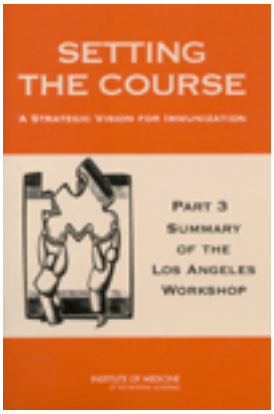

Setting the Course: A Strategic Vision for Immunization -- Part 3: Summary of the Los Angeles Workshop

Committee on the Immunization Finance Dissemination Workshops

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SETTING THE COURSE

A Strategic Vision for Immunization

Part 3
Summary of the Los Angeles Workshop

Committee on the Immunization Finance Dissemination Workshops

Board on Health Care Services
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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Support for this project was provided by the Centers for Disease Control and Prevention. The views presented in this report are those of the Institute of Medicine Committee on the Immunization Finance Dissemination Workshops and are not necessarily those of the funding agencies.

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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

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The Institute of Medicine workshop on immunization finance was organized through the efforts of numerous health care organizations and health care providers throughout the state of California. We acknowledge in particular the logistical support and gracious hospitality of the faculty and staff of the School of Public Health at the University of California in Los Angeles, under the leadership of Dean Linda Rosenstock and the guidance and assistance of Karen Markus. Natalie Smith and John Dunajski from the Immunization Branch of the California State Department of Health provided valuable guidance in identifying expert resources throughout the state. Jonathan Fielding, Cheri Todoroff, and David Gambill from the Los Angeles County Department of Health, Sandra Ross from the San Diego County Department of Health, and Kristin Brusuelas from the National Immunization Program of the Centers for Disease Control and Prevention did the same in pointing us toward experts in the Los Angeles and San Diego areas. Lynn Denton from the Texas Department of Health and Richard Butler from the Texas Tech University Health Sciences Center also provided helpful assistance and support in preparing for the workshop.

Additional guidance was provided by the Pacific Business Group on Health, the California chapters of the American Academy of Pediatrics, the California Medical Association, Michael Marcy from Kaiser Permanente in Los Angeles, and Steve Baranov from Immunize LA Kids. Staff from the National Immunization Program of the Centers for Disease Control and Prevention in Atlanta helped to identify immunization program directors and public health advisers throughout the state of California and also prepared data analyses and exhibits to inform the workshop discussions.

The Center for the Advancement of Distance Education at the University of Illinois provided on-site technical support in audiocasting the January 17 workshop to a national audience. An archival file of the speakers' remarks and electronic slides can be found at the IOM website: www.iom.edu/iom/iomhome.nsf/pages/hcs+immunization+finance+dissemination.

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 NRC'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., The Johns Hopkins University

Sara Rosenbaum, J.D., The George Washington University

Sandra Ross, P.H.N., Health and Human Services Agency, San Diego, CA

Cheri Todoroff, M.P.H., Los Angeles Immunization Program

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions nor did they see the final draft of the report before its release. The review of this report was overseen by Neal A. Vanselow, M.D., Rio Verde, Arizona. Appointed by the National Research Council and Institute of Medicine, 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.

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Executive Summary

Immunization is essential to disease prevention efforts in public health, but the nation's immunization system faces financing challenges that are affecting the delivery of services. A 2000 report from the Institute of Medicine (IOM), *Calling the Shots: Immunization Finance Policies and Practices* (IOM, 2000), pointed to the instability of the fundamental infrastructure that supports immunization programs throughout the United States, including unpredictable federal funding levels, growing financial burdens and operational complexities in immunization services, shortcomings in public- and private-sector investments in vaccine purchases and immunization programs, and fluctuations in coverage plans in the public and private health care sectors that create uncertainties regarding vaccine purchase and service delivery arrangements.

The report recommended renewing and strengthening the federal–state partnership at the heart of the national immunization system, as well as strategic investments in immunization efforts and closer collaboration between public and private health care systems. As a framework to guide these efforts, IOM identified six fundamental roles for the nation's immunization system: (1) controlling and preventing infectious disease; (2) assuring vaccine purchase; (3) assuring service delivery; (4) sustaining and improving coverage levels; (5) conducting surveillance of immunization coverage and safety; and (6) implementing effective immunization finance policies and practices.

In January 2002, health officials, public health experts, health care

providers, health plan representatives, health care purchasers, and community leaders met at the University of California at Los Angeles to explore the implications of the IOM findings and recommendations for California in general and for Los Angeles and San Diego County in particular. The one-day workshop was the third in a series of four meetings organized by IOM with support from the Centers for Disease Control and Prevention to foster informed discussions about challenges for immunization finance and future financing strategies for immunization activities and the public health infrastructure that supports those activities.

This report of the Los Angeles workshop summarizes the findings of the IOM study, reviews progress in responding to the IOM recommendations at the federal level, and highlights continuing challenges in immunization finance for the nation and at the state and local levels in California. Progress in responding to the IOM recommendations includes increases in federal funding for immunization infrastructure grants, discussions with the states to define a formula for the distribution of those grant funds, and efforts to improve the measurement of immunization coverage. In California, efforts at the state and local levels have helped in achieving immunization coverage levels comparable to the national average. Aiding clinics and private providers in assessing the immunization status of their patients has helped improve coverage rates. For employers, providing coverage for immunizations and other preventive services can be a cost-effective investment that reduces absenteeism.

But California, its communities, and its health care providers and health plans face important challenges. The economic downturn is expected to mean reductions in state and local funding for immunization services. There is concern that nationwide shortages of several vaccines may result in lower immunization coverage rates. The high cost of new vaccines and the increasing cost of older vaccines are having a major impact on state and local budgets and their vaccine purchasing power. The high cost of vaccines also results in serious financial risk for many private providers who depend on reimbursements to cover the cost of their vaccine purchases.

Workshop participants also commented on the financial and administrative problems that arise because children enrolled in California's Healthy Families Program are not eligible for federally funded vaccines available through the Vaccines for Children program. Immunization registries are a welcome development, but their use imposes a sometimes prohibitive administrative burden on private providers. Immunization rates among the privately insured might be adversely affected if employers adopt plans that provide lump-sum benefits for preventive care and allow employees to decide how to allocate those benefit dollars.

Workshop participants encouraged efforts to find less burdensome

methods to capture data for immunization registries and to move to a more comprehensive statewide system. To address concerns about both the shortages and the rising costs of vaccines, it will be important to explore the public policy tools available to create appropriate incentives for the production and distribution of vaccines. Also emphasized at the workshop is the special difficulty that public health and the immunization system face. These services can seem invisible when they work because people are not getting sick, but the public health system has suffered from neglect because of its invisibility. Leadership is needed to ensure that immunization issues remain visible and receive appropriate attention.

Introduction

Immunization is an essential public health tool for preventing serious illness and death from certain infectious diseases. In June 2000, the Institute of Medicine (IOM) report *Calling the Shots: Immunization Finance Policies and Practices* (IOM, 2000) pointed to disturbing signs of instability in the nation's immunization system, as well as in the public health infrastructure supporting it: growing financial burdens and operational complexities in the delivery of immunization services, shortcomings in public- and private-sector investments in vaccine purchases and immunization programs, and an unsettled health insurance environment in both the public and private sectors that contributes to uncertainties regarding coverage for vaccines and immunization services.

The national immunization system is a partnership that relies on multiple and diverse relationships involving federal agencies and programs, health officials in state and local governments, health care providers, employers, insurers and health plans, vaccine manufacturers, and others in the private sector. The Centers for Disease Control and Prevention (CDC) requested that IOM undertake a special effort to reach these various groups as part of the dissemination activities for *Calling the Shots*. Three regional workshops and a national meeting are being held to review the findings and recommendations of the IOM report and to examine their implications for health care policy at state and local levels, the coverage of immunization benefits under private health plans, and the delivery and quality of heath care services, especially in disadvantaged communities.

The IOM workshop discussions 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 policy makers.

The first of the three regional workshops, held in June 2001 in Chicago, Illinois, 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 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).

This report summarizes the discussions of the third regional dissemination workshop, which examined immunization issues in California, with a special focus on Los Angeles and San Diego counties. The meeting, which was held in January 2002 at the University of California at Los Angeles (UCLA), was organized by IOM in collaboration with the School of Public Health at UCLA and the Los Angeles County Health Department. Participants included 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; staff from CDC; consultants and other contributors to *Calling the Shots*; and members and staff of the IOM planning committee. (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.)

Background

In the United States, the purchase of vaccines and the delivery of immunization services depend on a complex mix of public and private funding and services. Although children's immunization coverage rates reached high levels during the past few decades, a measles epidemic in 1989–1991 drew attention to the continuing health threat from vaccine-preventable diseases if immunization rates fall. Following the measles epidemic, the federal government substantially increased grants to states for immunization program activities (immunization "infrastructure" grants) through what is known as the Section 317 program. This CDC-administered program, which began in 1963, also provides federal assistance to states for vaccine purchase. Vaccines for Children (VFC), a federal program implemented in 1994, added new funding to purchase vaccine for qualifying children, primarily those enrolled in Medicaid or without health insurance coverage for immunization.

Other developments in the 1990s also affected the immunization system. New, more expensive vaccines were added to the recommended schedule of immunizations. VFC and new approaches to Medicaid encouraged greater reliance on health care providers in the private sector for the delivery of immunization services, while the growth of managed care contributed to fundamental changes in the larger health care delivery system. In the wake of these changes, state and local health departments had a smaller role in the direct provision of immunization services. They frequently took on a new role, however, that placed greater emphasis on monitoring indicators of community health status and service delivery

(IOM, 1996, 1997), including assessing immunization coverage rates, and on responding to immunization and other specific health care needs of hard-to-reach populations.

Although the states welcomed new federal immunization funding in the mid-1990s, many of them found it difficult to expend the sudden and significant increases in Section 317 immunization infrastructure awards during the one-year grant period. As a result, states "carried over" large amounts of these grant funds to subsequent years. By 1996, the U.S. Congress had cut back funding for Section 317 infrastructure grants, indicating its uncertainty that the states needed, or could manage, federal assistance in this area. In 1998, Congress asked that the Institute of Medicine (IOM) conduct a study of the Section 317 program and of broader questions regarding appropriate levels of effort to achieve national immunization goals.

The IOM study committee met in 1999 and 2000 to collect relevant information and to develop a framework to guide its deliberations. In support of the study, a research team at the University of Michigan was commissioned to conduct a series of structured telephone interviews with immunization program officials in all 50 states regarding the effects of changes in federal policies and funding during the 1990s on the goals, priorities, and activities of state immunization programs (Freed et al., 2000). IOM staff and consultants developed eight case studies of public-sector immunization efforts in Alabama, Maine, Michigan, New Jersey, North Carolina, Texas, Washington, and Los Angeles and San Diego counties in California (Fairbrother et al., 2000b).[1] Site visits to Detroit, Houston, Los Angeles, and Newark allowed for discussions with local providers and immunization program representatives that supplemented the case study materials. A workshop examined issues related to "pockets of need." The committee also commissioned background papers on topics such as adult immunization, registries, measuring immunization coverage (Fairbrother et al., 2000a), and federal immunization policy (Johnson et al., 2000). Selected materials from the case study reports and commissioned papers were published in October 2000 in a supplement to the *American Journal of Preventive Medicine*.

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

A National Perspective on the Immunization System

At the Los Angeles workshop, opening presentations from David Smith, president of Texas Tech University Health Sciences Center and chair of the Institute of Medicine (IOM) committee organizing the workshop, and Walter Orenstein, director of the National Immunization Program at the Centers for Disease Control and Prevention (CDC), provided an overview of immunization issues facing the country, the findings and recommendations on immunization finance from the IOM study, and CDC's response to those recommendations.[2]

THE NATIONAL IMMUNIZATION PICTURE

Immunization Coverage

Over the course of the 20th century, the introduction of new vaccines and efforts to ensure that children are appropriately immunized produced substantial reductions in illness from many serious diseases (see Table 1). Dr. Orenstein reported that it even appears that measles may no longer be endemic in the United States. Nevertheless, many children and

[2]An audiocast of each presentation and the speaker's visual aids are available in electronic form at the workshop website: www.iom.edu/iom/iomhome.nsf/pages/hcs+immunization+finance+dissemination.

TABLE 1 Change in Annual Morbidity from Vaccine-Preventable Diseases: Prevaccine Baseline and 2001

Disease	Prevaccine Baseline Date	Average Annual Baseline Cases	2001 Cases	% Decrease
Diphtheria	1920–1922	175,885	2	100.00
Haemophilus influenzae, type b and unknown (< 5 years)	1985	20,000	183	99.20
Measles	1958–1962	503,282	108*	100.00
Mumps	1968	152,209	231	99.80
Pertussis	1922–1925	147,271	5,396	94.70
Poliomyelitis	1951–1954	16,316	0	100.00
Rubella	1966–1968	47,745	19	99.60
Tetanus	1922–1926	1,314	27	97.30

*Provisional data
SOURCE: Adapted from CDC (2002a).

adults have not received recommended vaccines, and disease outbreaks remain a threat if immunization coverage is below optimal levels. Dr. Smith pointed to Texas, where a pertussis outbreak has resulted in seven deaths.

Despite improvements in immunization coverage during the 1990s, national immunization rates for 2-year-olds and for adults aged 65 years and older have not yet reached the current public health objective of 90 percent coverage. For 2000, the National Immunization Survey (NIS) found that 76 percent of children ages 19 to 35 months had received all the vaccine doses necessary to complete the 4:3:1:3 immunization series[3] (see www.cdc.gov/nip/coverage/NIS/00-01/toc-00-01.htm). Although coverage rates for many individual vaccines approach and even exceed 90 percent, the various missed doses lower the rates for a complete immunization series. The decline in the rate for the 4:3:1:3 series from 79 percent in 1998 is a source of concern, as are the persistent disparities in rates across states (see Figure 1).

[3]The 4:3:1:3 series refers to four or more doses of diphtheria and tetanus toxoids and whole-cell or acellular pertussis vaccine (DTP or DTaP); three or more doses of poliovirus vaccine; one or more doses of any measles-containing vaccine; and three or more doses of *Haemophilus influenzae* type b (Hib) vaccine.

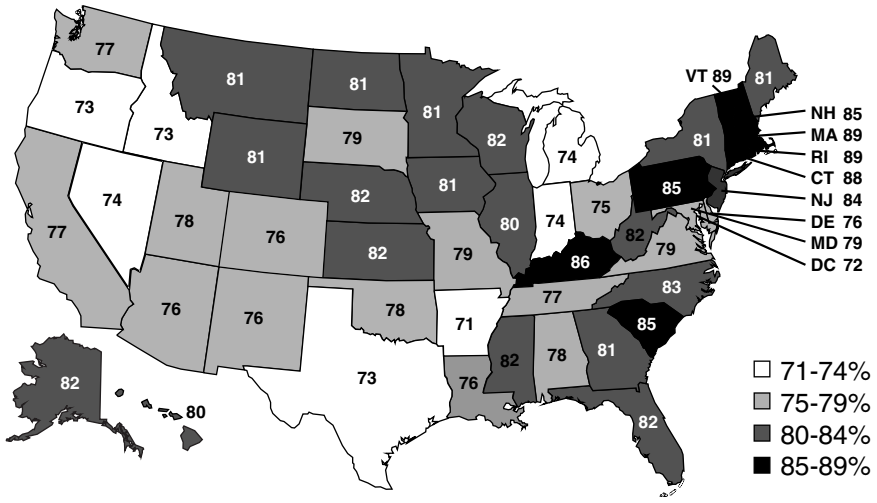

FIGURE 1 Estimated vaccination coverage with the 4:3:1:3 series, by coverage level and state. Source: *Calling the Shots.* Institute of Medicine (2000).

Among older adults (ages 65 and over) living in the community (i.e., not in nursing homes or other institutional settings), 67 percent reported in 1999 that they had received an influenza vaccination in the previous year, and 54 percent had ever received a pneumococcal vaccination (CDC, 2001). Immunization rates for high-risk adults ages 18 to 64 are particularly low, with data for 2000 showing that only 32 percent of this group had received an influenza vaccination in the previous year (CDC, 2002b). Low influenza immunization rates among "high- risk" children and adults younger than age 65—those with asthma or other chronic health conditions—are of particular concern.

Immunization levels are also persistently lower among low-income children and adults. Although the annual NIS and other state-based immunization surveys provide estimates of general population immunization coverage levels, they frequently rely on telephone household surveys that do not include estimates for pockets of high-risk, underimmunized populations represented by groups such as public housing districts or neighborhoods characterized by deep poverty (U.S. General Accounting Office, 1996). For example, one survey of coverage rates in 1997 for inner-city, African-American children in Los Angeles found that only half (50.6 percent) of the control group (which did not participate in a case management intervention) were up to date at 1 year of age, a marked contrast with the NIS estimates of 83 percent for the nation and 86 percent for Los Angeles County (Wood et al., 1998). Similarly, a 1994 Chicago

area study found coverage rates for the 4:3:1 series of 29 percent among African-American children living in public housing in contrast to 47 percent citywide coverage rates (Kenyon et al., 1998). Nationally, the disparity in immunization rates between children in households with incomes below the poverty level and children in higher income households is about 9 percentage points.

Federal Financing for Immunization Program Activities and Vaccine Purchase

Federal financial support for the immunization system is provided principally through the Section 317 program and Vaccines for Children (VFC). Under the Section 317 program, each state and territory and five large urban areas receive annual grants for the purchase of vaccine and for the operation of immunization program activities (infrastructure funding). The Section 317 awards are the major source of federal support for essential immunization system activities such as surveillance of vaccine coverage and efforts to improve coverage. Dr. Orenstein reported that about $182 million is available for program operation grants for 2002.

VFC, a federal entitlement program, funds the purchase of vaccine for participating health care providers to administer to eligible children. Roughly $795.5 million is available for VFC for 2002 (see www.cdc.gov/fmo/fmofybudget.htm). CDC estimates that more than 40,000 private providers are participating in VFC. In addition, federal contracts with vaccine manufacturers make it possible for states to use either federal or state funds to obtain additional vaccines at discounted prices. More than half of all vaccine is purchased under these federal contracts, with 36 percent purchased through VFC and 15 percent purchased through Section 317 (IOM, 2002b).

CHALLENGES FOR THE IMMUNIZATION SYSTEM

Dr. Smith and Dr. Orenstein noted that the nation's immunization system is facing challenges that could undermine past achievements and hinder the effort still needed to reach targeted levels of immunization coverage. Some of these demands include sustaining current rates of coverage with the addition of new and more expensive vaccines to the immunization schedule, responding to concerns about the safety of vaccines, serving an increased number of people as a result of recommendations for expanded adolescent and adult vaccination, and adapting to changes in the health care delivery system that can affect the availability and affordability of vaccines in the private sector.

The continuing addition of vaccines and vaccine doses to the recom-

mended childhood immunization schedule is increasing the complexity and the cost of meeting immunization requirements. Between 1975 and 2000, 25 changes were made to the pediatric immunization schedule, and more changes and additions are anticipated. For example, a recommendation for influenza vaccination for all children is being considered. With children now needing up to 20 vaccine doses by age 2, the demand for immunization services is placing a growing burden on the health care delivery system. Combination vaccine products help reduce the number of separate injections required, but the use of products with different combinations of vaccines can make it more difficult to manage the immunization requirements of children who receive immunizations from multiple providers.

The high cost of newer vaccines, reflecting in part the increased costs of production and distribution, is having a marked impact on federal, state, and local budgets for vaccine purchase. The cost of these vaccines is also creating financial burdens for families, private providers, and insurers. The pneumococcal conjugate vaccine, added to the pediatric immunization schedule in 2000, costs roughly $46 per dose under the CDC purchase contract and nearly $59 per dose at regular prices (www.cdc.gov/nip/vfc/cdc_vac_price_list.htm). By comparison, comparable per-dose costs for the polio vaccine are approximately $8 and $15, respectively.

A problem that has emerged in the past couple of years is persistent shortages of vaccines. Dr. Orenstein reported that vaccines against 8 of the 11 vaccine-preventable diseases among children were in short supply at the time of the workshop, a situation he described as unprecedented. In addition, supplies of the influenza vaccine have been limited or delayed in the past 2 years. The shortages appear to reflect a mix of vaccine production problems and a decline in production capacity resulting from the decisions of some manufacturers to stop making certain vaccines. CDC is advising states and health care provider organizations on modifications to the immunization schedule to accommodate the shortages, but it appears that many providers are not keeping up with the changing recommendations. The vaccine shortages and reduced number of vaccine producers are contributing to upward pressures on vaccine prices. Dr. Orenstein noted that the National Vaccine Advisory Committee would be examining issues of vaccine supply at a meeting scheduled for February 2002.

Vaccine safety is another concern. CDC routinely monitors reports of adverse events following immunization for signals of unacceptable health problems. In response to a question about the tensions between CDC's roles in promoting immunization and in monitoring vaccine safety, Dr. Orenstein pointed out that a separate agency, the Food and Drug Admin-

istration, is responsible for licensing or recalling vaccines. He also noted that responses to vaccine safety concerns over the past few years have included modification of some vaccines by manufacturers and removal of the rotavirus vaccine from the immunization schedule. In addition, CDC supports vaccine safety studies, including the work of an IOM committee that is reviewing several safety topics over a 3-year period and the Vaccine Safety Datalink project.

To respond to other needs, CDC is also focusing attention on adult immunization, on the improvement of the surveillance and measurement tools used to monitor immunization, and on the implementation of evidence-based activities aimed at improving immunization rates. In response to questions from workshop participants about immunization registries, Dr. Orenstein noted that CDC is involved in their development through its funding to states as well as through participation in efforts to develop technical standards. In collaboration with the National Vaccine Advisory Committee, CDC has developed guidance on ways to address the confidentiality and privacy concerns associated with registries. CDC is also working with the American Academy of Pediatrics on how to improve participation in immunization registries by private physicians.

IOM CONCLUSIONS AND RECOMMENDATIONS

Dr. Smith reviewed the key conclusions and recommendations from *Calling the Shots*. The report calls for a renewal and strengthening of the federal–state partnership that is a fundamental element of the national immunization system. The report also recommends strategic investments in immunization efforts and closer collaboration between public and private health care systems to coordinate immunization roles and responsibilities in the wake of health care reforms.

The IOM study committee identified six fundamental roles for the nation's immunization system:

1. Control and prevent infectious disease.
2. Assure the purchase of recommended vaccines for the total population of U.S. children and adults, with particular emphasis on the protection of vulnerable groups.
3. Assure access to such vaccines within the public sector when private health care services are not adequate to meet local needs.
4. Sustain and improve immunization coverage levels within child and adult populations, especially in vulnerable communities.
5. Conduct populationwide surveillance of immunization coverage levels, including the identification of significant disparities, gaps, and vaccine safety concerns.

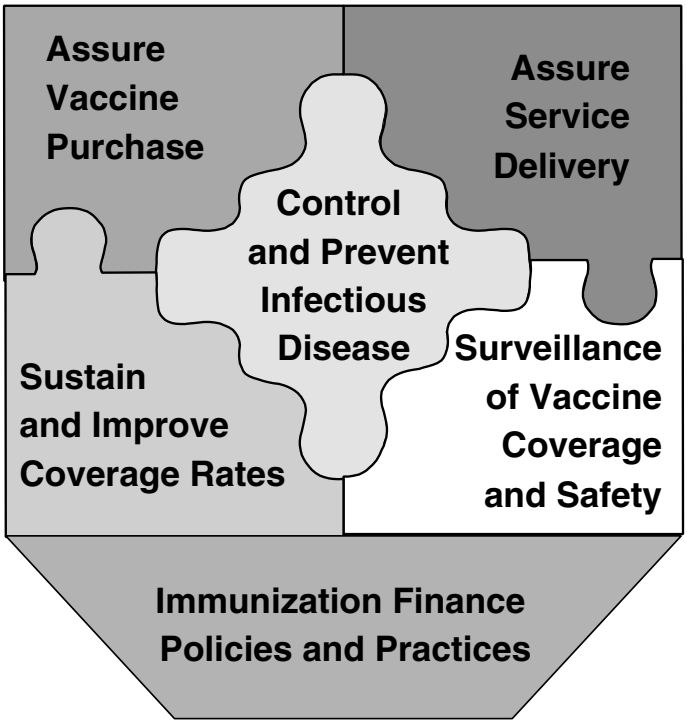

FIGURE 2 Six roles of the national immunization system.

6. Use primary care and public health resources efficiently in achieving national immunization goals.

The committee used this framework to guide its finance recommendations. The report concluded that adequate, stable, and predictable funding was necessary for the development of effective state immunization programs and that the fluctuations in Section 317 infrastructure funding during the 1990s made it difficult for states to achieve program goals. Furthermore, with only a 1-year grant period, many state immunization programs could not invest in multiyear programs to support long-term strategic planning or data collection efforts.

The committee also concluded that immunization policy should be national in scope, but flexible enough to accommodate important political, socioeconomic, and structural differences among states and communities. Furthermore, federal and state governments share responsibility for supporting vaccine purchase and the infrastructure essential for achieving and sustaining national immunization goals. Data reviewed

for the study showed that some states appeared to provide little or no state funding for immunization while others invested substantially more than they received from federal sources. Finally, the private sector, through health plans and individual health care providers, has the capacity to do more to ensure the delivery of appropriate immunization services to their members and patients, but such efforts do not replace the need for a public health infrastructure capable of assuring that the immunization needs of the whole population are addressed.

The study recommendations addressed federal and state funding levels, grant mechanisms for immunization programs, and the need for better measurement of immunization coverage. The committee concluded that annual budgets for the purchase of vaccine for children have been adequate in the past; however, this finding was made prior to the addition of the pneumococcal conjugate vaccine to the recommended schedule for children. The committee recommended increases in both federal and state budgets to provide for the purchase of additional vaccine for those high-risk adolescents and adults under age 65 who do not qualify for other federal assistance. The committee also recommended increases in financial and administrative support from federal and state governments for immunization infrastructure programs.

In addition to budgetary increases, Dr. Smith noted that the IOM report proposed new operational and reporting requirements for the federal grants linked to the six fundamental roles of the national immunization system. The committee recommended that CDC should use a formula grant mechanism to distribute Section 317 awards to states. The formula should reflect essential minimum funding levels and state need, capacity, and performance. In addition, a requirement for a state funding match should be added, and the federal grants should have a 2-year budget cycle to give states greater flexibility to plan and implement multiyear efforts. Finally, the IOM report recommended that federal and state agencies develop a set of consistent and comparable measures for use in monitoring the immunization status of children and adults enrolled in private and public health plans as well as the immunization status of populations in defined geographic areas.

CDC RESPONSES TO IOM RECOMMENDATIONS

Dr. Orenstein outlined CDC's responses to the IOM report and recommendations. He first emphasized the value of articulating the six broad roles of the national immunization system. This framework helps explain the importance of a range of activities that includes not only vaccine purchase and direct delivery of immunization services, but also surveillance and coverage assessments.

IOM recommended that CDC provide Congress with estimates of the cost of vaccines added to the childhood immunization schedule so that those estimates can be factored into the Section 317 budget. Dr. Orenstein commented that although Congress has not requested such estimates, CDC is seeking better information about factors affecting vaccine pricing and the demand for publicly purchased vaccine. A new IOM study will examine vaccine financing strategies that reflect the roles and responsibilities of the public and private sectors in the purchase of vaccine and associated administrative costs. The study will also consider the effect of vaccine pricing on incentives for further vaccine research and production and will assess prospects for future vaccine prices.

Little progress has been made at the federal level in increasing funding for the purchase of vaccine for adolescents and adults. CDC is, however, trying to address this issue in other ways such as urging public and private health plans to include or improve coverage for adolescent and adult immunizations. CDC is also encouraging states to enroll health care providers who treat adolescents in VFC so that they can obtain free VFC vaccine for eligible patients. The enrollment of more adolescents in State Child Health Insurance Programs is also seen as an opportunity to improve access to lower cost immunization services for this population. In addition, standards for adult immunization practices, comparable to the standards developed in the 1990s for young children, were recently issued, and work is beginning on standards for immunization of adolescents. The Task Force for Community Preventive Services will be developing evidence-based guidelines for immunization interventions aimed at certain target populations.

Dr. Orenstein reported welcome increases in funding for Section 317 immunization infrastructure grants in 2001 and 2002. Even so, the funding level remains about $18 million to $19 million short of the $200 million that IOM recommended. CDC is exploring whether to extend the grant period to 2 years, but Congress reauthorized the Section 317 program before such a proposal could be submitted. CDC is working with grantees to reduce the reporting burden associated with these grants and to improve the documentation of state financial and in-kind contributions to immunization activities.

The formula grant mechanism that IOM recommended for the distribution of Section 317 infrastructure funds offers the advantages of greater equity and transparency in funding decisions, but it poses a challenge in that some states will end up receiving less funding. The recent budget increases will help ease the impact of the reallocation of funding, and CDC has agreed that a state's funding will decrease by no more than 5 percent per year. CDC is working with the states, through the Association of State and Territorial Health Officials and the Association of Immu-

nization Managers, to develop criteria and weights for a funding formula. The proposal currently under consideration gives a weight of 12 percent to a funding base to cover minimum program needs, 78 percent to need as reflected in factors such as population size and immunization coverage rates, 5 percent to performance, and 5 percent to discretionary funding needs (e.g., responding to disease outbreaks).

CDC's other major effort in response to the IOM recommendations is to improve the measurement of immunization coverage. Toward this end, CDC is working with the National Committee for Quality Assurance to modify immunization measures in the Health Plan Employer Data and Information Set (HEDIS) to better reflect immunization recommendations. New vaccines are to be incorporated into HEDIS measures within 3 years of their addition to the immunization schedule. A new HEDIS measure will reflect the recommendation for influenza immunization for adults ages 50 to 64. In addition, changes to the NIS will allow for greater comparability with HEDIS data and for the measurement of immunization coverage at more ages.

Dr. Orenstein ended his remarks by noting the conclusions in *Calling the Shots* regarding the federal and state roles in the immunization system. With states as the ultimate stewards of public health, state legislatures and state governments should be expected to sustain an immunization infrastructure. The federal role is to supplement and support state efforts. Thus, Dr. Orenstein hoped that the workshop would aid CDC in finding ways to help states fulfill their roles in the immunization system.

State and Local Immunization Issues in California

State and local health departments are both essential components of the immunization system. Responsibility for broad program oversight and management generally rests at the state level. Local health departments play a critical role in implementing immunization programs through activities that can include operating immunization clinics, conducting community outreach, and with the advent of Vaccines for Children (VFC), working with participating private providers who deliver most immunization services.

CALIFORNIA DEPARTMENT OF HEALTH SERVICES

Natalie Smith, chief of the Immunization Branch of the California Department of Health Services, reviewed the state's leading immunization activities and concerns related to the components of the immunization system outlined in *Calling the Shots*. She observed that serving a population of 35 million people poses substantial operational and financial challenges for the state. In terms of vaccine purchase, about 60 percent of the state's vaccine doses are purchased with public funds (federal, state, or local), but about 80 percent of vaccinations are delivered by private providers. Dr. Smith noted that VFC funds cannot be used to purchase vaccine for children covered under the Healthy Families Program, California's State Child Health Insurance Program (SCHIP). The health plans that contract with the California Healthy Families Program are responsible for reimbursing the costs of the vaccines to the providers. The

TABLE 2 Estimated Vaccination Coverage for the 4:3:1:3* Series Among Children Ages 19 to 35 Months, United States and California, 1996–2000

	Percent				
Area	1996	1997	1998	1999	2000
United States	76	76	79	78	76
California	74	74	76	75	75
City of Los Angeles	75	72	76	76	76
San Diego County	74	78	77	75	76
City of Santa Clara	80	69	84	82	76
Rest of state	72	76	75	74	75

*Four or more doses of DTP, three or more doses of poliovirus vaccine, one or more doses of any measles-containing vaccine, and three or more doses of Hib vaccine

SOURCES: CDC, National Immunization Survey (www.cdc.gov/nip/coverage).

state also purchases 700,000 doses of influenza vaccine for use by county health departments to help assure the delivery of immunization services to the high-risk population. Dr. Smith noted, however, that the cost of influenza vaccine had more than doubled in a single year, going from $1.80 per dose in 1999 to $4.45 per dose for 2000.

As part of its surveillance activities, the state monitors both immunization coverage rates and immunization exemptions granted for personal beliefs. Immunization rates for 2-year-olds in California are comparable to rates for the nation as a whole (see Table 2 and www.cdc.gov/nip/coverage). The latest data for 2000 from the National Immunization Survey (NIS) show that 75 percent of California's 2-year-olds are fully immunized for the 4:3:1:3 series, compared with the national average of 74 percent. Preliminary estimates for the 2001–2002 school year indicate that about 1.2 percent of children entering kindergarten were not immunized because of exemptions for their families' personal beliefs. In some counties, up to 5 percent of children have been exempted. Where exemption rates are high, the state health department is concerned about increased risk for disease outbreaks.

The immunization rates for older adults (ages 65 and over) exceed the national average but still fall short of the national public health goal of 90 percent coverage. Dr. Smith reported that California data for 2000 show that 70 percent of older adults reported having received an influenza vaccination in the previous year. The national rate for 1999 was 67 per-

cent (CDC, 2001). For 2000, California also estimates that 61 percent of older adults had ever received a pneumococcal pneumonia vaccination, compared with the national estimate of 54 percent in 1999 (CDC, 2001). Rates in California are lowest for high-risk adults ages 18 to 64 and for African-Americans.

Efforts to sustain and improve immunization coverage include adding varicella to the immunizations required for day care and school entry. Dr. Smith reported that NIS data show that varicella coverage rates for 2-year-olds had reached 76 percent in 2000, up from just 26 percent in 1996–1997. She expressed concern, however, that the current shortages of DTaP and varicella vaccines might contribute to lower coverage rates. Health plans, which must report their immunization coverage rates as a Health Plan Employer Data and Information Set measure, are also becoming concerned about the impact of vaccine shortages.

Immunization registries can aid in monitoring immunization coverage rates and in efforts to identify children in need of immunization services. Dr. Smith noted that in California registries had begun at the county level and that efforts are now under way to establish regional systems. California has submitted an application for funding from Medicaid to help support registry activities. A workshop participant urged state-level leadership in developing a comprehensive registry to overcome the problem of incomplete and scattered records, which can arise when families move from one community to another.

With California's large population, the amount of state and federal immunization funding available per child is relatively modest compared with many other states. The state received $18.3 million in federal immunization grant funds for 2001, down from a peak of $36.5 million in 1996. A multiyear approach to federal Section 317 grants, as recommended by the Institute of Medicine (IOM), would aid the state in maintaining a more stable funding base for its immunization program. Dr. Smith noted that new federal funding for activities related to bioterrorism, some of which will be relevant for the immunization program, may be awarded on a multiyear basis.

California also supports efforts to implement the IOM recommendation for formula-based funding for Section 317 awards. A formula would help clarify the basis for federal funding decisions and is expected to produce a more equitable allocation of funds. In addition, Dr. Smith suggested targeting funds for "pockets of need" and giving greater attention to the implications of new vaccines and immunization recommendations for adolescents and adults. Overall, she urged maintaining an adequate level of funding to help break the "immunization cycle," with disease outbreaks stimulating rapid but temporary funding increases (Roper, 2000).

LOS ANGELES COUNTY

The immunization financing issues facing Los Angeles County were discussed by Jonathan Fielding, county health officer and director of public health. With a population of 9.5 million and an annual budget of about $460 million, Los Angeles is larger than many states. The county is also exceptionally diverse. About 45 percent of its residents are Hispanic, 31 percent are non-Hispanic white, 12 percent are Asian or Pacific Islander, and 9 percent are African American. English is not the primary language of 49 percent of the county's residents, and 35 percent are foreign born. Dr. Fielding noted that as many as 100 languages are spoken in Los Angeles. Overall, 22 percent of residents are living in poverty, but among children ages 0 to 4 years, 36 percent are poor. In 1999–2000, 20 percent of children were uninsured, but there is concern that the percentage of uninsured children may increase as a result of the current economic downturn.

Despite these challenges, Los Angeles County's immunization coverage rates, at about 76 percent for 2-year-olds in 2000, are similar to state and national rates. Rates for children in low-income families are slightly lower, but the difference is not statistically significant. The incidence of vaccine-preventable disease has also been reduced significantly over the past decade, although the number of pertussis cases has increased (see Table 3).

The county's immunization program receives 30 percent of its funding from the state and 70 percent from federal sources. For 2001, the total amounted to $5.4 million. In addition, the county funds the delivery of immunization services at 49 facilities operated by its Department of Health Services (DHS). However, more than 90 percent of immunizations in Los Angeles County are delivered by about 5,000 private providers. Of this group, about 1,100 participate in VFC.

TABLE 3 Vaccine-Preventable Diseases, Los Angeles County, 1990–2000

Year of Onset	1990	1995	2000
Measles	4,052	7	5
Mumps	102	42	29
Rubella	106	3	3
Pertussis	93	103	102
Haemophilus influenzae type B	208	6	1

SOURCE: Los Angeles County Health Department (2002).

Dr. Fielding outlined serious financial challenges for the county and its immunization efforts. Current funding from state and federal sources is about one-third less than the $8 million available in 1997. This funding decrease has made it necessary to reduce immunization clinic staff and services along with outreach and education activities, including assessments and referrals from WIC[4] clinics and the production of health education materials. Further reductions in state funding are expected for 2002 and 2003. In addition, a fiscal crisis for the county means that lost state funding is not likely to be replaced locally, and closure of some facilities where immunization services are provided is expected.

In terms of publicly funded vaccine purchase, Los Angeles County depends heavily on the federal VFC program. For 2001, about 3.4 million doses of vaccine costing $60 million were obtained through VFC. The county purchased an additional 110,000 doses of vaccine, at a cost of $400,000. Dr. Fielding emphasized the challenges facing the county in the future. Substantial increases have already occurred in the cost of some vaccines (i.e., influenza and tetanus and diphtheria toxoids [Td]) and might occur for other vaccines. Moreover, demand for vaccines for adults (e.g., hepatitis A and B and pneumococcal vaccines) is increasing. Those vaccines cannot be obtained through the VFC program (but could be purchased with Section 317 funding, if funds were available).

Dr. Fielding also noted, as Dr. Natalie Smith had, that chronic vaccine shortages are becoming a concern because they pose a risk of reducing immunization coverage rates. Los Angeles DHS facilities have occasionally had to turn people away because requested vaccines were unavailable. In addition, private providers who have not been able to obtain vaccines are looking to the health department to provide those immunizations, even though the health department is subject to the same supply constraints. Referrals also appear to be coming from private providers concerned about inadequate reimbursement for vaccine and immunization services.

The current priorities for the immunization program in Los Angeles include ensuring the availability of free childhood immunizations, developing better programs to serve the children who are hardest to reach, directing additional resources to education and quality assurance activities for the large population of private providers delivering immunization services, and strengthening the immunization registry. Dr. Fielding

[4]WIC refers to the Special Supplemental Nutrition Program for Women, Infants, and Children. The program is funded by the U.S. Department of Agriculture and administered by state health departments, tribes, and territories. Most states contract with local health departments, community clinics, and other nonprofits to deliver the services.

noted that resources for provider education and quality assurance are inadequate, even for VFC providers alone. He also emphasized the importance of improving providers' use of the immunization registry. Not only should they submit data on a regular basis, but they should also check the immunization status of children before giving new doses.

Dr. Fielding identified several general concerns regarding financing for immunization services. Stable funding is needed for planning and sustaining immunization activities, including outreach and education. A more stable vaccine supply is also needed. Other concerns include funding for purchase of adult vaccines and combination vaccines and increased support for immunization infrastructure and immunization registries. Dr. Fielding also highlighted two issues related to private health insurance coverage for immunizations. Clearer guidelines are needed for judging the "medical necessity" of, and therefore coverage for, influenza vaccinations. Also, some employers may be considering a change in the way they offer benefits for preventive health care. Instead of offering coverage for certain services such as immunization, they may offer a fixed-dollar benefit and allow employees to decide how to allocate those benefit dollars. Dr. Fielding expressed concern that such an approach might make it more difficult to align personal and public health priorities related to immunization. He concluded that progress has been made in responding to the IOM recommendations on immunization finance policies and practices, but that growing financial problems such as those facing California and Los Angeles could overtake those gains.

SAN DIEGO COUNTY

Sandra Ross, immunization program coordinator for the San Diego County Health and Human Services Agency, discussed that county's immunization activities and financing concerns. In San Diego County, an immunization program plan, developed in 1991 following the measles epidemic, is implemented by an extensive community coalition involving more than 150 community agencies and organizations. The health department provides leadership, but outreach efforts are delivered primarily through community partnerships. The broadly based coalition has helped generate political and legislative support for immunization activities. All activities and interventions have been data driven. Some of the activities included in the immunization program are community coverage assessments through telephone surveys and the review of kindergarten and day-care records; community education and outreach, especially immunization assessment and referral activities, such as activities for clients at WIC clinics; development and management of the immunization registry; and assessment of immunization coverage rates and provider

behaviors in public clinics and at private provider sites. Efforts are being made now to expand beyond the original focus on children to address adult immunization needs as well.

Immunization rates for 2-year-olds have risen since the start of the initiative. Estimates for 2000 from the NIS show that 78 percent of children have completed the 4:3:1 series,[5] and the county's own telephone survey puts the level at 86 percent. The annual review of kindergarten records is extensive enough to produce retrospective estimates of immunization rates for 2-year-olds by race and ethnicity, a level of detail not available from the telephone surveys. Those estimates show that coverage rates for 2-year-olds have been highest among white children, ranging from 71 percent in 1992 to 75 percent in 1997. Over the same period, rates among Hispanic children rose steadily from 56 to 70 percent. Rates for Black children, who include both African-American and foreign-born children, have remained the lowest, but rose from 56 percent in 1996 to 68 percent in 1997. Ms. Ross suggested that this increase reflected the results of special focus on the black community. She noted, however, that the outreach worker for that project is no longer available.

The county also conducts a telephone survey to monitor immunization coverage rates among adults ages 65 and over. For 2000, 75 percent had received an influenza vaccination in the previous year, and 69 percent had ever received a pneumococcal vaccination. Only 57 percent of older adults had an up-to-date tetanus immunization.

The annual cost to fully implement San Diego's immunization program was originally estimated at $4 million, but actual funding has approached that level for only one year. For 2001, the program had $2.56 million from the state and $720,000 from the county, but future funding levels are uncertain. Funding reductions following the peak level in 1996 has meant that only some of the planned and implemented activities could be sustained. Furthermore, lack of stable and predictable funding has limited the establishment of regular full-time positions at the health department. As a result, the immunization program now relies on about 50 contract staff, but that approach has put the county in conflict with the employee union.

In terms of services, the immunization program currently maintains free walk-in immunization services at more than 40 sites, and over 150 private providers are participating in VFC. Ms. Ross noted that public health clinics are often used on a one-time basis by people who are

[5]The 4:3:1 series refers to four or more doses of diphtheria and tetanus toxoids and whole-cell or acellular pertussis vaccine (DTP or DTaP); three or more doses of poliovirus vaccine; and one or more doses of any measles-containing vaccine.

transitioning between health plans or seeking a regular health care provider. Systematic assessments of providers' immunization records are conducted on an annual basis using CDC's AFIX (Assessment, Feedback, Incentives, eXchange) strategy. The assessment program covers 13 public health clinics, 36 community health centers, and 132 private practices. Coverage rates have improved in all settings since the AFIX reviews began. To deliver additional training to providers and their staffs, the immunization program has begun to rely on videotapes and other distance-learning resources, which minimize the need for either instructors or participants to travel to attend educational programs.

The immunization program also manages the county's immunization registry. Provider participation in the registry is being adversely affected by associated costs, however. Telephone charges for continuous access to the registry system have been as high as $1,000 per month for some providers. To overcome this problem, a web-based access system is being developed. Ms. Ross also observed that private providers have less money from managed care contracts than in the past to cover the cost of office operations, which includes data entry for the immunization registry. The immunization program lacks the resources to assist providers with data entry.

Ms. Ross noted that the immunization coalition has found that the community accepts the value of immunization and that parents rely on their doctors to provide immunizations when they are needed. As a result, outreach activities in San Diego County are focused on helping clinics and private providers improve immunization coverage among their patient populations rather than on community education. Immunization assessment services are available to the public by telephone, from the immunization coalition's website (www.immunization-sd.org), and through coalition partners that provide record assessment and referrals.

WIC clinics have been conducting immunization assessments for their clients, but it is proving difficult to capture that activity in the immunization registry or to gain access to the clinic records to evaluate the effectiveness of the WIC assessments without federal approval. An immunization assessment program is also being tried for clients of CalWorks, the state welfare program. The health department is training CalWorks staff to conduct immunization assessments and to use the immunization registry. The pilot looks very effective, but the continuation of those activities will depend on the availability of immunization program funds.

OBSERVATIONS FROM IOM CASE STUDIES

Los Angeles and San Diego counties were the subject of one of the case studies for the IOM review of immunization finance policies and

practices. Gerry Fairbrother, from the New York Academy of Medicine and an author of the Los Angeles–San Diego case study, discussed key findings. As counties, both Los Angeles and San Diego have sizable populations, with Los Angeles being larger than five of the seven case-study states. In both counties, at least 90 percent of immunizations are given by private providers. Some aspects of the county-level immunization programs are shaped by state policies. California, in contrast to some states, does not mandate that private health insurance plans provide "first-dollar" coverage for immunizations and does not have a "universal purchase" policy that makes required vaccines available without charge to all children in the state.

California's experience with federal immunization infrastructure funding through the Section 317 program mirrored that of other states: A rapid increase in funding was followed by both an increase in spending and repeated carryover of a portion of each year's award. Funding, spending, and fund carryover all peaked in the mid-1990s, then rapidly declined. Most of the funds carried over by California had been spent by 1997. Los Angeles and San Diego counties followed a similar course of rising infrastructure funding that peaked in mid-decade. Dr. Fairbrother pointed out, however, that even though the state could carry over funds from year to year, the counties could not and therefore had even less assurance of stable funding.

As Dr. Fielding and Ms. Ross had described, the expansion of immunization program activities that occurred during the period of increasing funding has been followed by program cutbacks as funding has declined. Dr. Fairbrother highlighted the impact of the cutbacks on changes in the delivery of immunization services within the WIC nutrition program administered by the U.S. Department of Agriculture. The WIC program serves a large portion of the population of infants and young children; 45 percent of infants nationally and 70 percent in Los Angeles and San Diego counties are eligible for WIC services (Fairbrother et al., 2000b). In the 1990s, many local WIC programs elected to add immunization assessment and referral activities, usually with supplemental funding from local immunization programs. At the national level, reduced funding for immunization efforts led to tensions with the WIC programs. Many immunization programs cut their support for the immunization assessment and referral activities, but expectations for continued collaboration with WIC clinics remained.[6]

[6]The Clinton Administration issued a presidential order for a plan for immunization assessment and referral activities at WIC clinics, which resulted in a mandate for such efforts, starting in October 2002.

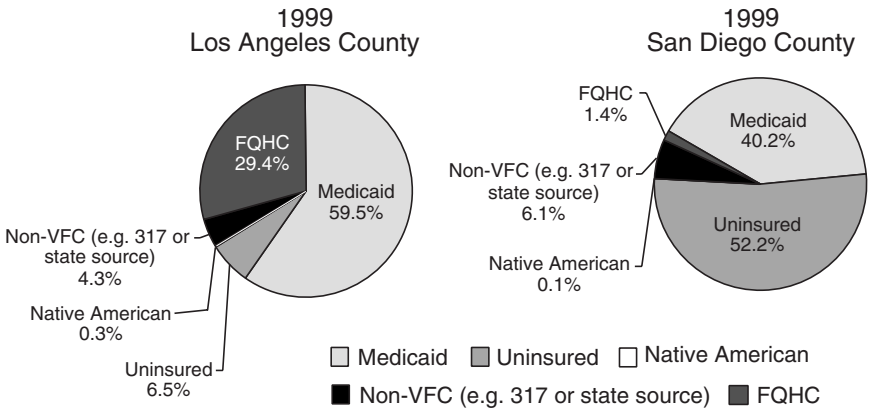

FIGURE 3 Sources of eligibility for children participating in the Vaccines for Children (VFC) program in Los Angeles and San Diego Counties, 1999. Note: FQHC represents vaccines distributed to children who receive their immunizations in federally qualified health centers. Source: Fairbrother et al., 2000b.

During the 1990s, immunization programs in California and elsewhere were also affected by the introduction of VFC and SCHIP and the growth of Medicaid managed care programs, which helped shift the delivery of most immunization services to private providers. However, VFC increased the availability of publicly purchased vaccine. The case study showed that Los Angeles and San Diego differ in terms of how publicly purchased vaccine is used. In Los Angeles, about 60 percent of the children who receive such vaccine do so through Medicaid and only about 7 percent are uninsured. In San Diego, 40 percent of the children receiving publicly purchased vaccine are on Medicaid and 52 percent are uninsured. As Dr. Natalie Smith noted, children enrolled in the Healthy Families Program are not eligible for vaccine obtained through VFC. This creates an added burden for providers participating in the Healthy Families Program because they must order and track that vaccine separately from the VFC vaccine. Moreover, provider payments for immunization services are relatively low because they were set based on an expectation of other funding for vaccine purchase.

The IOM case studies for the California counties and other states showed the problems that unpredictable federal funding posed for state and local efforts to plan and undertake certain activities for their immunization programs. They also demonstrated that while health departments were playing a smaller role in the direct delivery of immunization ser-

vices, they needed new policy tools—such as information management systems and collaborative partnerships with health plans and private providers—to manage their growing and sometimes unfamiliar responsibilities for oversight of the delivery of those services.

DISCUSSION

Questions and comments from workshop participants touched on various concerns for the immunization programs of the state and of local health departments. Given the likely constraints on future federal and state funding for immunization infrastructure activities, the prospects for county-level funding were discussed. In both Los Angeles and San Diego, however, county funding is expected to decline from current levels. For example, San Diego County may discontinue its support for the immunization registry. In Los Angeles, cuts are expected for the DHS facilities and staff where the health department provides immunization services.

Dr. Fielding commented on the challenges of meeting the immunization needs of the highly diverse population of Los Angeles. He noted that the county lacks good data on the full range of ethnic subgroups being served. He emphasized, however, that keeping immunization connected to other aspects of health care is a priority and that one approach taken by the health department has been to establish service contracts with several clinics based in particular ethnic communities. Those clinics, which have 700,000 visits per year, help provide access to culturally competent health care staff. The ethnic diversity in the county is so great, however, that the health department cannot afford to produce community education materials in all relevant languages.

Also discussed was the experience at the state and local levels in working with private providers on quality assurance for immunization services. To detect and correct problems such as improper vaccine storage and handling practices, the state has been working in partnership with the California chapters of the American Academy of Pediatrics and the American Academy of Family Physicians to visit about 1,000 VFC physician practices each year. The state also works with managed care organizations to address quality improvement issues. Additional oversight and training occur at the local level.

A workshop participant encouraged efforts to reduce the administrative burden associated with data entry for immunization registries. Less burdensome data entry might increase provider participation. A workshop participant noted that the Centers for Medicare and Medicaid Services has awarded a grant to the L.A. Care health plan to assess the information system needs of its participating providers.

Practical Challenges for Private Providers

With private providers now delivering most immunization services, it is important to understand the financial and operational challenges that are connected with those services.

CHALLENGES FOR THE PRIVATE PROVIDER IN CALIFORNIA

Quynh Kieu, a pediatrician in solo practice in Orange County and chair of the Vaccine Issues Task Force for the California chapter of the American Academy of Pediatrics (AAP), reviewed several financial and administrative problems facing the state's private providers.

Vaccine Costs and Reimbursement Rates

Immunization has become a financial liability for many physicians. In 2000, the addition of four doses of the pediatric pneumococcal conjugate vaccine (Prevnar) to the recommended immunization schedule drew attention to the problem. As a recommended vaccine, providers were required to offer it to some children, such as those covered by Medicaid and some managed care plans, and were being asked to administer it to other children. A federal contract to purchase the vaccine for children who were eligible under the Vaccines for Children (VFC) program did not exist for many months even though the vaccine had been added to the recommended schedule for Medicaid children. As a result, providers had

to purchase the vaccine at a retail cost of nearly $60 per dose without provisions for reimbursement or additional capitation payments under their existing health plan contracts. This financial liability sometimes leads providers to refer children to the health department to obtain immunizations that their health plan is supposed to cover.

Both increasing vaccine costs and inadequate reimbursement from public and private insurers are contributing factors. Dr. Kieu noted that the cost per child of the vaccines in the recommended pediatric immunization schedule has risen from $36 in 1982 to $628 in 2001. The current shortage of some vaccines is also helping to increase prices. She also reported that for fall 2001, she had to purchase influenza vaccine at $12.50 per dose because a distributor that had offered the vaccine at a lower price had no vaccine available. The AAP has estimated that the cost of administering each vaccine dose is about $15.

Although vaccine can be obtained through VFC for children enrolled in Medicaid, providers must bear the cost of purchasing vaccine for other children and then seek reimbursement. Under the Healthy Families Program, for which VFC vaccine cannot be used, providers are reimbursed at Medicaid rates for the cost of the vaccine, but receive no payment for vaccine administration costs. For children with private insurance, providers must purchase vaccine at retail rates. Reimbursements may not cover the full cost of vaccine, and some private insurance plans may have limited or no coverage for immunizations. Furthermore, business failures among managed care plans and provider organizations can leave the individual provider with unrecoverable claims for vaccine that already has been administered.

Costs related to immunization services are adding to a general increase in the financial burden for providers (see Box 1). Since 1990, the average capitation payment by managed care plans to cover the cost of all pediatric care has declined by 35 percent in California. Dr. Kieu noted that such payments are less than those in many other states. With the current costs and capitation payments, physicians face a loss of about $270 per year for each child to whom they provide care.

Dr. Kieu also suggested that the growing prominence of concerns about vaccine safety—reflected in a scheduled California State Senate hearing on the subject—contributes to the financial challenges for providers. The additional time needed to address parents' concerns is not reflected in reimbursement rates for immunization services.

Administrative Burdens

Offering immunization services includes a substantial administrative overhead for physicians and their office staff. To support the clinical task

of administering an injection, a practice must also see to ordering and managing separate inventories of VFC and non-VFC vaccine, monitoring refrigeration temperatures each day, maintaining and reviewing patient records on immunizations, following up missed immunization appointments, and submitting claims and reports to multiple health plans and to the immunization registry. Periodic reviews of medical records by the health department and health plans also place demands on physician and staff time. Dr. Kieu estimated that medical practices face at least one such review each month.

The burdens of participating in an immunization registry are a particular concern. Data that must be entered in patient records and insurance claims must be entered again for a registry. Dr. Kieu suggested that the development of more efficient data entry techniques would help encourage registry participation by private providers. She mentioned possibilities such as bar code scanning to capture vaccine dose and lot information and web-based data entry systems.

Reducing Financial Burdens and Risks

Dr. Kieu took the position that in delivering immunization services, private providers should not face financial risk for performing a public health function. She outlined several steps that might be taken to reduce this risk for California physicians. A statewide registry would provide more accurate information about children's immunization status, but providers will need assistance in the form of new technology or financial support for administrative costs to meet the data entry demands. California has already responded to the financial problems that can be created when new vaccines are added to the immunization schedule, as happened with the addition of the pneumococcal conjugate vaccine. Legislation passed in January 2001 protects providers from financial hardship when new vaccines are introduced, but Dr. Kieu noted that some health plans were slow to provide the compensation called for by the new legislation.

Public purchase of vaccine for all publicly insured children or the establishment of reimbursements or billing ceilings that are adequate to cover vaccine costs would also aid providers. The California AAP chapter has proposed the creation of a VFC-like system for ordering and distributing vaccine for children enrolled in the state's Healthy Families Program. Dr. Kieu cited an estimate that such a system would result in a cost savings to the state of $200 per child. With the differences in private insurance benefits, she also suggested that the state might mandate that the private insurers provide full coverage for immunization services.

BOX 1
Partial List of Necessary Procedures to Immunize a Child

PROCEDURES		RESPONSIBLE PERSON		
1.	Be ever alert of the changing vaccine events.	M.D.		
2.	Sit down to order from vaccine representative.	M.D.	Mgr	
3.	Negotiate for best price.	M.D.	Mgr	
4.	Order substantial amount for best price break.		Mgr	
5.	Lay out cash $10,000-$25,000 each month or so (no interest income).			
6.	Receive shipment and inventory.	R.N.	Mgr	
7.	Store properly.		R.N.	
8.	Refrigerate cost.		office	
9.	Monitor temperature and log entries several times a day.		R.N.	
10.	Maintain proper disposal standards.	office	R.N.	
11.	May be audited at any time.	M.D.	Mgr	R.N.
12.	Discuss with each patient his immunization needs.	M.D.	R.N.	
13.	Call nurse to prepare immunization.	M.D.		
14.	Prepare immunization with proper technique.		R.N.	

OFFICE OPERATIONS AND DELIVERY OF IMMUNIZATION SERVICES

John Fontanesi, from the University of California at San Diego, presented findings on immunization services from work flow and time management studies of the delivery of well-child care. Immunization serves as a useful proxy for preventive care in general. The analyses of Dr. Fontanesi and his colleagues suggest that operational factors in clinics

PROCEDURES	RESPONSIBLE PERSON	
15. Give immunization after mother signs for injection and child is restrained properly by nurse, occasionally with help from parent.		R.N.
16. Smooth child with bandaid.	office	R.N.
17. Record immunization with all data in record.	M.D.	R.N.
18. Record immunization in parent's/child's permanent immunization card (yellow card).		R.N.
19. Cost of syringe, needle, cotton ball, alcohol, and gloves for nurse.		office
20. Proper disposal of syringe and sharps containers.		office
21. Proper coding of bill for immunization.	office	
22. Receive multiple payments and post to proper accounts.		Mgr
23. Malpractice insurance.	M.D.	

Other Miscellaneous Costs:

- wasted vaccine, accidental or decided not to give on prepared date.
- more time is required by the physician to convince parent that immunization is necessary.
- time is spent several times a year to get an increase in immunization payment reimbursement.

and provider offices may do more to influence whether immunizations are delivered than factors such as family attitudes toward immunization or socioeconomic status. For example, lack of documentation on immunization status proved to be an important contributing factor to missed opportunities to provide hepatitis B immunizations to adolescents.

Since the mid-1960s, the length of the average well-child visit has increased from 12 minutes to 20 minutes. Among the factors contributing to the longer visits are providers' efforts to comply with an increasing

array of clinical practice guidelines as well as an increase in reporting forms. Immunization must compete for time with the other services called for by those guidelines. Dr. Fontanesi's studies have found that the time required to administer an immunization is about 3.5 minutes and has remained constant. Although the time required for a single immunization is not great, the total number of required immunizations creates a more substantial demand on national health resources. For example, the national birth cohort included 3,959,417 live births in 1999. Providing a single immunization for each of these children will require 230,965 person hours. Completing the recommended 4:3:1:3:3 series[7] will require 2,540,610 person hours for an entire national birth cohort of about 4 million children.

Dr. Fontanesi suggested that additional provider and staff time could be made available to meet immunization and other health care needs by reducing redundancies in administrative tasks. For example, his studies found that a group of 9 clinics used about 200 different forms to record or report information on children under the age of 3 years. Of these forms, 72 required information about immunizations, and many of them were required by federal programs. However, less than 85 percent of immunizations administered were recorded in patient records, leading to underestimates of immunization coverage. Having contracts with many managed care plans also added to the administrative burden for clinics and provider practices. Each plan had a separate process for credentialing providers, required a separate Health Plan Employer Data and Information Set (HEDIS) audit for immunization coverage (along with other HEDIS measures), and expected different quality improvement activities.

Better methods for managing patient flow and office procedures may also help ensure that children receive necessary immunizations. Observation has shown variation among clinics in the length of the average visit and in the time spent at each stage of the visit (e.g., registration, waiting, examination). Furthermore, at a single clinic, those times vary from patient to patient. However, the differences are not related to whether a child received an immunization during the visit. Dr. Fontanesi observed that it is necessary to reduce such variability to improve the overall quality of service delivery. Work flow is affected by factors such as differences between scheduled and unscheduled visits or between pa-

[7]The 4:3:1:3:3 series refers to four or more doses of diphtheria and tetanus toxoids and whole-cell or acellular pertussis vaccine (DTP or DTaP); three or more doses of poliovirus vaccine; one or more doses of any measles-containing vaccine; three or more doses of *Haemophilus influenzae* type b (Hib) vaccine; and three or more doses of hepatitis B vaccine.

tients who arrive on time or late. For example, immunization cards are reviewed more often during unscheduled visits, but patient charts are more likely to be available for scheduled visits.

Dr. Fontanesi also emphasized the importance of reducing inefficiencies in office procedures to gain time for other tasks. Providers and staff may need to ask for more information from families to ensure that office records are accurate. He noted that parents are more likely to bring a child's immunization record to a visit if they are specifically asked to do so. Dr. Fontanesi's observations also showed that because of a lack of time or effective mechanisms, most practices missed the opportunity to assess when a child's next immunizations were due. Improving the delivery of immunizations and other well-child care will require an adequate investment in the assessment of current office procedures and in tools and training to achieve greater efficiency and effectiveness.

Health Plans and Employers

Health plans and employers play a major role in shaping the financial environment for the delivery of immunization services. For the private sector, decisions by health plans and employers together help determine the cost and scope of coverage available to employees.

HEALTH PLAN PERSPECTIVES

Collaboration with the Public Sector

Many children enrolled in Medicaid and in State Child Health Insurance (SCHIP) programs, such as California's Healthy Families Program, receive immunization services through managed care health plans. Helen DuPlessis, chief medical officer for L.A. Care, reviewed some of the quality improvement activities that managed care organizations have undertaken to improve immunization rates. She also discussed the need for better collaboration between health departments and managed care organizations and others in the private sector to make more effective use of limited resources.

For managed care organizations, quality improvement activities related to immunization include the use of Health Plan Employer Data and Information Set (HEDIS) measures to assess the performance of health plans. Even though these measures have shortcomings, they have the advantage of being standardized across all health plans. Dr. DuPlessis

also cited several examples of other immunization-related activities in health plans across the country. These activities include analyzing missed immunization opportunities in providers' practices, sending immunization reminders to parents, and providing recall and reminder information to providers.

Dr. DuPlessis acknowledged that the HEDIS data show the need for further improvement in immunization rates for children enrolled in Medicaid. But achieving those improvements will require better collaboration between the public and private sectors to overcome the challenges that each faces. Most health departments have a limited capacity to deliver immunization services and so must rely on health plans and private providers. Similarly, when immunization registries are not available or are not comprehensive, health departments lack real-time data on immunization coverage. Health plan records can help fill that gap.

Providers could also benefit from assistance from other sources to overcome some of the challenges they face in trying to meet their obligation to provide immunization services. As noted by others at the workshop, the administrative burden in managing vaccine inventories and documenting immunization services is substantial. This includes the complications related to assessing the eligibility of children for VFC vaccine and to tracking multiple funding streams for purchasing vaccine. Staying informed about frequent changes in the immunization schedule is further complicated in California by inconsistencies between the state's Child Health and Disability Program and Medicaid's Early and Periodic Screening, Diagnostic, and Treatment guideline in the specifications for the timing of immunizations. Furthermore, the information management systems used by many private providers are not capable of identifying patients who need immunizations or of supporting easy use of immunization registries.

Effective collaborations between the public and private sectors would help in identifying the resources that various parties can contribute to meeting immunization needs and in defining their responsibilities in that process. Dr. DuPlessis cited the effort to establish a consolidated immunization registry in northern California as a promising example of the broadly based collaborations necessary to strengthen the immunization system and improve coverage rates. Plans to expand the activities of the immunization coalition in the Los Angeles area promise to help make more efficient use of the region's resources for immunization.

Estimating Vaccine Needs

Kaiser Permanente is a large staff-model health maintenance organization that purchases vaccines as well as many other pharmaceutical prod-

ucts for use by its members. Lisa Rieg, the infectious diseases pharmacist for the California division of the organization, discussed the process of forecasting vaccine requirements and emerging concerns regarding future vaccine purchases.

Kaiser subscribers receive all routine immunizations without any copayment or other additional charge, and coverage rates are more than 90 percent for many of the recommended vaccines. Kaiser also participates in clinical trials for new vaccines and in the Vaccine Safety Datalink project. An electronic database on immunization records alerts providers to immunizations that patients require and allows for production of quarterly reports on immunization coverage rates. The database also aids in appropriately allocating supplies of vaccines that are in short supply. Dr. Rieg noted that the southern California division of Kaiser Permanente has been slow to participate in VFC because of the administrative burdens associated with tracking eligible patients and the vaccine inventory. Another factor has been the inability to ensure that the VFC program will supply the vaccine products that Kaiser uses for all other members.

Forecasting vaccine requirements involves consideration of several factors. It is important to understand the disease a vaccine is directed against and the risk it poses to the population Kaiser serves. Also necessary is information about a vaccine's efficacy and safety profile, as well as its cost effectiveness. Another consideration is whether a vaccine is or will be included in the recommended immunization schedule for children or adults. Estimates of the number of doses required depend on the number of children or adults who would receive a vaccine as part of a routine schedule (e.g., an annual birth cohort for most pediatric vaccines) and whether additional doses are needed for "catch-up" programs for a newly recommended vaccine or for special efforts to improve coverage.

Unanticipated factors can affect the accuracy of these forecasts. Accurately estimating the cost of a new vaccine has proved especially difficult, and most estimates have been too low. Slow acceptance of a new vaccine by providers or patients can result in lower usage, but interest spurred by clinical needs or publicity can increase demand. For example, publicity about the Lyme disease vaccine stimulated demand even though the disease risk is low in southern California. A patient education program was undertaken to inform members about appropriate uses of the vaccine.

Dr. Rieg indicated that, so far, the increase in vaccine costs has been minimal compared with the cost increases for other pharmaceuticals. Kaiser has benefited from its ability to negotiate lower prices for high-volume purchases and to establish long-term contracts. However, vaccine costs seem likely to increase more steeply in the future. Prices for new vaccines, like the pneumococcal conjugate vaccine, are proving to be much higher than expected. As purchasing contracts end, Kaiser has less

ability to influence prices because of the vaccine shortages and the smaller number of vaccine manufacturers.

Looking to the future, Dr. Rieg noted concerns at Kaiser about the cost of new vaccines, especially those for which demand is expected to be high, such as multivalent pediatric vaccines and an AIDS vaccine. The possibility has been raised that copayments or other forms of cost sharing with plan members will be necessary for immunization services. At the same time, there is concern that added member costs might tend to lower immunization rates. In addition, with the current shortages of several vaccines, the stability of the vaccine supply is of growing concern.

AN EMPLOYER'S VIEW OF IMMUNIZATION COVERAGE

In the United States, most private health insurance coverage is obtained through plans offered by employers. Therefore, employers' concerns and priorities play an important role in determining the coverage for immunizations available to many children and adults. Pamela Hymel, vice president for human resources at Hughes Corporation, discussed some of the factors that influence employer decisions.

At Hughes Corporation, coverage for preventive care in general and immunization in particular is seen as a good investment to improve productivity. Preventive care helps reduce absenteeism by reducing illness among employees and their children and helps control costs for treatment. Coverage for immunization and other preventive services also contributes to employees' satisfaction with their health plans. Ms. Hymel noted that large employers have public health responsibilities that they can help meet by providing coverage for immunizations.

To encourage use of preventive services, Hughes Corporation tries to minimize both financial and logistical barriers. The company's health insurance plans provide first-dollar coverage for immunizations. In addition, offering influenza immunizations at worksites makes that service more readily available to employees and reduces lost work time.

Data and measurement are important for employers' assessments of the return on their investment in preventive services. Ms. Hymel noted that for its preferred provider organization plan, Hughes Corporation currently allocates 5 percent of its spending to preventive services. With indications of an acceptable return on investment, the company would be willing to increase those benefits. Health plan reports using various HEDIS measures help employers monitor whether employees and their families are receiving useful preventive services. Employers are also able to use HEDIS measures to establish quantitative performance standards for evaluating the health plans they offer. Good data on the costs and

benefits of preventive care can help a company make the case to other employers for investing in preventive services.

As employers face increases in the cost of their health plans—Ms. Hymel reported a 14 percent increase for Hughes Corporation—employers must make decisions about the benefits to offer and the costs to pass on to employees through premiums, copayments, and coverage limits. In response to a question, Ms. Hymel noted the availability of health insurance products with a lump-sum benefit for preventive services. Although she does not favor that approach, some employers are considering it. Ms. Hymel concluded by observing that although employers are unlikely to lead immunization campaigns, they are likely to offer support based on good business reasons, such as improved productivity and lower health care costs.

Concluding Observations

To conclude the workshop, Dr. Fielding provided some summary observations. The workshop discussions highlighted the difficulties that the lack of stable funding creates for localities. Uncertain funding for immunization infrastructure has limited opportunities for longer term planning and commitments and therefore made it difficult for the health department to be a good partner in community immunization efforts. However, states will be receiving new funding for public health infrastructure investments as part of the federal effort to strengthen the nation's ability to respond to bioterrorism. Officials should be considering how those funds can be used most effectively at the state and local levels. Improvements in areas such as disease surveillance and public health laboratories promise benefits for the nation's immunization system as well.

With much greater responsibility for immunization services resting with private providers and health plans, the need for consultation between the public and private sectors becomes increasingly important. Programs like Vaccines for Children (VFC) and the State Child Health Insurance Program have improved access to immunization services, but other approaches will be needed to improve immunization coverage among the children who are hardest to reach. Dr. Fielding noted that the lack of VFC eligibility for children in California's Healthy Families Program poses financial problems for both the private providers serving those children and the state. He also expressed concern about the pros-

pect that employers might adopt a lump-sum approach to health insurance benefits for preventive services. If employees choose not to use those benefits for appropriate immunizations, declining immunization coverage rates would increase the risk of disease outbreaks.

Vaccine pricing and supply issues are looming larger. Persistent production problems for some vaccines and the decisions by manufacturers to stop producing other vaccines are reducing vaccine supplies and pushing prices up. The price increases in combination with the reductions in federal and state funding for immunization programs result in a substantial reduction in immunization-related purchasing power at the local level. Dr. Fielding also commented that immunization financing questions cannot be separated from issues related to vaccine development and production. He urged renewed examination of public policy tools (e.g., extended patent protection) that could provide added incentives for vaccine development and production.

Registries are an important tool for immunization programs, but they require improved usability. The long-anticipated availability of electronic medical records systems could resolve many of the current problems of burdensome and duplicative data entry. But further work is still needed to produce effective and affordable systems.

Dr. Fielding concluded with the observation that public health is often said to be invisible when it works because people are not getting sick. But the public health system has suffered from neglect because of its invisibility, and leadership is needed to ensure that immunization issues remain visible and receive appropriate attention. Dr. David Smith followed up, posing the possibility that the current problems of unstable funding, rising vaccine prices, and uncertain vaccine supplies might be creating conditions for a "perfect storm" that could result in serious disease outbreaks. Emphasizing the importance of advocacy on behalf of any of a broad range of immunization needs, he encouraged workshop participants to use the immunization system framework laid out in *Calling the Shots* as a basis for seeking legislative attention for these issues and for reaching out to other, less familiar partners.

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Appendixes

A

Institute of Medicine
Committee on Immunization Finance Workshop

SETTING THE COURSE
A Strategic Vision for Immunization
Part 3: Summary of the Los Angeles Workshop

Final Agenda
January 17, 2002

In collaboration with the
School of Public Health
University of California at Los Angeles
and the
Los Angeles Health Department

Tom Bradley International Hall
University of California at Los Angeles
Los Angeles, California

7:45 AM Continental Breakfast

8:15 AM **Session 1: Workshop Introduction**
(Moderator, Edward McCabe)

- Edward R.B. McCabe, Physician-in-Chief, Mattel's Children's Hospital at UCLA, Professor and Executive Chair, UCLA Department of Pediatrics

- David Smith, President, Texas Tech University Health Sciences Center and Chair, IOM Committee on Immunization Finance Dissemination Workshops
- Walter Orenstein, Assistant Surgeon General, Director, National Immunization Program, Centers for Disease Control and Prevention
- Linda Rosenstock, Dean, School of Public Health and Associate Dean and Professor, School of Medicine, University of California, Los Angeles
- Participant introductions

9:30 AM **Session 2: Southern California Overview**
(Moderator, David Smith)

- Natalie Smith, Director, Immunization Program, California Health Department
- Jonathan Fielding, Director, Los Angeles Health Department
- Sandra Ross, Immunization Program Coordinator for the Health and Human Services Agency, County of San Diego Department of Health Services
- Gerry Fairbrother, Child Health Program, New York Academy of Sciences

10:45 AM **Break**

11:00 AM **Session 3: Private Provider Perspectives**
(Moderator, Garth Splinter)

- John Fontanesi, Community Health Pediatrics, University of California at San Diego
- Quynh Kieu, Pediatrician, Orange County, CA and Co-Chair, California Chapter American Academy of Pediatrics State Government Affairs Committee and Chair, Vaccine Issues Task Force

General Discussion

12:15 PM **LUNCH**

1:15 PM **Session 4: Future Strategies for Financing Immunization Programs**
(Moderator, Maxine Hayes)

- Helen DuPlessis, L.A. Care
- Lisa Rieg, Kaiser Permanente Drug Information Services
- Pam Hymel, Hughes Corporation

2:30 PM **Closing Remarks**

- Jonathan Fielding, Los Angeles Health Department
- David Smith, Texas Tech University Health Sciences Center

3:00 PM **Adjourn**

B

INSTITUTE OF MEDICINE
Immunization Finance Dissemination Workshop

Tom Bradley International Hall
University of California at Los Angeles
Los Angeles, California

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January 17, 2002

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C

Website Referrals

The IOM workshop presentations and discussions were audiocast over the Internet through a collaborative agreement between IOM and the Center for the Advancement of Distance Education at the University of Illinois School of Public Health. Further information regarding the audiocast of this and prior workshops and the IOM report *Calling the Shots* is available from the following websites:

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