

INSTITUTE OF MEDICINE

Shaping the Future for Health

FINANCING VACCINES IN THE 21ST CENTURY: ASSURING ACCESS AND AVAILABILITY

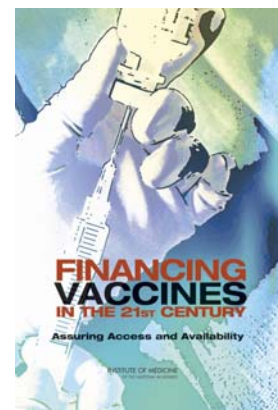
Immunization of children and adults against life-threatening diseases represents one of the great triumphs of the public health system in the United States, and one of the best bargains in medicine in terms of cost-effectiveness. The national immunization system has been successful in developing a host of important new vaccines and achieving high rates of immunization, especially for children.

However, this system faces difficult challenges for the future. Significant disparities remain in assuring access to recommended vaccines across geographic and demographic populations. These disparities result, in part, from fragmented public-private financing in which a large number of children and adults face limited access to immunization services. Access for adults lags well behind that of children, and rates of immunizations for those who are especially vulnerable because of chronic health conditions such as diabetes or heart and lung disease, remain low.

Access to immunizations is complicated by an expanding array of approved vaccines, higher costs of recent additions to the vaccine schedule, increasing fragmentation of public and private insurance coverage for immunization, and growing burdens on clinicians for determining eligibility and immunization status.

In addition, recent shortages of vaccines have highlighted the fragility of vaccine supply. Currently, public funds pay for more than half of all childhood vaccine purchases in the U.S. Government purchasing policies have sought to limit expenditures and decrease the cost of vaccines. Companies face declining financial incentives to develop and produce vaccines, and the number of producers of recommended vaccines for the U.S. market has declined from more than 25 companies 30 years ago to only five today.

In order to sustain the achievements of the national immunization system to date and enhance the development of vaccines against new diseases for the future, the national immunization system must balance the need for better access to recommended vaccines with enhanced incentives for investment in vaccine development and production.



Nearly 11 percent of children in the U.S. have insurance that does not include coverage for vaccinations.

Common vaccines such as tetanus, polio, and adult pneumococcal are supplied to the U.S. market by single companies.

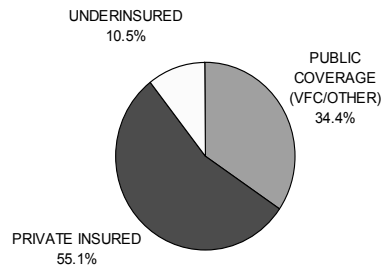


Figure: Insurance coverage of immunization, children aged 0–5 (2000).

Sources: Bureau of the Census (2000); calculations by the committee based on an analysis by Wood (2002).

THE CURRENT IMMUNIZATION SYSTEM

Although the long-term health benefits of immunization are apparent, the societal value of vaccines does not receive explicit attention in calculating the level of public and private resources that should be allocated to purchasing and administering vaccines. Many health plans and consumers may not be able, or may not be willing, to bear the full financial burden of vaccines, and government agencies are often able to distribute vaccines only to certain eligible populations.

The National Immunization Program of the Centers for Disease Control and Prevention (CDC) asked the Institute of Medicine (IOM) to review current immunization financing and then develop strategies that improve the way vaccines are purchased and distributed in the U.S. health care system. As a first step, the committee examined the societal benefits of vaccines, the scope of government investment, and emerging problems of the current financing approach.

What are the Social Benefits of Vaccines?

Vaccines are now available for preventing 11 once common childhood diseases and for preventing diseases responsible for high rates of sickness and death among adults (including influenza, pneumonia, and hepatitis). Although vaccines were at one time principally regarded as services for infants and young children, they now provide important protection across the lifespan, from infancy to old age.

A unique feature of vaccines is that they not only provide a health benefit to the individual receiving the vaccine; the benefit extends to others in the community, reducing their chances of exposure to a disease. This “herd immunity” protects vulnerable individuals who are too young, too frail, or too poor to receive the vaccines, or face other barriers to immunization.

Vaccines provide a wide range of social benefits, including (1) reducing the medical costs of diseases that are prevented, (2) enhancing the length and quality of life, and (3) improving the productivity and social contributions of families who would otherwise be burdened by disease.

For every dollar spent on diphtheria/pertussis, the country reaps a \$27 social benefit. For measles, a \$1 investment yields a benefit of \$13.50.

Who Pays for Vaccines Now?

A public-private partnership has formed the foundation for purchasing and distributing vaccines in the U.S. over the past 50 years. A strong bi-partisan consensus has supported a federal role in purchasing and distributing vaccines ever since the discovery of the polio vaccines in the 1950s. The government has long shared the burden for immunization coverage with the private insurance industry. There are concerns that the private role is eroding in the face of increasing immunization costs. Further, although most vaccines are administered by private health care providers, referrals from private physicians to public clinics continue to be a significant problem.

U.S. government purchases about 55% of the total childhood vaccine market.

The National Immunization Program of the Centers for Disease Control and Prevention (CDC) administers the vaccine purchase program for the federal government. Each state government has its own immunization program, which estimates the level of vaccines needed to assure access to immunization among underserved groups of children and adults. Vaccines purchased by CDC are shipped to public health clinics and private healthcare providers participating in programs for disadvantaged patients. At present, the U.S. government spends more than \$1 billion annually to purchase childhood vaccines alone. Additional public funds are used to reimburse the costs of administering vaccines (through Medicaid and SCHIP payments, for example) and to reimburse physicians and other health professionals who buy vaccines for older adults through Medicare.

CDC negotiates a federal contract for each vaccine product, using large volume purchases as leverage to obtain discounts on the manufacturer's list price. The 50 states also rely upon the federal discount price for vaccines purchased with state revenues. In recent years the discount has declined significantly. The discount pricing process also has the effect of deflating payments to pharmaceutical companies, which tends to discourage future investments in vaccine development.

Why is the Cost of Immunization Increasing?

Only a few vaccines were available 50 years ago and most of the vaccine products could be bought for pennies. Today, higher costs of immunization reflect the growing number of products, as well as the higher costs associated with producing safe and effective vaccines. Although the price of prevention is growing, it continues to represent a cost savings to society because of the reduced burden of illness and lost productivity from vaccine-preventable diseases.

The cost of immunizing children with the 20 recommended doses of vaccines (at discounted government prices) has jumped from \$200 to \$400 per child from 1997 to 2001. For private sector providers, the costs in 2001 were even higher—around \$600.

Newer vaccines and a growing list of recommended vaccines have also greatly added to the expense. For example, the addition of the varicella and pneumococcal conjugate vaccines for infants resulted in a doubling of the Vaccines for Children (VFC) budget from \$500 million to over \$1 billion between 2000 and 2002. VFC is the major government vaccine purchase program for disadvantaged children.

What are the Shortcomings of the Current Financing Approach?

The IOM found that the current financing, development and distribution system for vaccines in the U.S. has several deficiencies:

Increasing disparities in access to recommended vaccines. Substantial variation (almost 20 percent) in immunization rates currently exists within and across states. While some states assure access to all children, others do not. Low rates of immunization are particularly located in areas of poverty. Government programs have improved access for children but have not always addressed the needs of older adolescents and adults. For example, only 18% of adults considered at high risk because of having a chronic condition like heart disease have ever received a pneumonia shot.

Table: Number of Producers of Selected Vaccines for the U.S. Market, 2003

Vaccine	Number of Producers
<i>Haemophilus influenzae</i> type b	3
Influenza	2
Hepatitis A	2
Hepatitis B	2
Diphtheria and tetanus toxoids and acellular pertussis (DTaP)	2
Measles–mumps–rubella (MMR)	1
Tetanus toxoid	1
Tetanus–diphtheria ^a	1
Inactivated poliovirus	1
Varicella (chickenpox)	1
Pneumococcal conjugate (PCV-7)	1
Menigococcal	1
Pneumococcal polysaccharide (adult)	1

Source: CDC

^aA small amount of Td is produced by the Massachusetts Public Health Biological Laboratories.

Eroding insurance coverage and increasing provider burden. Many young children, adolescents, and high-risk adults have no or limited insurance for recommended vaccines. About 55% of children age 5 and under have private health insurance that covers immunization, 34% have public insurance, and 11% are underinsured for immunizations. For adults, just 16% have private insurance, 9% have public coverage, 59% are underinsured, and 17% are completely uninsured. Even those with insurance increasingly have to pay higher deductibles and co-payments for immunizations. Fragmented insurance coverage increases provider burden in determining eligibility and payment source, and increases missed opportunities for immunization when patients must be referred to another provider.

Increasing costs of the immunizations. Higher vaccine prices will exacerbate such problems as: demands on public and private health budgets; uneven distribution patterns; delays in vaccine negotiation process for federal and state contracts; variation in vaccine benefits of public and private insurance plans; and increased caseloads in public health clinics and other safety net organizations.

Shortages in the supply of vaccines and disappearing manufacturers. Significant tensions exist between the need to control public and private expenditures on vaccines and the need to encourage investment in their development. During 2001-2002 there were severe shortages in the vaccine market. These highlighted concerns about the size of the government presence in the vaccine market, low vaccine prices relative to production costs, and the scale of private investment in vaccines. Vaccines frequently generate lower revenues than drugs and, thus, provide a less attractive opportunity for private investment by the pharmaceutical industry. Financial incentives that ensure an adequate rate of return on investment are necessary. Current government strategies have not addressed the relationships between financing vaccine purchases and the stability of the U.S. vaccine supply.

Inadequate basis for determining the value of individual vaccines. The recommendations of the Advisory Committee on Immunization Policy (ACIP) and other advisory groups have significant implications for public and private expenditures on vaccines. Yet ACIP recommendations are made prior to negotiation of a government purchase price. Also government purchasers currently must rely upon the prices that are offered by the vaccine industry as the starting point for their negotiations. The vaccine industry has not publicly disclosed the cost structure that supports the prices for its products, and this raw data is often considered proprietary information. Nor does the ACIP have a mechanism for determining the societal benefit of different vaccines.

SHIFTING TO A NEW *MANDATE, SUBSIDY AND VOUCHER* PLAN

The IOM's Committee on the Evaluation of Vaccine Purchase Financing in the United States recommends a new and different approach to vaccine financing by the government. The committee reviewed a variety of market-oriented, government intervention, and incremental approaches. One approach considered by the committee—a combined *mandate, subsidy, and voucher* plan—was best able to address the twin goals of improving access and availability of vaccines. The key elements of the approach are:

- an insurance benefit *mandate*, requiring coverage of recommended vaccines in all private and public health insurance plans;
- a universal government *subsidy* for reimbursement of private and public insurers and providers for vaccinations; and
- a government *voucher*, based on the subsidy, for uninsured children and adults to receive immunizations through the provider of their choice.

Recommendation 1: *The committee recommends the implementation of a new insurance mandate, combined with a government subsidy and voucher plan, for vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).*

The proposed plan consists of five core elements: (1) a vaccine coverage mandate that would apply to all private and public health plans (including Medicare, Medicaid, and the State Children's Health Insurance Program); (2) a new federal subsidy to cover mandated vaccine costs and administration fees; (3) a voucher system for uninsured populations; (4) a process to distinguish between vaccines that have strong and weak societal benefits; and (5) a process to calculate subsidy levels for different vaccines based on estimates of their societal benefits.

A subsidy strategy will structure government support for vaccines on the societal *value* of the vaccine rather than just its current market *price*. That is, the subsidy would take into

account the savings to society of preventing a disease or condition. The calculation of the subsidy would require an evidence-based assessment of savings including health care expenses, continued workplace productivity, and other societal benefits such as improvements in quality of life. The amount of the subsidy for any given vaccine would be determined by an independent advisory body using a standardized economic method of determining societal benefit.

The federal government would reimburse health insurance plans—through subsidy payments—both for vaccine purchase costs and administration fees. This subsidy will create an incentive for manufacturers because it represents a government-backed investment in their product prior to manufacture. This approach would preserve elements of market competition while providing enhanced incentives for vaccine research and development.

Implementation will likely result in overall higher federal expenditures for vaccines because of expanded public coverage, but this will also provide greater protection to all Americans and achieve cost savings for expenditures associated with the treatment of vaccine preventable disease.

Recommendation 2: *The Secretary of the Department of Health and Human Services should propose changes in the procedures and membership of ACIP so that its recommendations can associate vaccine coverage decisions with societal benefits and costs, including consideration of the impact of the price of a vaccine on recommendations for its use.*

The ACIP would continue its present practice of recommending current and new vaccines for all or selected populations. In addition, ACIP would determine: (1) whether vaccines have sufficient benefit to warrant inclusion in the new insurance mandate and subsidy program, and (2) the actual monetary value of the subsidy. Broadening the ACIP membership to include additional expertise (e.g., health economics and finance, consumer issues) will assist them in determining the societal value for the subsidy. While the expertise of representatives of the insurance and vaccine manufacturing industries is also needed, they should not be voting members of the ACIP to ensure there is not a conflict of interest.

Recommendation 3: *As part of the implementation of recommendations 1 and 2, the National Vaccine Program Office should convene a series of stakeholder deliberations on the administrative, technical, and legislative issues associated with a shift from vaccine purchase to a vaccine mandate, subsidy, and voucher finance strategy. In addition, CDC should sponsor a postimplementation evaluation study (e.g., in 5 years). CDC should also initiate a research program aimed at improving the measurement of the societal value of vaccines, addressing methodological challenges, and providing a basis for comparing the impact of different measurement approaches in achieving national immunization goals.*

A change of this magnitude is warranted to address the fundamental and systemic problems confronting the national immunization system. In formulating its recommendations, the committee has sketched the broad outlines of long-term strategic reforms. These recommendations do not address all aspects of the shift from the existing vaccine purchase programs to a mandate, subsidy, and voucher plan, nor do they incorporate the comprehensive legislative agenda that would be necessary to achieve these reforms. A major national debate and examination of the committee's proposals among diverse stakeholders is necessary prior to full implementation of these recommendations.

The committee urges a series of steps to facilitate implementation of the proposal, including: a series of public meetings with key stakeholders and experts; the development of an evaluation study to assure that the broad objectives of the national immunization system are met; and the development and funding of a research agenda to establish a stronger evidentiary base in key areas, such as the impact of insurance and cost-sharing on immunization, the impact of alternative vaccine payment arrangements on clinician behavior and referral rates, the relationship between vaccine prices and supplier investments in research and development.

What are the Benefits of the New Strategy?

The committee determined that the *mandate, subsidy, and voucher* strategy was the best way: (1) to secure future financing for the production and distribution of vaccines and (2) to make certain that financial considerations do not discourage children and adults from receiving appropriate immunizations. In sum, the major benefits of the proposal include:

Eligibility and cost barriers are eliminated, leading toward higher immunization rates. Since all Americans would either have insurance coverage or a voucher, barriers (e.g., eligibility, cost) to receiving vaccines would be eliminated or at least reduced. Access is simplified for both patients and providers. Additionally, universal eligibility would prevent the potential for shifting higher vaccine costs from one group to another.

Vaccine supply is stabilized and initiative rewarded. Importantly, the subsidy would be calculated while vaccines are still in development to ensure incentives for the development of new vaccines. This will help foster a dynamic, private vaccine market with incentives to minimize interruptions in supply.

Public-private partnership continues without intermediary federal role in purchasing. Both private insurers and states would continue to be involved in vaccinations, but direct purchase of vaccines by the federal government would be replaced. Delays now associated with government contract negotiations, discretionary funding cycles, and shortages will be eliminated. A market-oriented approach is preserved.

What Steps are Needed Next?

To put this new *mandate, subsidy, and voucher* strategy into action, multiple steps are necessary. Recommendations 1 and 2 represent a significant departure from current law and practice. Numerous legislative, regulatory, administrative, and technical challenges will arise during this transition. But with this new approach, more people in the U.S. will have access to protective vaccines, and the stability of manufacturers will help ensure the future availability of life-saving vaccines.



For More Information...

Copies of *Financing Vaccines in the 21st Century: Assuring Access and Availability* are available for sale from the National Academies Press; call (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area), or visit the NAP home page at www.nap.edu. The full text of this report is available at <http://www.nap.edu>

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