administration, provides immunizations as part of (*a*) the comprehensive primary care services offered through the Community and Migrant Health Centers in federally designated underserved areas, and (*b*) State efforts funded through the maternal and child health block grants.

Public Health Service, Indian Health Service (IHS), provides immunization services to the Native American population through IHS health facilities.

Health Care Financing Administration provides national direction and oversight for immunization services provided through State-administered Medicaid Programs.

Department of Housing and Urban Development
Facilitates the delivery of immunization services to children living in public housing facilities.

Department of Agriculture
Conducts cooperative efforts with CDC to increase immunization coverage among preschool-age children who participate in the Special Supplemental Food Program for Women, Infants, and Children (WIC).

Department of Education
Fosters relationships at State and local levels to assure the availability of immunization services for children of migrant farm workers.

'The Childhood Immunization Initiative calls for elimination of indigenous transmission of measles, diphtheria, poliomyelitis, tetanus, and Haemophilus influenza *type b disease. . .'*

only exception is hepatitis B, for which the objective is 70 percent coverage by 1996 and 90 percent coverage by 1998.

The Childhood Immunization Initiative calls for elimination of indigenous transmission of measles, diphtheria, rubella, poliomyelitis, tetanus (for children under age 15), and *Haemophilus influenzae* type b disease in children under age 5 (table 4). Goals for pertussis, mumps, and hepatitis B are in the process of being established. For comparison, the table shows the numbers of reported cases of vaccine-preventable disease for 1992 and cases reported through early December 1993.

The objective is to establish realistic goals and to ensure that those responsible for reaching the goals have all the necessary tools to achieve them. This effort will take teamwork and commitment from both the public and private sector. "Partnership with the private sector is a key tool for successfully immunizing all of our youngest children," said Donna Shalala, Secretary of the Department of Health and Human Services. With all of us working together, we will be able to protect our children from needless disease (*9*).

Disease Monitoring and Surveillance

Surveillance of infectious disease is a critical component of the childhood immunization initiative that provides an early response capability for disease outbreaks. Improved surveillance allows identification of specific areas where immunization rates are low and special efforts are needed. Improved surveillance additionally will permit monitoring of vaccine effectiveness following the introduction of new vaccines

into a susceptible population. About $5 million in grants to enhance surveillance were awarded to States in January 1994.

Three means of acquiring better immunization coverage data are being established.

- Data on national immunization coverage will be obtained through the National Health Interview Survey on a quarterly basis. Beginning in 1994, a subsample of parental responses will be validated against health care providers' records.
- Immunization coverage in 78 major areas, including 50 States, the District of Columbia, and more than 20 large urban areas, will be measured using random digit dialing surveys. Data will be available beginning on a quarterly basis in November 1994.
- A manual, currently under development, will describe the techniques for conducting special probability sampling for determining immunization coverage in municipalities. Those techniques will allow municipalities to evaluate their progress periodically.

Improving Vaccines and Their Use

Efforts are underway to simplify existing childhood vaccination schedules and develop new vaccines or combination vaccines. Overall, vaccines are among the safest and most effective medicines. However, like other medicines, vaccines can cause side effects. These are usually mild—a slight fever, a sore arm, a mild rash—and do not last very long. On rare occasions the effects can be more serious. The initiative provides for an expansion of the current high standards for vaccine safety. An enhanced program for vaccine safety is being planned to achieve the maximum benefit from vaccines and to maintain public confidence. Emphasis will be placed on the development and licensure of new and safer or more effective vaccines.

Improved Federal Partnerships

Immunization has traditionally been a State responsibility, and the levels of delivery of immunization services vary among cities and States. At the Federal level, four departments and their agencies support immunization efforts directly or by promoting immunization through their involvement with mothers and children in programs for education, food, housing, or other social assistance (see accompanying box) (*10*).

An Interagency Committee on Immunization coordinates Federal support for immunization. The Committee consists of 4 Federal Departments (Health and Human Services, Agriculture, Housing and Urban Development, and Education) as well as 10 separate offices and agencies. The strength of the committee lies in its diversity of approaches to the delivery of immunization services. For example:

- The DHHS Administration for Children and Families has adopted performance standards for Head Start Programs, which serve infants, toddlers, and pregnant women, that require providing or arranging for completion of all recommended childhood immunizations.
- CDC provides national direction and leadership, project grant support, and technical assistance to State and local health agencies in planning and implementing immunization programs. CDC has developed and distributed "Standards for Pediatric Immunization Practices," setting forth the recommended national standards for administration of vaccines by health professionals in public and private settings.
- The Department of Agriculture is conducting demonstration projects to explore various mechanisms for increasing immunization rates among participants in the Special Supplemental Food Program for Women, Infants, and Children (WIC).
- The Department of Housing and Urban Development is improving the access and delivery of immunization services to economically disadvantaged and minority children living in public housing.

Table 4. Cases of vaccine-preventable diseases, 1992 and 1993, and goals for 1996 and 2000

Disease	*1992*	*[1]1993*	*1996*	*2000*
Measles	2,237	277	0	0
Rubella	160	188	0	0
Poliomyelitis	4	0	0	0
Diphtheria [2]	4	0	0	0
Tetanus [2]	45	42	0	0
Haemophilus influenzae type b [3]	592	([4])	0	([4])
Pertussis	4,083	6,132	([5])	500
Mumps	2,572	1,630	([5])	0
Hepatitis B	16,126	11,112	([5])	([5])

[1] Data for 1993 are for cases through Dec. 4, 1993.
[2] Goals are for within 25 years.
[3] Goals are for within 5 years.
[4] Data not available.
[5] Data to be determined.

Conclusion

To realize the full disease-prevention value of current and future vaccines, we must have in place a comprehensive delivery system—one that ensures parents are motivated, health care providers are prepared, and vaccines are available to all children on

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schedule. The Childhood Immunization Initiative is a comprehensive program that will move the nation significantly forward on this major preventive-health goal.

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