

Financing Immunization of Adults in the United States

WA Orenstein¹, GT Mootrey², K Pazol¹ and AR Hinman³

Immunization is one of the most effective and cost-effective prevention measures available.¹ As a result of universal vaccination of children, polio has been eliminated in the United States and much of the world, measles and rubella are no longer endemic diseases in the United States, and most of the other vaccine-preventable diseases of childhood are at or near record lows. A recent review of clinical preventive services by Partnership for Prevention gave childhood immunization a perfect score of 10, based on clinically preventable burden and cost-effectiveness.²

IMMUNIZATION IN ADULTS

In contrast to the marked success of vaccination of children in reducing morbidity and mortality of vaccine-preventable diseases, the record among adults is far less impressive. There are several reasons for this, which have been reviewed recently.³ Among them are the following: (1) vaccines recommended for adults are generally not as effective as vaccines recommended for children; (2) many diseases against which adults are vaccinated are not clinically distinctive, thereby decreasing the awareness among both professionals and the public of the impact of vaccination; (3) recommendations for adult vaccination are frequently based on determining whether a given adult has an underlying condition, lifestyle, or other life situation, in contrast to childhood immunizations, which are age-based; (4) there is no “well adult” system of primary care provider visits comparable to the “well child” visit schedule for young children; thus, there may be problems in reaching adults to provide vaccinations. Further, many adults do not have a classic primary care provider, relying instead on subspecialists who may be even less apt to provide vaccinations; (5) professional societies representing physicians who treat children—such as the American Academy of Pediatrics and the American Academy of Family Physicians—play a major part in developing and promoting the child and adolescent immunization schedule and working to assure that the

barriers their members face in vaccination are overcome, whereas medical societies representing physicians who treat adults have not given immunization the same priority; (6) the public sector plays little role in actually administering immunizations to adults nor a quality assurance role to improve vaccination performance of adult immunization providers; (7) financing of some adult immunizations has been insufficient to offer economic incentives to health-care personnel to provide vaccinations; and (8) supply of vaccines such as influenza vaccine has been erratic, discouraging providers from planning major vaccination efforts for their patients.

The purpose of this review is to describe some of the challenges to reducing vaccine-preventable morbidity and mortality in adults with a particular focus on financing issues.

POLICIES FOR VACCINATING ADULTS

Recommendations for vaccinating adults are made by the Advisory Committee on Immunization Practices (ACIP), a committee of 15 experts in vaccines, immunization, infectious diseases, pediatrics, family medicine, internal medicine, and public health, which makes its recommendations to the Centers for Disease Control and Prevention (CDC).^{4,5} In addition to the voting members, there are *ex officio* members representing federal agencies as well as a variety of liaison members who have input into the deliberations such as representatives of several professional organizations. This schedule is endorsed by many organizations including professional societies. The CDC signifies its acceptance of the recommendations by publication in the *Morbidity and Mortality Weekly Report (MMWR)*. Each year, an adult immunization schedule is published in two parts: (1) based on underlying condition and (2) based on age.⁶ As of 2007, the following vaccines are recommended universally for one or more age groups:

- tetanus and diphtheria toxoids (Td)—every 10 years after completion of a primary series;

¹Emory University School of Medicine, Atlanta, Georgia, USA; ²Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Atlanta, Georgia, USA; ³Task Force for Child Survival and Development, Atlanta, Georgia, USA. Correspondence: WA Orenstein (worenst@emory.edu)

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- tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap)—a one time dose for all persons between 10 and 64 years of age;
- influenza vaccine—annually for all adults ≥ 50 years of age and younger adults with certain chronic conditions, occupations, and life situations;
- pneumococcal polysaccharide vaccine (PPV23)—all adults ≥ 65 years of age and younger adults with certain chronic conditions;
- zoster vaccine—all adults ≥ 60 years of age; and
- human papillomavirus vaccine (HPV)—all women up to the age of 26 years.

In addition, vaccines against hepatitis A, hepatitis B, measles, mumps, and rubella (MMR), varicella, meningococcal (MCV4 or MPS4), as well as other diseases are recommended for subgroups of adults, based on risk, underlying condition, or international travel.

FINANCING OF VACCINATIONS RECOMMENDED FOR ADULTS

Costs of vaccines recommended for adults

Table 1 provides prices of vaccines based on Federal contracts, negotiated by the CDC, or catalog prices, which presumably represent the costs to purchase vaccines in the private sector (although discounts apparently are common).⁷ Prices for older vaccines, such as influenza and PPV23, are generally $< \$30$ per dose. However, the costs for newer vaccines, such as HPV, MCV4, Tdap, and zoster, are considerably higher. For example, the cost of a three-dose series of HPV ranges from \$290.25 on the Federal contract to

\$361.50 based on catalog prices. The zoster vaccine catalog price ranges from \$145.35 to \$152.50 per dose.

In the past, discounts from catalog prices achieved through the Federal contract averaged approximately 50%. In contrast, discounts for more recently recommended vaccines have generally been on the order of 20%.

Public sector financing

Section 317 discretionary grant program. Section 317 of the Public Health Service Act provides funds through the CDC to state and local health departments for both vaccines and program operations. There are no eligibility requirements.^{5,8} For children, most of the funding goes for those served in public health department clinics, many or most of whom are underinsured (persons with insurance that does not cover a particular vaccine). For persons > 18 years of age, 317 funding is the major source for the direct purchase of vaccines with federal public sector funds. The 317 funds must be appropriated each year by the Congress. The great majority of 317 funding goes for childhood immunization. Since 1999, the level of 317 funding has remained relatively flat, despite a marked increase in the need for such funds as a result of major increases in the number of vaccines and doses added to the childhood immunization schedule.⁹ A total of only 4.5% of the \$234,897,000 funds appropriated in 2005 for purchase of vaccines was estimated to have been used for adult vaccines. In 2007, in a report to Congress, the CDC estimated that \$170 million was needed to purchase vaccines for adults through the 317 program.⁹ This estimate was based on the assumption that the 317 program should cover

Table 1 Adult vaccine price list^a

Vaccine	CDC cost/dose	CDC cost for vaccine series ^b	Private sector cost/dose	Private sector cost for vaccine series ^b
Hepatitis A ^c	\$18.85–\$18.86	\$37.70–\$37.72 (2)	\$58.28–\$63.51	\$116.56–\$127.02 (2)
Hepatitis A and B ^d	\$37.64	\$112.92 (3)	\$82.83–\$83.10	\$248.49–\$249.30 (3)
Hepatitis B ^c	\$23.78–\$24.73	\$71.34–\$74.19 (3)	\$50.35–\$59.70	\$151.05–\$179.10 (3)
HPV ^c	\$96.75	\$290.25 (3)	\$120.50	\$361.50 (3)
Influenza inactivated ^c	\$10.153–\$13.751	Single dose/year	\$11.72–\$15.54	Single dose/year
Influenza live intranasal ^c	\$17.65	Single dose/year	\$17.95	Single dose/year
MMR ^e	\$17.60	Single dose ^f	\$44.84	Single dose ^f
MCV4 ^c	\$73.09	Single dose ^g	\$89.43	Single dose ^g
PPV23	\$14.86–\$16.91	Single dose ^h	\$26.08–\$29.28	Single dose ^h
Td ^d	\$9.86–\$10.36	Single dose ⁱ	\$15.99–\$19.19	Single dose ⁱ
Tdap	\$30.75	Single dose ^j	\$36.25–\$37.43	Single dose ^j
Varicella ^c	\$59.15	\$118.3 (2)	\$74.56	\$149.12 (2)
Zoster vaccine live	\$107.93–\$113.24	Single dose	\$145.35–\$152.50	Single dose

HPV, human papillomavirus; MCV4, meningococcal conjugate; MMR, measles, mumps, and rubella; PPV23, pneumococcal polysaccharide; Td, tetanus and diphtheria toxoids; Tdap, tetanus toxoid, reduced diphtheria toxoid and acellular pertussis. ^aCDC Vaccine Price List. Accessed 7 July 2007 from <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm>. ^bNumber in parentheses indicates number of doses in multidose vaccine series. ^cVaccine cost includes \$0.75 per dose Federal Excise Tax. ^dVaccine cost includes \$1.50 per dose Federal Excise Tax. ^eVaccine cost includes \$2.25 per dose Federal Excise Tax. ^fA second dose of MMR is recommended for adults who (1) have been recently exposed to measles or in an outbreak setting; (2) have been previously vaccinated with killed measles vaccine; (3) have been vaccinated with an unknown type of measles vaccine during 1963–1967; (4) are students in postsecondary educational institutions; (5) work in a health-care facility; or (6) plan to travel internationally. ^gRecommended for persons ≤ 55 years; quadrivalent polysaccharide vaccine must be substituted for older individuals. ^hSingle dose plus one-time revaccination after 5 years for (a) persons ≥ 65 who were < 65 years at the time of primary vaccination and (b) persons with certain high-risk conditions. ⁱOne dose every 10 years for persons previously vaccinated according to schedule. ^jGiven once in place of Td.

uninsured adults whose income was <200% of the poverty level. The low level of current 317 funding compared to estimated needs raises concerns that some uninsured and underinsured adults may not have access to recommended vaccines. This includes groups such as persons at high risk of hepatitis B who may not be able to receive vaccines at sexually transmitted disease clinics.

State or local funds. States or localities can appropriate their own funds to purchase vaccines for adults. They are also able to use those funds to purchase from the Federal contract. However, in 2006, only 22 states used their resources to purchase vaccines for adults, and purchases ranged from a low of \$505 to nearly \$2.5 million (CDC, unpublished data).

Medicaid. Medicaid is the major financing source for immunizing adults 19–64 years of age who are enrolled in the program. Each state administers its own Medicaid program and has a policy for coverage of adult immunization services. However, each state has flexibility in determining the type and extent of covered services. Additionally, with greater than 500 health plans serving Medicaid enrollees, it may be challenging for states to monitor the scope of services actually provided to Medicaid beneficiaries.¹⁰ A September 2002 to November 2003 national survey of 120 Medicaid plans in 36 states reported that the majority of plans provided coverage for the five major vaccines for adults recommended at the time.¹⁰ Approximately 88% of plans covered varicella, 90% MMR, 93% influenza and PPVS23, and 95% hepatitis B. However, it is not clear whether reimbursement in those plans was adequate to cover the costs of the vaccines, non-vaccine costs, such as ordering, storage, record keeping, and administration, as well as a reasonable return on investment for the providers. Data collected by the CDC regarding Medicaid fees for administration of vaccines to children in 2005 show wide state-to-state variation, from as little as \$2 per dose to \$18 per dose. Nearly two-thirds of states reimburse less than \$10 per dose. For example, Connecticut, Hawaii, and New Hampshire reimbursed administration at \$2 per dose, whereas New York reimbursed administration at \$17.85 per dose.¹¹

Medicare. Influenza vaccine, PPV23, and hepatitis B vaccine are covered for patients participating in Medicare part B, almost all of whom are ≥ 65 years of age.⁸ This includes reimbursement for the cost of the vaccines as well as an administration fee. In 2006, the administration fee for influenza, PPV23, and hepatitis B vaccine was on average approximately \$18 if only one immunization was received, and \$10 for any additional immunizations received at the same time.¹² Physicians must buy vaccines in advance. Medicare does not cover the cost of establishing or maintaining inventories. Medicare part B will also cover these three vaccines administered by community vaccinators in mass clinics, including in pharmacies and supermarkets.

All other vaccines are covered under Medicare part D for persons who elected to enroll in part D coverage for prescription drugs. As physicians are not generally part of the network of participating pharmacists, they have several options. They can write a prescription and have the pharmacy administer the vaccine. They can purchase and administer the vaccine and bill the patient directly allowing the patient to seek reimbursement from Medicare, or they can establish relationships with pharmacists or insurance plans to reimburse them for their expenses. Although asking a patient to pick up a vaccine at a pharmacy and bring it to a doctor's office is possible, this practice should be discouraged because of concerns that thermal storage requirements of the vaccine (particularly zoster vaccine) may not be followed with subsequent loss of potency. As of 2007, physicians may bill Medicare part B for administration fees for vaccines covered. However, starting in 2008, individual insurance plans in part D must institute administration fees and the mechanism for how the physician would be reimbursed has not yet been established.¹³ In 2007, the Medicare Payment Advisory Commission (MedPAC) recommended that all vaccines be covered under part B (<http://www.medpac.gov/about.cfm>).

Private sector financing

Private insurance. Most vaccines recommended for children are covered by private insurance plans. The same appears true for adults. Between September 2002 and November 2003, Davis *et al.*¹⁰ surveyed 1,210 plans offered by employers. Responses were received covering 732 plans. Of those plans, 84% covered influenza, 81% PPV23, 77% MMR, 75% hepatitis B, and 73% varicella. Employers who self-insured were substantially less likely to provide immunization benefits for hepatitis B, MMR, and varicella than those who purchased commercial insurance. There have been substantial changes in the immunization schedule of vaccines recommended for adults since 2003, including the addition of zoster vaccine, a single dose of Tdap, MCV4 for college freshman, and catch-up vaccination with HPV, which have substantially increased the cost of obtaining all ACIP-recommended vaccines for adults. Plans state they typically cover ACIP-recommended vaccines, although there may be a delay in initiating coverage. In addition, there may be co-pays or deductibles in some plans.

Other. One program that has the potential to be of assistance to some adults is the Vaccine Patient Assistance Program, sponsored by Merck. This program helps provide vaccines produced by Merck (*i.e.*, HPV, MMR, PPV23, hepatitis B, hepatitis A, varicella, and zoster) for individuals aged 19 years and older who (1) reside in the United States, (2) do not have health insurance, and (3) have an annual household income less than \$20,240 for individuals, \$27,380 for couples, or \$41,300 for families of four.¹⁴ Before vaccine can be administered in this program, the patient's health-care provider must determine whether the patient is an

appropriate candidate for the program, the patient must submit an application for each vaccine and each dose of vaccine (if part of a series), and the health-care provider must receive confirmation of an approved application from Merck. This program is currently available only through private providers.

Out-of-pocket expenses. Approximately 19.0% of adults 18–64 years of age lack health insurance¹⁵ and thus must pay for immunizations out of pocket if they cannot receive them free of charge from local health departments, which, as shown above, do not assign many resources to adult immunization. Among adults aged 19–64 years, 4.2% are not only uninsured, but are also living at or under 200% of the poverty line and will face financial challenges for paying for vaccines out of pocket. (The figure of 4.2% was calculated from the total US population age 19–64 years as determined from US Census projection data for 2007, and from the number of uninsured persons aged 19–64 years living at or below 200% of the poverty line as presented in the Report to Congress on 317 Immunization Program⁹.)

POTENTIAL APPROACHES TO REDUCE FINANCIAL BARRIERS TO IMMUNIZATION OF ADULTS

Several groups have offered recommendations to improve the financing of adult immunizations. The National Vaccine Advisory Committee has recommended, among other things, the following:

- (1) Expanded funding through Section 317 to support adolescent and adult immunization programs including vaccine purchase.
- (2) Promotion of “first-dollar” insurance coverage for immunization, and promoting prompt coverage and recalculation of capitation rates when new vaccines are recommended.
- (3) Assurance of adequate reimbursement for administration of vaccines.
- (4) Expanded discussion about the need, desirability, and feasibility of a variety of approaches to ensure that adults have access to vaccines, even if they do not have insurance.¹⁶

The Infectious Diseases Society of America recommended that:

- (1) Funding for Section 317 program receive annual, sustainable, and dependable funding for adult immunization including resources for infrastructure and vaccine purchase. Funds should cover all ACIP-recommended vaccines for the majority of underinsured and uninsured adults. Congressional appropriations should be increased each time a new vaccine for adults is added to the immunization schedule.
- (2) State Medicaid programs should cover all ACIP-recommended vaccines.
- (3) Legislation should be enacted to develop standards for immunization coverage for all insurance plans including

those covered by the Employee Retirement Income Security Act of 1974 (ERISA), which covers employers who self-insure.

- (4) Reimbursement should be adequate to cover non-vaccine costs of vaccination.
- (5) All vaccines recommended for persons covered by Medicare should be moved into Part B.
- (6) The Centers for Medicare and Medicaid Services (CMS) should work to assure physician billing codes adequately cover the full costs of providing immunizations.^{17,18}

One potential approach to financing immunizations for uninsured adults, modeled on the highly successful Vaccines for Children (VFC) program, was discussed during an Immunization Congress sponsored by the American Academy of Pediatrics and the American Medical Association, held in Chicago in 2007 (<http://www.cispimmunize.org/immunizationcongress.htm>).

The VFC program, an entitlement managed by the CDC through State and local health departments, provides free vaccines to persons <19 years of age if they meet one or more of the following eligibility criteria: persons on Medicaid, who are uninsured, or are Alaska Natives/American Indians.⁸ In addition, persons <19 years of age who are underinsured can also receive vaccines purchased through VFC but only at a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). Among the advantages of VFC are the following: (1) free vaccines are provided to eligible persons at any enrolled provider site, which can include physician offices, health department clinics, and other sites; (2) it empowers the ACIP, by voting to incorporate a vaccine in the program, to see its recommendations are automatically translated into availability for eligible persons; there is no need to seek additional Congressional appropriations; and (3) providers do not have to advance funds to establish an inventory of covered vaccines; they are staked to an initial inventory and get free vaccine replacements as they use up their supply. The VFC does not provide funds for vaccine administration and participating providers must agree not to deny vaccines to persons who cannot pay administration fees. Providers can be reimbursed for vaccine administration by Medicaid for patients enrolled in that program.

A Vaccines for Uninsured Adults (VFUA) program could cover all vaccines recommended by the ACIP for universal use in adults; coverage could be automatic when the ACIP votes a vaccine into the program. In addition, it could overcome one of the limitations with VFC, if it included coverage for administration fees. The VFUA would cover persons who are uninsured and could also cover persons who are underinsured and for whom vaccines are recommended but may not be able to afford them, particularly for the more costly vaccines such as HPV and zoster. Also, it could help cement collaboration between public health practitioners and private providers of vaccines to improve

performance, a collaboration that has played an important role in the successes of the childhood immunization program.

In summary, adults account for a substantial health burden preventable by vaccination.^{19–29} The CDC estimates that more than 42,000 adults die annually from vaccine-preventable diseases.^{26–29} Hundreds of thousands of hospitalizations occur each year from influenza-related illness alone.²⁴ An estimated one million cases of herpes zoster occur each year with an increasing risk for potentially disabling post-herpetic neuralgia with increasing age.²⁵ Substantial economic burdens associated with vaccine-preventable diseases in adults are becoming more evident, but more research is needed.^{30–33} Significant financial barriers exist to vaccinating adults under the present system, which should be removed to achieve optimal control of these vaccine-preventable diseases.

CONFLICT OF INTEREST

Drs Hinman, Mootrey, and Pazol have no conflicts of interest or financial disclosures. Dr Mootrey is a government employee and has participated as part of her duties. Dr Orenstein has received grant support for clinical trials and research from Merck, Sanofi Pasteur, and Chiron Foundation/Novartis. He is on two data safety monitoring boards for clinical vaccine trials, Encorium (formerly Dynport) for bioterrorism threats and Glaxo-SmithKline for pneumococcal vaccine. Dr Orenstein is also a member of the 317 coalition, a group that advocates for improved support for the 317 grants to states and local health departments.

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