Reducing Financial Barriers to Vaccination in the United States: Call to Action

Vaccines are among the most successful preventive measures available to modern medicine. Their application is responsible for the dramatic reduction in the incidence of 10 vaccine-preventable diseases during the 20th century in the United States. The potential for disease prevention with vaccines has continued in the 21st century with the licensure and recommendation of vaccines against 6 additional diseases for routine use among children and adolescents. These vaccines hold the promise of prevention of morbidity and death both for individuals who receive them and for society as a whole. However, these new vaccines are expensive, in part because of the complex process of development, licensure, and manufacture. The cost to purchase all recommended vaccines for a child up to age 19 at the federal contract price increased more than sevenfold for boys and more than ninefold for girls between 1995 and 2008. This has threatened to slow the implementation of vaccination programs and to delay achievement of the high population coverage necessary to yield the benefits of community immunity.

Concerns that the financing of vaccines could become a major barrier to successful vaccination programs in the United States date back at least 2 decades. After widespread measles outbreaks in the late 1980s and early 1990s, attributable largely to failure to vaccinate, the federal Vaccines for Children (VFC) program was implemented in 1994, providing a comprehensive approach to solving the vaccine financing problem and ensuring accessibility to vaccines for many of our nation’s poorest children. VFC has been very successful in supplying vaccines free of charge for children in the Medicaid program, uninsured children, underinsured children served at federally qualified health centers, and Native American and Alaskan Native children. VFC has enabled these children to receive vaccines in their medical homes, which are predominantly private physician practices (large and small) across the country. Fragmentation of care is avoided because children who receive most of their care from private providers do not need to seek vaccinations in health department clinics. Furthermore, VFC decreases the need for public-sector facilities to deliver vaccines, and VFC has been a major factor supporting vaccine-manufacturing enterprises in the United States. Despite early concerns that VFC would threaten the private market for vaccines, as well the large price difference between the public and private sectors for traditional vaccines such as the measles-mumps-rubella vaccine, VFC has turned out to be a stable funding source for traditional vaccines and an “instant market” for newly licensed vaccines, given that it purchases vaccines for ~43% of children; vaccine purchase is ensured for slightly less than one half of children when a new vaccine is made part of the VFC program (Centers for Disease Control and Prevention, unpublished data, 2007). Additional public funds provided through state resources or federal Section 317

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Abbreviations
VFC—Vaccines for Children
NVAC—National Vaccine Advisory Committee

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discretionary grants are used to purchase vaccines for an additional 11% of children (Centers for Disease Control and Prevention, unpublished data, 2007), by using the federal vaccine contract negotiated on behalf of the VFC program.

Despite the success of VFC in stabilizing the vaccine market and providing access to routinely recommended vaccines for publicly insured children on par with privately insured children, the influx of new, more-expensive vaccines after 2000 has created strains regarding vaccine purchases for the 57% of children who are not covered by VFC and has renewed concerns about payment among care providers and public health officials that vaccine financing is a barrier to access to vaccines. Although data on population coverage levels for newer vaccines are not yet available, available evidence indicates that the high cost of the new vaccines has created disincentives both for states to contribute additional funds to cover groups of at-risk children not covered by VFC and for state Medicaid directors to purchase the vaccines for their insured patients.

Vaccine costs are only one aspect of the financing of vaccination. The non-vaccine costs of vaccination include those for personnel time for ordering, administering, and recording vaccinations, time for counseling parents, storage equipment, overhead, and much more. With regard to the non-vaccine costs of vaccination, problems are apparent. For example, there is no reimbursement for vaccine administration for uninsured children covered by VFC. In this supplement to Pediatrics, a number of articles demonstrate the wide variation in what practices currently pay for vaccines, as well as the significant differences in what practices are paid for both the vaccine products and the administration of vaccines.

Judging by the number of expert panels convened and summary reports written to examine the problem and to recommend solutions, there has been no lack of response to the perceived crisis in vaccine financing brought on by the number of costly vaccines recommended recently for routine use. These reports include a 1999 National Vaccine Advisory Committee (NVAC) report,\(^6\) 2000 Institute of Medicine report,\(^7\) 2004 Institute of Medicine report,\(^8\) and 2005 NVAC report,\(^9\) which had 10 vaccine financing recommendations.\(^10\)

In 2006, NVAC convened another vaccine financing working group. What was different this time? First, the magnitude of the apparent vaccine financing crisis had increased even since the Institute of Medicine and NVAC reports of 2004 and 2005, with the recommendations for meningooccal vaccine and tetanus-diphtheria-acellular pertussis vaccine for adolescents, hepatitis A vaccine for nationwide use, rotavirus vaccine for infants, human papillomavirus vaccine for adolescent girls, and universal annual influenza vaccine for all children 6 months to 18 years of age. From 2005 to 2009, the cost for the vaccines alone (purchased at the federal purchase price) to vaccinate a child fully increased from $545 to $1105 for boys and $1407 for girls.\(^2\)

Second, there was recognition that more data were needed to supplement the anecdotal concerns regarding the magnitude of the problem and its various aspects, from the cost of purchasing vaccines to the expanding costs of maintaining vaccine inventories, the expenses of administering vaccines, and the levels of reimbursement for the vaccine and nonvaccine costs of vaccination in the complex environment of health insurance. A number of the articles in this supplemental issue of Pediatrics were in direct response to the need, as identified by the NVAC working group, to have more-concrete data on which to base recommendations. In addition, office expenses may be increasing with the emergence of “vaccine hesitation” among parents. This means that physicians must spend significantly more time counseling parents about the risks and benefits of vaccines, which creates additional stress.\(^11\)

Finally, there was an understanding that solutions arrived at by an expert panel soliciting input from stakeholders, as had been the case with previous panels, might have less chance of success than solutions arrived at by a panel composed of the stakeholders themselves. In addition, it was important to include a broader range of stakeholders (eg, employers, state legislators, Medicaid directors, and consumers) than in previous efforts, working to reach a consensus. The NVAC Vaccine Financing Working Group was formed with specific representation of those groups and worked through a consensus process.

The NVAC vaccine financing recommendations published here differ from those in previous reports in a number of significant ways. For public-sector vaccine purchases, the primary focus is not on federal Section 317 funding. Recommendations for increased Section 317 funding have not had significant success in the past and do not represent a permanent solution, requiring an annual battle for necessary increases in appropriations in the federal budget. The NVAC recommendation for limited expansion of eligibility for VFC to cover underinsured children in public health department clinics addresses a small but significant gap in vaccine coverage that is putting pressure on many state immunization programs. This recommendation falls short of recommending VFC coverage for underinsured children in private practice settings, which was viewed by...
the group as too threatening to the private vaccine market. Although this is not optimal, VFC coverage of underinsured children in public health department clinics would at least provide a safety net for those children, who traditionally are served by the private sector, although extra office visits would be needed. The NVAC did not seriously consider universal vaccine purchase, a third-rail issue with the pharmaceutical industry. This limited expansion of VFC seems to have the support of all stakeholders, including the pharmaceutical industry, but does not address the full range of vaccine financing issues.

The NVAC recommendations focus in more detail on the issues of practice management and the cost and reimbursement of vaccine administration than did previous reports. In 2009, administration of vaccines has become a very complex endeavor. With potentially hundreds of thousands of dollars worth of vaccines to maintain, more sophisticated refrigerators and freezers are needed, along with temperature monitors, alarm systems, backup power supplies, insurance against catastrophic loss, and dedicated, trained staff members to manage the supply. With increased parental interest and, in some cases, concern about vaccines, professional time spent on parental education has increased. Paperwork for charting, reimbursement, and immunization registry entries, even if in streamlined, electronic forms, is always present. These costs need to be recouped in the reimbursement for providing vaccinations, and important NVAC recommendations focus on ensuring that these costs are tallied and included in standard reimbursement codes.

For public-sector vaccine administration, NVAC decided not to endorse a state-by-state approach to fixing Medicaid administration fees, although fees in many states are grossly inadequate, but rather to address public-sector administration fees at a national level as part of an entitlement program. Adding vaccine administration to VFC is probably the most-costly recommendation in the report, with approximately $800 million in increased federal costs, although states would save $300 million in their Medicaid programs (National Vaccine Program Office, unpublished data, 2009). However, this was thought to be necessary to fix the structural deficiency in VFC whereby providers could not be assured of reimbursement for vaccine administration for an important group of patients. Adding vaccine administration to VFC also should fix another critical problem, that is, the wide variations in state reimbursement rates for vaccines administered to children enrolled in Medicaid. Assumption of vaccine administration fees by the federal government is likely to lead to more-uniform and fairer reimbursements, as currently occurs with influenza vaccine given to Medicare enrollees.

To address vaccine financing in the private sector, NVAC focused on establishing a voluntary insurance industry standard for first-dollar coverage. This was performed with the input and support of representatives of both health insurers and employers, critical groups in determining health insurance benefits for large numbers of employees. In the development of the NVAC recommendations, an Adolescent Immunization Working Group proposed federal law to mandate that Employee Retirement Income Security Act-exempt health insurers provide first-dollar coverage for vaccinations. Both health insurers and employers made it clear that mandated insurance coverage for vaccines would meet with their vigorous opposition. In the end, the group settled on the “industry standard” language.

Finally, it was clear from the work of Freed et al5,6 and articles in this supplement that, in general, physicians in practice are in need of technical assistance regarding business management issues. These issues relate to the ability of physicians to purchase vaccines and to negotiate insurance contracts effectively. Work of this sort is underway but should be greatly expanded.

The consensus process used by the NVAC to develop these latest recommendations is cause for hope that the stakeholder partners can be mobilized to press for needed changes. Although the current economic situation is dire, not all of the NVAC recommendations require large amounts of money to accomplish. Even the funded amounts needed to enact the more-expensive recommendations to upgrade the VFC program pale in comparison with the amounts of money being discussed for the economic recovery. It is time for all of the partners who participated in the development of the NVAC recommendations to make their adoption a priority. This is the only way in which the promise of immunizations to improve health will be met, now and in the future. The federal American Recovery and Reinvestment Act of 2009 contains additional funds for Section 317 programs that will incorporate some of these recommendations.

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