The President's Child Immunization Initiative—A Summary of the Problem and the Response

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Synopsis

After only 24 days in office, President Bill Clinton announced a comprehensive childhood immunization initiative designed to assure that all children in the United States lead healthier lives by receiving age-appropriate immunizations against preventable diseases such as polio, mumps, measles, whooping cough, and diphtheria. As part of his economic stimulus proposal, the President requested $300 million for Fiscal Year 1993 to reinforce the nation's immunization infrastructure by providing funding for communities to extend clinic hours, provide more staff, and increase information and education efforts and for the planning and implementation of a national immunization tracking system. In its Fiscal 1994 budget request, the Administration asked for a doubling of the Centers for Disease Control and Prevention's immunization program funding to $667 million.

In cooperation with key congressional committees, the Administration has also prepared legislation that would provide recommended childhood vaccines to States for free distribution to health care providers who serve children enrolled in Medicaid or who don't have health insurance that covers immunization services. Providers could not charge for the vaccine but could charge a fee for administration. State Medicaid programs would also be required to reimburse providers reasonably for vaccine administration. This measure is designed to improve universal access to immunization services by helping to remove financial barriers that impede children from being immunized at the appropriate age.

ON FEBRUARY 12, 1993, President Bill Clinton told parents and health care providers at an immunization clinic in Alexandria, VA, "It is unacceptable that the United States is the only industrial country that does not guarantee childhood vaccination for all children. . . . It is ironic that the country that develops and produces the majority of the world's vaccines does not have an effective or affordable mechanism for distributing them to doctors and clinics who treat children" (*1*).

The President went on to follow through on a long-term commitment by unveiling an initiative to ensure that all of America's children are immunized on schedule against vaccine-preventable diseases such as polio, mumps, measles, whooping cough, and diphtheria. The initiative will be implemented over the next 4 years.

The President's immunization initiative is an essential first step in a broader National Vaccine Plan that will serve as a long range blueprint for reaching the Healthy People 2000 national goal of covering 90 percent of the children in the country by their second birthday (*2*).

The Cost-Benefit of Vaccines

Childhood vaccines are the proverbial ounce of prevention. They save innumerable lives, prevent untold suffering, and reduce medical costs by the best of all possible means—avoiding sickness. Of particular importance in the current era of escalating health care costs is the fact that effective childhood vaccines are highly economical and thus represent an efficient use of resources. Past estimates indicate that for every dollar expended on measles, mumps, and rubella (MMR) vaccine and

The Advisory Committe on Immunization Practices' recommended schedule of vaccinations for all children

Age	DTP	DTaP	OPV	MMR	Hib [1]Option 1	Hib [1]Option 2	HBV Option 1	HBV Option 2
Birth	...	...	...	...	...	...	X	...
2 months	X	...	X	...	X	X	[2]X	[2]X
4 months	X	...	X	...	X	X	...	[2]X
6 months	X	...	...	...	X	...	...	...
12 months	...	...	...	...	...	X	...	...
15 months	[3]X	[3]X	[3]X	[4]X	X	...	...	...
6–18 months	...	...	...	...	...	...	[2]X	[2]X
4–6 years (before school)	X	X	...	[5]X	...	...	...	...

[1] Vaccine is given in either a 4-dose schedule in option 1 or a 3-dose schedule in option 2, depending the type of vaccine used.
[2] Hepatitis B vaccine can be given simultaneously with DTP, OPV, MMR, and Hib at the same visit.
[3] Many experts recommend these vaccines at 18 months.
[4] In some areas, this does of MMR may be given at 12 months.
[5] American Academy of Pediatrics recommends that this dose be given at entry to middle school or junior high school.
NOTE: DTP = Diphtheria, tetanus, and pertussis vaccine; DTaP = Diphtheria, tetanus, and acellular pertussis vaccine; OPV = Live oral polio vaccine; MMR = Measles, mumps, and rubella vaccine; Hib = Haemophilus b conjugate vaccine; HBV = Hepatitis B vaccine.

immunization activities, $14 in societal costs is saved (*3*). According to a similar analysis, for each $1 spent on pertussis vaccination, $2.10 in health care costs is saved (*4*).

The recent measles epidemic of 1989–91 makes explicit the full magnitude of the harm that can be done by a so called "mild" children's disease (fig. 1). For a long time, measles was regarded by the general public and many health professionals as an unpleasant but not very dangerous part of life. Most people probably are not aware that this resurgence of measles resulted in more than 55,467 cases, 132 related deaths, 11,251 hospitalizations, more than 44,100 hospital days—with an estimated $150 million in direct medical costs. Added to these costs are innumerable work and school absences. These are costs that could have been avoided by immunizing children with vaccine that cost about $24 a dose in the private sector and $16 in the public sector in 1988, according to data from the Centers for Disease Control and Prevention (CDC).

The Problem

Despite the health, social, and economic benefits of immunization, millions of children in the United States are not receiving available vaccines at the appropriate time in life. Approximately 80 percent of the recommended childhood vaccine doses should be received before age 2 to protect children during their most vulnerable years. To be fully protected against vaccine-preventable disease, a child must be immunized against nine diseases, according to the schedule shown in the table. Full immunization requires that a child be inoculated 18 times with 5 vaccines, and all but 3 of the 18 doses should be received by age 2. This regimen requires five visits to the physician's office after birth. Unfortunately, many children do not receive their basic immunizations on schedule (fig. 2).

Ironically, we are able to protect nearly 98 percent of children in the country today because of State laws that require immunization for enrollment in school. And, essentially, children in middle and upper income families who have access to basic health care services have high immunization rates. Today's public health system, however, fails to deliver age-appropriate immunizations to those infants in populations that are the most difficult to reach, the poor or otherwise disadvantaged. In some inner cities, less than 50 percent, and in some areas as few as 10 percent, of the preschoolers have been fully immunized by age 2.

These risk factors are highly correlated with a failure to immunize children on schedule (*5*):

- low educational level,
- large family size,
- low socioeconomic status,
- members of ethnic or minority groups,
- receiving services through public health clinics,
- single parent families,
- starting the immunization series late, and
- inadequate insurance coverage for immunization services.

These factors suggest that to improve use of immunization services, families need functional access—to affordable and available services—along with motivation and knowledge. Thus, the responsibility for achieving high immunization coverage levels is shared by parents, health care providers, and public health agencies.

Other factors that impede the delivery of immu-

nization services are the complexity of the current health care delivery system for immunizations and its variations from city to city and State to State. The Federal Government, State and local governments, the private sector, and voluntary organizations all play important roles in the delivery of immunization services. There is no coordinated approach, however, for either the purchase of vaccine or the delivery of services to reach all children.

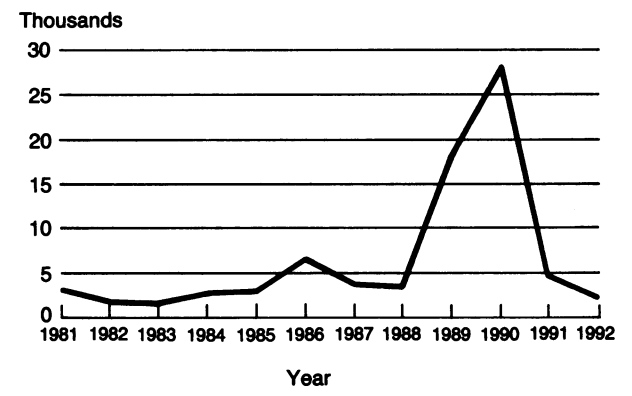
Since the passage of the Vaccination Assistance Act of 1962, a Federal grant program administered by CDC has provided financial and technical assistance to supplement State and local health department efforts to provide immunizations. It is estimated that half of the nation's children receive their immunizations in the public sector. Their parents do not pay for the vaccines received—a total of $122.18 at current public sector prices—but may pay a small fee (approximately $5) for administration (*6*). In addition, other Federal funds provide support for delivery of immunization through the Medicaid Program, the Maternal and Child Health Block Grants, and federally sponsored community and migrant health centers.

The other half of the nation's children are immunized by private physicians as part of their overall well-child preventive care. Their parents either pay for this service directly out of pocket or have third-party insurance reimbursement coverage. The current private-sector price for the vaccines each child should receive totals $245.65, with an estimated cost per physician visit of $13; the total for completing the recommended immunization series would be $323.65 (*6*).

Although there is considerable dispute over how heavily cost weighs as a barrier to immunization, many believe it is fueling the breakdown of vaccine delivery in the private sector and clogging the immunization pipeline in the public sector. Between 1981 and 1992, the private sector price of a single dose of diphtheria, tetanus, pertussis (DTP) vaccine rose from 33 cents to nearly $10. A dose of polio vaccine quadrupled in cost from $2.10 to $9.91. Measles, mumps, rubella (MMR) vaccine nearly tripled to $25.29. By comparison, the CDC contract price for DTP in September 1992 was $5.99; for polio, $2.09, and for MMR, $15.33. In part, these cost increases can be attributed to recommendations for new vaccines, to additional doses of existing vaccines, and to an excise tax used to fund the vaccine compensation program.

The shortcomings of the immunization system were recently documented in a report issued by the

Figure 1. Measles cases, by year, United States, 1981-92



National Vaccine Advisory Committee, "The Measles Epidemic: The Problems, Barriers and Recommendations" (*7*). The report indicated that the principal cause of the epidemic was the failure to deliver vaccine to vulnerable pre-school age children on schedule. There are four known barriers to successful immunization that can be addressed within the context of the current primary health care system. They are (*a*) missed opportunities for administrating vaccines; (*b*) resource short-falls in the health care delivery system; (*c*) inadequate access to care; and (*d*) incomplete public awareness and lack of public demand for immunization.

Specific recommendations in the advisory committee report include:

- The improved availability of immunization services by enhanced support of State and local health departments, increased coverage of immunization as part of basic health insurance coverage, increased use of the immunization opportunities under the Medicaid Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program, and increased public awareness of the importance of preschool immunization.
- Improved management of immunization delivery by the establishment of standards for immunization practices, improved coordination among Federal programs for the delivery of immunization services, and the establishment of coordinated systems to link recipients of the Women, Infants, and Children (WIC) food program and the Aid to Families with Dependent Children (AFDC) Program to immunization services.
- Improvement of the ongoing measurement of immunization status through the establishment of a national system for the assessment of immunization

coverage, particularly for high-risk populations and in urban and rural areas.

The President's Immunization Initiative

In response to the nation's problems in the delivery of immunization services, President Clinton's initiative is intended to strengthen the immunization infrastructure and make the delivery of vaccines more "user friendly." To support the initiative, the President requested an immediate infusion of funds into vaccine delivery as part of his economic stimulus proposal. For the remainder of Fiscal Year 1993, an additional $300 million was requested to strengthen the public sector delivery infrastructure, which would have created an estimated 4,000 to 5,000 new jobs. However, the economic stimulus proposal was not enacted by the Congress. These funds would have helped communities increase clinic hours, establish new service locations, hire additional nurses and outreach staff, expand informational and educational programs, purchase more vaccines, and begin to establish a national immunization tracking system.

In the continuing belief that these resources are desperately needed at the local level to improve vaccine delivery systems and immunization services, the President's fiscal year 1994 budget request for the immunization program at CDC almost doubles, from $341 million in fiscal year 1993 to more than $667 million in fiscal year 1994. With this renewed commitment, CDC will be able to fund the State immunization action plans for infrastructure development. Efforts will be carried out in all 50 States, 13 Territories, and 24 urban areas to expand their community-based immunization plans.

The collaboration fostered through the national, State, and local plans offers communities the opportunity to draw upon the combined resources and knowledge of a cross-section of public, private, and voluntary groups and agencies. Just as important, it may offer a forum from which a broader range of individuals and organizations, particularly those usually underrepresented in the immunization policy decision-making process, such as parents and members of minority groups, can work together to devise ways to improve the delivery of immunization services. This will help communities create new networks to provide access and improve the quality of immunization services.

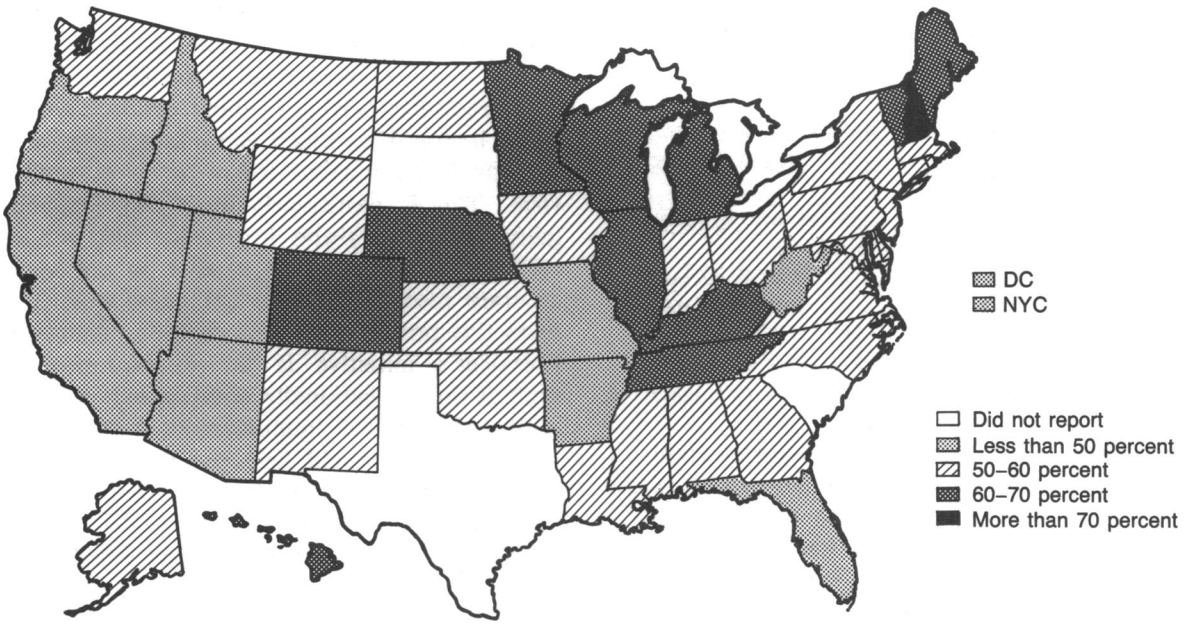
A key component of the President's initiative is an increase in the national information and education outreach efforts inaugurated by CDC earlier this year. This program brings needed information to parents and health care providers and focuses their attention on the importance of achieving the full immunization of children at the earliest appropriate age. These efforts were initiated on April 12, 1993 with a Presidential proclamation establishing a "National Preschool Immunization Week." The annual observance of this week has great potential for providing a national focus on preschool immunizations and for moving forward the many local programs and coalitions working to improve immunization levels.

Another important educational effort currently under way is the establishment of "Standards for Pediatric Immunization Practices." These national standards are recommended for use by all health professionals providing care in public or private settings who are involved in the administration of vaccines or the management of immunization services for children. Some of the standards may also be relevant in the administration of vaccines to adults. The standards have been adopted by the National Vaccine Advisory Committee, the Public Health Service, and the American Academy of Pediatrics and represent the most desirable immunization practices that health care providers should strive to achieve (box).

Improved access to immunization servies. Under the new legislation proposed by President Clinton, vaccines would be provided to States for free distribution to health care providers who serve children enrolled in Medicaid or who don't have health insurance that covers immunization services. Such providers would not be allowed to charge patients for the cost of vaccines, but could continue to require a fee for vaccine administration. However, no one could be denied immunization because of the inability to pay. Several health professional organizations, such as the American Academy of Pediatrics, have endorsed this waiver and have encouraged their members not to charge the administration fee in such hardship cases.

Preliminary to the expanded bulk purchase of vaccine, Secretary of Health and Human Services Donna E. Shalala has begun price negotiations with vaccine manufacturers participating in the CDC procurement program. As part of this program vaccine prices will be based on data supplied to the Secretary by manufacturers, regarding (*a*) costs related to research and development, production, distribution to States and health care providers, (*b*) profit levels sufficient to encourage future investments in vaccine research and development, and (*c*) the ability to maintain an adequate supply of

Figure 2. Immunization status[1] of school enterers at the second birthday, U.S., 1991–92[2]



[1]4 diphtheria, tetanus, pertussis; 3 polio, 1 measles, mumps, rubella.

[2]Map shows status of 2-year-olds in North Dakota and Tennessee in 1991.

vaccine for disease outbreak control. To ensure a secure and long term supply of vaccines and to stimulate competition among manufacturers, contracts would be put out for competitive bidding to multiple manufacturers of various vaccines.

Implementation options would allow the Secretary to provide vaccines either directly to health care providers or through those States that agree to distribute vaccine through their public health system. Currently, Connecticut, Idaho, Maine, Massachusetts, New Hampshire, Rhode Island, South Dakota, Vermont, Washington, and Wyoming provide some or all of the recommended childhood vaccines directly to health care providers.

Free vaccine would continue to be distributed through Federal health care providers, community health centers, migrant health centers, health centers serving residents of public housing or the homeless, other federally qualified health centers, and through providers serving Indians under the Indian Self-Determination Act or the Indian Health Care Improvement Act.

Immunizations under the Medicaid Program. The Medicaid program provides coverage of the cost of immunizations to eligible children, yet a significant number of these children do not receive immunizations at the appropriate age. Immunizations appropriate to age and health history is a required component of Medicaid's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program for eligible people younger than age 21. Under the Medicaid Program, States are instructed to assess whether each child enrolled in the program has been immunized against diphtheria, pertussis, tetanus, polio, measles, rubella, and mumps, and whether booster shots are needed. In many States, however, Medicaid reimbursement rates for immunization services are criticized as being too low, causing providers to cease providing vaccines to Medicaid recipients.

The legislation proposed by the President is designed to increase immunization levels of children receiving Medicaid by assuring appropriate reimbursement to providers for vaccine administration. State Medicaid programs would be required to set immunization administration fees high enough, that is, competitive enough, to guarantee access to providers on a par with the general population. Administrators of State Medicaid programs would calculate payment rates for vaccine administration separately from payment rates for office visits or other services (*8*).

These program changes are intended to ensure that Medicaid physicians immunize Medicaid eligible children in their offices, rather than referring them to overburdened public health clinics for vaccines. Because vaccines will be distributed free to Medicaid health care providers, States will be in a better position to finance the increased reim-

Standards for Pediatric Immunization Practices

Standard 1. Immunization services are readily available.
Standard 2. There are no barriers or unnecessary prerequisites to the receipt of vaccines.
Standard 3. Immunization services are available free or for a minimal fee.
Standard 4. Providers utilize all clinical encounters to screen and, when indicated, immunize children.
Standard 5. Providers educate parents and guardians about immunization in general terms.
Standard 6. Providers question parents or guardians about contraindications and, before immunizing a child, inform them in specific terms about the risks and benefits of the immunizations their child is to receive.
Standard 7. Providers follow only true contraindications.
Standard 8. Providers administer simultaneously all vaccine doses for which a child is eligible at the time of each visit.
Standard 9. Providers use accurate and complete recording procedures.
Standard 10. Providers co-schedule immunization appointments in conjunction with appointments for other child health services.
Standard 11. Providers report adverse events following immunization promptly, accurately and completely.
Standard 12. Providers operate a tracking system.
Standard 13. Providers adhere to appropriate procedures for vaccine management.
Standard 14. Providers conduct semi-annual audits to assess immunization coverage levels and to review immunization records in the patient populations they serve.
Standard 15. Providers maintain up-to-date, easily retrievable medical protocols at all locations where vaccines are administered.
Standard 16. Providers operate with patient-oriented and community-based approaches.
Standard 17. Vaccines are administered by properly trained individuals.
Standard 18. Providers receive ongoing education and training on current immunization recommendations.

bursement within the savings they will realize from their vaccine purchase agreements.

Immunization information systems. To assure that all children are immunized at the appropriate age, it is necessary to identify those children who need to be immunized, which vaccines are needed, and to provide any needed follow-up or outreach services. This is particularly important for children (about 40 percent) who go to more than one health care provider and whose parents do not maintain accurate records of their immunizations. To address this problem, an essential component of the President's initiative is the establishment of a state-of-the-art nationally coordinated information system to monitor immunization coverage levels. Such a system would help parents to ensure that their children are receiving vaccines according to recommended schedules.

The legislation proposed by the President provides for a collaborative Federal and State effort to track the immunization status of the nation's children. Immunization levels would be monitored at the local level to track progress toward meeting State and national immunization goals. Federal grants would be provided to States to establish and operate immunization tracking systems containing specific information on each child starting from birth. Such information would include at a minimum: (*a*) immunization history, (*b*) types and lot numbers of vaccines received, (*c*) health care provider identification, (*d*) demographic data, and (*e*) notations of any adverse reactions associated with the vaccine. The information system will have the ability to identify the State tracking system in which the child's immunization record is located. In addition, the national system will link all State tracking systems and transfer actual immunization records when the child relocates to a new State.

Providers would be required to report to the State tracking information regarding each vaccine administered. The efficacy and safety of vaccine would be monitored by linking vaccine administration records with adverse events and disease patterns. The legislation also would require that security measures be established to assure the confidentiality of the information collected. The national immunization tracking system would be fully operational by 1998 (*8*).

Once established, the system will be used to help parents know if their children are properly immunized, as well as to assess vaccine coverage, vaccine effectiveness, adverse events, and evaluate the performance of the nation's immunization programs.

It can also serve as the basis for a patient recall system. An additional objective is the surveillance of disease to assure that vaccines are having the desired impact and that the chosen vaccination strategy is appropriate to meet the disease threat. With detailed information on vaccine coverage and disease incidence, program resources can be directed where they are most needed and lead to effective and efficient use of scarce resources.

National Vaccine Injury Compensation Program. Another important element of the President's initiative is the reauthorization of the National Vaccine Injury Compensation Program (NVICP). The statutory authorization for this program expired on October 1, 1992. The program ensured fairness to injured persons and liability protection for Federal, State, and local immunization programs, vaccine manufacturers, and providers. It was designed to provide prompt and fair compensation to the families of children who died or were injured as a result of routine recommended immunizations and to reduce the adverse impact of the tort system on vaccine supply, cost, and innovation. The legislation proposed by President Clinton would reauthorize payment for compensable injuries attributable to vaccines administered on or after October 1, 1992. It would also provide for the permanent extension and reinstatement of the vaccine excise tax, so that funding for the compensation program would continue to be preserved.

Another component of the proposed legislation includes the provision that any vaccine recommended for universal administration to children would be compensable under the national vaccine injury compensation program. Finally, vaccine information materials currently required to be distributed to parents and guardians would be simplified. The detailed list of items that must be addressed in the information materials would be replaced with a concise and understandable statement of the benefits and risks of the vaccine, and parents would be advised of the availability of the National Vaccine Injury Compensation Program.

Conclusion

The President's Comprehensive Child Immunization Act of 1993, as originally proposed, was introduced in the Congress as S. 732 and S.733 by Sens. Edward Kennedy (D-Mass.) and Donald Riegle (D-Mich.) and as H.R. 1640 in the House of Representatives by Rep. Henry Waxman (D-Calif.). On April 21, 1993, a special joint hearing was held on this legislation by the Senate's Labor and Human Resource Committee and the House of Representatives' Subcommittee on Health and the Environment. Testifying before the joint committee, Secretary Shalala stated "Joint congressional hearings have been traditionally reserved for issues of the highest importance; and I can think of no issue that is more deserving of your time and interest than the immunization of our children against preventable infectious diseases such as mumps, measles, polio, and whooping cough" (*8*). Additional hearings were also held by the Senate Finance Subcommittee on Health for Families and the Uninsured.

To reinforce the importance of immunization to the health of the nation's children, Secretary Shalala has announced the creation of a National Immunization Program that will report directly to the CDC Director. The establishment of this high level organization within CDC to oversee the national efforts for childhood immunization will increase the visibility, focus on the importance, and prepare for future improvements of the childhood immunization program.

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