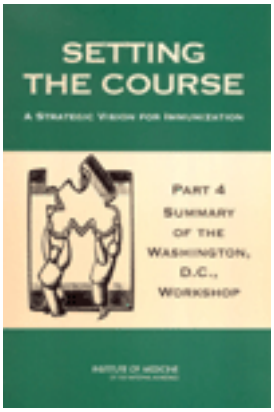


**Setting the Course: A Strategic Vision for Immunization -- Part 4: Summary of the Washington, D.C. Workshop**

Committee on the Immunization Finance Dissemination Workshops

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# SETTING THE COURSE

## A Strategic Vision for Immunization

## Part 4
## Summary of the Washington, D.C., Workshop

Committee on the Immunization Finance Dissemination Workshops

Board on Health Care Services

INSTITUTE OF MEDICINE
*OF THE NATIONAL ACADEMIES*

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*"Knowing is not enough; we must apply.*
*Willing is not enough; we must do."*
—Goethe



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## REVIEWERS

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

**Bernard Guyer,** M.D., M.P.H., Chair, Department of Population and Family Health Sciences, Johns Hopkins University Bloomberg School of Public Health

**Sara Rosenbaum,** J.D., Director, Center for Health Policy Research, School of Public Health and Health Services, The George Washington University

**Sandra Ross,** Immunization Program Coordinator, Health and Human Services Agency, San Diego, California

**Jane E. Sisk,** Ph.D., Professor**,** Department of Health Policy, Mount Sinai School of Medicine

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the final draft of the report before its release. The review of this report was overseen by Neil Vanselow, M.D., Rio Verde, AZ. Appointed by the National Research Council, he was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

## ACKNOWLEDGMENTS

The Institute of Medicine (IOM) workshop on immunization finance was organized with the assistance of several health care organizations and health care providers throughout the metropolitan area of Washington, DC, including the Association of State and Territorial Health Officialss, the American Academy of Pediatrics, the American Association of Health Plans, and the Washington Business Group on Health. Staff from the National Immunization Program of the Centers for Disease Control and Prevention (CDC) in Atlanta helped to identify immunization program directors and public health advisers who served as speakers and participants in the workshop. CDC officials also prepared data analyses and exhibits to inform the workshop discussions.

The IOM workshop was audiocast on March 18, 2002. Electronic files of the speakers' presentations are available at the IOM website: www.iom.edu/iom/iomhome.nsf/Pages/Immunization+ Finance+dc+agenda.

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# Executive Summary

Although not always apparent, the need to maintain a quality infrastructure in support of immunization goals remains a high priority across the nation. Developing a plan to determine how the costs of this effort should be allocated across the federal, state, and private health agencies is a significant challenge, especially during times of declining budgets and competing demands on public health resources.

The annual costs of achieving high levels of immunization coverage for children and adults in the United States on a routine basis are significant, exceeding more than $120 million for infrastructure and program support alone. These investments support diverse efforts within the Centers for Disease Control and Prevention (CDC) and state health departments—supplemental purchases and administration of vaccines for disadvantaged populations; routine monitoring and surveillance efforts; and special national, state, and local initiatives designed to improve levels of immunization coverage among difficult-to-reach populations. Although children are the traditional focus of the national immunization system, the availability of vaccines to protect adolescents and adults requires innovative approaches and new strategies. Yet persistent financing challenges impede efforts to assure that vaccines are available to all who need them.

Federal and state governments have developed a national partnership for immunization. In recent years, the multiple finance arrangements that support this partnership have become unpredictable. In 2000, the Institute of Medicine (IOM) produced a report *Calling the Shots: Immuniza-*

*tion Finance Policies and Practices* (IOM, 2000a) that illustrated the uncertainties and instability of the public health infrastructure that supports U.S. immunization programs. The IOM report proposed several strategies to address these concerns and to strengthen the immunization infrastructure.

In March 2002, a group of 50 health officials, public health experts, health care providers, health plan representatives, health care purchasers, and community leaders met at The National Academies in Washington, DC to explore the implications of the IOM findings and recommendations for the federal and state governments. Private health plans and business-sector representatives also participated in the meeting to discuss their role in fostering high levels of immunization coverage. The one-day workshop was the fourth and last in a series of meetings organized by IOM with support from the CDC to foster informed discussions about future financing strategies for immunization and the public health infrastructure.

This report of the Washington, DC workshop summarizes the findings of the IOM study, reviews the implementation of the IOM recommendations, and highlights continuing immunization finance challenges for the nation as a whole as well as state and local health departments. The participants identified strategies to preserve and support traditional public health efforts such as outreach, education, and monitoring and surveillance, and also examined the new demands on the immunization system associated with delivering a higher proportion of vaccines in the private health sector. The stresses and tensions associated with the shift in immunization service settings raised new concerns about the roles of public health departments and the manner in which those roles should be financed. The special difficulties of the public health system in maintaining vigilance when visible signs of infectious disease outbreaks are not apparent received much attention.

# Introduction

In June 2000, the Institute of Medicine (IOM) released a report resulting from an 18-month study of the national immunization finance system in the United States (Institute of Medicine, 2000a). The IOM study was originally requested by the Senate Appropriations Committee of the U.S. Congress, which had expressed concerns about the sudden shifts in federal immunization budgets and uncertainties about the nature of the federal and state partnership in supporting immunization efforts.

The IOM report, titled *Calling the Shots*, offered a conceptual framework for immunization programs to clarify the types of roles that required support in the public health system. In developing this report, the study committee drew upon research literature from multiple disciplines; eight case studies (Fairbrother et al., 2000)[1]; a national survey of state-level immunization programs (Freed et al., 2000); site visits to the cities of Detroit, Newark, Houston, San Diego, and Los Angeles; and a national workshop in September 2000 that focused on issues related to addressing the immunization problems of pockets of need within the United States. The committee also commissioned background papers on topics such as adult immunization, registries, measuring immunization coverage (Fairbrother et al., 2000), and federal immunization policy (Johnson et al.,

[1]Each case study is available electronically via the website of The National Academies Press at *www.nap.edu/html/case_studies.*

2000). Selected portions of these materials were published in a supplemental issue of the *American Journal of Preventive Medicine* in October 2000.

The findings of the IOM report noted that although childhood immunization levels are high, federal, state, and private-sector investments in vaccine purchases and immunization programs are lagging behind emerging opportunities to reduce the risks of vaccine-preventable disease. Furthermore, three key trends have produced significant instability in the national immunization system:

1. Rapid acceleration in the science of vaccine research and production;
2. Increasing complexity of the health care services environment of the United States (represented by trends such as the emergence of managed care as the primary health care providers for low-income populations); and
3. Recent reductions in federal immunization grants to the states, which followed on the heels of dramatic increases in the early 1990s.

In response to these trends, the IOM report recommended that the federal and state governments increase their investments in the public health infrastructure for immunization. The study committee recommended that a total of $1.5 billion be allocated in federal and state resources over 5 years, an annual increase of $175 million over current spending levels. The committee also recommended that Congress replace the current Section 317 discretionary grants to the states with a formula approach to provide a base level of support for all states as well as additional amounts related to each state's need, capacity, and performance.

Following the publication of *Calling the Shots*, IOM convened three regional workshops to review the findings and recommendations of the report and to identify areas of consensus as well as unresolved concerns that require future attention by public and private officials in strengthening the national immunization system. The IOM immunization workshop series and summary reports of each meeting are designed to achieve the following goals:

- Foster awareness of the conclusions and recommendations of *Calling the Shots*;
- Strengthen interactions among public- and private-sector health officials to build consensus about immunization infrastructure initiatives, measurement approaches, and financing plans; and
- Identify unresolved public health and health finance issues and concerns at the regional, state, and local levels that require further attention from public and private policymakers.

The first of the three regional workshops, held in June 2001 at the University of Illinois School of Public Health in Chicago, examined statewide concerns in Illinois and Michigan and the challenges facing the cities of Chicago and Detroit in sustaining efforts to improve immunization rates (IOM, 2002a). A second workshop was held in October 2001 at the Texas Medical Association in Austin, Texas. Discussions at that meeting highlighted concerns of private providers throughout the state and opportunities for greater public–private collaboration in financing vaccine purchase and service delivery (IOM, 2002b). The third regional workshop was held in January 2002 at the University of California at Los Angeles (UCLA), with a special focus on public health partnership efforts in Los Angeles and San Diego Counties (IOM, 2003). The meeting, which was organized by IOM in collaboration with the School of Public Health at UCLA and the Los Angeles County Health Department, featured presentations by state and local health officials; health care providers; representatives of health plans and corporate health care purchasers; faculty from UCLA and the University of California at San Diego; community leaders; and Centers for Disease Control and Prevention (CDC) staff.

This report of the Washington, DC workshop summarizes the findings of the IOM study *Calling the Shots*, reviews the status of implementation of the IOM report recommendations at the federal and state levels, and highlights continuing challenges in immunization finance for the nation as a whole and for individual state and local health departments. Participants in the workshop included members of the original study committee and the workshop program committee; consultants and other contributors to *Calling the Shots*; state and local health directors; representatives of national health care and public health organizations, health plan associations, and business groups; health care providers; congressional staff; and staff from the CDC National Immunization Program and other federal agencies concerned with immunization. (See Appendixes A, B, and C for the workshop agenda, a list of participants, and addresses of Internet websites that pertain to the IOM report and the workshop discussions.)

# A National Perspective on the Immunization System

As noted in *Calling the Shots*, the federal and state governments built a dynamic and flexible immunization system during the 1990s that has adapted to extensive changes in the science of vaccines, in demographic patterns, and in service delivery patterns in the health care sector. The report describes the national immunization system as "a national treasure that is too often taken for granted." The "system" actually consists of an intricate maze of public- and private-sector activity, some of which is extensively coordinated through governmental policies and programs, but much of which occurs independently through immunization efforts within private medical offices. Within this system, vaccines are either sold directly to health care providers or are purchased by public health agencies and then distributed to the providers through state-administered immunization programs.

## THE NATIONAL IMMUNIZATION PARTNERSHIP

David Smith, vice chair of the Institute of Medicine (IOM) Committee on Immunization Policies and Practices and chancellor of the Health Sciences Center of Texas Tech University, opened the Washington, DC workshop with an overview of the national immunization system and the findings and recommendations of the IOM study. He observed that childhood immunization rates are the highest on record: more than 90 percent of all U.S. children have completed the recommended series of immunization by the time they are ready to enter school, and 79 percent of all

young children are up to date by age 2. Despite these achievements, the national childhood immunization rate still falls short of the recommended goal of 90 percent coverage for all 2 year olds. Adult rates, though improving, are especially low among those with chronic health conditions (such as heart and lung disease or diabetes), and those adults are especially vulnerable to communicable disease. Furthermore, although national- and state-level disparities in immunization levels among racial and ethnic groups have declined, persistent gaps remain among the most disadvantaged populations of children. For example, one study of children in East Los Angeles indicated that only 49 percent of young children in a very poor neighborhood were up to date with their immunizations, compared with 71 percent of all children in the Los Angeles area (Shaheen et al., 2000). Similar findings were reported in Chicago, where 29 percent of African-American children in public housing were up to date compared with 59 percent of children from the same racial group nationwide (Kenyon et al., 1998). Dr. Smith noted that one million 2 year olds are not fully immunized in the United States, and the challenge is to reduce this gap, given the birth cohort of 11,000 new babies each day.

Focusing on key immunization challenges for the future, Dr. Smith called attention to the growing complexity of the immunization schedule, the development of new vaccines that will need to be integrated into the health care system, and concerns about vaccine safety. He illustrated the number of changes that occurred in the immunization schedule from 1975 to 2000 (Figure 1) and cited additional examples of vaccines that are in early stages of research or development (Table 1).

Organizing a system to deliver the growing number of vaccines for children and adults in the public and private sectors has required a national immunization partnership consisting of multiple interests, including federal and state health agencies, clinicians, health care plans, and employers. The highly decentralized nature of this system is also one of its strengths, Dr. Smith noted. Its flexible nature has allowed the immunization system to adapt to different needs and resources within local health care environments. However, the instability of federal and state roles within this system has grown in recent years, diminishing the capacity of health care providers to adapt to patterns of rapid acceleration in vaccine science, the emergence of new health care arrangements for disadvantaged populations (such as the creation of the new State Children's Health Insurance Plan), and the immunization needs of adolescents and adults.

In her comments, IOM committee member Sara Rosenbaum from The George Washington University observed that the leadership exerted by the federal government in allocating funding for immunization programs within the states needs to be carefully reexamined within the new conceptual framework developed in the IOM study. Taking the Section 317 grant

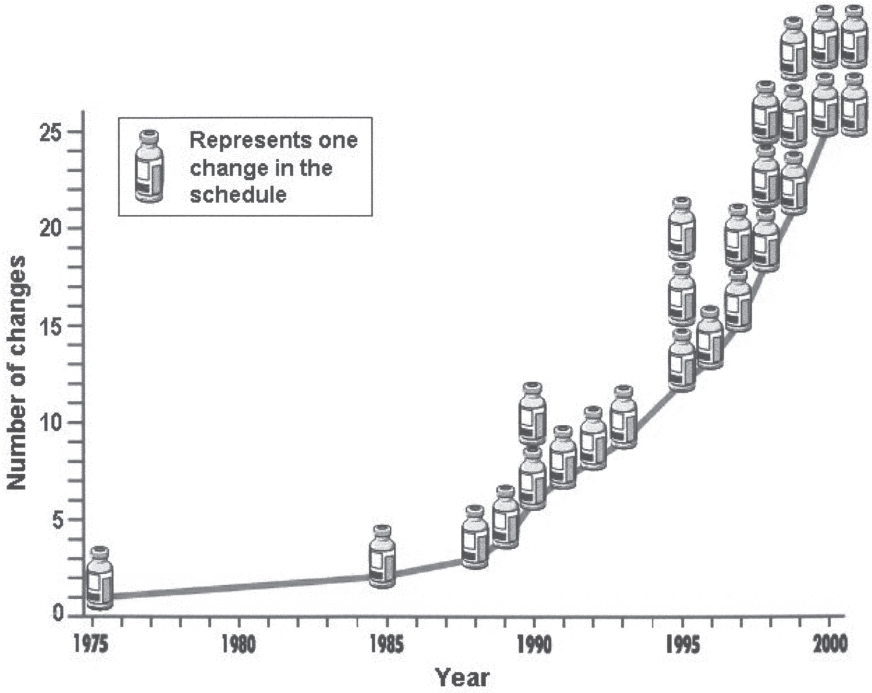


**FIGURE 1** Changes in the childhood vaccine schedule, 1975–2000.

program from a pure federal allocation process, for example, to a newer partnership with both the public and private sectors requires a renegotiation of guiding assumptions, shared roles, and new responsibilities. She indicated that stimulating a dialogue about financing health programs with the states will be difficult during periods of fiscal restraint and decreasing revenues. Yet the findings of the report deserve periodic revisiting and updating to address new and unexpected circumstances within the national immunization system.

William Schaffner from Vanderbilt University, a member of the program committee for the IOM workshops, commented that the expectation of a prompt response from the states in addressing problems within the immunization infrastructure may be unrealistic. The lack of cultural memory of disease outbreaks, in particular, leads to passivity and complacency in supporting ongoing immunization efforts. In addition, addressing the vaccine needs of the adult population within a system that is designed primarily for pediatric groups is challenging. Nevertheless, the vast majority of vaccine-preventable disease occurs annually among

adults, and an insufficient amount of resources exists to build an adequate infrastructure to meet their needs. Furthermore, many private and public health insurance plans for adults do not include benefits for routine vaccines or provide extremely low reimbursement fees for physicians who administer vaccines. For example, Medicare does not include compensation for the administration of vaccines for adults under age 65.

## THE INSTITUTE OF MEDICINE STUDY

The U.S. Senate Committee on Appropriations commissioned the IOM study in 1999 to examine recent trends that affect the level of resources available for the national immunization system. IOM was asked, in particular, to focus on the history of the Section 317 program, a federal public health grant activity administered by the Centers for Disease Control and Prevention (CDC) that supports state-administered immunization programs. The Section 317 program consists of two types of awards: vaccine purchase and infrastructure support. Although resources for vaccine purchase awards have remained relatively stable during the 1990s (total annual awards to the states average about $160 million), the level of support for infrastructure has experienced rapid increases, followed by dramatic declines. The baseline annual average for FY 1994–1999 for the infrastructure awards was $271 million, compared to a level of $123 million for FY 2000. As a result, much uncertainty remains about the level of federal funding that is adequate to support a national immunization infrastructure program and the types of incentives that will encourage states to support these efforts.

Dr. Smith summarized the conclusions of the IOM report:

- The repetitive ebb and flow cycles in the distribution of public resources for immunization programs have created instability and uncertainty that impeded project planning at the state and local levels in the late 1990s and delayed the public benefit of advances in the development of new vaccines for both children and adults. This instability now erodes the continued success of immunization activities.
- Immunization policy needs to be national in scope. At the same time, the implementation of immunization policy must be flexible enough to respond to special circumstances that occur at the state and local levels.
- Federal and state governments each have important roles in supporting not only vaccine purchase, but also infrastructure efforts that can achieve and sustain national immunization goals.
- Private health care plans and providers have the capacity to do more in implementing immunization surveillance and preventive programs within their health practices, but such efforts require additional

**TABLE 1** Vaccines in Widespread Use, 1985–2020

| 1985 | 2000 | 2020[a] |
|---|---|---|
| Adult influenza | Adult influenza | Adult influenza[c] |
| Adult pneumococcal polysaccharide | Adult pneumococcal polysaccharide | Adult pneumococcal polysaccharide |
| Diphtheria, pertussis, tetanus, and components | Diphtheria, tetanus, acellular pertussis, and components[b] | DtaP[c] |
| Measles, mumps, and rubella (MMR) | MMR[b] | Measles, mumps, rubella, and varicella[c] |
| Oral poliovirus | Inactivated poliovirus[b] | Eradication of polio expected |
| | *H. influenzae* type b[b] | Hib[c] |
| | Hepatitis A[b] | Hepatitis A[c] |
| | Hepatitis B[b] | Hepatitis B[c] |
| | Varicella[b] | Varicella with MMR |
| | Pediatric conjugate of pneumococcal polysaccharide | Pediatric conjugate of pneumococcal polysaccharide[c] |
| | *Borrelia burgdorferi* | *Borrelia burgdorferi* |
| | Meningococcal polysaccharide A,C,Y,W-135 | Conjugated meningococcal polysaccharide A,B,C,Y,W-135[c] |
| | | Adult tetanus, diphtheria, acellular pertussis, and components[c] |
| | | Chlamydia |
| | | *Coccidioides immites* |
| | | Cytomegalovirus |
| | | Enterotoxigenic *E.coli* |
| | | Epstein-Barr |

assistance, oversight, and incentives. At the same time, comprehensive insurance and high-quality primary care services do not replace the need for public health infrastructure.

Building from these conclusions, the IOM committee developed a conceptual framework that identifies six key roles for the national immunization system (Figure 2). This framework subsequently provided the organizational structure for recommendations in the IOM report (Box 1). The recommendations call for additional public investments at the federal and state levels to strengthen the immunization infrastructure and to expand the system beyond a childhood population to reach adults at risk of vaccine-preventable disease.

**TABLE 1** Continued

| 1985 | 2000 | 2020[a] |
|---|---|---|
| | | *Helicobacter pylori*[c] |
| | | Hepatitis C[c] |
| | | Herpes simplex |
| | | *Histoplasma capsulatum* |
| | | Human papillomavirus[c] |
| | | Child influenza[c] |
| | | Insulin-dependent diabetes mellitus (therapeutic) |
| | | Melanoma (therapeutic) |
| | | Multiple sclerosis (therapeutic) |
| | | Mycobacterium tuberculosis |
| | | *Neisseria gonorrhea* |
| | | *Neisseria meningitidis* B |
| | | Parainfluenza[c] |
| | | Respiratory syncytial virus[c] |
| | | Rheumatoid arthritis (therapeutic) |
| | | Rotavirus[c] |
| | | *Shigella* |
| | | Streptococcus, Group A[c] |
| | | Streptococcus, Group B |

[a]Priority candidate vaccines, drawn from IOM, 2000b.
[b]Vaccines covered by Vaccines for Children (VFC) as of February 2000.
[c]Vaccines likely to be recommended for universal use (including VFC coverage for childhood vaccines).

NOTE: Latin disease names are in italics.

## RESPONSE FROM THE CENTERS FOR DISEASE CONTROL AND PREVENTION

Walter Orenstein, Director of the National Immunization Program of the CDC, described the IOM report as a great success and offered his thanks to IOM for the efforts involved. He described actions taken within Congress and CDC in response to the report's recommendations.

Congress appropriated about half of the recommended funds to support the Section 317 operations grants infrastructure in FY 2001 ($42.5 million), and an additional $18.7 million was expected in FY 2002. These increases were expected to bring the annual grant award budget for the Section 317 infrastructure program to about $182 million, which is a sub-

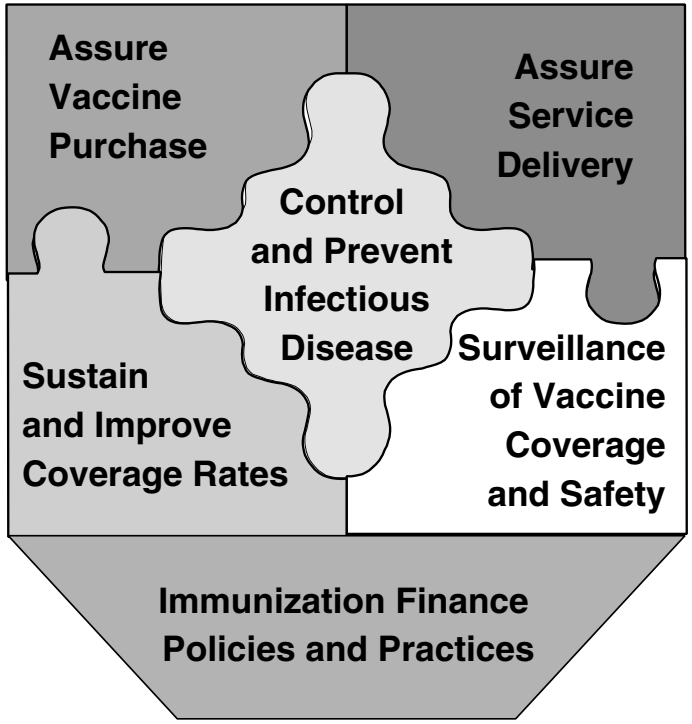


**FIGURE 2** Six roles of the national immunization system (IOM, 2000a).

stantial increase over recent funding, but still below the $200 million annual level recommended by the *Calling the Shots* report.

In addition, CDC has convened a group of stakeholders to consider the merits of improving the allocation of discretionary infrastructure grants by considering the critical elements described by IOM. Key partners in this effort include the Association of State and Territorial Health Officials and the Association of Immunization Managers. This advisory group is considering ways to implement the criteria recommended by IOM—a base-level award for each state, plus additional amounts that reflect calculations of need, capacity, and performance. CDC is further refining these criteria to identify specific measures that might yield an index indicator in each area. Under estimates of need, for example, multiple measures might be included in the following areas: population size, birth cohort, percentage of immigrants, rurality, level of poverty, and immunization levels.

CDC has also reduced federal grant reporting requirements from 18

**BOX 1**
**IOM Recommendations, *Calling the Shots***

*Recommendation 1:* The annual federal and state budgets for public health providers appear to be adequate, but additions to the vaccine schedule are likely to increase the burden of effort within each state.

*Recommendation 2:* Additional funds are needed to purchase vaccines for uninsured and underinsured adult populations within the states. The IOM committee recommends that Congress increase the annual Section 317 vaccine budget by $50 million per year to meet residual needs for high-risk adolescents and adults under age 65 who do not qualify for other federal assistance. The committee further recommends that state governments likewise increase their spending for adult vaccines by $11 million per year.

*Recommendation 3:* State immunization infrastructure programs require increased financial and administrative support to strengthen immunization capacity and to reduce disparities in child and adult coverages. The committee recommends that states increase their immunization budgets by adding $100 million over current spending levels, supplemented by an annual federal budget of $200 million to support state infrastructure efforts.

*Recommendation 4:* Congress should improve the targeting and stability of Section 317 immunization grant awards to the states by replacing the current discretionary grant award mechanism with formula grant legislation.

*Recommendation 5:* CDC should initiate a dialogue with federal and state health agencies, state legislatures, state governors, and Congress immediately so that legislative and budget reforms can be proposed promptly when Section 317 is up for reauthorization in FY 2002.

*Recommendation 6:* Federal and state agencies should develop a set of consistent and comparable immunization measures for use in monitoring the status of children and adults enrolled in private and public health plans.

to 8 component areas that are more closely aligned with the 6 fundamental roles outlined in IOM's conceptual framework (Figure 2). To foster more consistent and comparable immunization measures, CDC is looking into harmonizing the Health Plan Employer Data and Information Set (HEDIS) methodology with that used in the National Immunization Survey (NIS). This effort involves several discrete activities, including the updating of HEDIS measures, the development of HEDIS-like measures within the NIS, the addition of an insurance module to the NIS, and the piloting of an adult office-based assessment of immunization coverage.

Dr. Orenstein observed that several topics emerging in the regional workshops based on the IOM report have also drawn attention from CDC.

For example, he noted that confusion about health insurance immunization benefits in ERISA-exempt (Employee Retirement Income Security Act) plans had surfaced, and CDC is now developing a brochure for benefits managers to address questions about the variation in immunization benefits within health plans. In addition, a number of providers had raised concerns about the complexity of multiple vaccine sources and funding streams, and the cost disincentives associated with immunization.

CDC is sponsoring a new study on vaccine finance within IOM that will address some of these concerns. The new vaccine finance study will examine the roles and responsibilities of the public and private health sectors in the purchase and administration of vaccines, and will consider alternative finance strategies from multiple perspectives, including the role of such strategies in achieving national health goals, in the service delivery mechanisms for various vaccines and population groups, in delivering recommended vaccines to underserved populations, in reducing the time lag and disparities associated with the introduction of new vaccines to the recommended schedule, and in addressing the effects of multiple new vaccine products. This study will begin in late 2000 and is expected to produce a final report in 2003.

In conclusion, Dr. Orenstein stated that infrastructure is a vital part of the immunization program and that access to increased resources will help rebuild state and local programs. Although federal investments are essential, states also bear fundamental responsibilities in sustaining an immunization infrastructure.

# Building the Immunization Infrastructure

The next session of the workshop featured speakers representing perspectives from state and local health departments in different areas of the United States. These speakers highlighted concerns about existing problems in the immunization infrastructure and the impact of the Institute of Medicine (IOM) report on future finance strategies to support the immunization system. The speakers included Donald Williamson, director of the Alabama Department of Public Health; Natalie Smith, director of the Immunization Program for the state of California; Dianne White Delisi, state legislator from the Texas State House of Representatives; and Jonathan Fielding, director of the Los Angeles County Health Department.

## STATE PERSPECTIVES

Dr. Williamson observed that "the IOM report could not have come at a worst time" in terms of the impact of recent downturns of the national economy on state health budgets. According to a recent report of the National Association of State Budget Officers, more than 50 percent of states are experiencing severe financial problems in the form of Medicaid increases and revenue shortfalls. This difficult fiscal environment discourages additional state investments in immunization programs and results in cuts in many important areas, including registries and outreach programs, reminder/recall efforts, and immunization linkages with Women, Infants, and Children (WIC) nutritional programs. In addition,

the suggestion in the IOM report that the Centers for Disease Control and Prevention (CDC) develop a federal formula grant for support of an infrastructure program may serve as a disincentive that causes states to reduce their support because of a perception that a formula would require a "lock-in" by states at their current funding levels.

On a more positive note, Dr. Williamson observed that the IOM report successfully drew national attention to the problems of immunization infrastructure, and legislative champions emerged to support the recommendations in budget negotiations. The IOM recommendations were consistent with a 1999 report by the National Vaccine Advisory Committee, which called for a $200 million annual budget for the state infrastructure program. At the state level, the IOM report provided a vehicle for conversations about the complexity of immunization infrastructure and provided an important rationale to support state advocacy efforts for increases in public health budgets. The IOM report also stimulated more attention to the absence of resources to support efforts to achieve higher levels of immunization among adults. Dr. Williamson indicated that the Association of State and Territorial Health Officials had received some anecdotal reports about a few states increasing their vaccine purchase budgets, but such efforts tend to occur among states that already have sizable investments in immunization. He commended CDC on the improvements in the draft guidance efforts for Section 317 awards.

Despite these gains, Dr. Williamson observed that several outstanding issues still require attention. The creation of the new State Children's Health Insurance Plan (SCHIP) program, for example, has shifted the vaccine delivery systems for certain populations from a federal entitlement to a health benefit that is supported in part by state budgets and is subject to change based on SCHIP eligibility requirements. A number of private health plans also do not offer full coverage for all recommended vaccines, creating further fragmentation in the immunization system. The introduction of higher priced vaccines, such as the new infant pneumococcal conjugate vaccine, is creating a two-tiered vaccine delivery system in some states. Certain populations are eligible for state-purchased vaccines if they meet key criteria, while others who have minimal health care insurance (such as indemnity plans) must pay for vaccine if it is not covered in their health benefits. One particularly grave concern within the states is the impact of recent vaccine shortages on school entry requirements. The modification of the immunization schedule in some jurisdictions will result in students moving through the health care system without the recommended vaccines. This situation can prolong their period of exposure to vaccine-preventable disease. These shortages are occurring during periods of public health cutbacks, further reducing chances for capturing vulnerable populations in a systematic manner.

Natalie Smith, director of the Immunization Branch of the California Department of Health Services, presented highlights from recent immunization data analyses. Data from the National Immunization Survey indicate that California has maintained a 5-year (1996–2000) average level of 75 percent immunization coverage in the 4:3:1:3 schedule for 2 year olds. In addition, a rapid uptake of the varicella vaccine has occurred in California, rising from 26 percent coverage in 1996–1997 to 76 percent in 2000. Hepatitis B immunization levels among seventh-grade students have also increased during this same period, from 15.8 percent in 1998 to 73.4 percent in 2001. Significant gains also have occurred in the annual flu and "ever" pneumococcal rates among adults, from 54 percent and 35 percent coverage in 1993 for influenza and pneumococcal, respectively, to 70 percent and 61 percent, respectively, in 2000.

Despite these positive trends, several worrisome trends persist. A recent state health budget cut has eliminated support for the infant pneumococcal conjugate program. The costs of flu vaccine contracts in California have increased significantly, rising from $1.625 per dose in 1999 to $4.488 per dose in 2001. The new SCHIP program in California is a standalone entity. Because the children are not enrolled in Medicaid, they are no longer eligible for the federal entitlement provided through Vaccines for Children (VFC), and the state has not budgeted funds to purchase vaccines for the providers.

The increasing scope and complexity of the childhood immunization schedule is particularly troubling. Dr. Smith illustrated how the conceptual framework of the IOM report could be adapted to the array of programs that constitute the immunization system in California. In some cases, the public health department will supplement federal vaccine programs with purchases from state revenues (this was done in purchasing hepatitis A and pneumococcal conjugate vaccine). In other situations, the state health department will offer immunizations directly to high-risk populations, as was done with the distribution of flu vaccines to high-risk persons.

Dr. Smith illustrated the relationship between public health budgets and communicable disease levels with a graph that compared trends in federal grant funds for immunization in California with the incidence of measles cases (Figure 3). Although infectious disease outbreaks remain low, the recent decline in the size of federal awards (from a high of $36.5 million in 1996 to $18.3 million in 2001) is troubling. She suggested several financial strategies that could help break the disturbing cycle of outbreaks associated with lowered immunization budgets, including stable and multi-year funding, targeting some awards to pockets of need, the extension of VFC coverage to the SCHIP population, a stable vaccine supply, and an emphasis on immunization across the lifespan.

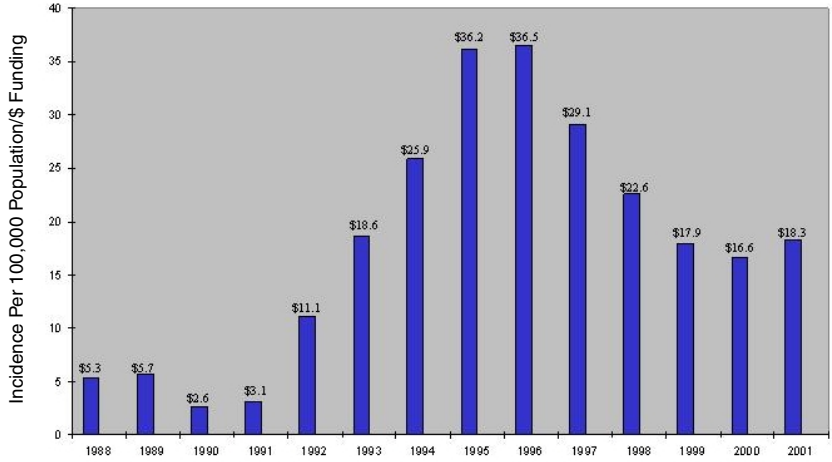


**FIGURE 3** Measles incidence per 100,000 population compared to available federal grant funds ($ in millions), California, 1988–2000.
SOURCE: Natalie Smith, California Department of Health Services, IOM workshop, 2002.

Dianne White Delisi, a state legislator from Texas, provided an additional perspective in addressing the problems of immunization finance and public support for infrastructure. She observed that political dynamics such as the effects of census figures on redistricting efforts have created a sense of flux in many state legislatures throughout the country. Many new political leaders have emerged who are unfamiliar with public health concerns and the intricacies of the federal–state financial partnership. The impact of increasing Medicaid expenses—resulting from both increased costs as well as wider enrollment— cannot be ignored because these higher expenses are a key factor in state funding increases for health. Keeping the rising costs of health care under control also has been cited among the top public concerns in recent national polls. But the growing costs of public health insurance programs create pressures to reduce spending in other areas of health, such as immunization. The recent cases of anthrax exposure in Washington, DC and elsewhere have called national attention to the deterioration and gaps in public health infrastructure in responding to infectious disease outbreaks. But the public is also concerned about the growing complexity and cost of the immunization schedule. It is difficult to address the tremendous variation in health plan benefits for vaccines without considering insurance regulation such as "first dollar coverage" policies that have been adopted in some states.

## LOCAL PERSPECTIVES

Jonathan Fielding, director of public health for Los Angeles County, described recent immunization trends in his county that warrant attention. Federal funds currently support about 70 percent of the county's budget for immunization services. The remainder is financed through state revenues (20 percent) and local funds (10 percent). California in general and Los Angeles County in particular are facing bleak financial prospects. As a result, overall cuts in public health programs, including immunization programs, are expected.

Although the county has achieved high rates of immunization coverage, occasional outbreaks of vaccine-preventable disease are a persistent problem. Recent cases of pertussis have been reported, for example. The public must become reacquainted with the importance of immunization, and ways must be developed to provide continuing, reliable support for both vaccine supplies and program activities. Outreach to immigrant and transient populations is especially important.

Dr. Fielding indicated that the rising costs of the newer vaccines are troubling, and these increases raise many questions about the extent to which vaccines are a public or private good. The goal of universal access to immunization has solid public support, but the increased splintering in the ways in which immunization services are financed requires attention. Although states have important roles in this area, they should not be expected to carry the burden of costs beyond a specified amount. The federal government is viewed as the primary supplier of vaccines for the safety net population.

Certain components of the immunization infrastructure also require federal attention and support. The development of immunization registries, for example, requires financial assistance if local health departments are to improve their monitoring and surveillance of key health indicators. Yet it is difficult for counties to bear these infrastructure costs when they are also expected to cover safety net services for indigent populations. For example, a managed care plan in Los Angeles recently announced that it would not reimburse costs for hepatitis A vaccines for adolescents; the local health department is expected now to provide that vaccine for the plan's subscribers.

Finally, Dr. Fielding pointed out that the economics of vaccine finance require closer attention to how current vaccine prices affect investments in the production of future vaccines. Concerns about recent vaccine shortages have called attention to the problems that some companies experience in sustaining the production of low-cost vaccines when investments in such products must compete with higher rates of return for more profitable pharmaceutical products.

## NATIONAL SURVEY OF STATE-LEVEL IMMUNIZATION POLICIES, PROGRAMS, AND PRACTICES

In collecting background materials for *Calling the Shots*, the IOM Committee on Immunization Finance Policies and Practices commissioned a national survey of the ways in which states financed immunization policies, programs, and practices in the 1990s. Gary Freed, Sarah Clark, and Anne Cowan in the Division of General Pediatrics at the University of Michigan conducted the survey through a series of structured telephone interviews with state immunization officials. The results of the survey, published in the *American Journal of Preventive Medicine* in October 2000 (Freed et al., 2000), are summarized here to provide additional perspective on state-level experiences in providing financial support for infrastructure activities. The survey data provide a deeper understanding of the rationale behind key decisions at the state level, the major influences on state immunization program goals and priorities, the effects of federal policies and fluctuations in federal funding on state programs, and other factors affecting state immunization efforts in the 1990s. The survey results focus on three key areas: vaccine purchase, immunization program infrastructure, and other programs and regulations.

(1) *Vaccine Purchase.* States use different funding sources to support their vaccine purchases according to the nature of their immunization delivery system (see Table 2). Prior to the creation of the VFC program in October 1994, most states had one of three systems of immunization delivery: public clinics only, Medicaid replacement, or universal purchase (UP). These efforts could be grouped according to the populations served. States that had public-clinics-only policies delivered vaccines that were purchased with federal or state funds only to populations (primarily children) who presented for immunizations in local clinics. States that participated in Medicaid replacement efforts were able to supply private providers, in addition to their public clinics, with replacement vaccines for Medicaid-enrolled children. Contributions from state Medicaid agencies varied considerably, ranging from no contribution to full funding for all vaccines delivered to Medicaid enrollees. In the universal purchase states, vaccines were supplied to public clinics and participating private providers for all children in the state. In the UP states, state revenues provided a significantly larger proportion of financing for state-supplied vaccines.

Following the implementation of the VFC program, states realigned their policies and practices. The federal government is now responsible for supplying vaccines for children in certain populations: the uninsured, Medicaid eligible, Alaska Native and Native American, and underinsured children who received vaccines at designated public clinics (federally qualified health centers). As a result, states expanded their efforts into programs that can now be grouped within the following categories: VFC

**TABLE 2** Vaccine Supply Policy, January 2000

| | VFC Only[a] | Enhanced VFC[b] | Universal Purchase[c] |
|---|---|---|---|
| | Alabama | Arizona | Alaska |
| | Arkansas | District of Columbia | Connecticut |
| | California | Florida | Idaho |
| | Colorado | Georgia | Maine |
| | Delaware | Hawaii | Massachusetts |
| | Indiana | Illinois | Nevada |
| | Iowa | Maryland | New Hampshire |
| | Kansas | Michigan | New Mexico |
| | Kentucky | Minnesota | North Carolina |
| | Louisiana | Mississippi | North Dakota |
| | Missouri | Montana | Rhode Island |
| | New Jersey[d] | Nebraska | South Dakota |
| | Ohio | New York | Vermont |
| | Oregon | Oklahoma | Washington |
| | Pennsylvania | South Carolina | Wyoming |
| | Tennessee | Texas | |
| | Virginia | Utah | |
| | West Virginia | | |
| | Wisconsin | | |
| Total | 19 | 17 | 15 |

[a]These states provide publicly purchased vaccine to private health care providers only for VFC eligibles.

[b]These states provide publicly purchased vaccine to all health care providers for both the VFC and underinsured populations. "Underinsured" is defined as those who have health insurance that does not include immunizations as a covered benefit.

[c]A universal state offers all vaccines recommended by the Advisory Committee on Immunization Practices to all health care providers to serve all patients, including those who are fully insured.

[d]The VFC program was implemented in the private sector on January 1, 1999.

SOURCE: Institute of Medicine (2000a).

only, enhanced VFC, and UP. Once again, each system represents different approaches and different levels of investment that frequently reflect variations in the historical public health traditions and resources of each state. Under VFC-only programs, states rely solely on federal vaccine purchase funds to supply vaccines to eligible children in public and private health settings. These states seek to supply vaccines to all children in public health clinics (including those not eligible for VFC), and use their Section 317 funds to provide vaccines for children who do not meet VFC eligibility criteria. States that fall within the enhanced VFC category make a greater effort to provide state-supplied vaccines for underinsured chil-

dren who receive vaccines from private providers. The states that have adopted universal purchase practices supply vaccines to public clinics and participating private providers for all children in the state, as was done prior to the creation of VFC. Within this category, children's eligibility for state-supplied vaccine does not differ by their insurance status.

(2) *Immunization Program Infrastructure*. In response to the measles epidemics of 1989 and 1990, the federal government appropriated funds to help states develop Immunization Action Plans to improve their immunization rates, especially for children. The 1993 Children's Immunization Initiative subsequently increased funding to support infrastructure investments and allowed states to expand their immunization programs. The rapid increase in these funding patterns presented several challenges, however. States had little time to plan multi-year activities and often received funding late in the fiscal year that needed to be spent before the end of the year. Federal funds were also distributed through multiple allocations that made it difficult to assess needs and determine the most effective use of funds. The states did not have the capacity to make long-term commitments, and in some cases could not hire full-time or permanent staff because of individual state budgetary or personnel restrictions. By the mid-1990s, a large amount of "carryover" funds for infrastructure programs remained in the Section 317 budget, causing Congress to reduce the infrastructure budget and decrease the scale of state grants. As a result, states had diminished resources to implement or complete expanded activities that were initiated a few years earlier.

The vast majority of state infrastructure activities for immunization are financed through Section 317 funds. Although VFC represents a broader entitlement program focused on vaccine purchase, only a small proportion of the VFC funds can be spent on personnel or activities, and these must be directly related to the administration of VFC vaccine. A few states have used VFC funds to support some infrastructure efforts focused on the eligible populations, but these practices are infrequent and generally require close collaboration between health finance and public health officers at the state level. While about half the states (25 states) receive some direct state funding for infrastructure support, only 4 states are able to finance more than 40 percent of their infrastructure budget with state revenues. These state-generated funds are typically directed toward the support of registry development or immunization program staff. Four states have redirected state funds used for vaccine purchase to infrastructure support. The remaining states (21) receive no direct state funding for program infrastructure.

(3) *Other Programs and Regulations.* The University of Michigan survey identified a broad range of activities within the states that have significant impacts on the financing or functioning of immunization programs. These

other activities include the following: Medicaid program policies and practices, SCHIP policy and practice, health insurance regulation, WIC program policies and practices, and school and daycare requirements. These other areas can directly affect the size of the population served by VFC, Section 317 vaccines, and state-supported efforts.

In conclusion, Dr. Freed observed that the 1990s expansion of immunization efforts and infrastructure programs within the states depended greatly on the availability of increased federal funding. Little state funding was appropriated specifically for immunization delivery infrastructure during this time, and state legislatures frequently rejected specific requests for assistance by state immunization programs. As a result, decreases in federal immunization budgets (most notably the Section 317 grants) jeopardized the ability of state immunization programs to continue activities that supported increases in their immunization rates among disadvantaged populations.

The University of Michigan survey reported that during this same period of federal cuts, states were expected to continue to follow an extensive blueprint of mandated programs developed by CDC. State immunization programs expressed frustration about their inability to make choices among competing priorities during periods of fiscal restraint. Although CDC was consistently viewed as a valuable source of information, guidance, and technical expertise, the program administration of the state grants became an increasing source of concern. State survey respondents indicated that national leadership must include flexibility for the unique and specific situations that occur across the states and allow greater discretion in establishing immunization priorities at the state level.

## CASE STUDY FINDINGS

In addition to the 50-state survey, the IOM Committee on Immunization Finance Policies and Practices commissioned a set of eight case studies of state and local immunization programs to examine how states incorporate federal funds (particularly Section 317 grants) into their local immunization programs. Individual case study reports are available as PDFs online (http://books.nap.edu/html/case_studies) and were subsequently published in a synthesis article in the *American Journal of Preventive Medicine* (Fairbrother et al., 2000). The case studies examined policies and practices in seven states: Alabama, Maine, Michigan, New Jersey, North Carolina, Texas, and Washington, and one two-county study of Los Angeles and San Diego in California. The case studies relied on materials provided through state and federal administrative records; interviews with state and local health department officials, including immunization program directors, Medicaid agency and budget analysts, and CDC

public health advisers to the jurisdictions; and secondary sources for background factors and state-level trends. The synthesis article was distributed to participants in the March 2003 workshop.

A critical finding of the case study reports is the transformation that occurred within state and local immunization programs during the 1990s. Fairbrother and colleagues (2000) observe that the shifting role of the public health clinics was one of the few generalizations that could be drawn from their study of nine different jurisdictions. This transformation in the immunization system includes several key components:

- Public-sector clinics are now delivering a decreasing share of immunizations.
- "Medical homes" have become more important as the site of delivery than free-standing immunization services.
- The success of immunization efforts depends on forces that are beyond the capacity of state immunization programs. These external forces include the ability of managed care, particularly Medicaid managed care, to ensure timely immunizations.

As a result of these shifting roles, the nature of the immunization infrastructure supported by Section 317 funds has been transformed from one that focuses primarily on service delivery to a broader and more complex set of functions that involves partnerships among public health, health financing, and other entities in both the public and private sectors. New activities associated with infrastructure investments include investments in immunization registries, quality improvement, coordination with program staff outside public health agencies, and assurance of age-appropriate immunization throughout the lifespan. The declining levels of Section 317 budget awards to the states have forced many health departments to make difficult choices between the continuation of older, mainstream immunization services and newer coordinating and program outreach efforts at the state and local levels.

The case study authors conclude that immunization programs function as an organic component of local health care financing and delivery systems. Although the Section 317 grants traditionally played a vital role in supporting immunization infrastructure, recent awards are too unstable and unpredictable to elicit the strategic planning, programming, and own-source spending that would be optimal for state and local programs. Additional support is required for appropriate staffing, interagency collaboration, and the development of clearly articulated authority to guide immunization activities.

# Private-Sector Roles in the National Immunization Partnership

The pace of transformation has occurred at different rates within different sectors of the national immunization system and individual states. In the March 2002 workshop, several speakers addressed the emerging roles played by private providers, health plans, and the business sector within the public and private partnership that now guides immunization efforts. These speakers included Samuel Katz, department of pediatrics, Duke University; David Tayloe, community pediatrician in private practice in Goldsboro, North Carolina; Carol Wilhoit, director of quality improvement for Blue Cross Blue Shield of Illinois; John Fontanesi, Community Health Pediatrics Department, University of California at San Diego; and Suzanne Mercure, National Business Coalition on Health.

## IMMUNIZATION AND PEDIATRIC PRACTICE

Samuel Katz observed that although Congress has articulated a clear role for the federal government in facilitating the distribution of vaccines and sharing support for delivering immunization services to safety net populations, there is great ambiguity about the extent to which the federal government should finance state and local infrastructure programs and public- and private-sector collaboration efforts. The contribution of individual components such as data collection, community outreach, registries, program coordination, documentation and communication of "best practices," and other types of programmatic efforts to the achievement of

national immunization goals needs to be demonstrated in legislative settings if these initiatives are to obtain broad support. This challenge is a difficult task that is often neglected during budgetary debates, when public health programs must compete with other worthy causes at the national and state levels.

David Tayloe described several significant changes in immunization practices within his rural practice over the past 25 years. In the period from 1977 to 1994, more than 50 percent of children in the state of North Carolina received their vaccines in public health clinics. The delivery system changed after 1994 because of the establishment of the Vaccines for Children program and the universal childhood vaccine distribution program in North Carolina. Today only 20 percent of the child population goes to the public health sector for vaccines. Higher immunization rates also occurred during this period of change. In the earlier period (1994), 60 percent of children were up to date with immunization. Today, North Carolina leads the nation in the percentage of 2 year olds who are fully immunized (about 88 percent).

Dr. Tayloe described the increasing complexity of the vaccine schedule, which is particularly striking. In 1977, six shots (involving three different vaccines) and four doses of oral vaccines were required to comply with recommended immunization standards. In 2002, 23 shots of 8 different vaccines were required. In earlier years, the vaccine name and date of administration could be written into the individual child's medical record and the parents' shot record. Now, the medical record requires more extensive documentation, including the vaccine name, date of administration, and lot number. In addition, information must be recorded not only in medical and parental records, but also posted on the state vaccine log to justify the next shipment of vaccines from the state vaccine program. Furthermore, vaccine storage is now more complicated, requiring compliance with detailed regulations, separation of public and private vaccine stocks, and an emergency plan.

In 1977, local physicians did not have to think about liability prevention. Today, Dr. Tayloe indicated, they are expected to provide vaccine information statements to each patient and to obtain parental signature prior to administering each vaccine. The provider is expected to describe all possible risks and complications to parents and explain the need to report unusual symptoms to the Vaccine Adverse Events Reporting System.

Other more recent changes have also occurred in the methods by which providers obtain vaccines and are reimbursed for immunization fees. Before 1994, Dr. Tayloe observed, Medicaid expected providers to give vaccines during well-child visits and bill the state program for the cost of the vaccines. Private patients paid cash for vaccines because insur-

ance coverage was rare, or went to the public health department for free vaccines. Today, quality standards such as the Health Plan Employer Data and Information Set (HEDIS) measures have created incentives for many health plans to offer immunization benefits. The public program has changed as well. The state of North Carolina (a universal purchase state) buys all vaccines and sends them to providers. Providers are then responsible for billing private insurers or Medicaid for the vaccine administration fee.

Dr. Tayloe described how the medical home concept is implemented within his own practice, which serves approximately 400 children daily in four offices in rural parts of North Carolina. The main office is open until 10 PM on weeknights and also provides services on weekend days. Providers try to immunize every child who enters any office, but they frequently encounter barriers related to family education, antivaccine rhetoric, cultural diversity, reimbursement practices, local public health bureaucracy, shortages in the vaccine supply, and complacency associated with the lack of parental experience with vaccine-preventable infectious diseases. He indicated that his practice reports an average of one case of pertussis annually, usually involving infants who have received only one dose of DTaP. During the 15 years before the availability of vaccine for *haemophilus influenza* type B, the community also experienced 10 to 20 cases of meningitis/epiglottitis/sepsis that resulted in one death and one child with severe deafness.

John Fontanesi reviewed findings from a study of workflow and time/motion observations of immunization practices in 10 community clinics and 5 private primary care practices (Fontanesi et al., 2000; 2001). Researchers in the San Diego study developed an observational checklist of patient encounters that describes operational conditions that affect the cost and likelihood of immunization. By studying the operational or environmental conditions that affect immunization practices, they sought to identify factors that could explain missed opportunities and to compare the impact of these factors with those of provider characteristics, attitudes, and beliefs. Dr. Fontanesi indicated that this type of study of immunization practices could serve as a proxy for other primary preventative care services.

Dr. Fontanesi presented a systems mapping of clinic stages to describe the operational environment of a busy pediatric practice. Research studies suggest that the amount of time available for direct patient/provider contact during a well-child exam has gradually increased from 10 minutes in 1978 (O'Bannon et al., 1978) to 20 minutes in the late 1990s (Fontanesi et al., 2000). Within this encounter period, the time associated with administering a vaccine (3.5 minutes) has remained relatively constant. Multiplying this time by the number of live births and injections

that are required as part of the 4:3:1:3 schedule produces a total of 32.3 million person-hours to immunize all U.S. children.

Dr. Fontanesi commented that missed opportunities for immunization frequently occur because providers do not have physical access to a patient's immunization record in a timely manner when the patient is receiving clinical care. Health care providers are frequently overburdened with limited time and redundant administrative forms that diminish their ability to assess the immunization needs of their patients or to remind their patients of the need for follow-up visits when the administration of vaccines requires multiple visits. As examples, he noted that more than 200 clinical practice guidelines have been published for primary care prevention for 0 to 2 year olds. Nine clinics interviewed in the San Diego study provided 200 separate forms to be used for children under age 35 months. Their data indicated that fewer than 85 percent of immunizations administered were ever documented, often because of the administrative burden to nonclinical staff. Dr. Fontanesi suggested that the data associated with multiple recordkeeping forms, often required as part of different access, documentation, and quality assurance policies that are intended to protect the consumer, may actually interfere with care as currently executed. The reduction in redundant forms, audits, and other activities could release critical time resources that could then be allocated to more productive efforts. He noted that quality should be viewed as an investment that requires a consistent and comprehensive approach in building capacity to be effective. Improving immunization rates and other quality-of-care practices will require reductions in the variability now associated with clinical practice.

The time allotted for immunizations competes with nonimmunization time needs that might be more pressing. Immunization appears to lengthen waiting room times by 2 minutes and extends total clinic time by the same proportion.

Despite these challenges, opportunities exist to improve recordkeeping and vaccine administration practices. For example, Dr. Fontanesi observed that patients spend substantial time in examining rooms that might be directed toward immunization efforts (27 percent room time with provider; 73 percent room time without provider).

## HEALTH PLAN INCENTIVES FOR PROVIDERS

Carol Wilhoit from Blue Cross Blue Shield of Illinois (BCBSIL) described collaborative practices between health care plans and clinicians to improve childhood and adult immunization rates. As large private commercial products of BCBSIL, HMO Illinois and Blue Advantage HMO enroll more than 900,000 members and contract with approximately 90

medical groups (MGs) and independent provider associations (IPAs). The health maintenance organization (HMO) pays MGs/IPAs (not individual providers) on a capitated basis. The compensation package includes a quality improvement (QI) fund that allocates part of the compensation package as an incentive for improving quality of care. The HMOs met with representatives from the medical groups and IPAs in 1996 to discuss collaborative approaches to QI.

Within this collaboration, the HMO performs certain roles (such as developing project criteria, identifying target populations, selecting random samples, and performing and reporting data analysis). The MGs/IPAs also perform certain activities, including the review of administrative and medical records, providing abstracted data and supporting documentation, and developing and implementing interventions (such as flowsheets, medical record stickers, postcards, and so forth) that may be recommended by the HMO or developed locally. The HMO has rewarded performance using two approaches: payment for participation and payment based on the level of performance.

Using the example of influenza vaccination, Dr. Wilhoit illustrated how the HMOs sought to change practice with respect to vulnerable populations, particularly asthmatics, diabetics, and members age 65 and older. In the first stage, the plan encouraged each MG/IPA to document data and submit records to the HMO for reporting of MG/IPA-specific rates, for which the groups received payments from the QI fund. Payments ranged up to six figures, depending on the size of the group. Baseline rates for the targeted population were 21.8 percent (1996), 22.7 percent (1997), and 22.8 percent (1998). Beginning in 2000, the HMOs shifted the quality fund payment to reward performance (the 1999 MG/IPA flu shot rate) instead of just program participation (i.e., providing medical record data). The flu shot rate for the HMO network increased and rates also improved substantially for many MGs/IPAs. For example, Dr. Wilhoit observed that 4 groups had achieved more than 40 percent coverage rates for the targeted population in 1998; by 2000, 12 groups had reached this level of coverage. Similarly, three groups had achieved 35 to 40 percent coverage rates in 1998; nine groups were performing at this level in 2000. The number of groups performing at the very low end also declined: 70 groups had achieved rates below 20 percent coverage in 1998. By 2000, only 30 participating groups fell within this category. Rewarding performance led to higher flu shot rates.

In a second example, Dr. Wilhoit described how the HMOs sought to evaluate the impact of those providers who explained the importance of vaccination to their high-risk patients. A 1997 member survey indicated that the influenza immunization rates for high-risk members whose physician explained the importance of a flu shot was 79 percent, compared

with a 19 percent rate for patients to whom the "importance" message was not presented by the physician. Since 1998, BCBSIL has distributed preventive care and diabetes flowsheets to its physicians. The flowsheets also appear to increase influenza immunization rates within the diabetic population (32 percent of diabetics with flowsheets in the BCBSIL HEDIS Comprehensive Diabetes Care sample for 2000 who had a diabetes flowsheet in the medical record had received an influenza vaccination, compared to 17 percent who did not have a flowsheet).

Improving childhood vaccination rates is a more difficult challenge because of the complexity of the childhood immunization schedule and the uncertainties among both providers and parents as to whether children are up to date at specified times. In 1997, Dr. Wilhoit reported, BCBSIL sent surveys to parents of the 83 children in their 1996 HEDIS sample who did not meet criteria for the recommended vaccine series. Slightly more than half (57 percent) of the parents completed the survey. Of the respondents, 46 of 47 incorrectly thought their child had been fully immunized by age 2. Using these data, the HMOs convened focus groups with MGs/IPAs and parents of children under 2. In these discussions, parents indicated that they wanted their doctors to remind them about timely immunization because the schedule was too complex for them to monitor on their own, and the providers wanted to have lists of children who were not up to date and easy-to-use reminder cards that could be incorporated into their routine office practices. The use of immunization flowsheets has also led to improvements in adolescent immunization rates for hepatitis B and measles, mumps, and rubella—77 percent of adolescents with flowsheets had complete immunization compared with 11 percent who did not, according to 1999 data.

Dr. Wilhoit indicated that BCBSIL had initiated a new quality improvement project in collaboration with the departments of public health from Chicago Cook County and the state of Illinois. Under this new plan, at least 50 percent of the plan's pediatricians (and some family practice physicians) will participate in an assessment, feedback, and information exchange intervention, which will include information about immunization procedures and the current immunization rate of the practice. The MG/IPA will prepare a corrective action plan for each physician practice whose immunization rate is below 60 percent.

In conclusion, Dr. Wilhoit observed that physician promotion of preventive services is a key determinant of whether patients receive recommended services. Flowsheets are highly correlated with complete immunization, and additional compensation can motivate performance improvements as well. Immunization requirements for school attendance, and other public policy interventions, are strong influences on immunization rates at the population level.

Carey Vinson from the American Association of Health Plans commented that even though immunization levels are an important measure of quality in HEDIS assessments of private health plans, market forces are eroding the private sector's capacity to address public health goals. Some states, such as Pennsylvania, require managed care organizations to offer immunization benefits as a standard feature of health benefit plans. However, the continuing additions of new and more expensive vaccines are creating more costs that the plans must absorb or pass on to their subscribers in the form of higher premiums, deductibles, or co-payments. He suggested that these increasing and often uncontrollable costs discourage some employers from offering immunization benefits and can lead to tradeoffs with other benefits that are more stable and less costly.

## BUSINESS-SECTOR ROLES

Suzanne Mercure, project manager for the National Business Coalition on Health (NBCH), described the role of the business community in supporting immunization efforts and achieving national immunization goals as part of employee health benefit plans. NBCH represents 85 employer coalitions, with outreach to 11,000 employers, 21 million employees, and their dependents. The coalition supports community health reform and seeks to improve the value of health care provided through employer-sponsored health plans by focusing on total cost (direct and indirect) and quality (clinical, service, and safety). The coalition has selected the topic of adult influenza vaccination for attention because of their view that this type of vaccination is an inadequately provided preventive service that is simple to administer, appealing to employers, and consistent with the recommendations of the Community Prevention Task Force. NBCH works with multiple partners in a Cooperative Agreement with the Centers for Disease Control and Prevention (CDC) in three sites (Connecticut, southeastern Michigan, and Colorado) to test different interventions, such as the use of payroll insert letters for all employees, telephone call reminders from a high-risk member health plan, the development of a common data set, and an employer tool kit.

The employer tool kit consists of several items: an information sheet that presents a "business case" for adult influenza immunization, information about local flu shot clinics for employees, worksite clinic planning guides, ideas for working with health plans, and consumer information campaign materials.

Evaluations of the partners project are underway in two sites, Colorado and Connecticut. The Connecticut evaluation consisted of a member survey for year 2000 interventions. The survey data indicated that various reminder/outreach approaches for employees (phone, postcard, phone/

post, and payroll inserts) had no discernible effect because nearly half the population already had been vaccinated prior to the intervention reminder cards or calls. The maximum reminder effect may already have been achieved in the absence of the intervention effort. An evaluation of the Colorado intervention is now underway.

Julianna Gonen, Ph.D., Director of the Center for Prevention and Health Services for the Washington Business Group on Health, provided an additional perspective about the role of the business sector in implementing efforts to help achieve national immunization goals. She noted that most large employers offer comprehensive health plans that include immunization benefits; some plans even include first-dollar coverage for some vaccines, which protects the employee from paying for immunization services through a deductible or co-payment. In addition, many employers offer access to influenza vaccines at their worksite and educate their employees about the importance of immunization. Recent shortages of the influenza vaccine have affected these efforts, but this disruption may be only temporary. In fact, in some cases the shortages appear to increase interest in and demand for the influenza vaccine.

Dr. Gonen indicated that employers turn to many different sources for information on coverage policy, including the CDC National Immunization Program, medical societies such as the American Academy of Pediatrics and the American Medical Association, individual health plans, and private consultants. There is increasing interest in identifying programs that demonstrate evidence of impact and contribute to improvements in community immunization levels. Yet employers still need guidance, including access to "consumer-friendly" websites for employees concerned about the value or safety of certain vaccines, and the development of toolkits to help them implement successful immunization programs.

Given the significant annual increases in health care costs, Dr. Gonen observed that employers are developing strategies to help control or reduce their health care expenses. Some employers are passing on increased costs to their employees in the form of higher deductibles or co-payments. Whether preventive services can be protected within these cost control strategies is uncertain without a clear business case as well as consumer-level information about their importance. Consumers who are given greater discretion over allocating their employer's health care contribution may have little incentive to spend dollars on preventive services such as immunization compared with expenses that appear to have more immediate and tangible benefits, such as routine medical care or even cosmetic surgery.

# Unresolved Problems and Future Challenges

Each of the three prior Institute of Medicine regional workshops—in Chicago, Austin, and Los Angeles—identified key challenges and unresolved prob-lems that required further attention. The participants in the Washington, DC workshop repeated many of these concerns.

## INCREASING VACCINE COSTS

Workshop participants frequently observed that public and private investments in immunization efforts were easy to justify when the burden of infectious disease was apparent to all. Ironically, the success of the national immunization program in decreasing disease outbreaks and achieving high immunization levels has caused the public to grow complacent and to question the need to sustain investments in infrastructure programs that support these efforts. Concerns about appropriate methods for distributing the costs of public health infrastructure persist despite the willingness of the federal government to assume a larger share of these costs over the past decade.

## CHANGING PARTNERSHIPS

No single agency, public or private, can expect or be expected to solve immunization problems alone. Federal, state, and local health departments traditionally have engaged in constructive partnerships to support the national immunization system and to implement efforts such as out-

reach, reminder/recall, service delivery, public education, and the development of registry programs. Given the tremendous shift in the delivery site for childhood immunizations over the past decade (from the public to the private sector), new initiatives are required to strengthen collaboration with private-sector health care providers, employers, and private health plans in supporting immunization efforts for all populations and, eventually, all age groups. These initiatives require further attention to issues such as the use of immunization measures in quality assessment efforts, the administrative burden associated with private-sector participation in registry development and consumer education, the health care provider's role in assessing immunization status and providing access regardless of the insurance status or income level of the patient, and keeping up with a changing and more complex immunization schedule.

Appropriate data and information tools help health care plans and individual providers to improve immunization rates among their pediatric and adult patients. But the expenses associated with sustaining these infrastructure elements, especially in pockets of need, require more careful planning and financial support if such support efforts are to be sustained on a routine basis. Furthermore, the importance of learning from the experience of private providers, who see critical barriers and limitations in both public and private financing for the purchase of vaccines and payment for immunization services, should not be overlooked.

## IMMUNIZATION AND HEALTH SECURITY

New concerns about bioterrorism and the rapid emergence of unknown infectious disease are drawing attention to the importance of public health surveillance and response capacity at all levels of government. Within these discussions, workshop participants in the regional meetings observed that the quality of the immunization system is a fundamental indicator of the integrity and quality of the public health infrastructure. If the nation cannot ensure that the 11,000 children born each day receive the routine immunizations they need, it may not be able to adequately protect the health of all 280 million Americans in times of crisis. Although crisis can stimulate action, sustained efforts are necessary to maintain the public health infrastructure and achieve immunization goals.

## SIMPLIFYING THE IMMUNIZATION SYSTEM

Advances in the discovery, development, and production of vaccines have led to an increasingly complex immunization schedule and greater fragmentation in the vaccine delivery system. Some states have attempted to remove financial barriers to immunization and ease the administrative

burden on their health care providers by adopting a universal purchase strategy that is partly financed through state revenues. Others depend on the federal government to meet their vaccine needs, resulting in a patchwork of different eligibility criteria and inventory control requirements within public and private health plans that frustrate both the public and health care providers. Some participants have urged the development of public and private partnerships designed to ease these financial burdens and to simplify vaccine purchasing arrangements while retaining the goal of providing universal access to recommended vaccines.

## STABLE FUNDING

Tighter health care budgets within many states have led to the reduction or elimination of special immunization programs, such as hepatitis B campaigns or outreach efforts within private pediatric practices. Uncertain funding for immunization infrastructure has also reduced opportunities for longer term planning and commitments and makes it difficult for the health department to be a good partner in community immunization efforts. Efforts to sustain improvements in areas such as disease surveillance and public health laboratories may benefit from new funds associated with bioterrorism initiatives, but the scope and allocation of such funding is not yet certain. Experience with programs such as Vaccines for Children and the State Child Health Insurance Program has demonstrated that stable and predictable funding streams can lead to significant improvements in immunization levels, but other approaches are still needed to benefit the children who are hardest to reach. As one participant observed, in the Los Angeles workshop, public health is invisible when it works because people do not get sick. The persistent convergence of recurring problems such as unstable funding, rising vaccine prices, and vaccine shortages could create conditions that will eventually contribute to disease outbreaks. Legislative initiatives at both the national and state levels will be required to address these concerns through enhanced resources and stable funding strategies.

# Final Observations

The Institute of Medicine (IOM) report *Calling the Shots* and the four regional workshops that followed its publication provide a snapshot of current tensions and uncertainties within the national immunization system. Although states retain the primary responsibility for determining the public health priorities of their communities and developing policies and programs to address those needs, the federal government exercises a profound influence on the quality and scope of state immunization programs. By providing funds, vaccine, personnel, and technical assistance, the National Immunization Program at the Centers for Disease Control and Prevention is a key force in shaping the areas that receive attention within the states and highlighting certain strategies that can achieve national as well as state-level goals.

As noted in the IOM report, the repetitive ebb and flow cycles in the distribution of public resources for immunization programs have created instability and uncertainty that impeded project planning at the state and local levels in the late 1990s, and delayed the public benefit of advances in the development of new vaccines for both children and adults (Conclusion 1). Although federal and state governments have important roles to play in reducing this instability, private health care plans and providers are additional partners that have the capacity to do more in implementing immunization surveillance and preventive programs within their health practices. The business sector, which is responsible for purchasing health care benefits for employees and their dependents, is another component

in the evolving national immunization system whose role has not yet fully developed.

Under some circumstances, patchwork efforts and informal collaboration can achieve significant results. The growing diversity of health care plans in both the private and public sectors has led to an increasing fragmentation in the service delivery system and financing strategies for immunization. Participants in the workshop stressed the importance of addressing this fragmentation through new partnerships that can generate consistent program priorities and performance measures. Such efforts will require additional resources to support routine infrastructure efforts as well as special initiatives. No single agency or program has the capacity to do it all, but synergistic efforts have the potential to achieve programs that have greater stability and higher levels of immunization coverage, especially in underserved areas.

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# Appendixes

# A

# Workshop Agenda

Institute of Medicine
Committee on the Immunization Finance Dissemination Workshops

Financing the U.S. Immunization System:
The Need for a Strategic Vision

**FINAL AGENDA**
**MARCH 18, 2002**

**Lecture Room**
**National Academy of Sciences**
**2101 Constitution Avenue, NW**
**Washington, DC**

**8:30 AM** **Welcome and Introductory Remarks**

- *Rosemary Chalk, Senior Program Officer, Institute of Medicine, moderator*
- *Susanne Stoiber, Executive Officer, Institute of Medicine*
- *David R. Smith, Chair, IOM Committee on the Immunization Finance Dissemination Workshops and interim chancellor, Texas Tech University*
- *Walter Orenstein, Associate Surgeon General and Director, National Immunization Program, Centers for Disease Control and Prevention*

**9:15 AM** **Building the Infrastructure to Support National Immunization Goals: State and County Perspectives**
*David R. Smith, moderator*

- *Donald Williamson, Alabama Department of Public Health*
- *Natalie Smith, Immunization Program for the State of California*
- *Dianne White Delisi, Texas State House of Representatives*
- *Jonathan Fielding, Los Angeles Health Department*

**10:45 AM** **The Role of Private-Sector Providers: Service Delivery, Recordkeeping, and Performance Incentives**
*Samuel Katz, Department of Pediatrics, Duke University, moderator*

- *David Tayloe, community pediatrician in private practice in rural North Carolina, representative from the American Academy of Pediatrics*
- *Carol Wilhoit, Blue Cross Blue Shield of Illinois*
- *John Fontanesi, Community Health Pediatrics Department, University of California at San Diego*
- *Suzanne Mercure, National Business Coalition on Health*

**12:15 PM** **Lunch**

**1:30 PM** **Unresolved Problems and Future Challenges**
*David R. Smith, moderator*

- *Sara Rosenbaum, School of Public Health and Health Services, The George Washington University*
- *William Schaffner, Department of Preventive Medicine, Vanderbilt University*
- *Julianna Gonen, Center for Prevention and Health Services, Washington Business Group on Health*
- *Carey Vinson, American Association of Health Plans*

**2:45 PM** **Congressional Views**

- *Brian Hickey, Senate Subcommittee on Health*
- *Dayle Lewis, Office of Representative Steny Hoyer (D-MD)*

**3:30 PM** **Concluding Remarks and Adjourn**

- *David Smith, Texas Tech University*

# B

# List of Workshop Participants

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# C

# Website Referrals

Further information regarding the audiocast of the IOM workshops and the report *Calling the Shots* is available from these websites:

www.iom.edu/iom/iomhome.nsf/Pages/HCS+Immunization+Finance+dissemination

www.nap.edu/catalog/9836.html

www.nationalacademies.org/includes/shots.htm

http://books.nap.edu/html/case_studies

www.cdc.gov/nip/news/iom-rpt-6-00.htm