Immunization Costs and Programmatic Barriers at an Urban HIV Clinic

Ellen F. Eaton,1 Andrzej Kulczycki,2 Michael Saag,1 Michael Mugavero,1 and James L. Raper3
1Infectious Disease, 2Ryals School of Public Health, and 3University of Alabama at Birmingham

Background. Although the increasing number of recommended immunizations is essential for patients infected with human immunodeficiency virus (HIV), the potentially uncompensated costs of expanded immunizations will present significant challenges for clinics and health systems serving HIV-infected patients.

Methods. We estimated costs of providing Gardasil, Prevnar, and Zostavax to eligible patients at a US Ryan White Part C academically affiliated HIV clinic in 2013. Clinic expenditures were calculated using vaccine price and administrative fees. Revenue was calculated using insurance reimbursement data for vaccination and administration. Three scenarios were used: 100% uptake of vaccines, adjusted uptake based on published rates, and adjusted reimbursement according to pre-Affordable Care Act (ACA) insurance status.

Results. 2887 patients (27% Medicare, 13% Alabama Medicaid, 26% Commercial, 34% Uninsured), received care with wide variation in immunization reimbursement ($0 to $210) by insurance and vaccine. The net yield (revenue minus expenditure) was calculated for each vaccine. Prevnar was most costly: annual net yield of −$60 691. Provision of all 3 vaccines would lead to a net yield of −$97 122. Adjusting for reduced uptake led to annual clinic losses of $44 119. Using pre-ACA reimbursement for immunization of the uninsured led to reduced clinic losses (−$62 326), attributable to reimbursement via Ryan White funds.

Conclusions. A cost analysis of 3 vaccines shows great variation in insurance coverage, with potential losses of almost $100 000 for one HIV clinic if eligible patients received vaccinations in one calendar year. Adequate, cost neutral reimbursement should be instituted if medical providers and health systems are to achieve Advisory Committee on Immunization Practices immunization recommendations for both HIV positive and negative adults.

Keywords. HIV; immunization; vaccination; insurance; affordable care act.

Due to effective antiretroviral therapy, human immunodeficiency virus (HIV) has become a chronic illness. Providers aim to prevent morbidity by routine health maintenance, screening, and, increasingly, vaccination. Most vaccines are safe and effective in patients with well-controlled HIV. Patients with HIV are at increased risk of vaccine-preventable conditions due to shared risk factors and also suffer more morbidity due to immunocompromised status [1]. Immunization is one of the most effective tools to prevent complications in persons living with HIV (PLWH). Several immunizations were recently added to the vaccination schedule for PLWH [2]. Unfortunately, many PLWH are not receiving recommended vaccines [3]. By analyzing costs associated with 3 adult vaccines recommended for preventing human papillomavirus (HPV), pneumococcal and herpes zoster related complications, this study seeks to explore important financial and programmatic barriers that prevent optimal vaccination.

Despite ample data on efficacy and safety, data are lacking on the financial implications of expanded immunization recommendations. Beyond the rising number and costs of recommended vaccines, there are less-tangible costs associated with acquisition, storage, wastage, labor, patient education, and record-keeping. If no other financial support is provided, such as through the US Vaccines for Children’s Program, these costs can be crippling to clinics that serve uninsured and underinsured populations.
METHODS

Eligibility

The sample population came from the 1917 Clinic, the HIV clinic affiliated with the University of Alabama at Birmingham. Clinic leadership has deferred Gardasil and Prevnar purchase due to cost factors; therefore, a formal analysis was performed to understand pricing and reimbursement. Eligible patients were selected based on ACIP vaccine eligibility for Gardasil and Prevnar. Thus, the cost analysis of Gardasil included all HIV-infected patients through age 26. All patients seen for a routine visit during the time period were included in the Prevnar cost calculation regardless of age. ACIP does not currently recommend for or against Zostavax in well-controlled HIV-infected patients, but experts believe it is likely safe in those with CD4 count >200 cells/µL [1]. For this reason, along with frequent patient and provider requests for Zostavax, it was included in the analysis for those with CD4 count >200 cells/µL, VI <20 copies/mL, and age ≥60 years, the age recommended in immunocompetent hosts. This is a conservative estimate; future recommendations will likely include all ages of well-controlled HIV-infected patients [1].

Expenditure and Revenue Calculations

Clinic expenditures were calculated using vaccine cost including both price of vaccine and administration; this analysis included the complete 3-dose series of Gardasil and single doses of Prevnar and Zostavax. Vaccine pricing was measured using 340 B Prime Vendor Pricing (PVP). Clinics serving PLWH may apply for discounts through PVP, a voluntary, pharmacy discount program permitting eligible safety net hospitals and clinics to obtain medications and immunizations at the lowest available prices [16]. Administration fees were calculated using the standard fees charged by our health system: $48 for initial vaccine, $26 for subsequent dose(s) of same vaccine, and $26 for Prevnar administration for Medicare patients. The administration fee is designed to cover intangible costs of immunization such as vaccine acquisition, book-keeping, storage, refrigeration, wastage, and required staffing.

To calculate clinic revenue, our billing database was queried for insurance reimbursements, or “allowables,” for Gardasil, Prevnar, and Zostavax and their respective administration. We stratified insurers into 4 categories: Medicaid, Medicare, Commercial Insurance, and Uninsured. Commercial insurance was defined as all third party insurers excluding Medicaid, Medicare and Ryan White Care Act, and other state or federally funded programs. We assumed that all commercial insurers reimbursed at the same amount as Blue Cross/Blue Shield of Alabama, which insures the largest percentage of our commercially insured patients (See Table 1). For primary analysis, immunization of uninsured patients was covered by commercial insurance in keeping with the ACA individual mandate and Health Resources and Services Administration (HRSA) policy [17]. For the purposes of this study, we assumed that all uninsured patients were AIDS Drug Assistance Program (ADAP) eligible and receiving Blue Cross/Blue Shield insurance.
We calculated the number of total patients eligible for the vaccines in our clinic population to estimate the cost of provision of Gardasil, Prevnar, and Zostavax. We also sought to understand the costs of immunizing only new patients in subsequent years assuming that existing patients had already been immunized. We used the average number of new patients seen annually in our clinic (based on the last 8 years) to calculate the cost of immunizing eligible patients in subsequent years. The first cost calculation assumed 100% uptake of the recommended immunizations and that all patients eligible for Gardasil received all 3 doses. A second simulation was run to account for adjusted vaccine uptake for each of the 3 vaccines based on published data of actual immunization rates in similar patient populations [14, 18, 19]. Uptake rates in this scenario were 60%, 40%, and 50% for Gardasil, Prevnar, and Zostavax, respectively. The third simulation calculated clinic net yield if immunization of uninsured patients was reimbursed by Ryan White Care Act (RWCA) funding rather than commercial insurance coverage, which came into effect following the ACA in 2014. This simulation assumed 100% vaccine uptake.

Data Analysis
For each of the 3 vaccines, we collected the reimbursement per dose across insurers before calculating the mean, median and maximum reimbursement paid for each vaccine. Next, we calculated the “net yield” for each vaccine, including both the price of vaccine and administration, and reimbursement according to insurance. Net yield is equal to the reimbursement for the vaccine purchase and administration minus the price per dose paid including administration. All analyses were conducted using Microsoft Excel 2010 (Redmond, Washington).

**RESULTS**

The number of patients receiving care from 1 January 1 to 31 December 2013 was 2887. The 8-year average annual number of new patient visits was 267. Table 1 illustrates clinic demographics. Table 2 presents reimbursement amounts according to insurer. There was great variation in the reimbursement for each vaccine according to insurer type. For example, Medicare does not reimburse our clinic for Gardasil or Zostavax under Medicare Part D but covers the vaccines if the patient takes a prescription to a select commercial pharmacy for vaccine receipt and administration. Likewise, Alabama Medicaid does not reimburse for Gardasil for individuals over age 19 despite ACIP recommendations. On the other hand, commercial insurers reimburse up to $166.44 and $210.32 per dose of Gardasil and Zostavax, respectively. Reimbursement for vaccine administration is highly variable as well. Medicaid does not reimburse for the Gardasil vaccine or administration, but commercial insurance reimburses $24.20 for the administration of the first dose of Gardasil (not shown). Clearly, losses of even $10.00 per patient are significant when multiplied across all 2887 patients.

Net yield was calculated for each of the 3 vaccines in the total clinic population and for eligible new patients. According to the base case scenario, Prevnar was the most costly of the 3 vaccines with a mean net yield of $−60 691 (Table 3). Because 60% of those eligible for Prevnar received vaccine coverage via Blue

### Table 1. Clinic Demographics

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age (Yrs)</th>
<th>CD 4 (Cells/µL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>&lt;24</td>
<td>3%</td>
</tr>
<tr>
<td>Male</td>
<td>25–44</td>
<td>40%</td>
</tr>
<tr>
<td></td>
<td>45–54</td>
<td>34%</td>
</tr>
<tr>
<td></td>
<td>≥55</td>
<td>23%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>Insurer</th>
<th>Viral Load (copies/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>Uninsured</td>
<td>34%</td>
</tr>
<tr>
<td>Black</td>
<td>Commercial</td>
<td>26%</td>
</tr>
<tr>
<td>Other</td>
<td>Medicaid</td>
<td>27%</td>
</tr>
</tbody>
</table>

### Table 2. Reimbursement for Vaccine Purchase According to Payer

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Mean</th>
<th>Maximum</th>
<th>Minimum</th>
<th>PVP Pricing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gardasil</td>
<td>$83.22</td>
<td>$166.44</td>
<td>0</td>
<td>$141.99</td>
</tr>
<tr>
<td>Prevnar</td>
<td>$145.39</td>
<td>$153.96</td>
<td>$138.69</td>
<td>$150.20</td>
</tr>
<tr>
<td>Zostavax</td>
<td>$150.79</td>
<td>$210.32</td>
<td>0</td>
<td>$182.53</td>
</tr>
</tbody>
</table>

### Table 3. Net Yield by Vaccine and Scenario

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Populationa</th>
<th>Net Yield</th>
<th>Sum of Net Yield</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gardasil</td>
<td>All Patients</td>
<td>$−7729</td>
<td>$−97 122</td>
</tr>
<tr>
<td>Prevnar</td>
<td></td>
<td>$−60 691</td>
<td></td>
</tr>
<tr>
<td>Zostavax</td>
<td></td>
<td>$−28 702</td>
<td></td>
</tr>
<tr>
<td>Gardasil</td>
<td>New Patients</td>
<td>$−609</td>
<td>$−48 918</td>
</tr>
<tr>
<td>Prevnar</td>
<td></td>
<td>$−45 920</td>
<td></td>
</tr>
<tr>
<td>Zostavax</td>
<td></td>
<td>$−2389</td>
<td></td>
</tr>
</tbody>
</table>

### Scenario Annual Net Yield, 2015 Annual Net Yield, Subsequent Years

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Annual Net Yield, 2015</th>
<th>Annual Net Yield, Subsequent Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Case</td>
<td>$−97 122</td>
<td>$−48 918</td>
</tr>
<tr>
<td>Adjusted Uptake</td>
<td>$−44 119</td>
<td>$−20 440</td>
</tr>
<tr>
<td>RWCA</td>
<td>$−62 326</td>
<td>$−45 323</td>
</tr>
</tbody>
</table>

### Abbreviation: RWCA, Ryan White Care Act.

aAll includes any patient seen for routine provider visit between 1/1/13 and 12/31/13. New includes average annual number of new patient visits.
Cross/Blue Shield (previously insured and new enrollees), the large losses related to Prevnar are due to differences in pricing ($150.20/dose) and reimbursement by commercial insurers ($138.69/dose). Even more costly were losses related to vaccine administration: commercial insurance covered only $24.20 for vaccine administration while the fee is $48.00, leading to a loss of almost $24.00 per patient on administration fees alone. Administration of all 3 vaccines to all eligible patients in just 1 year would lead to a net loss of $97 122.00 (Table 3). Maintenance of this program by providing all vaccines to eligible patients in subsequent years would lead to clinic losses of $48 918.00, assuming patient population and insurance remains stable.

Scenario 2 includes adjusted immunization consistent with published rates of Gardasil, Prevnar, and Zostavax vaccination. Net clinic losses incurred to vaccinate all eligible patients with all 3 vaccines in this scenario were $94 119 annually, and subsequent annual losses of $20 440.00 would be required to maintain this degree of uptake. The final scenario included Ryan White Program (RWP) funding as reimbursement for immunization of the uninsured and led to reduced net clinic losses: $62 326.00 compared to $97 122.00 in the base case. A majority of the savings were due to improved reimbursement of Prevnar, which led to annual savings of $34 796.

**DISCUSSION**

The number of vaccines recommended for HIV-infected patients is rising, but reimbursement for these essential preventive tools is lacking. Currently 5 vaccines (Influenza, Tdap, Pneumococcal, Hepatitis B virus, and HPV) are recommended for all PLWH, and 2 additional vaccines are recommended for those with well-controlled HIV (MMR, Varicella) [2, 6]. Our cost analysis of 3 vaccines showed a loss of almost $100 000 for one HIV clinic if all eligible patients received vaccination; losses were reduced to $62 326.00 if pre-ACA reimbursement was used. Reimbursement rates for Gardasil, Prevnar, and Zostavax were highly variable (Table 2), consistent with previous reports [20]. Of the insurers, Alabama Medicaid reimbursed at a lower level for all 3 vaccines. The significant net loss from incomplete reimbursement is surprising and disappointing; it not only diverts up to $100 000 from competing operating costs but also compromises other service provisions that contribute to patients’ health and effective clinic operations (eg, appropriate staffing, equipment and supply availability, infrastructure modernization). Not surprisingly, many providers forgo the purchase and administration of ACIP-recommended vaccines for the sake of sustainability or necessity [21].

Financial and programmatic barriers to vaccination are not unique to HIV clinics; all vaccine providers are at risk for significant losses. In the United States, up to 49% of primary care providers report delaying the purchase of pediatric vaccinations due to cost, and 17%–21% strongly disagree with the assertion that reimbursement levels for vaccine purchase and administration are adequate [5]. A similar national survey found that only 27% of adult primary care providers stock all adult vaccines, with high inventory costs and poor reimbursement rates being key reasons for failure to stock all recommended vaccines [6]. Some health policy experts argue that immunization is at risk for future financial demise [7]. In addition to net losses in our study, many primary care clinics experience greater costs due to higher vaccine pricing if ineligible for the discounted 340 b PVP vaccine pricing used in this analysis.

Medicare patients face unique challenges to immunization. As Medicare Part D medication plans cover Gardasil and Zostavax, these vaccines can only be accessed through a commercial pharmacy and cannot be administered and reimbursed as a Medicare Part B, ambulatory service in the clinic setting. This creates additional barriers: prescription, co-pay, and additional transportation to the pharmacy may be required. Even if Medicare Part D-covered patients overcome the aforementioned barriers and receive vaccinations, it is challenging to track the receipt of vaccines administered at commercial pharmacies. Most EMRs do not interface with unaffiliated pharmacy database systems, which is crucial for patient care and accurate recordkeeping.

Vaccine coverage for uninsured patients remains particularly dynamic following the ACA and subsequent changes in the RWP. Previously, many HIV clinics stocked and administered vaccines with assistance from the RWP; Part D provided vaccines and Part B allowed the AIDS Drug Assistance Program (ADAP) through which many PLWH received medications [22]. Federal funding and discounts have allowed PLWH to receive extensive medical and support services for over 2 decades, but as a discretionary grant program dependent on annual congressional appropriations, funding has not kept pace with need and continued funding of uninsured PLWH is unclear.
Many uninsured PLWH have enrolled in commercial insurance via the ACA market-place insurance exchanges, and consequently pharmaceuticals and vaccinations are reimbursed as allowed by their insurer. As of 1 January 2015, all ADAP-eligible clients are expected to enroll in health insurance according to HRSA policy [17]. As the RWP is a payer of last resort, grantees must make reasonable efforts to secure non-RWP funds whenever possible for services to individual clients. In Alabama, enrollees receive coverage via a Blue Cross/Blue Shield plan, but coverage varies from state to state [23]. Notably, new plans are required to provide ACIP-endorsed vaccines free of copay in the next plan year following the year of recommendation via an “in-network provider,” a requirement designed to increase vaccination uptake. Although designed to reduce patients’ out of pocket costs, this provision will not be cost-neutral unless clinics are reimbursed in full for both the vaccine and administrative fees. If insurance plans provide incomplete vaccine coverage, clinics must absorb the difference, and cost will remain a significant barrier to immunization. Lastly, it remains unclear who qualifies as an “in network” provider (commercial pharmacy vs clinical provider), particularly for subspecialty clinics providing primary care services. Previously, Ryan White grantee clinics provided some vaccines on-site at the point of care without patient copays, but new insurance enrollees will have to ensure their provider is in-network to avoid copays—an additional barrier [24].

The implications of incomplete vaccine reimbursement may also cost patients financially. Some insurers choose not to cover a particular vaccine for the recommended population or cover it only via an external commercial pharmacy thereby complicating acquisition. In addition, insured may face copays and deductibles. Copayments vary significantly from carrier to carrier, one vaccine to the next, and state to state in complex ways. Inevitably, some patients are unable to provide copayment, and additional financial assistance is necessary for vaccine receipt. These patients benefit from vaccination at the point of care as available resources (philanthropic and patient assistance funds, RW grant-related income sources) can offset vaccine costs in a clinic setting.

Several limitations should be considered. The study evaluated a single site in Alabama, which is the largest HIV clinic in the state. Results elsewhere may vary based on clinic size, demographics, insurance status of the population, state Medicaid plans, and expansion status (Supplementary Table). Findings are most generalizable to clinics with similar patient demographics (Figure 1). Second, we assumed all commercial insurers reimburse similarly, which may not be the case in other regions. Third, there are no data on actual vaccine uptake in our clinic population; scenario 2 incorporated varying uptake. Fourth, our clinic participates in 340B PVP that minimizes costs. Lastly, the impact of ACA provisions remain unclear and can affect the 34% of our patient population who are eligible for insurance (Figure 1).

Despite these assumptions, our findings represent a plausible real-world scenario and are indicative of the situation that may prevail at other HIV and non-HIV primary care clinics. Moreover, results should inform clinic administrators and policy makers who need to plan for additional immunization. This study identifies key clinical and financial issues faced by medical clinics. It also raises questions facing HIV medical providers and health systems as they strive to optimize care and navigate successfully in the rapidly changing post-ACA financial reimbursement environment. More research is needed to further inform this pressing clinical and policy issue.

Supplementary Data

Supplementary materials are available at Clinical Infectious Diseases online (http://cid.oxfordjournals.org). Supplementary materials consist of data provided by the author that are published to benefit the reader. The posted materials are not copyrighted. The contents of all supplementary data are the sole responsibility of the authors. Questions or messages regarding errors should be addressed to the author.

Notes

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All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

References


