abstract

OBJECTIVE: The goal was to understand vaccine manufacturers’ perspectives on vaccine financing as a barrier to immunization.

METHODS: Individual telephone interviews with representatives of the 6 manufacturers that produce routinely recommended vaccines for children and adolescents in the United States were conducted in November and December 2006.

RESULTS: Although manufacturers acknowledged that the price of newer vaccines presents challenges to optimal vaccine use, they asserted that children and adolescents have access to vaccinations through public and private insurance. Respondents suggested that the system could be improved through adequate funding of the public-sector safety net. Respondents stated that providers should receive timely reimbursement for the full costs of vaccine purchase and administration, and manufacturers who sell directly to health care providers may provide flexible payment terms for vaccine purchases. Manufacturers supported targeted expansion of the Vaccines for Children program to allow children with incomplete insurance coverage for vaccines to receive vaccines at health department clinics. Manufacturers perceived delays in publication of Advisory Committee on Immunization Practices recommendations as a potential barrier to vaccine uptake. They viewed the perceived lack of public value for vaccines as a potential barrier to adequate reimbursement and optimal utilization. Respondents also maintained that their ability to negotiate vaccine prices through the private market is a crucial priority.

CONCLUSIONS: Manufacturers assert that children and adolescents have access to immunizations through public and private insurance. Manufacturers think that they have mitigated the challenge most directly in their control: the large financial outlays required for up-front vaccine purchases. Pediatrics 2009;124:S540–S547


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KEY WORDS
financing, immunization, manufacturers, vaccination, vaccine

ABBREVIATIONS
ACIP—Advisory Committee on Immunization Practices
CDC—Centers for Disease Control and Prevention
HDC—health department clinic
NVAC—National Vaccine Advisory Committee
VFC—Vaccines for Children

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Vaccine manufacturers are central stakeholders in the US immunization enterprise. Because vaccine development is a complex, lengthy, costly process, manufacturers rely on the ability to price vaccines to produce positive returns on their investment and to invest those returns, in part, in research on and development of new vaccines.1–5

After licensure by the Food and Drug Administration, vaccines are purchased and delivered through a mixed public/private-sector system. Immunizations for most children and adolescents through 18 years of age in the United States are covered by commercial private insurance or the public-sector Vaccines for Children (VFC) program. VFC is an entitlement for children through age 18 who are served by Medicaid, who are without health insurance, or who are American Indian/Alaska Native. Under VFC, vaccines are provided to VFC providers free of charge and are administered without cost to the patient. Medicaid provides an administration fee to providers who serve Medicaid-enrolled children in VFC. Although providers can request payment for vaccine administration for VFC patients who are not enrolled in Medicaid, VFC vaccines legally cannot be withheld because of inability to pay an administration fee. Although most US children and adolescents have immunization benefits through public or private insurance, not all have coverage for all vaccines. Underinsured children represent the largest financing gap in the US vaccination program (Fig 1). Underinsured children are children who are enrolled in and entitled to benefits under a health insurance plan but for whom benefits are not available with respect to the cost of ≥1 vaccine. Children whose insurance covers only selected vaccines are considered underinsured with respect to the vaccines not covered and are VFC-eligible for those noncovered vaccines only. Children whose insurance caps coverage for vaccines at a certain amount are considered underinsured once that amount is reached. In the private sector, children with commercial health insurance may be enrolled in plans that do not cover all recommended vaccines.6 In the public sector, VFC provides vaccines to underinsured children only at federally qualified health centers and rural health clinics, which have limited capacity and geographic reach. Many states attempt to address the underinsured gap through state funding and federal funding through the Section 317 grant program to the states; however, such funds are discretionary and have not kept pace with the costs of new vaccines.7

In 1995, the federal contract price to vaccinate a child fully through age 18 was $223. In 2008, the vaccine for human papillomavirus became available and was recommended for use for girls. Including human papillomavirus vaccine, the cost to vaccinate a child through age 18 in 2008 was $1105 for boys and $1407 for girls. This represents 396% and 531% increases from 1995 for boys and girls, respectively (Fig 2). These increases are attributable in part to the greater number of vaccines on the routine schedule and to the higher prices of newer vaccines.8,9 These increased costs have raised concerns about the ability to provide vaccines to all children through both public-sector and private-sector delivery systems, particularly because private-sector providers have asserted that the need for significant capital to purchase and to maintain vaccine inventories is threatening their ability to continue providing vaccinations.10–12 In contrast, public-sector vaccines are purchased with government funds, are administered by public-sector and private-sector providers, and do not incur inventory costs. Privately purchased vaccines are sold and distributed to health care providers directly by the manufacturers who produce the vaccine or through a chain of distributors. Publicly purchased vaccines generally are ordered through state and local grantees by using the Centers for Disease Control and Prevention (CDC) federal contract and are distributed by a federally contracted central distributor to providers. As the suppliers of vaccines, manufacturers are central to addressing challenges to the immunization system. To understand the gaps in knowledge related to how manufacturers perceive the strain of vaccine financing in the current immunization delivery system, the National Vaccine Program Office, on behalf of the National Vaccine Advisory Committee (NVAC), surveyed all manufacturers who produce vaccines for the pediatric and adolescent markets, to assess their perspectives regarding vaccine financing as a barrier to uptake and steps man-

![Figure 1](https://example.com/figure1.png)

**FIGURE 1**
Public and private insurance coverage at 0 to 17 years of age.10,27
Manufacturers could take to address such barriers specifically.

METHODS

As a part of an effort by NVAC to examine challenges to the current US vaccine financing system and to explore solutions to ensure continued access to vaccines for children and adolescents, the National Vaccine Program Office invited senior-level executives, primarily directors of government affairs and public policy, at the 6 manufacturers that produce all vaccines routinely used to immunize children and adolescents in the United States to participate in individual 2-hour telephone interviews. Vaccine financing questions developed by NVAC were sent to the 6 manufacturers before the interviews. Manufacturers were asked to be prepared to discuss the open-ended questions provided and to have appropriate staff experts participate in scheduled interviews.

The purpose of the interviews was to assess manufacturers’ perceptions about vaccine financing as a barrier to immunizations and steps manufacturers could take to address challenges to immunization delivery. Interviews were conducted in November and December 2006 by Ms Shen and Dr Rodewald. Responses from all interviews were aggregated and sent to respondents to be reviewed for accuracy. Because of the small number of manufacturers, quantitative analysis was not performed. Participants’ responses are reported in aggregate and represent the views of their respective companies.

RESULTS

Overview

All 6 manufacturers agreed to be interviewed. Results are reported under 2 thematic headings. In most but not all cases, manufacturers shared the same views.

Perceptions About Vaccine Financing and Barriers to Uptake

What Are Your Perceptions Regarding Vaccine Financing as a Barrier to Immunizations?

Respondents stated that the current immunization delivery system could be enhanced to ensure optimal use of vaccines. They pointed out that the current system covers children and adolescents through age 18 through either private insurance coverage or coverage under the VFC program for both uninsured and underinsured individuals. Respondents were strongly supportive of public-sector programs, including increased funding for the Section 317 grant program, which provides a critical safety net for individuals who would not otherwise be vaccinated.

Would You Support Enhancing VFC to Cover Underinsured Children at Public Health Department Clinics in Addition to Federally Qualified Health Centers and Rural Health Clinics?

Respondents expressed support for expanding VFC eligibility to underinsured children served in health department clinics (HDCs), however, most did not support expanding VFC to cover underinsured children in private medical settings. Respondents remarked that serving underinsured children at HDCs not only would close a gap in access to immunizations but also would do so with little impact on private-sector market sales. (Legislation was introduced to support a targeted expansion of the VFC program to HDCs after these interviews were conducted.)

Why Not Expand VFC to Cover Underinsured Children in Private Medical Settings?

Respondents asserted that increasing the availability of “free,” federally pur-
chased vaccines for underinsured children in private medical practices could serve as an incentive for health care purchasers (eg, employers) to choose benefit packages that do not cover immunization. Payers could drop immunization benefits, knowing that the public-sector safety net would cover underinsured children without causing them to leave their private-sector medical home, which would shift the cost of providing vaccines from the private sector to the public sector.

Are There Other Aspects of Vaccine Financing You Perceive as Potential Barriers to Immunization?

Respondents stated that providers should be reimbursed for the full costs of vaccine purchase and administration (including time spent addressing questions about vaccination, especially regarding vaccine safety). Respondents also stated that, because private providers constitute a large proportion of the delivery system in the United States because they purchase and provide immunizations, the financial challenges these providers face in maintaining a medical practice as a business may compromise the current immunization delivery system.

Respondents noted that their customers (ie, providers) have various payment agreements with payers (eg, health insurance plans) and report a wide range of reimbursement levels from different payers. Respondents asserted that current levels of reimbursement for vaccines and vaccine administration may not cover the full costs of providing immunizations.

What Specifically Do You Know About the Adequacy of Vaccine Administration Fees?

Respondents stated that current levels of reimbursement for vaccine administration may represent a barrier to immunization in both public and private sectors. They added that they support increased public-sector funding for administration fees, particularly for Medicaid, because current Medicaid administration fees are well below the maximal allowable federal ceiling, and they support updating the maximal allowable reimbursement levels.

What Proposals Would You Support to Increase the Likelihood of Commercial Health Insurance Plans Covering All Advisory Committee on Immunization Practices-Recommended Vaccines and What Strategies Would You Recommend?

Respondents proposed providing incentives to insurers to encourage full implementation of first-dollar coverage (ie, coverage with no deductibles or copayments) for all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines and their administration, for all types of health plans. Among suggested strategies to increase benefits coverage for recommended vaccines were tax incentives to health care payers for providing coverage for immunization; pay-for-performance measures that include immunizations as a goal; better communication and coordination between health insurance plans, payers, and beneficiaries and the public health community; more-coordinated and faster insurance coverage for new vaccines; linking coverage decisions to ACIP or American Association of Pediatrics recommendations; and more-scientific studies on the cost savings, cost benefits, and cost-effectiveness of immunization programs. Manufacturers asserted that evidence should inform coverage and reimbursement decisions. Mandates for insurance coverage of vaccination were not supported by the respondents, primarily because the respondents oppose mandates for private-sector industries on principle.

Are There Other Areas of Vaccine Financing That You Perceive May Be a Barrier to Immunizations?

Although it is not directly a financing issue, respondents cited the length of time it takes to publish ACIP recommendations formally as a barrier to immunization. ACIP recommendations may not be published in the CDC Morbidity and Mortality Weekly Report for months or even >1 year after a new recommendation has been approved by ACIP. Once a new recommendation has been approved through ACIP vote, it becomes a provisional CDC recommendation and is posted on the ACIP Web site (www.cdc.gov/nip/recs/provisional/recs/default.htm); however, ACIP recommendations do not become official recommendations until they are accepted by the CDC director and are published in the Morbidity and Mortality Weekly Report. Respondents noted that many private insurance plans use ACIP recommendations as triggers for coverage and payment. Respondents asserted that private insurance coverage decisions contingent on the ACIP process may profoundly affect uptake of new vaccines well into the first year of availability, because many US individuals rely on private insurance to enable them to receive vaccinations. Moreover, respondents stated that this uncertainty in demand for vaccines affects their ability to predict the needed supply of vaccines.

What Do You See as a Top Priority in Addressing Vaccine Financing?

Respondents asserted that a strong private market for vaccines is critical to the long-term health and stability of the vaccine industry. Respondents stated that their priority is to ensure the freedom to set vaccine prices and that higher prices in the private sector
allow them to negotiate lower prices in the public sector. They acknowledged that stakeholders in the vaccine delivery system face financing challenges, primarily because of the higher costs of newer vaccines and inadequate reimbursement for vaccine purchase and administration, but they maintained that lowering vaccine prices is not an option. Respondents emphasized that vaccine development is a long, risky, costly investment, and the risk is high because most vaccine candidates fail to reach licensure. Consequently, the ability to price vaccines is important. Respondents stated that sales of licensed products are both a source of revenue and a source of funds to invest in new innovative vaccines.

Respondents also strongly indicated a perceived lack of public appreciation for the value of immunization in preventing disease and improving health and well-being. Because several vaccine-preventable diseases have been virtually eliminated and rates of others have been drastically reduced, respondents reasoned that ongoing benefits of routine immunization may not be fully visible to the public. Although it is not directly a financing issue, respondents thought that this lack of appreciation might translate into lack of adequate reimbursement for vaccinations, in addition to reduced demand for vaccines. Respondents encouraged increased education of and communication to health care providers, payers (eg, employers), insurers, and the public about the nature of vaccine-preventable diseases, the safety and efficacy (ie, risks and benefits) of vaccines for these diseases, and the importance of fair reimbursement to support continued immunization against vaccine-preventable diseases, through adequate financing and delivery systems.

**Steps Manufacturers Can Take to Address Barriers to Immunization**

**What Specific Steps Has Your Company Taken to Address the Lack of Value Placed on Vaccines?**

Respondents said that their companies help increase the societal value of vaccines by supporting demonstration projects and educational programs to build the evidence base for the value of vaccines. Respondents also stated that they support and encourage the publication of scientific articles and position papers on the cost savings and health outcomes of vaccination programs; more education of employers and purchasers of health care with respect to policy coverage and appropriate reimbursement to providers for immunization services; and communication and coordination between payers, purchasers, insurers, and the public health community regarding the value of providing access and supporting reimbursement for vaccinations. One company representative also stated that the company provides technical assistance to health care providers with respect to reimbursement issues (such as claims paperwork and patient eligibility) that may delay provider reimbursement.

**What Specific Steps Has Your Company Taken to Address the Concern That the Higher Cost of Newer Vaccines Has Created Problems for Private Providers Because of the Capital Outlay Required to Purchase and to Maintain a Vaccine Inventory?**

Not all manufacturers sell directly to providers; some use third-party suppliers such as distributors, and some use a combination of both distribution models. Manufacturers that sell vaccines directly to health care providers stated that they provide flexible payment terms in the form of deferred payments and discounts.

**To What Extent Are Deferred Payment Plans and Discounts Offered by You or Your Distributors and to What Extent Could Such Plans Lower the Cost to Physicians Who Purchase Vaccines to Build an Inventory?**

Respondents said that discounts typically are given to health care providers for receipt of on-time, nondeferred payments (usually within 30 days). Deferred payment terms vary according to manufacturer and typically range from 30 to 120 days. Payment terms are negotiated separately for each vaccine. Respondents stated that most providers pay within 30 to 120 days. One manufacturer allows 180-day deferred payment terms for newer products, and another manufacturer allows for the return of unused vaccines at their full purchase price. Manufacturers that use distributors said that they could not speak for their distributors but they stated their belief that most distributors use some form of deferred payment.

**DISCUSSION**

Manufacturers recognize that development of future vaccines depends on successful sales of currently licensed vaccines. Manufacturers assert that individuals through age 18 have access to vaccines under the current public- and private-sector delivery system. Manufacturers point to high rates of coverage in the pediatric population as evidence of a system that is working. These rates contrast with lower rates of immunization for adults and the need for a reliable safety net in the adult population. Manufacturers have established patient assistance programs for adults but not for children because of existing public-sector safety-net programs such as VFC and the Section 317 grant program. Furthermore, in contrast to their opposition during the conception of VFC, when many manufacturers opposed...
the notion of universal government purchase because of the fear of low prices, manufacturers support the current funding balance whereby public-sector purchases (including VFC, Section 317 grant program, and state-funded purchases) constitute approximately one half of the pediatric vaccine market (Fig 3). These public-sector purchases provide a reliable, steady market for pediatric vaccines, in large part because of the substantial number of doses purchased through VFC. A private-sector market also exists, which allows manufacturers more freedom to set prices. Manufacturers emphasized that they would be concerned if the current balance were to shift toward more public-sector purchases, because they assert that a significant shift toward public-sector universal purchase would eliminate their ability to derive sufficient profits from vaccines, jeopardizing future investments in vaccine development. Manufacturers also maintain that universal-purchase systems limit providers’ choice of vaccine product and can result in lower negotiated prices because of large-volume purchases. Instead, manufacturers support the current public/private-sector proportions in the pediatric market (Fig 3).

Manufacturers acknowledged the critical role ACIP recommendations play in providing guidance to providers on when and to whom to provide vaccinations, thus defining the market. In addition, ACIP has an operational role in designating which vaccines should be provided to VFC-eligible children. Purchases through public-sector programs, including VFC, support approximately one half of the market for pediatric vaccines (Fig 3) and one third for adolescent vaccines (Fig 4) and expand the market by providing vaccines to children and adolescents who otherwise likely would forgo vaccination because of cost concerns.

Manufacturers support public-sector programs and are open to the expansion of VFC eligibility to underinsured children served in HDOs. This bridges one of the gaps to universal vaccine access without affecting the private-sector market, because this group of children otherwise likely would remain unvaccinated. However, manufacturers are cautious about significant increases in government purchases (ie, shifting more purchases from the private sector to the public sector).

Manufacturers concluded that they have responded in part to providers’ financial challenges in managing the large financial outlays and expensive carrying costs of maintaining vaccine inventories, by offering flexible pricing and payment terms for private-sector sales. However, some providers still face challenges. Other industries have been successful in managing expensive inventories through a consignment model in which capital is not tied up in inventory, although there still are carrying costs to maintain inventory. Consignment provides a model to manage inventory in a supply chain in which goods are delivered to the provider and payment for goods is made only after goods are sold.

After these interviews were conducted in 2006, additional programs intended to support private health care providers in managing inventory control and financial outlays associated with providing vaccinations have been initiated by manufacturers to address specific reimbursement challenges of private providers. Examples include a pilot program that bills providers for vaccine purchase only after the vaccine is administered and a program that provides a limited number of replacement vaccines.
doses of an administered vaccine if a patient’s private insurance does not provide reimbursement for that particular vaccine.25 Although manufacturers support full reimbursement for the purchase of vaccines and the associated costs to deliver the vaccines, they understand that current reimbursement levels for purchase and delivery do not account for the costs of purchasing and maintaining vaccine inventories or the full cost of providing immunizations. Manufacturers have a stake and a role in ensuring a strong immunization delivery system, particularly as additional vaccines are added to the immunization schedule in the future.

The 6 manufacturers interviewed for this study represent the universe of manufacturers that sell child and adolescent vaccines in the United States.26 Because different vaccines cannot be substituted for one another,23 each vaccine competes in its own market, with few or no other licensed manufacturers. Because responses were aggregated from all manufacturers regardless of market size or position in the market, the position of a company in a particular market (eg, new entrant) might have influenced a particular manufacturer’s view and perspective, although most of the responses were homogeneous.

CONCLUSIONS

Although newer vaccines are more expensive and provide financial challenges to purchasers, payers, and consumers of vaccines, manufacturers assert that all children and adolescents have access to immunizations through public and private insurance. Manufacturers think they have mitigated the 1 financial challenge most directly in their control: the large financial outlays required for up-front vaccine purchases. However, if financial pressures continue to be a barrier as new vaccines are recommended, then manufacturers may be asked to do more. The results of this analysis helped to inform the recent NVAC vaccine financing recommendations to ensure delivery of all ACIP-recommended vaccines to all children and adolescents without financial barriers.27

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REFERENCES

3. Plotkin S. Why certain vaccines have been delayed or not developed at all. Health Aff (Millwood). 2005;24(3):651–654
5. Klein JI, Myers MG. Vaccine shortages: why they occur and what needs to be done to strengthen vaccine supply. Pediatrics. 2006;117(6):2269–2275


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