Gaps in Vaccine Financing for Underinsured Children in the United States

The number and cost of new vaccines routinely recommended for children and adolescents has increased considerably since 2003. New or expanded recommendations for meningococcal conjugate, tetanus-diphtheria-acellular pertussis (Tdap), hepatitis A, influenza, rotavirus, and human papillomavirus vaccines have led to a 7.5-fold increase in the cost to fully vaccinate a child in the public sector (from $155 in 1995 to $1170 in 2007).1,2

Despite high vaccination coverage and low incidence rates of most vaccine-preventable diseases,3,4 anecdotal reports from state policy makers and clinicians suggest that the US vaccine financing system is under increasing strain. Childhood vaccines in the United States are financed by a patchwork of public and private sources.5

Children who are privately insured often have insurance coverage for vaccines (Box). However, some children are enrolled in private health insurance plans that do not cover the cost of vaccines and they are considered underinsured for immunization. In 2000, it was estimated that 14% of children aged 0 to 17 years were underinsured in the United States, requiring families to either pay out-of-pocket for the cost of vaccines not covered or forgo receiving vaccines.3

Main Outcome Measures Percentage of states in which underinsured children are unable to receive publicly purchased vaccines in the private or public sectors.

Results Immunization program managers from 48 states (96%) participated in the study. Underinsured children were not eligible to receive publicly purchased meningococcal conjugate or pneumococcal conjugate vaccines in the private sector in 70% and 50% of states, respectively, or in the public sector in 40% and 17% of states, respectively. Due to limited financing for new vaccines, 10 states changed their policies for provision of publicly purchased vaccines between 2004 and early 2006 to restrict access to selected new vaccines for underinsured children. The most commonly cited barriers to implementation in underinsured children were lack of sufficient federal and state funding to purchase vaccines.

Conclusions The current vaccine financing system has resulted in gaps for underinsured children in the United States, many of whom are now unable to receive publicly purchased vaccines in either the private or public sectors. Additional strategies are needed to ensure financial coverage for all vaccines, particularly new vaccines, among this vulnerable population.

Context The number of new vaccines recommended for children and adolescents has nearly doubled during the past 5 years, and the cost of fully vaccinating a child has increased dramatically in the past decade. Anecdotal reports from state policy makers and clinicians suggest that new gaps have arisen in financial coverage of vaccines for children who are underinsured (ie, have private insurance that does not cover all recommended vaccines). In 2000, approximately 14% of children were underinsured for vaccines in the United States.

Objectives To describe variation among states in the provision of new vaccines to underinsured children and to identify barriers to state purchase and distribution of new vaccines.

Design, Setting, and Participants A 2-phase mixed-methods study of state immunization program managers in the United States. The first phase included 1-hour qualitative telephone interviews conducted from November to December 2005 with 9 program managers chosen to represent different state vaccine financing policies. The second phase incorporated findings from phase 1 to develop a national telephone and paper-based survey of state immunization program managers that was conducted from January to June 2006.

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Children (VFC) program. The VFC program is a federal entitlement program that provides funding for recommended vaccines for eligible children in the United States. This program is unique in that the Advisory Committee on Immunization Practices (ACIP), which is the national decision-making body that makes recommendations for vaccine use in the United States, has the authority to vote on whether the VFC program should purchase ACIP-recommended vaccines. If ACIP votes to include a new vaccine or expanded use of a vaccine in the VFC program, the funding must be provided for state immunization programs to purchase and distribute VFC vaccines to public and private clinicians.

In 2006, approximately half of all children aged 0 to 18 years in the United States were considered VFC eligible (J.M.S., Centers for Disease Control and Prevention, unpublished data, 2007). Certain groups of children are eligible to receive VFC in any setting, including those who are uninsured, Medicaid-enrolled, or of American Indian/Alaska Native descent. In addition, uninsured children are able to receive VFC vaccines when served in federally qualified health centers or rural health clinics. Unfortunately, these facilities do not exist in every community because of location requirements related to serving in medically underserved areas, which may limit access to vaccination for underinsured children. For underinsured children who are not able to access federally qualified health centers or rural health clinics due to lack of proximity to these sites, public health clinics have served as their safety net. Funding for underinsured children who seek vaccines in public health clinics has typically been provided by other federal sources, such as section 317 discretionary grants. Some states have also contributed state funding to purchase vaccines for vulnerable children in public health clinics. Declines in such funding in recent years combined with increases in the number of vaccines and higher vaccine costs have led to concerns over the gaps in the availability of new vaccines for the growing population of children who are underinsured.

Our goal was to evaluate the status of financing and distribution of new pediatric vaccines at the state level. We achieved this by (1) describing variation among states in the provision of publicly purchased vaccines to underinsured children and (2) identifying barriers to state purchase and distribution of new vaccines.

**METHODS**

**Study Design and Population**

We conducted a 2-phase study based on interviews with state immunization program managers. Immunization program managers are employed by state health departments to support immunization activities in their state. Program managers are responsible for purchasing vaccines using VFC funds, section 317 funds, and state funds (if available), and distributing these vaccines to public and private clinicians in their state. They also provide technical assistance to improve vaccine storage and handling practices and the quality of immunization delivery. Ten state immunization program managers were initially recruited for phase 1, and immunization program managers from all states were contacted for phase 2.

**Phase 1: Qualitative Interviews**

In the first phase, we recruited state immunization program managers to complete a 1-hour qualitative telephone interview from November to December 2005. States were chosen to include those with different types of vaccine financing policies (Table 1). A state’s vaccine financing policy describes which groups of children and in which settings (ie, private sector, public sector, federally qualified health centers, and rural health centers) the state will purchase vaccine with VFC funds, section 317 funds, or state funds. The public sector includes places such as state or local public health clinics and community health clinics. Policies range from very comprehensive approaches, such as a universal vaccine financing policy, in which the state purchases all vaccines for all children, to approaches in which the state only purchases vaccines for those children who are VFC eligible. Between these 2 extremes are states that are able to purchase vaccines to serve children who are underinsured with respect to immunization. States have the ability to change their vaccine financing policy as needed based on the availability of state funds.

Themes addressed in the qualitative interview included questions about the types of barriers encountered when implementing new vaccines and the consequences of these barriers. An open-ended format was used to allow for identification and further exploration of ideas in depth and for probing and clarification of responses. Interviews were audiotaped and transcribed for further review.

Nine state immunization program managers representing states with 1 of 5 vaccine financing policies gave ver-
bal informed consent for interviews and participated in phase 1. The vaccine financing policies included universal (state provides all routine childhood vaccines for all children in all settings); universal select (state provides some routine childhood vaccines for all children in all settings); VFC enhanced (state provides all routine childhood vaccines for VFC-eligible and underinsured children in all settings); VFC-enhanced select (state provides some routine childhood vaccines for underinsured children and all routine childhood vaccines for VFC-eligible children in all settings); and VFC only (state provides all routine childhood vaccines for VFC-eligible children only). Of the 9 program managers, 2 represented states with a universal vaccine financing policy, 2 with a universal select policy, 1 with a VFC-enhanced policy, 2 with a VFC-enhanced select policy, and 2 with a VFC-only policy. After review of the interview data, respondents' comments were organized into 2 common themes: (1) barriers to vaccine implementation (inconsistent, inadequate, or delayed financing [VFC, section 317, state] or supply of new vaccines) and (2) consequences of these barriers (delays in vaccine implementation, changes in vaccine financing policy, prioritization of subgroups to receive vaccine, availability of publicly purchased vaccine to underinsured children [ie, those children whose health insurance did not cover some or all routinely recommended vaccines] in the private and public sectors). These themes were subsequently used to formulate the questions in phase 2.

**Phase 2: National Survey**
In the second phase, we conducted a national survey of program managers from January to June 2006. We mailed a written survey to 50 state immunization program managers in the United States. In addition, we conducted 1-hour semi-structured telephone interviews with program managers who were not previously interviewed in phase 1. The written survey included quantitative questions regarding vaccine implementation in VFC-eligible and underinsured children, presence of financial and supply barriers to implementation, availability of publicly purchased vaccine to underinsured children in the private and public sectors, strategies used to address limitations in financing, and characteristics of the state immunization program. Survey questions were focused on 5 of the most recent vaccine recommendations made by the ACIP at the start of the study: varicella, conjugate pneumococcal, conjugate meningococcal, Tdap, and hepatitis A (universal). The expanded recommendation for influenza vaccination of 6- to 23-month-old children was not included in the study because issues associated with implementation vary from year to year depending on manufacturer supply and the availability of 1-time funding sources. Semi-structured telephone interviews, for which participants gave verbal informed consent, were also conducted to clarify and further probe responses to the written survey. Telephone interviews were audiotaped and transcribed for further review. This study was approved by the Harvard Pilgrim Health Care Institutional Review Board.

**Data Analysis**
In phase 1, coding and thematic analyses were performed to identify major dilemmas states faced when implementing new vaccines. Open coding was initially performed to identify themes or ideas in the transcripts and interviews. These themes or ideas were categorized into domains using axial coding techniques. Coding was performed iteratively and was continually refined until no further insights were achieved. To strengthen the validity of the coding scheme, 4 coinvestigators (G.M.L., D.R., J.E.S., and T.A.L.) reviewed selected transcripts and consensus was obtained on the final coding scheme. Important themes that emerged from these qualitative interviews were the basis for the nationwide survey for state immunization program managers in phase 2. All coding was performed using the computer program NVivo.

In phase 2, all written responses and interview transcripts were reviewed and independently coded for responses to both quantitative and qualitative questions by 2 individuals (C.G. and D.R.) using the coding scheme derived in phase 1. A third individual (G.M.L.) reviewed all discrepancies, which were subsequently resolved by consensus. Descriptive analyses included mean, median, range, and percentages.

**RESULTS**

**Study Population**
Forty-eight state immunization program managers participated in the study for an overall response rate of 96%. Program managers had been in their positions for a mean of 7.2 years (me-
dian, 5.5 years), with a range of 0 to 27 years. Only 34% of states had a health insurance mandate that required insurers to follow current ACIP or American Academy of Pediatrics recommendations for children and adolescents. Seventeen percent of states had a health insurance mandate that did not require insurers to cover all recommended vaccines and 49% of states did not have any health insurance mandate.

**Provision of Publicly Purchased Vaccines**

Many states were not able to provide state-purchased vaccines for underinsured children in the private sector, public sector, or both. For example, for vaccines given in the private sector, 46% of states did not provide publicly purchased varicella vaccine to underinsured children and 70% of states did not provide publicly purchased meningococcal conjugate vaccine to the underinsured (TABLE 2). For vaccines given in the public sector, 17% of states were unable to provide publicly purchased pneumococcal conjugate vaccine to underinsured children and 40% were unable to provide publicly purchased meningococcal conjugate vaccine. This meant that underinsured children were not able to receive state-purchased vaccine in either the private or public sectors in these states. None of the vaccines we studied was covered for all underinsured children in the United States.

**Changes in State Vaccine Policy**

Ten states reported that between 2004 and early 2006, new limitations in their ability to provide publicly purchased vaccines for underinsured children had arisen as a consequence of limitations in federal and state financing for vaccine purchase. Two states that formerly had universal purchase for all children changed their policies to provide certain newer vaccines to VFC-eligible children only. Five states that formerly had purchased all vaccines for all underinsured and VFC-eligible children began to provide certain newer vaccines only to VFC-eligible children. Three states that formerly purchased some vaccines to give to underinsured children changed their policy to provide vaccines only to VFC-eligible children. Interestingly, 1 state was able to advocate for and receive increased amounts of state funding for pneumococcal conjugate vaccine and thus was temporarily able to provide all publicly purchased vaccines to underinsured children at that time.

State immunization program managers reported a variety of approaches to decision making regarding changes in state vaccine financing policy. In some states, members of the immunization program or the state health department were primarily responsible for deciding how available funding would be spent. In other states, program managers had external advisory committees that provided guidance on the use and prioritization of vaccines to be purchased by the programs. Members of such committees included physicians, nurses, county and city health officials, and legal advisors. In addition, immunization programs that had previously received funding from state legislatures for vaccine purchase often requested additional state funding for new vaccines.

**Barriers to Vaccine Implementation in Underinsured Children**

Limitations in both federal (section 317) and state vaccine financing were reported as the dominant barriers to states’ providing vaccines to underinsured children. Lack of section 317 funding was cited as a barrier for 81% (Tdap) to 100% (pneumococcal conjugate) of state immunization programs that were not able to provide vaccines to underinsured children. State funding was either limited or unavailable for vaccine purchase for 94% or more of programs that were not able to provide vaccines to underinsured children. Vaccine supply or allocation was also cited as a barrier to implementation in this population, particularly for meningococcal conjugate (56%) and Tdap (27%) vaccines. In particular, monthly federal allocations due to limitations in vaccine supply resulted in some programs delaying the distribution of vaccine to clinicians until they thought they had been able to purchase an adequate amount of vaccine.

Program managers also described other issues that affected implementation in their state. Equity was a concern for several immunization programs. Delays in implementation occurred until funding was secured for the entire population (eg, VFC-eligible and underinsured children). Some program managers preferred not to implement a new vaccine that was replacing an older vaccine until supplies had been exhausted to minimize

### Table 2. Availability of Publicly Purchased Vaccine to Underinsured Children in the Private and Public Sectors by Vaccine

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Varicella</th>
<th>Pneumococcal Conjugate</th>
<th>Meningococcal Conjugate</th>
<th>Tdap</th>
<th>Hepatitis A (Universal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of ACIP recommendation</td>
<td>April 1996</td>
<td>June 2000</td>
<td>February 2005</td>
<td>June 2005</td>
<td>October 2005</td>
</tr>
<tr>
<td>Public sector vaccine price per series, $</td>
<td>59</td>
<td>249</td>
<td>73</td>
<td>31</td>
<td>25</td>
</tr>
<tr>
<td>In the private sector</td>
<td>22/48 (46)</td>
<td>24/48 (50)</td>
<td>30/43 (70)</td>
<td>21/41 (51)</td>
<td>19/33 (58)</td>
</tr>
<tr>
<td>In the public sector</td>
<td>2/48 (4)</td>
<td>8/48 (17)</td>
<td>17/43 (40)</td>
<td>2/41 (5)</td>
<td>5/33 (15)</td>
</tr>
</tbody>
</table>

Abbreviations: ACIP, Advisory Committee on Immunization Practices; Tdap, tetanus-diphtheria-acellular pertussis. aFor those programs that purchased vaccine at the time of the interview.
waste, such as when Tdap was recommended to replace tetanus-diphtheria toxoids (Td) vaccine for adolescents. School mandates affected implementation in both directions. In some cases, a school mandate was helpful in encouraging state legislatures to provide additional funding to ensure vaccine purchase for underinsured children. In other cases, program managers thought that they could not pursue school mandates until funding was sufficient to ensure that underinsured children would have access to vaccine before a requirement was enacted.

COMMENT

Among clinical preventive services, childhood immunization has been ranked at the top in terms of health impact and cost-effectiveness by the National Commission of Prevention Priorities. Despite the benefits of childhood vaccination and the high coverage rates achieved with older childhood vaccines, our study demonstrated gaps in the financing of new vaccines for children who are underinsured with respect to vaccination. Assuming 14% of children are underinsured in the United States, we estimate that 2.3 million children are unable to receive state-purchased meningococcal conjugate vaccine in the private sector, and 1.2 million children are unable to receive this vaccine even if they are referred to the public sector. Due to lack of funds to purchase newer vaccines for children who are not VFC eligible, many states have adopted more restrictive policies for provision of publicly purchased vaccines since 2004. The lack of sufficient section 317 funding and state funding for vaccine purchase has led some states to provide vaccine to VFC-eligible children but not to underinsured children. Disparities among states are worse for the most expensive and newest vaccines, including pneumococcal conjugate, meningococcal conjugate, and hepatitis A vaccines.

The public sector safety net for offering vaccine to underinsured children seems to be under considerable strain. Past studies have suggested that many private clinicians refer underinsured children to public health clinics for vaccination. Unfortunately, a growing number of states are no longer able to provide expensive vaccines, such as the meningococcal conjugate vaccine, to underinsured children in the public sector. Furthermore, the proportion of vulnerable US children whose insurance plans either do not cover vaccines or require families to pay out-of-pocket for preventive care is likely to grow. A recent article by the American Academy of Pediatrics found that 20% of employers are offering catastrophic health insurance plans (high-deductible health plans), up from only 5% in 2003, and only 30% of these plans covered preventive care before the deductible was met. These trends are of concern because inadequate insurance coverage has been associated with forgone health care among families who lack resources. Difficulties in access to vaccines for underinsured children increase the complexity faced by clinicians in both the private and public sectors. One vaccine may be not be available to the underinsured, whereas another vaccine may be available in the same state. This may result in confusion for physicians who may refer children to the public sector, even though a vaccine could be provided in the medical home, thus incurring a missed opportunity. The study by Davis et al found that 22% of physicians in universal states and 30% in VFC-enhanced states referred an underinsured child to a public health department clinic to receive pneumococcal conjugate vaccine, even though the state was providing vaccine free of charge in the pediatricians’ offices. Additionally, policies are dynamic depending on available funding that can fluctuate from year to year, which may result in added uncertainty from the physician’s perspective. Vaccine financing policies changed in 16 states between 2001 and 2003 and in 11 states between 2004 and 2006. Finally, immunization program managers in our study described a growing discomfort voiced by both private and public clinicians regarding their inability to give state-purchased vaccines to underinsured children. Being forced to turn away underinsured children or asking families to pay out-of-pocket for expensive vaccines is creating significant ethical dilemmas, particularly for public health practitioners whose role is to serve vulnerable populations.

Despite the ability of vaccines to prevent illness and death, our current system of vaccine financing has resulted in a gap for underinsured children. Current trends in health insurance products, including enrollment in high-deductible health plans that may or may not provide immunizations or other preventive benefits before a high deductible has been met, are likely to increase the magnitude of this gap and must be carefully monitored. Furthermore, the impact of the gap in vaccine financing for underinsured children on vaccination rates deserves further study once data on coverage rates for new vaccines become available. Evidence from past studies supports the premise that the availability of financing affects immunization rates. Meanwhile, strategies are needed to address the current needs of underinsured children and should include efforts to enhance immunization benefits through requirements or incentives for insurers and employers. Until such enhancements in private insurance coverage for immunization are implemented, however, support of the public sector safety net is critical to ensure the protection of this vulnerable group of children in the United States.

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REFERENCES