Hepatitis A and B Vaccination Practices for Ambulatory Patients Infected with HIV

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Few studies exist of adherence to guidelines for vaccination of persons infected with human immunodeficiency virus (HIV), especially in the era of highly active antiretroviral therapy (HAART). In a retrospective, cross-sectional analysis in the HIV Outpatient Study sites, 198 (32.4%) of 612 patients eligible for hepatitis B vaccine received at least 1 dose. In multivariate analysis, hepatitis B vaccination was associated with HIV risk category, education level, and number of visits to the HIV clinic per year. Among 716 patients eligible for hepatitis A vaccine, 167 (23.3%) received ⩾1 dose. Response to hepatitis B vaccination was associated with higher nadir CD4$^+$ cell counts ($P = .008$) and HIV RNA levels less than the level of detection ($P = .04$), although some response was documented at all CD4$^+$ levels. Although there were low rates of complete hepatitis vaccination in this cohort of ambulatory patients, prompt efforts to vaccinate patients entering care, receipt of antiretroviral therapy, and practice reminder systems may enhance vaccination practices.

Most persons infected with HIV are at risk for infection with ⩾1 of the hepatitis viruses: hepatitis A virus (HAV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Since the 1980s, hepatitis B vaccination has been recommended for men who have sex with men (MSM), injection drug users, and heterosexuals with a recent history of a sexually transmitted disease or multiple partners [1]. Hepatitis A vaccine has been available since 1996 and is also recommended for MSM, injection drug users, international travelers, and persons with chronic liver disease, including hepatitis C. In addition to including these recommendations from the Advisory Committee on Immunization Practices (ACIP), current US Public Health Service (USPHS)/Infectious Diseases Society of America (IDSA) guidelines recommend routine screening for HCV in all patients infected with HIV [2]. The adherence to these guidelines has not been reported extensively in cohorts of HIV-infected persons [3]. As treatment of HIV infection in developed countries evolves into one of chronic disease management, the inclusion of such preventive health interventions is important. There is also the national health objective that proposes a 75%–90% reduction in acute hepatitis B cases by 2010 among high-risk adults [4, 5]. We reviewed the screening and vaccination practices for hepatitis viruses in the HIV Outpatient Study (HOPS) sites to determine the actual implementation of USPHS/IDSA and ACIP guidelines.

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PATIENTS AND METHODS

This analysis was based on data from 9 clinic sites currently participating in the HOPS [6, 7]. These 9 clinic sites specialize in the treatment of HIV patients and are located in 7 cities (Philadelphia, PA; Oakland, CA [2 sites]; Washington, DC; Chicago, IL [2 sites]; Stony Brook, NY; Tampa, FL; and Denver, CO).

Since 1992, the HOPS has maintained a longitudinal record of physician-patient interactions that are electronically stored and submitted for central processing and analysis. Information from each outpatient visit to his or her HOPS clinician is entered into a database with a proprietary data entry tool called the "Clinical Practice Analyst" (Cerner). To date, HOPS has collected information on >7000 HIV-infected ambulatory (nonhospitalized) patients who were seen in ~165,000 outpatient visits to their HIV clinicians. These data include demographic characteristics, risk factors, symptoms, diagnoses, treatments, and laboratory results. The ethical conduct of this study undergoes yearly review by federal (Centers for Disease Control and Prevention; Atlanta, GA) and local institutional research review boards.

HOPS data updated as of 30 September 2002 were used for this analysis, but observations were censored as of 30 June 2002 to account for data entry lag. Patients were excluded if they were identified as not receiving their primary care from their HIV clinician or if they were self-pay patients (2% of the HOPS), so as not to include patients who may have received vaccinations from their physician for primary care, or who did not receive a vaccination because of financial considerations. Patients were only included if they were currently being seen by the HOPS clinician, had their first HOPS visit in 1998 or later, and had ⩾2 office visits and 6 months of observation. Length of observation for each patient was calculated as the time between the first and last visit with the HOPS physician.

Patients were considered eligible for a hepatitis B vaccination if they did not have a history of hepatitis B, a hepatitis B vaccination documented in their medical record, or laboratory evidence of HBV immunity or infection as of their first visit with the HOPS clinician. Laboratory evidence included a detectable serum HBV DNA, hepatitis B surface antigen, and antibody to hepatitis core antigen or antibody to hepatitis B surface antigen. HOPS clinicians also received an informal survey on patients with documented hepatitis C who were not given a hepatitis B vaccine to determine reasons why a hepatitis B vaccination was not provided.

Patients were considered eligible for hepatitis A vaccination if they were HCV positive, if they were hepatitis B surface antigen positive, or if their risk factor for HIV infection was injection drug use or male-male sex. HCV positivity was determined by either an HCV diagnosis documented in the medical record, a positive HCV antibody result, or a detectable HCV RNA result. Patients meeting these criteria were excluded if there was a history of hepatitis A, a hepatitis A vaccination, or a positive serologic test for antibody to HAV documented before their first visit with the HOPS clinician.

Age was determined as of the censoring date, 30 June 2002. Other demographic variables were based on patient's status as of the first visit with the HOPS clinician. Insurance status was based on the payer as of the last office visit. If multiple HIV risk factors were noted (at time of entry to the HOPS cohort), the HIV transmission risk category was determined by giving precedence to injection drug use, followed by male-male sex, and then by heterosexual sex. Encounters such as telephone calls or visits to provide a blood sample were not considered visits when counting total visits over the period of observation. Patients were counted as vaccinated if there was ⩾1 vaccination record.

$CD4^+$ cell count and virus load values for vaccinated patients were the most recent values within the 6 months before vaccination. For unvaccinated patients, $CD4^+$ cell count and virus load values represent the last values documented as of the end of follow-up. HAART was defined as ⩾3 antiretroviral (AR) drugs in a regimen in which ⩾1 of the AR drugs was a protease inhibitor, nonnucleoside reverse-transcriptase inhibitor, or abacavir; or 2 full-dose protease inhibitors. HAART status was based on HAART use at the time of vaccination or the status as of the end of follow-up for nonvaccinees.

Statistical analyses were performed by a standard statistical package (SAS software, version 8.2; SAS Institute). Bivariate analyses to identify differences in patient characteristics between eligible patients who did or did not receive vaccinations included the Pearson χ^2 test for categorical data and the Wilcoxon rank sum test for quantitative data.

Logistic regression was used to adjust for multiple variables that might be significantly associated with receiving a vaccination. The independent variables included were age, sex, race, insurance payer, education, HIV risk category, HCV infection, nadir $CD4^+$ cell count, and number of office visits per year. Additional or other $CD4^+$ cell counts, virus load, and HAART status were excluded from the model because these were not obtained at comparable points in time for vaccines and nonvaccinees. AIDS status was not included in the model because of its high correlation with nadir $CD4^+$ cell count. Although vaccination rates varied significantly among HOPS sites, a site was not included in the logistic regression models because the number of events available for analysis would not support the degrees of freedom that would result. However, to obtain some indication as to whether site variation accounted for any significant associations found in the above analyses, the variables that were found significant were retested adjusting for site to determine whether the association remained.

RESULTS

A total of 1071 patients met the inclusion criteria for this study among the 9 HOPS sites. Of them, 877 (81.9%) were screened for HBV infection and 613 (57.2%) were screened for HAV infection. A total of 612 patients (57.1%) were identified as being eligible for a hepatitis B vaccination; the remaining 459

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(42.9%) either had a history of hepatitis B, a hepatitis B vaccination, or laboratory evidence of immunity or infection before their first visit with the HOPS clinician or were documented as having a hepatitis B vaccination but with an unknown date. A total of 716 (66.8%) of 1071 patients were determined to be eligible for a hepatitis A vaccination, and 355 (33.1%) were not. Vaccination rates varied widely by site, with ranges of 4.4%–68.0% for hepatitis B vaccinations and 0.0%–34.0% for hepatitis A vaccinations (data not shown).

Hepatitis B vaccination. One hundred ninety-eight (32.4%) of 612 patients eligible for hepatitis B vaccination had documentation of receiving ⩾1 dose, and 104 (52.5%) of those 198 vaccinated had received ⩾3 doses. Among the patients vaccinated, 70.7% were receiving HAART at the time of vaccination, whereas 65.5% of the unvaccinated patients were receiving HAART. Of those who received a hepatitis B vaccination, 51 (25.8%) of 198 had postvaccination testing for antibody to hepatitis surface antigen; 19 (37.2%) of 51 of patients with follow-up results were recorded as having a positive surface antibody (i.e., "responders"). The majority (84.2%) of the 19 patients who responded to the vaccination had nadir $CD4^+$ cell counts of ⩾200 cells/mm^3, compared with 46.9% of patients whose illness did not respond to the vaccine ($P = .008$). The median $CD4^+$ cell count was also higher among responders (584 vs. 384 cells/mm^3; $P = .08$), and responders were also more likely to have an undetectable baseline virus load (63.2% vs. 33.3%; $P = .04$). Responders were also more likely to be receiving HAART (84.2% vs. 68.8%), but this difference was not statistically significant. However, to the extent that patients were receiving HAART, they were more likely to have a $CD4^+$ ⩾350 cells/mm^3 and/or an undetectable virus load.

In response to the informal survey to query clinicians about why a hepatitis B vaccination was not provided, reasons included (1) patient did not regularly attend the clinic or did not return after being offered a vaccination, (2) the physician did not consider the patient at high risk, (3) the $CD4^+$ cell count was considered too low, and (4) insurance would not pay for the immunization.

Bivariate, unadjusted analyses of patients eligible for hepatitis B vaccination suggested that women, nonwhites, publicly insured patients, high-risk heterosexuals (relative to MSM), and those with no more than a high school education were more likely to receive hepatitis B vaccination (table 1). Patients were also more likely to be vaccinated the more often they visited their HIV clinician. The vaccination rate was higher among the 83 eligible patients who were HCV coinfected (37.4% vs. 31.3%), but this was not statistically significant. After adjusting for all independent variables, only education level, HIV risk category, and number of HIV clinician visits per year were found to be significant predictors of whether a patient received hepatitis B vaccine (table 1). After adjusting these significant predictors with site, only visits per year and site were significant ($P = .01$ and $<.0001$, respectively).

Hepatitis A vaccination. Of the 716 patients eligible for hepatitis A vaccination, 167 (23.3%) had documentation of receipt of ⩾1 dose of hepatitis A vaccine. Ninety (53.9%) of 167 patients had a record of ⩾2 doses. Among those receiving hepatitis A vaccinations, 77.8% were receiving HAART, compared with 64.5% of the nonvaccinees at the end of follow-up.

Unadjusted bivariate analyses suggested that women, "other" HIV risk category (which includes high-risk heterosexuals), and patients with low virus loads were more likely to receive a hepatitis A vaccination (table 2). None of the variables remained significant in the multivariate analysis.

DISCUSSION

Although vaccinations for hepatitis, influenza, and pneumococcus have been included in the clinical care guidelines for HIV infected patients for several years [1, 2], few studies have examined the actual adherence to these recommendations or the factors associated with vaccine administration and responsiveness. In this analysis of ambulatory sites providing HIV care in the era of HAART, there was a low rate of administration of preventive vaccinations for HAV and HBV. Although 81.9% of patients were screened for HBV, only 32.4.0% of eligible patients received even 1 dose of vaccine. This rate is comparable to reports on vaccination rates seen in other HIV practices in the pre-HAART era [8–12].

Vaccine receipt appears to be associated with some clinical practice factors as well as patient characteristics. For hepatitis B, the rates of vaccine administration were somewhat better for those who had more frequent office visits and for those whose HIV risk category was high-risk heterosexual sex. Patients who are seen more regularly may receive more preventative and health maintenance interventions than do patients who have infrequent, acute, crisis-based visits. Only 50% of the patients who received a single hepatitis B vaccine dose went on to complete the series, suggesting that clinical visit volume alone is not a sufficient explanation. In the informal survey to providers associated with this analysis, one-third did not provide an explanation for missed vaccinations. It is not clear why the high-risk heterosexual group would have better vaccination rates. HIV patient populations differ demographically among the sites, and there could be other clinical factors to remind providers to vaccinate those persons or a difference in the provider's perception of risk for hepatitis infection [13–16].

The factors affecting hepatitis A vaccination rates are not demonstrated in this analysis. There was a lower rate of screening for previous infection with HAV compared with HBV. Screening before vaccination appears to be cost-effective in patients >40 years old, as immunity to hepatitis A is a function

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Table 1. Factors associated with receipt of hepatitis B virus vaccination in 612 eligible patients in the HIV Outpatient Study.

Factor	Vaccinated patients (n = 198)	Unvaccinated patients (n = 414)	Unadjusted OR (95% CI)	P	Adjusted OR (95% CI)	P
Sex						
Female	63 (31.8)	82 (19.8)	1.89 (1.29–2.78)	.0011	0.82 (0.42–1.60)	.56
Male	135 (68.2)	332 (80.2)				
Race						
Nonwhite	115 (58.1)	173 (41.9)	1.92 (1.36–2.71)	.0002	.94 (0.59–1.49)	.79
White	83 (41.9)	240 (58.1)				
Insurance						
Private/other payer	120 (62.5)	298 (73.4)	0.60 (0.42–0.87)	.0067	0.93 (0.57–1.52)	.78
Public payer	72 (37.5)	108 (26.6)				
Level of education						
High school or less	76 (47.2)	90 (28.1)	2.28 (1.54–3.39)	<.0001	1.68 (1.01–2.81)	.047
More than high school	85 (52.8)	230 (71.9)				
Risk group						
High-risk heterosexual	83 (43.0)	93 (23.4)	2.74 (1.87–4.01)	<.0001	2.43 (1.23–4.81)	.01
Other HIV risk groups	23 (11.9)	38 (9.5)	1.86 (1.05–3.29)	.03	1.21 (0.49–3.02)	.55
Men who have sex with men	87 (45.1)	267 (67.1)				
HCV coinfection status						
Coinfected	31 (15.7)	52 (12.6)	1.29 (0.80–2.09)	.30	1.19 (0.58–2.43)	.63
Not coinfected	167 (84.3)	362 (87.4)				
AIDS status						
AIDS	112 (56.6)	227 (54.8)	1.07 (0.76–1.51)	.69	…	…
No AIDS	86 (43.4)	187 (45.2)	…	…	…	…
Age, median years (25th–75th percentile)	41 (34–46)	41 (36–47)	…	.08	…	.08
Median no. of clinic visits per year (25th–75th percentile)	6.8 (4.7–9.5)	5.8 (4.3–7.7)	…	.0006	…	.04
Nadir $CD4^+$ cell count, median cells/mm^3 (25th–75th percentile)	263 (73–399)	245.5 (91.5–441.5)	…	.70	…	.67
$CD4^+$ cell count,[a] median cells/mm^3 (25th–75th percentile)	405.5 (227–624.5)	438 (248–649)	…	.42	…	…
Virus load[a], median copies/mL (25th–75th percentile)	400 (1–5900)	323 (1–6111)	…	.91	…	…

NOTE. Data are no. (%) of patients, unless otherwise indicated. Some values do not add to the total value because data on race, payor status, risk group, and/or education level were not known for all patients. HCV, hepatitis C virus.

[a] These values represent the value obtained before vaccination or the most recent value as of the end of follow-up for nonvaccinees.

of age in the United States [17]. The low rate of both screening and vaccination for hepatitis A in the HCV-coinfected and MSM cohorts in this report would appear to be a provider issue—for example, perception of risk for infection.

How do these HBV and HAV screening and vaccination rates compare with comparable vaccination interventions in HIV-infected persons for pneumococcus and influenza? The administration rates for those vaccines are low as well, even among experienced HIV caregivers [7, 8, 18, 19]. The national experience with screening and vaccinating high-risk adolescents and adults has been equally dismal, but when vaccination services are integrated into medical or other drug treatment services, rates of screening and vaccination have increased [18–24]. Low vaccination rates may result from inadequate documentation in patient records that can lead to missed opportunities for vaccination. A recent study documented the improved adherence to HIV clinical guidelines with the use of an electronic reminder system [25].

HIV clinical status and AR therapy adherence may also be considerations in the rate of vaccine administration. There are legitimate concerns about the immunogenicity of vaccines in patients with low $CD4^+$ cell counts. Several reports have demonstrated that HIV-infected patients do not mount a strong antibody response to hepatitis B or hepatitis A vaccination when there is advanced immunosuppression [26–33]. Postvaccination laboratory evaluation for response to hepatitis B vac-

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Table 2. Factors associated with receipt of hepatitis A virus vaccination in 716 eligible patients in the HIV Outpatient Study.

Factor	Vaccinated patients (n = 167)	Unvaccinated subjects (n = 549)	Unadjusted OR (95% CI)	P
Sex				
Female	22 (13.2)	42 (7.6)	1.83 (1.06–3.17)	.03
Male	145 (86.8)	507 (92.4)		
Race				
Nonwhite	62 (37.4)	203 (37.1)	1.01 (0.71–1.45)	.96
White	104 (62.6)	344 (62.9)		
Insurance				
Private payer	129 (77.2)	382 (72.4)	1.30 (0.86–1.95)	.21
Public payer	38 (22.8)	146 (27.6)		
Level of education				
High school or less	34 (25.8)	104 (23.7)	1.12 (0.71–1.75)	.63
More than high school	98 (74.2)	335 (76.3)		
Risk group				
Injection drug users	20 (12.5)	71 (13.4)	1.00 (0.59–1.72)	.99
Other HIV risk group	20 (12.5)	29 (5.5)	2.46 (1.34–4.50)	.003
Men who have sex with men	120 (75.0)	428 (81.1)		
HCV coinfection status				
Coinfected	42 (25.2)	108 (19.7)	1.37 (0.91–2.06)	.13
Not coinfected	125 (74.8)	441 (80.3)		
AIDS				
AIDS	92 (55.1)	296 (53.9)	1.05 (0.74–1.48)	.79
No AIDS	75 (44.9)	253 (46.1)	…	
Age, median years (25th–75th percentile)	42 (36–46)	42 (37–48)	…	.67
Median no. of HIV clinician visits per year (25th–75th percentile)	5.8 (4.3–8.1)	5.9 (4.2–8.2)	…	.81
Nadir $CD4^+$ cell count, median cells/mm^3 (25th–75th percentile)	235 (99–399)	253 (93–429)	…	.30
$CD4^+$ cell count,[a] median cells/mm^3 (25th–75th percentile)	391 (230–588)	437 (261–660)	…	.18
Virus load,[a] median copies/mL (25th–75th percentile)	98 (1–2382)	301 (1–8572)	…	.01

NOTE. Data are no. (%) of patients, unless otherwise indicated. Some values do not add to the total value because data on race, payor status, risk group, and/or education level were not known for all patients. HCV, hepatitis C virus.

[a] These values represent the value obtained before vaccination or the most recent value as of the end of follow-up for nonvaccinees.

cine occurred for a limited number of patients. The highest rate for postvaccination testing was 26.5% at one site. Although immunocompetent patients may not require routine postvaccination assessment for antibody development, immunocompromised patients may warrant a more intensive approach [1]. If immunogenicity is impaired in HIV-infected patients, then vaccination practice in clinical settings need to ensure that a serologic antibody response to hepatitis B is included after vaccination.

In this analysis, a positive hepatitis B surface antibody response was associated with nadir $CD4^+$ cell counts of >200 cells/mm^3 and undetectable HIV RNA levels. Some response to vaccination, however, was documented at all $CD4^+$ cell levels, even those considerably less than 220 cells/mm^3. Interestingly, HAART use per se, although greater in the vaccinated group, was not significantly associated with the detection of antibody response. The provider's intention to delay vaccination until there is a degree of immune restoration places the patient at risk to never receive the vaccination. Unless there is an adequate reminder system in place to prompt vaccine administration when the $CD4^+$ cell counts are >200 cells/mm^3, a patient may not receive the full schedule for hepatitis vaccines. Even then, patients who miss clinic visits may not be vaccinated. Clinicians may also need to increase their evaluation of vaccination ef-

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fectiveness by routinely including a hepatitis B surface antibody test after the vaccination series is completed.

The possible lack of insurance payments for hepatitis B vaccine in HIV-infected patients may be an underestimated barrier to providing this intervention. Patients with private insurance in this analysis were actually vaccinated at a lower rate than were patients who receive public funds for health services, although this difference was not statistically significant in multivariate analysis. Ryan White–funded clinics, which provide services to many publicly insured HIV patients, do a better job than private clinics of providing hepatitis virus vaccination and other preventive health services (Valverde et al., personal communication).

Although considerable attention is paid to AR drug therapy and clinical outcomes among HIV providers, there appears to be an inadequate performance of prevention screening and vaccination. This oversight is of concern for HIV-positive patients in general, most of whom belong to risk groups that overlap those for hepatitis B and hepatitis A. During the past decade, MSM and injection drug users each have accounted for 15%–20% of newly acquired HBV infections, and high-risk heterosexuals have accounted for 35%–40% [34]. Screening and vaccination are especially important for coinfected patients with hepatitis C, who not only are likely to have behaviors that place them at high risk for HBV and HAV, but whose chronic liver disease places them at increased risk for morbidity and mortality from hepatitis A.

The inclusion of routine viral hepatitis screening, vaccination, and postvaccination testing for any new patient to a clinical practice needs to be emphasized. We think that strategies to improve provider reminders about routine surveillance and vaccination for viral hepatitis in all HIV-infected persons may improve this situation.

STUDY GROUP MEMBERS

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