

GAO

Testimony

Before the Subcommittee on Health and Environment,
Committee on Commerce,
House of Representatives

For Release on Delivery
Expected at
10:30 a.m. EST
Thursday
June 15, 1995

VACCINES FOR CHILDREN

Refocusing the Program's Goal
and Implementation

Statement of Kwai-Cheung Chan
Director for Program Evaluation
in Physical Systems Areas
Program Evaluation and Methodology Division



063837/154482

Mr. Chairman and Members of the Subcommittee:

It is a pleasure to be here to share with you the results of our work on the Vaccines For Children (VFC) program. My statement is based upon our work in this area for the report that we are issuing today.¹ As you requested, today we will present our conclusions on (1) the extent to which vaccine cost has prevented children from being immunized on schedule, (2) VFC's implementation, and (3) promising options for improving children's immunization rates.

Before turning to the results of our work, let me briefly provide some basic information on VFC. Section 13631 of the Omnibus Budget Reconciliation Act of 1993 created VFC to begin by October 1, 1994, as an entitlement program for four groups of children through 18 years old: those eligible for Medicaid and those who are American Indians or uninsured. Underinsured children (those whose insurance does not cover childhood vaccinations) are also eligible for VFC vaccines but may receive them only in federally qualified health centers or rural health clinics. CDC views VFC's goal as increasing immunization rates, particularly among preschool children, by providing free pediatric vaccines and, thereby, reducing vaccine cost as a barrier.²

Its fiscal year 1995 cost estimates included \$412 million for vaccine purchase, \$24.5 million for vaccine distribution, \$9.2 million for vaccine ordering, and \$11.6 million for operations. The Centers for Disease Control and Prevention (CDC) has announced that doses of influenza vaccine for high-risk children and hepatitis B for adolescents will be added to the recommended schedule in fiscal year 1996, along with speedier catch-up immunization against measles. Newly approved varicella (chicken pox) and hepatitis vaccines will be considered. Only one of these five new additions to the vaccine schedule (the measles booster) will be covered by statutory price caps (that is, contract prices that were in effect in 1993). CDC officials estimate that VFC purchases of the new varicella vaccine could cost an additional \$35 million to \$560 million, depending on the extent of catch-up coverage recommended. CDC estimates that once catch-up has been completed, the annual cost of including varicella will range from \$35 million to \$70 million.

¹U.S. General Accounting Office, Vaccines For Children: Reexamination of Program Goals and Implementation Needed to Ensure Vaccination, GAO/PEMD-95-22 (Washington, D.C.: June 1995).

²The vaccines VFC provides to the states include antigens for measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, hepatitis B, and haemophilus influenza.

METHODOLOGY

To perform our review, we examined pertinent literature, data, and agency documents, met with CDC officials, and convened a panel of the principal investigators on four major CDC-funded studies that "diagnosed" and identified reasons for low immunization rates among inner-city preschoolers in Baltimore, Los Angeles, Philadelphia, and Rochester, New York. We also surveyed all 50 states and the District of Columbia and interviewed other federal and state officials, vaccine experts, representatives of vaccine manufacturers and distributors, and physicians.

STUDY RESULTS

Turning to our results, I would like to cover four areas that underpin our view that VFC's goal needs to be reassessed. These areas are vaccine cost, pockets of underimmunization, VFC's implementation, and promising options for improving children's immunization rates.

Vaccine Cost

From the available evidence, we conclude that the cost of vaccine for parents has not been a major barrier to children's timely immunization. Immunization rates for preschool children at the outset of VFC were at or near the 90-percent national goal for 1996. Further, immunization rates among school children now exceed 95 percent for all antigens in the basic series. Four major CDC studies suggest that other barriers are more important than vaccine cost. These and other studies identify many barriers, including inadequate clinic resources, clinic policies that deter vaccination, and various factors that cause providers to miss opportunities to immunize children at regular visits. In fact, when VFC began, most children who had not received age-appropriate vaccinations had already had access to free vaccine through Medicaid or public health clinics, but their health care providers had missed opportunities to vaccinate them during routine visits.

The evidence that CDC has relied on to suggest that vaccine cost is a major barrier tends toward more narrow investigations of particular factors, such as providers' referral patterns. We found that, for the purpose of assessing the role of vaccine cost in underimmunization, this research suffers from several conceptual and methodological problems. One is the failure to separate vaccine costs, which VFC addresses, from the larger provider fees associated with immunization, which it generally does not. The statute does stipulate that providers may not deny vaccine to a child who is unable to pay the administration fee. However, CDC has no measures to ensure the providers' compliance with this requirement. Another problem with the research is its inability to determine that the factors actually measured, such as

provider referrals to public health clinics, are valid indicators of whether children are or are not immunized. And, too, much of the research relies on opinion data collected in surveys rather than through an analysis of the immunization status of representative samples of children.

Pockets of Need

It is important to note that the problem of underimmunization is largely concentrated in certain population groups and areas often referred to as "pockets of need." In these groups and areas, there are disproportionate numbers of children who are not immunized for specific diseases, creating conditions ripe for disease outbreak. For example, CDC's analysis of the measles outbreaks in the 1980s shows that delayed immunization led to consistently reported cases over 10 years in only 17 of 3,137 U.S. counties, suggesting that special efforts to improve immunization coverage might be targeted there.

Program Implementation

Although CDC has devoted much effort and considerable resources to implementing VFC, and has made progress, VFC's implementation remains incomplete. We reported in July 1994 that the original CDC plan to implement VFC by October 1, 1994, was very ambitious given its scope, the inherent complexity and interdependence of tasks, and the need for strong leadership to coordinate the efforts of various federal, state, and private sector partners.³ We questioned CDC's ability to accomplish those tasks adequately before October 1994. However, the Department of Health and Human Services (HHS) asserted that these problems could be rectified and announced that VFC would be fully implemented by October 1, 1994.

For today's report, we reviewed the status of contract negotiation, provider enrollment, provider reimbursement, order processing and automation, vaccine distribution, accountability, and evaluation planning as of March 30, 1995. We found that six of these seven critical implementation tasks remain incomplete.

Vaccine Contracts

The only completed task is contracting to purchase vaccines. Even here, two problems have emerged. First, some states have objected that CDC's order processing methods do not permit them

³U.S. General Accounting Office, Vaccines For Children: Critical Issues in Design and Implementation, GAO/PEMD-94-28 (Washington, D.C.: July 1994).

to guarantee physicians specific brands of vaccine.⁴ Many physicians believe that different brands of vaccine are not interchangeable.

Second, CDC officials told us that the maximum doses of oral polio vaccine (OPV) that can be purchased under the current contract will not meet the estimated needs of all the states for fiscal year 1995. This problem may only get worse, since 14 states and the District of Columbia have yet to begin routine ordering for private providers.⁵ This would result in a shortage of the polio vaccine for VFC unless CDC draws it from the stockpile, which CDC officials describe as a last resort, or buys additional vaccine outside the existing contract. Buying OPV outside the contract at prices that exceeded the statutory caps would create questions about CDC's ability to comply with the law.⁶

Vaccine Distribution

CDC has had problems distributing VFC vaccines to private providers. CDC's policy has shifted considerably in this regard. At first, CDC officials indicated that since the law did not permit the agency to reimburse manufacturers separately for delivery of vaccine purchased under the price caps, it would distribute vaccine through a national distribution center under the General Services Administration. However, plans for a national distribution center were dropped in August 1994, and CDC, in apparent contradiction, attempted to amend its contracts with four vaccine manufacturers to provide separate payments for delivery services. CDC solicited and received sole-source bids from four vaccine manufacturers by December 1994 but withdrew its solicitation in April 1995 because many states had made alternative distribution arrangements with CDC's financial assistance. As of March 30, 1995, 15 of the 24 jurisdictions (23 states and the District of Columbia) that had expected to rely on a national distribution center had not begun routine vaccine delivery to private providers. As a result, private providers in

⁴Under current contracting arrangements, such a guarantee might not be possible 100 percent of the time, but systems might be improved to optimize the satisfaction of providers' preferences.

⁵These 15 jurisdictions represent more than 1.3 million children, or more than 45 percent of the children younger than 2 who the states estimated would receive VFC vaccine from private providers.

⁶If the OPV contract does not permit the purchase of sufficient quantities of vaccine to meet VFC's needs, it will be important for CDC to give VFC's acquisitions priority over those made at state option.

14 states and the District of Columbia will not be able to immunize entitled children with free VFC vaccines.

While the states that have decided to develop their own distribution systems will be fully reimbursed for distribution costs through VFC, these costs are not capped, and the states do not have to contribute to them. Other than reviewing state funding requests, CDC has provided no guidance to the states on how to deal with distribution costs, which have differed considerably depending on state solicitation and contracting procedures.

Provider Enrollment

While the states had enrolled most public health providers as of January 30, 1995, CDC and many states cannot gauge the proportion of private or Medicaid providers that have been enrolled. CDC does not know the numbers of eligible pediatricians, family practitioners, osteopaths, Medicaid providers, and other private providers and therefore cannot accurately assess the proportions of immunizing providers who have been enrolled.

In early 1994, CDC said that it hoped for 50-percent enrollment of private providers but had no state-specific goals. In January 1995, 46 states had begun their enrollment but only 30 of these could provide estimates of the proportion of providers who had been enrolled. Of these 30, only 13 reported 50-percent enrollment or more.⁷ Of the remaining 17 states, 8 reported 11 to 49 percent enrollment and 9 reported 10 percent or less. These 17 states represent about one third of the children likely to receive VFC vaccines through the private sector.

About 60 percent of the children who are eligible for VFC are also eligible for Medicaid and receive their other health care through providers enrolled in that program. The Health Care Financing Administration (HCFA) plans to terminate Medicaid vaccine payments in October 1995 where VFC vaccines are available to private providers. Thus, monitoring the proportions of Medicaid physicians who have enrolled in VFC is the only way of ensuring that Medicaid beneficiaries' access to immunization will not be disrupted. However, it is not clear whether HCFA can

⁷Of these 13, 7 were capable of expediting enrollment because they either had begun universal vaccine distribution since VFC or had implemented universal distribution programs before VFC. The 3 states reporting 90-percent enrollment or more had universal programs before VFC, but they serve less than 1 percent of the children younger than 2 who are likely to be immunized with VFC vaccines.

assess Medicaid beneficiaries' access to VFC-enrolled providers in order to determine when it is prudent to end these payments.

Provider Reimbursement

Under the law, providers' fees for administering VFC vaccine are to be based on their actual costs for providing this service. Although CDC has set caps on administration fees, it has based these caps on physicians' prevailing charges instead of costs. Consequently, in several states, permissible fees under VFC have exceeded Medicaid vaccine administration fees by as much as \$10. CDC's rationale for using prevailing charges was that data on the cost of administering vaccine were insufficient when it developed VFC's reimbursement policy and that physicians would not otherwise enroll. As we noted in July 1994, this policy can create a financial burden for parents, who may have to pay more than under a fee schedule based on administration costs, as stipulated in the law.⁸

Order Processing and Automation

CDC developed and provided the states with software and hardware, known as VACMAN, to assist them in ordering, tracking, and recording the costs of publicly funded VFC vaccines by processing bulk public and individual private-provider vaccine orders, recording data on all enrolled public and private providers, accounting for orders by funding source (whether Section 317, state, or VFC), and electronically linking CDC and the 64 state immunization projects. During fiscal year 1994, CDC developed and distributed this system at a cost of just under \$1 million.

CDC did not (1) allot enough time to test VACMAN operationally before the October 1, 1994, start date, (2) actively involve the system's users to ensure that their functional needs would be met, (3) perform alternative systems design and cost-benefit analyses to determine the best system to support VFC's objectives, or (4) perform independent quality-assurance testing of the system.

The result is that VACMAN is not designed to meet critical VFC needs, such as identifying underimmunized children or tracking those who have been vaccinated through the program. Twenty-two states said that for VACMAN to be useful, they need to link it with other systems and databases, but many states cannot. This hinders their ability to share data and fully support the VFC program.

⁸U.S. General Accounting Office, Vaccines for Children: Critical Issues in Design and Implementation, p. 2.

Many of VACMAN's system functions are not being used. For instance, CDC disabled private-provider ordering functions when the national system for distributing vaccines to providers was dropped. The states can use VACMAN only for bulk ordering, thus limiting their ability to track and account for vaccines ordered by private providers. Moreover, the states perceive VACMAN's accountability as limited--only 8 states told us that VACMAN meets all their accountability needs.

Moreover, VACMAN does not provide the states with overall project fund balances, so they may not know whether they have funds to cover orders as they place them, nor does it indicate whether a vaccine is on back order, so they cannot easily determine when or whether an order will be filled. Officials in 29 states said that they operate other systems to track and manage vaccines even though this may involve dual data-entry and redundant operations. CDC plans multiple revisions to the software through the end of this year.

Accountability

Believing that strict accountability measures, such as requiring providers to report vaccine usage, might prevent them from participating, CDC mandated only that the states require providers to complete three enrollment documents.⁹

CDC's initial plan had been to use the providers' own estimates of their vaccine needs as the basis for vaccine accountability. We noted in July 1994 that this plan was inadequate and that CDC lacked any independent means of verifying state vaccine needs, and we concluded that it would not be able to detect fraud and waste. Moreover, providers' enrollment remains low, despite VFC's minimal accountability requirements.

Reversing policy in November 1994, CDC gave the states 1 month to report comprehensive accountability plans for their supplies of free vaccine. These plans contain a variety of measures; many states plan to compare providers' profiles and ordering patterns to external databases such as immunization registries. But as of March 30, 1995, no states had submitted reports to CDC, and the agency cannot distinguish between the number of children who have been immunized under VFC and the number of doses of vaccine that have been distributed, nor can it accurately assess vaccine waste.

⁹Centers for Disease Control and Prevention, Vaccines For Children Operations Guide (Atlanta: May 1994), p. 22. The three enrollment documents are the provider's profile, the provider's enrollment form, and the patient's eligibility form.

The major federal accountability requirement is that providers estimate the number of their patients who are eligible for VFC and their vaccine needs. However, most states report that providers "greatly" or "somewhat" overestimate these numbers. CDC has found that several states relying on these estimates have projected vaccine needs that exceed the total numbers of children in the appropriate age ranges. Therefore, CDC has dropped its plans to use such data as a basis for accountability, engaging a contractor in February 1995 to study alternative measures.

In the absence of better accountability plans, CDC cannot ensure that VFC is reaching the target population, let alone underimmunized children in pockets of need, or to determine the level of waste and abuse.

Evaluation

As of May 1, 1995, CDC had released no plans for evaluating VFC, and 31 of the states we surveyed in December 1994 had no such plans. The states that did have plans generally acknowledged that they were not intended to evaluate the program's effect (versus assessing its implementation) or could not distinguish VFC's intervention from other factors that might be improving immunization rates. Forty states reported that they had initiated related programs at or near the time when VFC began. In the states that already had universal vaccine purchase programs, it is not clear that VFC will have any direct effect on immunization activities apart from changing the source of their financing.

CDC officials reported before VFC began that their draft VFC evaluation plans focused on the program's implementation, which CDC has begun to examine through periodic surveys of state immunization personnel.

In summary, we found ongoing problems in six of the seven areas of program implementation we examined. Although contract negotiation and enrollment of public health providers are largely complete, the enrollment of private providers appears to be low. While HCFA conducts a cost study, VFC policies governing providers' fees remain inconsistent with the law. At least 15 jurisdictions had not begun routine shipments of vaccine to private providers by March 1995. Moreover, VFC's automated order processing system was not developed in conformance with federal guidelines and, consequently, supports limited program functions and fails to meet important user requirements. CDC's accountability plans do not permit it to distinguish the number of children immunized with VFC vaccine from the number of doses of vaccine distributed and thus limit its capacity to monitor vaccine waste and diversion. Finally, evaluation plans were not ready as late as May 1995.

Collectively, these facts raise concerns about VFC's management and its coordination with other immunization programs. VFC's management, split across HCFA, CDC, and the states, offers little assurance of a smooth transition between VFC and other immunization programs. For example, while VFC operates in conjunction with Medicaid's immunization efforts, the two programs have not been adequately coordinated. HCFA has therefore been unable to set criteria for cut-off dates for vaccine reimbursement under Medicaid, and the data on Medicaid providers that are critical for developing VFC's provider-enrollment goals are not available.

Promising Options

CDC-funded studies have shown promise for improving immunization rates by coordinating immunization services with large public programs--such as the Special Supplemental Food Program for Women, Infants, and Children and Aid to Families with Dependent Children, which cover children who are known to be at high risk of delayed immunization and vaccine-preventable disease. Research also links improved immunization with provider-based strategies, such as assessing clinic immunization practices and offering feedback or creating reminder and recall systems or registries to reduce missed opportunities for immunization. One CDC official has testified, based on major CDC-funded research, that immunization rates for most antigens could be improved by as much as 15 percent simply by eliminating missed opportunities.

CONCLUSIONS

We conclude from the available evidence that vaccine cost has not been the major barrier for the parents of underimmunized children. Major studies indicate that free vaccine was generally available to them before VFC. Even a fully functional VFC is not likely to prevent outbreaks of vaccine-preventable disease. These outbreaks are likely to occur in pockets of need located mostly in urban areas across the nation. Data on underimmunized children in major metropolitan areas indicate that supplementary action independent of making vaccine free will be required and that efforts other than VFC may hold greater promise.

The Congress may want to consider refocusing VFC's goal from the improvement of general immunization rates to the achievement of higher immunization rates in pockets of need, where conditions are ripe for disease outbreaks among underimmunized children. A program with immunization targeted to pockets of need should be more cost-effective than the current approach. In conjunction, enrollment, accountability, automation, and evaluation efforts need to be adjusted to focus on children who are at the greatest risk for delayed immunization. Reminder and recall or tracking systems might help identify and reach them.

Mr. Chairman, this concludes my remarks. I would be happy to answer any questions that you or members of the Subcommittee may have.

(973432)

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are \$2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 6015
Gaithersburg, MD 20884-6015

or visit:

Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders may also be placed by calling (202) 512-6000 or by using fax number (301) 258-4066, or TDD (301) 413-0006.

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (301) 258-4097 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

**United States
General Accounting Office
Washington, D.C. 20548-0001**

<p>Bulk Mail Postage & Fees Paid GAO Permit No. G100</p>

**Official Business
Penalty for Private Use \$300**

Address Correction Requested
