

Balancing the Childhood Immunization Program with the Urgent Needs for Adult Hepatitis B Immunization

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In 10 years, do we want to look back on a decade in which the public health community protected a highly vulnerable population of young adults from hepatitis B virus (HBV) infection through a difficult and challenging process of prioritizing scarce vaccine resources, or one in which we missed our last opportunity to prevent HBV infection among a group of individuals who could not afford the simple protection of a vaccine?

Our current path is leading to the second outcome—a missed opportunity that will result in preventable suffering, death, and prolonged HBV transmission in the United States because ongoing HBV transmission occurs primarily among unvaccinated adults with risk behavior for HBV transmission.¹

Financing a hepatitis B vaccination initiative to reach young adults would benefit from new funding. However, given the current federal deficit situation, increased federal funding cannot be expected. Instead, we must do the best that we can with existing resources, combine the public health community's creativity with new private sector opportunities, and find a balance between the competing priorities of childhood vaccination and adult vaccination that allows for some forward progress toward protecting young adults from HBV infection.

Vaccinating adults has been a sparsely funded priority for many years, and there continues to be strong sentiment that an adult program should not be created at the expense of the better-funded childhood program.² The conventional wisdom has been that only with new funding, or when the childhood immunization program is fully funded, will it be feasible to reach out to at-risk adults. For the hundreds of thousands of adults who would benefit from a vibrant adult immunization program, such thinking is likely to prevent them from receiving recommended and needed protection in the near future.

The problem with waiting for the childhood program to be complete and fully operational is that the bar continues to be raised—not that the childhood program is getting weaker. Indeed, the childhood program is becoming stronger, more powerful,³ and better able to protect children, but also more dependent on scarce discretionary state and federal funding.²

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The immediate cause of the increased appetite for discretionary funding to vaccinate children is the welcome news that an increasing number of childhood infectious diseases are now preventable by vaccines. Invasive pneumococcal disease, invasive meningococcal disease, rotavirus, gastroenteritis, adolescent pertussis, and cervical cancer caused by human papillomavirus infections are joining the ranks of diseases that can be prevented through routine vaccination. However, vaccines to protect children against these diseases are more expensive than most of the earlier vaccines and require new funding to implement. For example, in 2006, it cost nearly \$1,200 to fully vaccinate a child with vaccine purchased from the federal vaccine contracts,⁴ compared with \$435 in 1987.²

Approximately 45% of children are covered by the Vaccines for Children (VFC) program, amounting to nearly 30 million children.⁵ VFC is an entitlement program created by Congress in 1993 to provide immunizations for uninsured children, Medicaid recipients, Native Americans, and Alaska Natives from birth through 18 years of age at their physicians' offices. VFC does not provide vaccines for those children who are underinsured (except at federally qualified health centers or rural health centers), nor does it pay for any administrative fees associated with vaccine provision for children other than those enrolled in Medicaid. Approximately 45% of children are covered by private insurance that pays for vaccines; however, many of the remaining 10% of children are underinsured, in that their private insurance plans do not provide for immunizations. Currently, discretionary federal and state funding is used to provide a safety net for children with financial needs but who are not entitled to VFC funding. The more costly, new vaccines are a major source of pressure on these discretionary funds.²

The increasing need for additional discretionary state and federal funding to secure a safety net for children not eligible for VFC vaccine has created a financial environment in which many vaccination efforts, both childhood and adult, are competing for scarce public sector resources. These resource needs have not yet been met, and they are unlikely to be realized to the extent needed for procuring and administering new vaccines that have recently been approved and likely to be approved soon. As a result, state and urban area immunization programs have only partly implemented many new childhood vaccine recommendations because they can no longer afford to purchase vaccines for needy children who are not eligible for VFC.⁶

In this competitive funding environment, compelling adult vaccination opportunities are being missed. Tragically, a key component of the strategy to eliminate

HBV transmission is caught in this funding dilemma. An age- and risk-defined population in need of immunization—adults who were not vaccinated when they were children—is not being reached. Many were born before the 1991 recommendation for universal infant hepatitis B immunization, while others were missed by the childhood and adolescent programs. The good news is that the overall incidence of acute HBV infection has declined by 78% between 1990 and 2005, and among children, the incidence declined by 96%.¹ However, the incidence of acute HBV infection remains greatest among adults, who comprise 95% of the estimated 51,000 new cases each year.⁷

Young adults who are now 25 to 45 years of age and older and engage in high-risk behavior are the cohort that needs to receive HBV vaccination.¹ Individuals who were vaccinated under the universal infant and adolescent programs will enter adulthood protected from HBV infection. We must endeavor to reach previously unvaccinated young adults to ensure they also are protected and do not serve as sources of transmission to others. Almost 80% of HBV transmission occurs from sexual contact. The Advisory Committee on Immunization Practices (ACIP) recently updated its HBV recommendations to include universal vaccination of all adults seeking care at sexually transmitted disease (STD) clinics.¹ This is a finite population that can and should be vaccinated. However, this opportunity is shrinking quickly as many among this population are gradually becoming infected and inadvertently spreading HBV among themselves and others.

If discretionary funding is so tight and the unmet needs so great, how can public health move forward on an adult HBV initiative? An answer lies in a dual, synergistic strategy:

- (1) CDC encourages immunization programs to consider use of Section 317 funding to purchase HBV vaccine for adults in public health venues such as STD clinics and human immunodeficiency virus (HIV) clinics. Vaccinating adults with hepatitis B vaccine should have a similar priority as fully implementing the new childhood vaccines.
- (2) Opportunities must be sought to facilitate hepatitis B immunization in the private sector. Private practice physicians should actively work to vaccinate their adult patients who are covered by commercial or government insurance or who qualify for Merck's Vaccine Patient Assistance Program.⁸

Raising the priority of vaccinating young adults to that of children serves notice that the federal Section 317 program is authorized and intended to

serve priority populations according to the states' needs. There are no eligibility restrictions on the use of Section 317 vaccine funding, and these funds can be used to vaccinate individuals of any age with any age-appropriate vaccine.² Thus, a state or urban area immunization program can use this flexibility to decide that the next vaccination program it implements will reach vulnerable young adults in public health venues, such as STD clinics. Selecting among competing priorities is a very difficult decision for immunization programs, and unfortunately, most programs are forced to make these decisions due to limitations on their funding. Approximately \$220 million has been appropriated to this program annually for the past five years, and less than 3% of Section 317 funding has been used each year to purchase HBV vaccine (CDC, unpublished data).

Additionally, as Dr. Orenstein has pointed out, it takes more than vaccine to vaccinate a population. Vaccine purchase funding is an important start, but ideally, funding will also be needed to support education, outreach, and assurance of access to vaccine.⁹ An important place to initiate public sector vaccination is in the public health STD clinics and HIV clinics. ACIP specifically recommends universal vaccination of the patients in these clinics as a standard of care.¹

Merck's Vaccine Assistance Program offers Merck adult vaccines, including hepatitis B vaccine, to income-eligible, uninsured adults in the private sector. This program provides a means to stretch an adult hepatitis B vaccination effort into a robust private-public partnership that reaches even more individuals with several important vaccines. Merck is evaluating whether and how a vaccine assistance program could be implemented in the public sector.⁸ If the program can be tailored to work in public health venues, it should be possible to reach a sizable population.

There is a pressing need for a strong public-private partnership (as in pediatric immunizations) that allows public health to organize private providers and other stakeholders to improve the administration of adult vaccines. Hepatitis B immunization of young adults provides a wonderful opportunity for progress. However, the private sector must first be recruited to administer the hepatitis B vaccine and then provided

the tools to effectively and successfully immunize the target population.

The public health community must constantly make difficult choices among competing priorities. Raising the priority of vaccinating vulnerable adults to the same level as vaccinating vulnerable children represents a difficult choice. Pursuing creative opportunities to improve adult hepatitis B immunization in the private sector is challenging but necessary. Making substantial progress in eliminating a contagious virus that infects more than 50,000 people a year¹ and imposes a large economic burden on society is the reward for making the choice to reach out and protect at-risk individuals from HBV. This will be a worthy and attainable future to strive toward, and it will provide models for implementation of other adult-targeted vaccines.

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