Financing the Delivery of Vaccines to Children and Adolescents: Challenges to the Current System

abstract

Recent increases in the number and costs of vaccines routinely recommended for children and adolescents have raised concerns about the ability of the current vaccine financing and delivery systems to maintain access to recommended vaccines without financial barriers. Here we review the current state of US financing for vaccine delivery to children and adolescents and identify challenges that should be addressed to ensure future access to routinely recommended vaccines without financial barriers. Challenges were considered from the perspectives of vaccine providers; state and local governments; insurers, employers, and other health care purchasers; vaccine manufacturers; and consumers. Pediatrics 2009;124:S548–S557

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KEY WORDS
vaccination, health policy, adolescent, child

ABBREVIATIONS
IIS—immunization information system
VFC—Vaccines for Children
AHIP—America’s Health Insurance Plans
FQHC—federally qualified health center
RHC—rural health clinic

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the US Department of Health and Human Services.

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In the 20th century, vaccines reduced morbidity and mortality rates for many diseases to record lows. Routine vaccination of children and adolescents with vaccines recommended before 1999 is estimated to prevent >14 million disease cases and 33,000 deaths over the lifetime of each birth cohort. Since 1999, there have been 8 new recommendations for routine vaccination among US children and adolescents (including pneumococcal conjugate vaccine, varicella vaccine, rotavirus vaccine, meningococcal conjugate vaccine, hepatitis A vaccine, tetanus-diphtheria-acellular pertussis vaccine, human papillomavirus vaccine, and annual influenza vaccine). Some newly recommended vaccines are the most expensive ever developed for routine use. The cost to administer vaccines has increased along with the number of recommended vaccine doses, reflecting greater costs related to vaccine storage, inventory management, and immunization information system (IIS) data entry. These increased costs have raised concerns about the ability of the current vaccine financing and delivery systems to maintain access without financial barriers to all vaccines recommended for routine use for children and adolescents. This article reviews the current state of US financing for vaccine delivery to children and adolescents and identifies challenges that should be addressed to ensure continued access without financial barriers to routinely recommended vaccines.

**US VACCINE FINANCING SYSTEM**

**Definitions**

The current US system for financing delivery of vaccines to children and adolescents is a mixed public/private-sector effort that funds both purchase and administration of recommended vaccines. Vaccine purchase refers to the cost of buying the vaccine itself, whereas vaccine administration refers to costs associated with giving the vaccine, such as obtaining vaccination history, counseling patients or parents regarding vaccines, and performing IIS data entry. How vaccine purchase and administration are financed depends on what type of insurance coverage a child or adolescent has.

**Health Insurance Coverage for Vaccination**

Most private health plans cover all vaccines routinely recommended for children and adolescents. In a 2005 study, 92% of insurance plans reported following Advisory Committee on Immunization Practices recommendations to determine covered vaccines; of those, 60% could extend coverage within 3 months after issuance of recommendations and 13% in <1 month. Coverage for vaccination benefits may vary according to insurance provider and product type (eg, health maintenance organization versus preferred-provider organization plans). Children and adolescents whose health insurance does not include coverage for ≥1 vaccine are considered underinsured. Underinsured children are children who are enrolled in and entitled to benefits under a health insurance plan but for whom benefits are not available for the cost of ≥1 vaccine. Children whose insurance covers only selected vaccines are categorized as underinsured for the noncovered vaccines and are Vaccines for Children (VFC)-eligible for the noncovered vaccines only. Children whose insurance caps coverage for vaccines at a certain amount are categorized as underinsured once that amount is reached. Children in a health plan with cost-sharing requirements for vaccination benefits (such as copayments or deductibles) are not considered underinsured.

**Vaccine Purchase Financing**

Currently, the public sector purchases ~53% of pediatric vaccine doses (Centers for Disease Control and Prevention, unpublished data, 2007) through 3 major sources of funding, namely, the VFC program, the Section 317 federal grant program to states, and state discretionary funds. VFC is an entitlement for children through 18 years of age who are eligible for Medicaid, have no health insurance, or are American Indian/Alaska Native. In addition, underinsured children and adolescents may receive VFC vaccines, but only at sites designated as federally qualified health centers (FQHCs) or rural health clinics (RHCs). An estimated 11% of young children and 20% of adolescents are underinsured for vaccines. Providers who take part in VFC receive vaccines for VFC-eligible children free of charge, with vaccine doses replaced as needed. All states use Section 317 program funds to vaccinate non–VFC-eligible children, who may be underinsured or fully insured, although the insurance status and number of children vaccinated varies according to state. Unlike VFC, the Section 317 program is not an entitlement; it depends on annual discretionary appropriations by Congress. These appropriations have not increased commensurate with the scope of new vaccine recommendations. Section 317 program appropriations increased 42% from fiscal year 2000 to fiscal year 2008, compared with a nearly 400% increase for VFC during the same period (Fig 1). State discretionary funds also are used to purchase vaccines for non–VFC-eligible children. Several “universal-purchase” states use a combination of state and Section 317 program funds to purchase recommended vaccines for all children (including privately insured children) in the state; the number of states exercising this option has
decreased recently because of increased vaccine costs.6

Private-sector physicians vaccinate the majority of children (Fig 2) and adolescents (Centers for Disease Control and Prevention, unpublished data, 2004). One success of VFC has been increasing the proportion of children vaccinated in the medical home, by reducing vaccination referrals.11–13 In fact, VFC-eligible children vaccinated in the medical home have vaccination coverage similar to that of privately insured children.14 However, in states in which underinsured children cannot receive publicly purchased vaccines from private providers, they may be referred to public health departments for vaccinations, which leads to missed opportunities to vaccinate and lower vaccination rates.15,16

Private-sector vaccine purchase accounts for slightly less than half of pediatric vaccine doses sold each year in the United States, a proportion that has remained relatively constant since the VFC program began in 1994 (Margaret S. Coleman, PhD, written communication, 2008). Providers typically negotiate private-sector vaccine purchase prices with vaccine manufacturers or distributors, negotiate vaccine reimbursement arrangements with health insurers, and then bill insurers for reimbursement after administration of a vaccine to a patient. Unlike other preventive services, providers incur up-front expenditures to purchase vaccines, and payment may be due to vaccine sellers before reimbursement for administered vaccines is obtained. A reimbursement model in which vaccine distributors purchase vaccine from manufacturers, assuming up-front inventory costs on behalf of physicians, is being tested by some vaccine distributors.

**Vaccine Administration Financing**

In addition to payment for the vaccine itself, providers are reimbursed for administering vaccines. In the public sector, vaccine administration reimbursement is available only for VFC-eligible children enrolled in Medicaid, who represented ~81% of VFC-eligible children in 2006.6 Many children and adolescents vaccinated in the public sector are underinsured or uninsured,6,7 and some privately insured children also receive vaccines at public health departments.8 However, there is no publicly funded vaccine administration reimbursement available for children vaccinated in the public sector who are not enrolled in Medicaid. VFC providers may request a vaccine administration fee from non–Medicaid-enrolled, VFC-eligible patients, but they legally cannot withhold VFC vaccines if the patient is unable to pay.

In the fee-for-service Medicaid program, reimbursement rates for VFC vaccine administration are set by state Medicaid agencies. The federal government matches state expenditures up to a federally established maximal rate for each state.17 These maximal rates were set by the Health Care Financing Administration, now the Centers for Medicare and Medicaid Services in 1994 and have not been updated. State-specific vaccine administration reimbursements for 2008 vary from $2 in some states to almost $18 in others, with a median of $9.45 per dose (Table...
1). Contributions by most states do not reach the amount needed to draw the maximal federal matching contribution allowable for vaccine administration. In Medicaid managed care, reimbursement for VFC vaccine administration typically is based on a process of negotiation between the vaccine provider and the health plan, similar to that used by private insurance plans.

In the private sector, providers and insurers negotiate terms for vaccine administration reimbursement, as they do for vaccine purchase. Vaccine administration may be reimbursed through fee-for-service payments based on American Medical Association Current Procedural Terminology codes or may be included in a capped visit payment. Current Procedural Terminology codes for vaccine administration cover a range of costs associated with vaccine delivery, including answering routine vaccination questions. A majority of private plans (77%) and Medicaid plans base payments on the Medicare Resource-Based Relative Value Scale system, which also takes into account provider labor, overhead, and malpractice costs. Clinicians can bill for an office visit by using evaluation and management codes if they perform a separate, medically necessary service aside from vaccination.

### CHALLENGES TO FINANCING DELIVERY OF CHILDHOOD AND ADOLESCENT VACCINES

#### Increasing Costs

The major stress on the current vaccine financing system is a dramatic increase in the cost to vaccinate children and adolescents, as a result of multiple new vaccination recommendations since 1999, many for vaccines against diseases that previously were not vaccine-preventable. By age 18, a girl born in 2008 is recommended to receive up to 52 vaccine doses (up to 49 for boys, who do not receive human papillomavirus vaccine), protecting against 16 diseases, compared with just 19 doses for a child born in 1998.

#### TABLE 1 Actual Versus Allowable Medicaid Fees Paid for VFC Vaccine Administration in 2008

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Data are from the Centers for Medicare and Medicaid Services.

a Rates are for the first vaccine dose and do not reflect increased reimbursement for combination vaccines permitted in some states.

b Data for Arizona and the District of Columbia were obtained by querying immunization program managers in those states; data for Arizona represent the lowest rate paid by any Medicaid plan.

c State and federal shares sum to greater than the total administration reimbursement because of rounding.
purchase vaccines has increased in the past decade.10 The cost at the federal contract price to vaccinate a child fully through age 18 increased from $155 in 1995 ($223 in 2008 dollars) to $1105 for boys and $1407 for girls in 2008 (Fig 3). Newly recommended vaccines are more expensive than vaccines recommended before 1995.22 Some contributors to this increased cost include the complexity of manufacturing techniques for newer vaccines, the cost of conducting increasingly large clinical trials, and the cost for manufacturers to remain in compliance with regulatory requirements.3

Costs to administer child and adolescent vaccines have increased along with the number and price of the vaccines themselves. These costs include storage needs and time required for IIS data entry and inventory management, among others.3 The expanded immunization schedule also requires substantial additional staff time for vaccine counseling and delivery,25 which decreases the time available for other duties. Of the 53% of pediatricians who reported decreased profit margins for childhood vaccination in 1 study, 64% identified increased practice costs for immunization as an important reason for the decrease.24 Beginning in 2009, clinical time for IIS data entry and monitoring and documentation related to vaccine refrigerator/freezer temperatures were included in the payment calculation for vaccine administration codes.25 These codes do not yet reflect the potential for increased costs or savings to providers with the use of combination vaccines.26

**Underinsured Children and Adolescents**

State and local health departments responsible for implementing immunization programs cannot always finance new vaccines uniformly for all children and adolescents in their jurisdiction. Several states have needed to scale back vaccination programs to exclude children on the basis of their insurance status.27–29

In the public sector, the VFC safety net is assigned to FQHCs/RHCs rather than to health departments, the traditional health care safety-net provider. FQHCs and RHCs have limited capacity and geographic reach and represent <10% of VFC providers. Because VFC vaccine administration is reimbursed only for children enrolled in Medicaid, these sites have limited incentive to conduct outreach to underinsured children or other children not enrolled in Medicaid.

Many states attempt to cover underinsured children with Section 317 and state funding; however, discretionary funds have not kept pace with purchasing needs for new vaccines.10 This has led to 2-tiered vaccine-financing systems in many states, under which the set of publicly purchased vaccines provided to underinsured children is not the same as the set provided to other VFC-eligible children.29 The ultimate effect of 2-tiered systems is de facto prioritization of vaccines not on the basis of the benefits of vaccination but on the basis of insurance status.28 Children who are eligible for VFC in any setting and privately insured children with full vaccination benefits are vaccinated as soon as their insurance coverage takes effect. Underinsured children are vaccinated only if they visit FQHCs/RHCs or if there is adequate discretionary funding to purchase vaccines for this population. Some state and local health departments bill insurers for vaccines administered to privately insured children at the health department,30,31 which allows Section 317 funds to be used to purchase additional vaccines for underinsured or uninsured children.31

To reduce underinsurance, many states have instituted laws requiring health plans regulated by the state to cover recommended vaccines.32

**FIGURE 3**

Costs to purchase universally recommended vaccines for a child up to 18 years of age in 1985, 1995, and April 2008.16 1985 and 1995 represent the average federal contract price to account for price changes within the respective year. April 2008 represents the minimum cost to vaccinate children and adolescents and is based on the federal contract price as of April 2, 2008. The 2008 cost to vaccinate includes the new ACIP expanded recommendation for influenza vaccine for all children aged 0 to 18 years. (Last updated April 8, 2008.) Hep indicates hepatitis vaccine; MCV4, quadrivalent meningococcal conjugate vaccine; PCV7, heptavalent pneumococcal conjugate vaccine; DTP, diphtheria-tetanus-pertussis vaccine; DTaP, diphtheria-tetanus-acellular pertussis vaccine; MMR, measles-mumps-rubella vaccine; Hib, *Haemophilus influenzae* type b vaccine; IPV, inactivated poliovirus vaccine; HPV, human papillomavirus vaccine; Td, tetanus toxoids-reduced diphtheria toxoids vaccine; Tdap, tetanus toxoids-reduced diphtheria toxoids-acellular pertussis vaccine. Numbers in the figure legend indicate the recommended number of vaccine doses.
Concerns about reimbursement for vaccine purchase may be increasing as more-expensive vaccines are recommended for routine use. Two recent studies showed significant variation in both the prices private pediatric practices pay for identical vaccines and the insurance reimbursements they receive. Some practices are reimbursed more than the costs of the vaccines themselves, whereas others receive reimbursement that is less than they pay for vaccines; in 1 study, 21% of practices received less in reimbursement than their actual costs for purchasing a dose of varicella vaccine. Some of the variability in vaccine purchase prices and reimbursements is likely attributable to suboptimal business practices in provider offices. For example, practices participating in purchasing cooperatives pay lower prices for vaccines, on average. Practices that pay high prices and receive lower-than-average reimbursements may not recoup their financial outlays from purchasing vaccines.

Practices that break even or make a small profit on vaccine purchase may still be spending more to deliver vaccinations than they receive, because of inadequate reimbursement for vaccine administration. In 1 study, practices broke even or made small profits from vaccinating privately insured children, on average, but were undercompensated for vaccinating VFC-eligible children. In general, private insurers reimburse more for vaccine administration than Medicaid reimbursements for VFC vaccine administration. However, even private insurance reimbursements vary widely and do not always cover a provider’s cost to administer vaccines. Providing vaccination services to both privately and publicly insured children and adolescents may be financially unsustainable for some practices, particularly if they serve larger proportions of VFC-eligible patients.

Recent studies suggest that financial strains have affected vaccination practices among private providers. Nearly one fourth of physicians in 1 study stopped doing business with certain insurers or ceased to vaccinate members of some insurance plans because of payment levels for vaccination. In another study, 49% of providers reported delaying purchase of new vaccines, most often human papilloma-virus and meningococcal vaccines, solely because of financial concerns. Furthermore, 5% of pediatricians and 21% of family physicians reported seriously considering whether to stop providing all vaccines to privately insured pediatric patients, because of vaccine cost or reimbursement issues (publicly insured children were not studied). These studies do not suggest that the US vaccine delivery system is in immediate danger; however, they do indicate trends that, if left unchecked, have the potential to affect access to vaccination services in the medical home.

**Other Considerations**

Vaccinating adolescents presents additional challenges. Adolescents may not have the same levels of vaccination benefits in their health insurance as do younger children and are less likely to be VFC-eligible. Adolescents also are less likely to seek preventive care and tend to access health care in a variety of settings outside traditional primary care provider offices. Financing solutions for vaccinating adolescents at venues outside the traditional health care system may be needed.

In the past, financial barriers to vaccination have been associated with lower rates of vaccination coverage. Patient cost-sharing reduces the use of many recommended preventive ser-
Recently, studies showed that higher out-of-pocket costs and interruptions in insurance coverage were associated with childhood vaccination rates 10 to 15 percentage points lower, compared with rates among children with continuous insurance and few out-of-pocket costs, for both public and private insurance. Studies demonstrated that state vaccine purchase policies supplementing the standard VFC program were associated with increased vaccination rates among underinsured children54 and increased access even to newer and more-expensive vaccines for children without insurance. Reducing out-of-pocket costs for vaccination also is associated with higher vaccination coverage.56

Despite building pressure on the current financing system, the consequences of these challenges are not yet readily visible. Vaccination rates are high (>90%) for most child and adolescent vaccines recommended for routine use before 2000.57 Coverage for more-recently recommended vaccines is low but increasing.59 However, there is concern that the financial barriers described above may delay uptake of newly recommended and future vaccines. Data from 2007 demonstrated that underinsured children and adolescents vaccinated at health departments had lower rates of coverage for expensive, recently recommended vaccines, compared with privately insured children.52 If financial barriers caused providers to stop offering vaccines entirely, then decreasing coverage rates might result in greater population susceptibility, potentially leading to an upsurge in outbreaks of vaccine-preventable diseases. Suboptimal vaccination coverage among low-income, inner-city children resulted in a major measles resurgence in the United States in 1989–1990 and led to the creation of VFC to eliminate cost as a barrier to vaccination.11

**CONSIDERATIONS FOR KEY STAKEHOLDERS**

**Groups Represented**

Successfully addressing financial barriers to vaccinating children and adolescents will require understanding the barriers to and acceptable solutions for covering the costs of vaccination from the perspective of different stakeholders. Perspectives presented below are based on input from organizations representing the interests of 5 key stakeholder groups that were invited to take part in the development of the National Vaccine Advisory Committee vaccine financing recommendations,60 that is, physicians and other health care providers; state and local governments; insurers, employers and other health care purchasers; vaccine manufacturers; and consumers (parents). Consumers were represented by members of national organizations that serve as liaisons between parents, the media, and policymakers, raising awareness of parental views and concerns related to vaccination. Considerations are presented from the point of view of each stakeholder group and do not represent the opinions of the authors.

**Physicians and Other Health Care Providers**

Health care providers serving children and adolescents try to balance providing needed care, including vaccinations, to patients and simultaneously acting as small businesses, keeping their practices running. Because most privately and publicly purchased pediatric vaccines are delivered by private providers, inequities in patient services may occur at provider offices if the private sector is able to cover new vaccines before the public sector (or vice versa). Vaccination providers face ethical dilemmas if they must decide whether to delay implementing a potentially beneficial preventive service, such as use of a new vaccine, until they are able to provide it to all patients regardless of insurance status.

**State and Local Governments**

Vaccine purchase policies and the existence of 2-tiered systems vary according to state; therefore, vaccination recommendations are not being implemented uniformly across the country.29,28 State immunization officials are reluctant to implement 2-tiered vaccination programs. Some states may delay implementation of newly recommended vaccines in the public sector until they are able to finance vaccines for underinsured as well as VFC-eligible children.29 Other states are unable to provide some newly recommended vaccines to underinsured children in the public-sector safety net at all. Both situations result in ethical tension and some children not receiving timely benefits from newly recommended vaccines.

**Insurers, Employers, and Other Health Care Purchasers**

Employers and health care purchasers try to provide employees with access to affordable health care and preventive services, including vaccinations, while controlling costs. Public and private insurance plans look for ways to reduce costs associated with providing health care while offering multiple options for benefit package design to employers and purchasers.

In an unpublished analysis by the AHIP, insurance mandates were not shown to increase childhood vaccination rates, although further research on this topic is needed. The US Chamber of Commerce, National Business Group on Health, and the AHIP strongly oppose mandates for insurance benefits. Such mandates constrain employers’ ability to develop benefit designs appropriate for their workforces.
Vaccine Manufacturers

Maintaining the private vaccine market, including the ability to set vaccine prices, is a priority for manufacturers.63 Vaccines must be profitable for manufacturers to supply currently licensed vaccines while remaining in compliance with regulatory requirements and to invest in the costly process of developing new vaccines.64 Vaccine manufacturers have expressed concern that a universal vaccine purchaser (ie, the federal government) would drive down vaccine prices, thereby reducing returns on investment and subsequent investments for research and development of new vaccines.63

Consumers (Parents)

Parents of children and adolescents needing vaccination balance the desire to protect their children’s health with personal financial constraints that may arise from their children’s insurance status. Parents have 2 primary concerns related to vaccine financing. First, does their child have insurance coverage for the vaccine? As noted above, >1 in 10 children and 1 in 5 adolescents is underinsured for vaccines. Second, which costs associated with vaccination, such as copayments, deductibles, or office visit fees, will not be covered by insurance? Even parents with insurance coverage for vaccines, or those living in states with universal-purchase programs, may seek vaccines at public clinics because they cannot afford the cost-sharing required to obtain vaccines at a doctor’s office or health department. Recent articles in the lay media indicate that parents of privately insured children whose insurance plans do not fully cover vaccines may be obligated to pay the entire cost out of pocket or forgo recommended vaccinations.10,65

CONCLUSIONS

The increasing cost and number of recommended vaccines may limit the ability of public and private payers to continue providing access to vaccines without financial barriers for all children and adolescents. Although current coverage rates are high for most vaccines, recent research documents building tensions resulting from increasing vaccine costs, variable reimbursements for vaccine providers, and practice expenses. The potential for these tensions to disrupt the current vaccine financing and delivery systems demonstrates a need for cooperative action by all stakeholders.

This review of the literature suggests that innovative strategies and efforts will be required to support implementation of newly recommended vaccines and to accommodate vaccines developed for routine use in the future. In response to the issues presented in this review, the National Vaccine Advisory Committee has issued a set of vaccine financing recommendations to facilitate access to all routinely recommended vaccinations without financial barriers for all children and adolescents.60

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