

Strategies to Sustain Success in Childhood Immunizations

The National Vaccine Advisory Committee

IN 1995, THE NATIONAL VACCINE Advisory Committee (NVAC) identified the need for a comprehensive review of the status of the immunization delivery system and interventions to improve immunization coverage of children. A Subcommittee on Immunization Coverage was appointed by the chairman of the NVAC to review these issues and included representatives from federal agencies, professional organizations, vaccine manufacturers, state and regional health departments, and academic centers. Presentations on immunization programs, strategies, and financing were made to the subcommittee by representatives from federal, state, and local agencies; professional organizations; insurers; businesses; and public and private health care providers. Published studies were also reviewed. Conclusions and recommendations in this report were reached by consensus process among the members of the subcommittee and submitted to the full committee for review, comment, and approval.

This report has been viewed by the NVAC as a follow-up to its 1991 report¹ on the measles epidemic that became a blueprint for the Childhood Immunization Initiative (CII). The CII was a comprehensive effort to improve the quality and quantity of immunization services; reduce vaccine costs to parents; increase community participation, education, and partnerships; improve systems to monitor diseases and immunizations; and improve vaccines and vaccine use.² The CII set 3 goals for

Objective Following an outbreak of measles in 1989-1991, a blueprint for change was developed to improve immunization coverage by addressing deficiencies in the immunization delivery system. A review was undertaken by the National Vaccine Advisory Committee (NVAC) to assess progress in improving immunization coverage, decreasing disease incidence, and developing an immunization delivery system to serve children in the United States. Based on this review, strategies were recommended to sustain success in immunization coverage.

Participants A Subcommittee on Immunization Coverage was appointed by the chairman of the NVAC in 1995 and included representatives from federal agencies, professional organizations, vaccine manufacturers, state and regional health departments, and academic centers.

Evidence Presentations on immunization programs, strategies, and financing were made to the subcommittee by representatives from federal, state, and local agencies; professional organizations; insurers; businesses; and public and private health care providers. Evidence from the published literature also was reviewed.

Consensus Process After review and discussion of evidence presented, conclusions and recommendations were crafted and endorsed by members of the subcommittee. The subcommittee's report was submitted to the NVAC for review, comment, and approval.

Conclusions Although incidence rates of traditional vaccine-preventable diseases are at all-time low levels and corresponding vaccination coverage rates are at all-time high levels, a system to ensure timely vaccination of the 11 000 US infants born each day that also incorporates newly recommended vaccines is incomplete. Key barriers include lack of financing of vaccination in many insurance programs and the lack of implementation of evidence-based interventions to raise coverage levels. The NVAC makes 15 recommendations to achieve a sustainable childhood immunization delivery system organized around (1) vaccination financing to ensure full insurance coverage of recommended vaccines and to support the Vaccines for Children program; (2) provider practices to ensure the implementation of recall/reminder systems and office-based assessment of coverage levels; (3) information systems for monitoring disease, vaccination coverage, and performance on immunization delivery; and (4) support for communities and families to ensure that the public is aware of the importance of vaccination, that resources are focused to help underserved children, that immunization linkages with WIC (the Special Supplemental Nutrition Program for Women, Infants, and Children) are enhanced, and that citizen coalitions can advocate improvements in the immunization delivery system.

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1996: to reduce the number of cases of most vaccine-preventable diseases to zero, to increase the immunization levels of 2-year-olds to 90% for the first and most critical vaccine doses, and to build a vaccine delivery system to maintain high coverage. The CII also set the

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goal that by the year 2000, the infrastructure should be complete and ensure that at least 90% of children receive the full vaccine series.

CURRENT IMMUNIZATION STATUS OF THE NATION'S 2-YEAR-OLDS

The CII disease prevention goals were met or nearly met.³ In 1996, no cases of polio caused by wild poliovirus and no cases of tetanus among children younger than 15 years of age were reported. The number of mumps cases was well below the target of 1600 cases. Reported cases of rubella, diphtheria, and invasive *Haemophilus influenzae* type b (Hib) disease among children younger than 5 years of age were at or near the lowest levels ever recorded. Measles cases were down to 433 indigenously acquired cases from more than 27 000 cases reported at the height of the epidemic in 1990.

The 1996 CII goal to increase immunization rates for critical doses was also met. More than 90% of the nation's children aged 19 to 35 months did receive the first and most critical doses in the primary series for diphtheria and tetanus toxoids and pertussis (DTP), Hib, polio, and measles vaccines.⁴ The goal that at least 70% of 2-year-old children receive 3 doses of hepatitis B vaccine was also achieved. However, only 77% had received the primary immunization series of 4 doses of DTP, 3 doses of poliovirus vaccine, 1 dose of any measles-containing vaccine, and 3 doses of Hib vaccine, commonly known as the "4:3:1:3 series." Approximately 1 million 2-year-old children still need 1 or more doses of vaccine to be fully immunized.

The third 1996 CII goal was to build an immunization delivery system to maintain high immunization coverage. Improved immunization rates have resulted from efforts on the part of local, state, and federal public and private organizations to develop such an immunization delivery system. A system is being built and many parts of that system serve children well, but a comprehensive, efficient system to ensure

that the 11 000 infants born in this country each day get all the vaccines they need to protect them is still a work in progress.

Improvements in the Availability of Immunizations

Vaccines for Children Program. In October 1994, the Vaccines for Children (VFC) program was implemented as part of the CII. This state-implemented, federal entitlement program pays for and distributes vaccine to public and private health care professionals (providers) for their Medicaid patients, uninsured patients, and Native American and Alaska Native patients. Children whose private health insurance does not cover immunizations are entitled to VFC vaccine, but only if administered at a federally qualified health center. Benefits to private providers include the provision of vaccine at no charge to the provider; the capability of providing immunization services in their offices to many patients who would normally be referred to health departments for vaccination, education, and quality improvement activities; and, in many states, augmented reimbursement for the administration of vaccines. The VFC program empowers the Advisory Committee on Immunization Practices (ACIP) by backing up its recommendations with funding for vaccines.

The VFC program is currently operational in all 50 states. Approximately 35% of the infant birth cohort is vaccinated with VFC-purchased vaccine. More than 43 000 provider sites had enrolled in the program as of January 1999; more than 30 000 of the sites are private. Health care providers participating in the VFC program vaccinate more than three quarters of all preschool children using a combination of VFC vaccine for their VFC-eligible children and private or state-purchased vaccine for the rest of their patients.⁵

The VFC program is keeping children in their medical homes. A national survey conducted after the implementation of the VFC program found that 44% of providers who received free

vaccine referred uninsured patients to public vaccine clinics compared with 90% of providers who did not receive free vaccine.⁶ A study conducted among private Medicaid providers in New York City demonstrated that the VFC program not only improved immunization coverage levels among vulnerable children, but that it also had a spill-over benefit of improving the performance of other clinical preventive services by recoupling vaccination into comprehensive primary care.⁷

Role of Private Insurers. Private insurers play a key role in the promotion of adequate immunization. Fifty-four percent of infants and 62% of children 1 through 5 years of age are covered by private health insurance.⁸

Approximately one half of traditional indemnity or fee-for-service private insurance plans include immunization benefits.⁹ It has been suggested that the increased cost of inclusion of immunizations in a family's standard benefits package may be a barrier to improving insurance benefits for children covered by traditional indemnity insurance. Also, the addition of new and possibly costly vaccines to existing immunization benefits has been cited as an impediment to insurance coverage of vaccines.¹⁰

Virtually all health maintenance organizations (HMOs) cover immunizations. The role of managed care in promoting immunizations is critical, as the number of people who receive health care in HMOs has increased from 6 million in 1976 to an estimated 56 million in 1995.¹¹ Enrollees in HMOs include more than 13 million Medicaid beneficiaries.¹²

State governments have improved the availability of immunizations by enacting legislation mandating coverage of immunizations by regulated insurance plans. Twenty-six states have insurance mandates in place.¹³ These laws cover only those insurance plans that are regulated by the state. Approximately 40% of the nation's employee health benefit plans are exempt from regulation under the federal Employee Retirement Income Security Act

(ERISA).¹⁴ However, employers who self-fund their insurance plans and are exempt from regulation under ERISA may be influenced by state mandates. One quarter of self-funded employers surveyed in Pennsylvania added immunization benefits to their health plans after a state law mandating coverage was passed; one half of them cited the mandate as influencing them to expand coverage.¹⁵

One third of infants and 29% of children aged 1 through 5 years are Medicaid enrollees. Providers who refer Medicaid patients to local health departments for immunizations have cited inadequate Medicaid reimbursement as a factor in their decision to refer.^{16,17} The VFC program addressed a large part of this problem by providing public-purchase vaccine to Medicaid providers at no cost. In addition, reimbursement rates for administration have improved in most states compared with previous fee-for-service Medicaid rates (Centers for Disease Control and Prevention [CDC], unpublished data, April 1997).

Improvement in Delivery of Immunizations

Standards for pediatric immunization practices were released in May 1992 and were widely promulgated in the medical and public health literature.¹⁸ The 18 standards were developed to provide guidance for the rapid, efficient, and consumer-oriented provision of immunization services as part of comprehensive primary care. In a prospective comparison of 2 public health clinics, there was a 40% improvement in immunization rates for children served at a clinic that had systematically implemented the standards compared with a control clinic where the standards were not systematically implemented, although some were in place as part of routine practice management.¹⁹

Monitoring Immunization Coverage

The National Immunization Survey is the primary means to measure national, state, and urban-area coverage

levels and progress toward national coverage goals. The National Immunization Survey collects immunization histories, the names and locations of the immunization providers, and demographic information for children aged 19 to 35 months in each state, the District of Columbia, and 27 urban areas. Age-eligible children are selected using random-digit telephone dialing methods, and adjustments are made for the bias associated with selection of only those families with telephones by using National Health Interview Survey data. Immunization information is also collected from the health care providers for sampled children; provider verification improves the accuracy of the data and adds additional information to help monitor the immunization delivery system.

NEW KNOWLEDGE ABOUT BARRIERS

Since the publication of the "Measles White Paper," extensive efforts have been made to systematically identify key barriers to immunization.²⁰ The most powerful and persistent barriers to timely immunization are poverty and factors associated with poverty.²¹⁻²⁴ Despite improvements in coverage levels for poor children, an 11-percentage point gap between children above and below the federal poverty level persists for completion of the 4:3:1:3 series.²⁵ For single antigens, the gap varies from 11% for the fourth dose of DTP to 4% for the third dose of polio vaccine.

Parental and provider attitudes about immunizations are not barriers for the majority of underimmunized preschool children. In general, parents and providers believe in the health benefits of immunizations. In a study of mothers of poor urban infants, underimmunization was more strongly associated with demographic factors than with overall belief in the importance of immunizations and the seriousness of the diseases they prevent.²⁶ Belief that the timing of immunizations is not important was the only attitude that was consistently associated with late re-

ceipt of immunizations. However, there are children whose parents are against vaccination and for this group, parental attitudes obviously pose a barrier. Underimmunized children entering school, including those with medical and religious exemptions as well as those whose parents refuse immunizations, currently constitute only 1% to 3% of the school population.

Critical Barriers to Immunization

Children often fall behind in their immunizations because their parents do not know when immunizations are due.^{27,28} Parents may not seek immunizations because they believe their child's immunizations to be up-to-date. Ninety percent of parents in a pediatric specialty clinic reported that their child's immunizations were up-to-date, but 24% of those whose records could be assessed needed immunization.²⁹ Inadequate immunization histories can also lead to the receipt of unnecessary immunizations. One third of children who received care in a public clinic system with a fragmented record keeping system received 1 or more unnecessary immunizations compared with 5% of children seen in private practices or public clinics with a more integrated record keeping system.³⁰

Provider practices play a critical role in underimmunization. Providers believe that they are providing appropriate immunization services, but they often overestimate immunization coverage in their practice.³¹ They may have no system to identify underimmunized children^{32,33} and do not operate recall/reminder systems. Making the requisite number of health supervision visits does not guarantee appropriate immunizations. In Baltimore, Md, inner-city children were underimmunized even though they had made appropriate health supervision visits.³⁴ In a national study of immunization rates at 8 months of age, 60% of underimmunized infants had at least 3 health supervision visits.³⁵ Failure to assess immunization status can contribute to missed opportunities to immunize re-

ardless of the type of visit.^{31,36} Even if immunization status is reviewed, inadequate records and inaccurate assessment of immunization status can result in missed opportunities.^{37,38} Some providers do not believe that all vaccine doses should be administered simultaneously,³⁹ and failure to administer all vaccines for which the child is due can lead to underimmunization.⁴⁰ Missed opportunities occur in clinics serving poor children,^{41,42} in managed care practices, and in other health care sites.⁴³ The most successful strategies to improve immunization rates by reducing missed opportunities may be those that involve simple changes to provider or practice routines.⁴⁴

The cost of immunization services poses a barrier.^{45,46} These costs include the cost of the visit to an immunization provider, the fee for vaccine administration, and the cost of the vaccine itself. Many insurance products fail to cover the entire cost of vaccination services. More than one half of pediatricians in a study conducted in 1992⁴ referred some of their patients to another source of care for immunizations. Most referring physicians reported financial hardship for patients as an important reason for referral. More than one half cited parent refusal of immunization due to cost. Referrals were not limited to uninsured children or those with publicly financed insurance. More than one half of physicians referred patients with private insurance that did not provide full coverage of immunization services.

NEW KNOWLEDGE ABOUT INTERVENTIONS

In addition to new knowledge about barriers, new knowledge has been gained about immunization interventions that work and those that do not. A recent review of the scientific evidence on the effectiveness of 17 interventions to raise immunization coverage levels was recently conducted and published.⁴⁷ Interventions that have been found to be effective include the following: enhancement of immunization services in WIC (the Special Supplemental Nutrition Program for

Women, Infants, and Children) clinics (especially for vulnerable children),^{48,49} use of recalls/reminders,^{50,51} provider-based tracking,⁵² and provider-based assessment of immunization rates with feedback.^{53,54} Efforts to reduce missed opportunities are potentially effective.⁵⁵ There has been little evidence to show effectiveness of 1-day immunization events^{56,57} or administration of immunizations at emergency department visits.^{58,59}

Successful interventions generally rely on the ability to obtain complete immunization histories, whether it is to determine the immunization status of a child who presents for care in the provider's office, to refer a child who has come for other services such as WIC, to send recalls/reminders to parents of children due or overdue for immunizations, or to examine broader issues of practice or program performance.

Technological advances in information systems provide a method to improve immunization delivery through the development of immunization registries that make many of the evidence-based interventions to raise and sustain high vaccination coverage possible. The NVAC supports development of immunization information systems⁶⁰ and completed and unanimously endorsed an immunization registry plan of action in January 1999.

KEEPING UP WITH CHANGE: CHALLENGES FOR THE FUTURE Vaccine Safety

A cornerstone of a successful immunization program is the need to use the safest vaccines possible and to assure the public and their immunization providers that policies and programs exist to continually ensure the safety of vaccines and their administration. The National Vaccine Program has developed a comprehensive Vaccine Safety Action Plan, which was endorsed by the NVAC in January 1999.⁶¹ The overall objective of the plan is to ensure the optimal safety of vaccines with a focus on surveillance and epidemiology, research and development, communica-

tion, and education. One component of the plan already implemented is the Vaccine Safety Datalink Project, which was established to fill the gaps in knowledge about vaccine-associated adverse events.⁶² This collaborative effort between the CDC and participating HMOs allows examination of the association between vaccine administration and medical outcomes using a large sample of children who have received immunizations at participating sites.

Development of New Vaccines and Changes to the Immunization Schedule

The past few years have seen remarkable developments in the formulation of new vaccines and the development of combination vaccines. Since 1991, many changes have been made to the recommended immunization schedule, including the addition of new vaccines, newly formulated vaccines, and combination vaccines as well as changes to the schedule for existing vaccines. More changes to this already complex schedule can be anticipated. Dissemination of information to providers and parents regarding new vaccines and changes to the schedule will remain essential to the maintenance of current immunization rates.

Changes in the Health Care Delivery System

Changes in the health care delivery system will continue to have an impact on the delivery of immunizations. The VFC program has resulted in the return of children to their primary providers for comprehensive health care. An increasing portion of Americans see providers in managed care settings. More and more children with publicly funded care are seen in the private sector by managed care providers. Public health services are being privatized in some areas. Recommendations to sustain improvements in immunization coverage must be made in the context of an emerging public-private partnership.

The complete immunization of 77% of our 2-year-old children for the 4:3:1:3 series is cause for encouragement, but

23% of these children are missing 1 or more vaccines to complete the series. The more children successfully protected, the harder it will be to identify those still at risk who are likely to be clustered in pockets of need, where barriers to vaccination still exist⁶³ even though the vast majority of children have access to a medical home for primary care.⁶⁴ Interventions like WIC linkages that help ensure the vaccination of difficult-to-reach children may be very helpful in underserved areas.

RECOMMENDATIONS

The NVAC makes the following recommendations to sustain success in immunization coverage. Development of the recommendations was guided by the knowledge gained about barriers and interventions as well as the overarching challenges for the future outlined above.

Financing

1. All health insurance plans, including ERISA self-insured plans, should offer first-dollar coverage for childhood vaccines that are recommended in the harmonized immunization schedule endorsed by the ACIP, the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

- First-dollar coverage should include adequate reimbursement for both vaccine and administration.
- All states should require, through law or regulation, first-dollar coverage for immunizations.
- The CDC should review and circulate model legislation and regulations.
- Congress should enact legislation to require first-dollar coverage for ERISA self-insured plans.
- All employers should ensure the health plans they offer to employees and their families include comprehensive childhood immunization coverage.

2. Managed care organizations and managed Medicaid plans should ensure complete immunization of their members using the current harmo-

nized schedule endorsed by the ACIP, the AAP, and the AAFP.

- State health department immunization program leadership should take an active role in setting the immunization standards and negotiating the state's contracts for Medicaid managed care.
 - The CDC should circulate to states and employers model managed care legislation, licensure requirements, and contract language that address the provision of immunization services.
 - Managed care organizations should use effective strategies to improve and maintain immunization coverage levels of their members. These strategies might include recall and/or reminder systems, practice-based coverage assessments, and provider incentives and education.
3. Indemnity health and self-insured plans should ensure complete immunization of their members using the current harmonized schedule endorsed by the ACIP, the AAP, and the AAFP.
- All packages offered by indemnity and self-insured health plans should include immunization benefits.
 - Plans should use billing or encounter data to evaluate coverage levels of insured children and recall those in need of immunization.
 - Plans should disseminate information for the improvement of immunization practices, including schedule changes, to participating child health care providers.
 - Plans should use effective strategies to improve immunization coverage levels of their members. These strategies might include recall and/or reminder systems, practice-based coverage assessments, and provider incentives and education.
4. The VFC program should be supported.
- States should work to increase provider enrollment.
 - State Medicaid programs should encourage all Medicaid-enrolled providers who immunize children to participate in the VFC program.
 - State and local immunization pro-

grams should work with their respective chapters of the AAP, the AAFP, and other provider groups to recruit their members into the VFC program.

- States should ensure that all vaccines as recommended by the ACIP are available to all VFC-eligible children.

Provider Practices

5. All immunization providers, public and private, should assess the immunization coverage levels of their patients annually.

- State and local health departments should ensure that all public clinics are assessed.
 - Private providers should assess their practices with the available support and assistance from state and local health departments, professional associations, and managed care organizations and other insurers.
6. All immunization providers, public and private, should operate recall and reminder systems.
- The CDC should develop a clearinghouse for the collection and dissemination of model recall and reminder systems.
 - The CDC should work with the AAP, the AAFP, and other professional organizations to promote routine use of recall and reminder systems among their membership.
 - State and local health departments should support the development and coordination of, as well as provider participation in, recall and reminder systems.

Monitoring

7. Immunization registries involving both public and private providers should be developed in each state.

- The CDC should conduct evaluations to monitor the status of registry development and to facilitate registry implementation, including private sector participation, through the identification of critical needs, best practices, and legal barriers.
- A stable funding mechanism for immunization registries needs to be

developed that combines resources from the federal government, state and local governments, and the private sector.

- The use of immunization registries to assist in the monitoring of adverse events and efficacy of the recommended vaccines should be explored.

- Immunization registries should be developed with the capabilities of identifying underimmunized populations at risk for vaccine-preventable diseases and supporting interventions that improve coverage levels.

8. The National Immunization Survey should be the primary means of evaluating the immunization delivery performance of the nation as well as the states and major urban areas, until immunization registries are fully functioning.

9. Health Plan Employer Data and Information Set (HEDIS) measures on immunization, both private sector and Medicaid, should be used by all purchasers and plans.

- HEDIS measures for evaluation of immunization coverage should continue to be updated and improved to better reflect actual coverage levels.

10. Evaluations of program performance as well as research into the most cost-effective strategies for achieving and sustaining high immunization coverage should be continued.

- Methods should be developed to monitor and evaluate the effectiveness of the changing health care system on immunization delivery.

- Integration of the delivery of immunizations into comprehensive primary care should be encouraged and evaluated to assess impact on overall child health and health care.

- Innovative state and local strategies to improve immunization coverage and efficiency of delivery should be evaluated.

- The safety as well as efficacy of current and new vaccines should continue to be evaluated.

11. Disease surveillance activities at the state and local levels are essential for

the prevention of disease and warrant support with federal and state immunization program funds.

- Laboratories have an essential role in surveillance, case investigation, outbreak control, and disease elimination. Laboratory capacity must be developed, maintained, and readily accessible to state and local public health officials.

- The quality of surveillance activities should be routinely monitored and continuous efforts made to improve surveillance and case investigation.

- States should comply with accepted indicators of surveillance quality and furnish that information to the CDC.

- Training of local health department personnel responsible for surveillance, case investigation, and outbreak control activities is essential and should be supported by immunization program funds.

Support for Communities and Families

12. Parents should be supported in their efforts to immunize their children.

- Public awareness campaigns to improve parents' knowledge about the importance of immunizations should be sustained and/or initiated, particularly in underserved areas.

- Providers and third-party payers should inform and remind parents about the current harmonized immunization schedule.

- Outreach through telephone, mail, and home visits, should be used to connect hard-to-reach families to well-child services, particularly immunizations, in a culturally sensitive manner.

13. Immunization programs should collaborate with WIC to assess the immunization status of each child enrolled in WIC and to refer underimmunized children to their provider.

- WIC clinics serving areas at greatest risk of vaccine-preventable diseases, especially those in underserved populations, should be the highest priority.

- Immunization programs should share the cost of assessing the immunization status of WIC participants.

- Colocating clinics and coscheduling of appointments among WIC, immunization services, and comprehensive child health care ("1-stop shopping") should be encouraged.

14. The CDC and state and local immunization programs should focus resources on underimmunized populations at risk of vaccine-preventable diseases.

- Resources should be concentrated on activities that improve immunization coverage for populations who are at risk for underimmunization.

- The CDC should work with the states to explore innovative methods for enhancing performance and ensuring accountability for the resources devoted to populations at risk for underimmunization.

- The CDC should continue to work with state and local health departments to identify high-risk populations, activities that are likely to be most effective at improving and sustaining high coverage levels, and methods to evaluate the impact of the activities.

15. Citizen coalitions should be encouraged in state and local communities to advocate for improvement and maintenance of high immunization coverage levels.

Committee History: The National Vaccine Advisory Committee (NVAC) was chartered in 1988 to advise and make recommendations to the director of the National Vaccine Program and the assistant secretary for health, Department of Health and Human Services, on matters related to the prevention of infectious diseases through immunization and the prevention of adverse reactions to vaccines. The NVAC is composed of 15 members from public and private organizations representing vaccine manufacturers, physicians, parents, and state and local health agencies and public health organizations. In addition, representatives from governmental agencies involved in health care or allied services serve as ex-officio members of the NVAC. This report has been approved by the assistant secretary for health of the Department of Health and Human Services.

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Much of our failure to understand human nature arises from neglect of this need to have our faculties excited and our lives thereby enhanced. The human animal cannot be itself without this exciting enhancement. Excitement is not merely good; it is indispensable to a proper human life.

—Lancelot Law Whyte (1896-1972)