

# Adherence to Guidelines for Hepatitis B, Pneumococcal, and Influenza Vaccination in Patients With Diabetes

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**IN BRIEF** This single-center, cross-sectional study was designed to assess adherence to national guidelines for the immunization of patients with diabetes and to evaluate predictors of vaccination with the hepatitis B, influenza, and 23-valent pneumococcal polysaccharide vaccines. In patients considered to be at increased risk for infection and infectious disease complications because of their history of diabetes, extensive nonadherence to immunization recommendations for all three vaccines was found. Nonadherence to the 2011 Advisory Committee on Immunization Practices' recommendation for hepatitis B vaccination was ubiquitous. Allocation of health care resources to increase vaccine coverage should remain a priority, with a focus on spreading awareness of the hepatitis B vaccine recommendation for people with diabetes.

Diabetes has long been perceived to be associated with an increased risk of infection and worse health outcomes. The rate of infection arising from many common viral and bacterial etiologies has been shown to occur more frequently in patients with diabetes (1–4). The odds of developing acute hepatitis B are estimated to be more than double in patients with diabetes compared with those without (4). The incidence of hospitalization and odds of death are consistently elevated in people with diabetes compared with those without, during both influenza epidemic and nonepidemic years (5,6). Studies have suggested that patients with diabetes who develop pneumococcal pneumonia are more likely than those without diabetes to progress to systemic bacteremia (7–9).

This apparent susceptibility to infection has been attributed to abnormalities in host defense mechanisms, including deficiencies in antibody response, cell-mediated immunity, leukocyte function, and colonization rates (9–11). The

higher risk of infection may also be explained by the large burden of chronic disease in this population and associated organ dysfunction. Despite the potential for impaired immune function, most people with diabetes are capable of generating an adequate humoral response and sufficient antibody titers from vaccination (12–14).

Morbidity and mortality associated with influenza and pneumonia are reduced in people who have received appropriate vaccination for each of these infectious diseases (9,15–17). The Advisory Committee on Immunization Practices (ACIP) and the American Diabetes Association both recommend annual vaccination with the influenza vaccine and at least one lifetime vaccination with the 23-valent pneumococcal polysaccharide vaccine (PPSV23) for individuals with diabetes or other conditions that increase the risk of complications from infection (Table 1) (18–22). As part of the *Healthy People 2020* initiative, the U.S. Department of Health and Human Services has designated goal

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**TABLE 1. Adherence to ACIP Recommendations for Vaccination of People With Diabetes and Healthy People 2020 Coverage Goals for Each Vaccine**

Vaccine	People With Diabetes Assessed for Adherence (n)	ACIP Recommendation (18–21)*	Healthy People 2020 Vaccine Coverage Goal (22) (%)	Adherence Rate (%)
Influenza	100	Annual vaccination of all patients $\geq 6$ months of age	90	41
PPSV23	100	One-time vaccination before the age of 65 years; revaccination after age 65 if $\geq 5$ years have passed since the previous vaccination	60 (for those aged 18–64 years) 90 (for those aged $\geq 65$ years)	37
Hepatitis B	39	Vaccination of patients aged 19–59 years; vaccination at clinical discretion for those $> 59$ years of age	Increase in the percentage of coverage for high-risk populations	0

\*ACIP recommendations are identical to those published by the Centers for Disease Control and Prevention and the American Diabetes Association.

vaccination coverage rates for high-risk adults aged 18–64 years of 90% annually for the influenza vaccine and 60% for PPSV23 (22). Data from the 2011 National Health Interview Survey indicated that only 16.6% of these high-risk individuals had ever received the PPSV23 (23). Coverage with the influenza vaccine for the 2012–2013 season was estimated to be 47% for high-risk individuals (24). Substantial improvement will be required to meet coverage goals for these vaccines.

Data from the Emerging Infections Program for the period of 2009–2010 indicated a higher case fatality rate among people with diabetes with acute hepatitis B virus infection than among those without the infection (4). Progression from acute to chronic hepatitis B infection occurs in ~5% of healthy individuals (25) but is thought to occur more frequently in people with diabetes (26). Hepatitis B infection can be prevented through administration of the three-dose vaccination. Based on data supporting the cost-effectiveness of this vaccine, ACIP released a recommendation in October 2011 that adults with diabetes between the ages of 19 and 59 years be vaccinated against hepatitis B as soon as possible after being diagnosed with diabetes (21). A baseline estimate of coverage with the hepatitis B vaccine for adults with diabetes was formu-

lated using the 2011 National Health Interview Survey; the percentage of people aged 19–59 years with diabetes who reported having received at least one dose was low (26.9%) (23).

### Objective

This study was designed to assess adherence to national guidelines for the immunization of people with diabetes and to evaluate predictors of vaccination.

### Design and Methods

This was a cross-sectional analysis of data extracted from the electronic medical record (EMR) system at Kent Hospital, a 359-bed public teaching hospital in Warwick, RI. Data were collected retrospectively through chart review. The study was conducted from 5 September 2013 to 26 January 2014. All patients admitted to the care of the internal medicine teaching service during this period were eligible for chart review. The index date was established as the date of admission.

Patients included in the analysis were required to be  $\geq 19$  years of age, to have a diagnosis of either type 1 or type 2 diabetes recorded in the EMR at the time of hospital admission, and to have confirmed use of at least one chronic medication for the treatment of diabetes before admission. Data collected for analysis included patients' age, ethnicity, sex, height,

weight, smoking status, outpatient diabetes medication regimen, diabetes type, most recent A1C within the past 12 months, drug and nondrug allergies, and documented history of respiratory, cardiovascular, mental health, oncological, cerebrovascular, hepatic, and autoimmune comorbidities. Diagnoses for new comorbidities during the index hospitalization were not included because the impact of undiagnosed comorbid disease on immunization history would be unclear. However, values for A1C, a marker of recent glycemic control, were included even if obtained during the index hospital stay.

EMR entries for the patients were reviewed for nursing screening and intervention documentation from previous inpatient admissions to determine immunization history. Screening is performed by nursing staff at the time of patients' admission to a specific nursing unit. The screening protocol assesses all previous tetanus, PPSV23, and hepatitis B immunizations, as well as influenza immunization within the past year. The EMR also contained outpatient prescription claims information obtained through contracts with pharmacy benefits providers. The prescription claims data were reviewed for evidence of outpatient immunization.

**TABLE 2. Demographic Characteristics of Patients With Diabetes and the Associated Bivariate Odds of Adherence With Immunization Guidelines**

Characteristic	Adherent With Influenza Vaccine (n = 41)		P	Nonadherent With Influenza Vaccine (n = 59)		P
	Mean (SD)			Mean (SD)		
Age (years)	67.98 (16.95)	64.67 (17.16)	0.34	65.57 (19.65)	66.30 (15.51)	0.85
Sex	% (n)	% (n)	OR (95% CI)	% (n)	% (n)	OR (95% CI)
Male	51.22 (21)	49.15 (29)	Reference	45.95 (17)	52.38 (33)	Reference
Female	48.78 (20)	50.85 (30)	0.92 (0.42–2.04)	54.05 (20)	47.62 (30)	1.29 (0.57–2.92)
BMI	Mean (SD)		P	Mean (SD)		P
	30.99 (7.93)	33.46 (10.62)	0.19	32.11 (8.46)	32.64 (10.33)	0.78
Comorbid diseases*	% (n)	% (n)	OR (95% CI)	% (n)	% (n)	OR (95% CI)
Respiratory	19.51 (8)	28.81 (17)	0.60 (0.23–1.56)	35.14 (13)	19.05 (12)	2.30 (0.92–5.79)
Cardiovascular	51.22 (21)	54.24 (32)	0.89 (0.40–1.97)	64.86 (24)	46.03 (29)	2.16 (0.94–5.00)
Cancer	17.07 (7)	16.95 (10)	1.01 (0.35–2.91)	8.11 (3)	22.22 (14)	0.31 (0.082–1.16)
Mental illness	31.71 (13)	22.03 (13)	1.64 (0.67–4.05)	35.14 (13)	20.63 (13)	2.08 (0.84–5.18)
Hepatic	9.76 (4)	8.47 (5)	1.17 (0.29–4.64)	16.22 (6)	4.76 (3)	3.87 (0.91–16.53)
Cerebrovascular	7.32 (3)	13.56 (8)	0.50 (0.13–2.03)	16.22 (6)	7.94 (5)	2.25 (0.63–7.95)
Autoimmune	14.63 (6)	6.78 (4)	2.36 (0.62–8.95)	16.22 (6)	6.35 (4)	2.85 (0.75–10.88)
Total comorbidities	Mean (SD)		P	Mean (SD)		P
	1.51 (0.81)	1.51 (1.26)	>0.99	1.92 (1.28)	1.27 (0.90)	<0.01
Smoking status	% (n)	% (n)	OR (95% CI)	% (n)	% (n)	OR (95% CI)
Never smoker	48.78 (20)	42.37 (25)	Reference	48.65 (18)	42.86 (27)	Reference
Former smoker	31.71 (13)	35.59 (21)	0.77 (0.31–1.92)	29.73 (11)	36.51 (23)	0.72 (0.28–1.83)
Current smoker	19.51 (8)	22.03 (13)	0.77 (0.27–2.22)	21.62 (8)	20.63 (13)	0.92 (0.32–2.67)

\*Reference was absence of the comorbid disease.

Adherence to the ACIP recommendations for influenza and pneumococcal vaccinations was assessed for all patients. Precautions related to or contraindications for vaccination, including allergies or severe hypersensitivities to vaccine components and a history of Guillain-Barré syndrome, were recorded. Immunization history comprised 12 months from the admission date for the influenza vaccination, with receipt of the vaccination within that time period representative of adherence to the annual influenza vaccination recommendation. Immunization history for the pneumococcal and hepatitis B vaccinations included all documented doses received. Adherence to recom-

mendations for the pneumococcal vaccine was determined based on patients' age and the timing of previous vaccinations. Patients <65 years of age must have received at least one dose to be considered adherent. Patients ≥65 years of age who had received one dose since turning 65 were considered adherent. Patients who were ≥65 years of age who had received a vaccination before turning 65 were considered adherent if that vaccination was received within the past 5 years or if they had received another vaccination since turning 65.

Patients between the ages of 19 and 59 years were evaluated for previous immunization with the hepatitis B vaccine. Patients documented as

having received at least three doses of the hepatitis B vaccine were considered adherent. Patients having received at least one dose of the vaccine but less than three were considered nonadherent and labeled as "vaccine series incomplete." Patients who had not received any doses were considered nonadherent.

Primary data analyses evaluated predictors of adherence to recommendations for each of the three vaccines. The Student's *t* test was used to compare the means of continuous variables with equal variance. Satterthwaite's approximate *t* test was used to compare means of continuous variables with unequal variance.  $\chi^2$  analysis was used to compare cat-

**TABLE 3. Diabetes-Related Characteristics of Patients With Diabetes and the Associated Bivariate Odds of Adherence With Immunization Guidelines**

Characteristic	Adherent With Influenza Vaccine (n = 41)	Nonadherent With Influenza Vaccine (n = 59)		Adherent With Pneumococcal Vaccine (n = 37)	Nonadherent With Pneumococcal Vaccine (n = 63)	
A1C (%)*	Mean (SD) (n = 32)	Mean (SD) (n = 45)	<i>P</i>	Mean (SD) (n = 28)	Mean (SD) (n = 49)	<i>P</i>
	8.12 (1.96)	8.92 (2.26)	0.11	8.56 (2.55)	8.61 (1.94)	0.92
	% (n)	% (n)	OR (95% CI)	% (n)	% (n)	OR (95% CI)
<7	31.25 (10)	17.78 (8)	Reference	28.57 (8)	20.41 (10)	Reference
≥7	68.75 (22)	82.22 (37)	0.48 (0.16–1.38)	71.43 (20)	79.59 (39)	0.64 (0.22–1.88)
Diabetes drug regimen	% (n)	% (n)	OR (95% CI)	% (n)	% (n)	OR (95% CI)
Oral drug therapy	39.02 (16)	40.68 (24)	Reference	29.73 (11)	46.03 (29)	Reference
Outpatient insulin	60.98 (25)	59.23 (35)	1.07 (0.47–2.42)	70.27 (26)	53.97 (34)	2.02 (0.85–4.77)
Diabetes type	% (n)	% (n)	OR (95% CI)	% (n)	% (n)	OR (95% CI)
Type 2	42.31 (33)	57.69 (45)	Reference	33.33 (26)	66.67 (52)	Reference
Type 1	36.36 (4)	63.64 (7)	0.78 (0.21–2.88)	63.64 (7)	36.36 (4)	3.50 (0.94–13.04)

\*A total of 23 patients did not have available A1C values.

egorical data if all cells contained values >5. Fisher's exact test was used for the comparison of categorical data involving at least one cell with a value ≤5. Bivariate odds of adherence were calculated for each level of categorical variables. SAS version 9.3 (SAS Institute, Cary, N.C.) was used for the statistical analyses. The statistical significance level was set a priori at  $\alpha = 0.05$ . This study was approved by the Kent Hospital institutional review board.

## Results

During the study period, 364 records were reviewed, and 100 patients with diabetes were identified as eligible for inclusion. Vaccine coverage rates and *Healthy People 2020* vaccine coverage goals are reported in Table 1. The number of patients deemed appropriate to have received the hepatitis B vaccine was 39 (39%). Of these, none had initiated or completed the three-dose vaccination series. Immunization adherence rates were 41% for the influenza vaccine, 37% for the pneumococcal vaccine, and 19% for both

vaccines. The odds ratio (OR) for adherence to the influenza or pneumococcal vaccination recommendation was 1.97 (95% CI 0.86–4.50) if patients were also adherent to the other vaccination recommendation. No complete contraindications to vaccination were recorded, although two patients had documented egg allergies.

Patients' demographic characteristics, diabetes-related variables, and the corresponding bivariate odds of adherence to vaccination recommendations are presented in Table 2 and Table 3. The groups did not differ significantly with regard to sex, age, or BMI. The most common ethnicity was white (92%). The majority of patients (79%) were current or former smokers, and 60% of patients had used insulin as an outpatient before admission. Patients with better glycemic control as indicated by an A1C value <7% were slightly more likely to have received an influenza vaccination, although this finding did not reach statistical significance ( $P = 0.11$ ). The presence of individual

comorbid diseases and an increasing total comorbid disease burden failed to predict adherence to influenza vaccination recommendations ( $P > 0.99$ ). The odds of adherence to the pneumococcal vaccination recommendation were nonsignificantly increased in the presence of individual comorbid diseases, with the exception of cancer, for which the odds decreased (OR 0.31 [95% CI 0.082–1.16]). The mean number of comorbid diseases present was significantly greater for patients adherent to the pneumococcal vaccination recommendation ( $P < 0.01$ ).

## Discussion

This study found that patients at high risk for infection and infectious disease complications because of their history of diabetes were largely nonadherent to ACIP immunization recommendations. The coverage rate of 41% for the influenza vaccine in this population is less than the estimated 47% rate in high-risk individuals (defined as having either diabetes, asthma, or cardiovascular disease)

aged 18–64 years nationally for the 2012–2013 season (24). The influenza vaccination rate in this study was also substantially less than the 66.2% rate reported for adults  $\geq 65$  years of age during the same time period (24). The pneumococcal vaccine coverage rate of 37% in this study approximated an average of 2011 national estimates of 66.5% for white adults  $\geq 65$  years of age and 20.1% for high-risk adults aged 18–64 years (23). The absence of any patients adherent to recommendations for the hepatitis B vaccination in this study is inconsistent with the 26.9% national coverage estimate or people with diabetes from 2011 (23). Immunization rates for all three vaccines failed to meet targets established by the *Healthy People 2020* initiative (22).

The greater odds of pneumococcal vaccination associated with an increasing burden of comorbid disease aligns with other studies evaluating predictors of pneumococcal vaccination (27,28). In this study, patients with comorbid diseases, including chronic heart, lung, and liver disease, as well as cigarette smoking, had multiple indications for pneumococcal vaccination, and providers may have been more likely to identify such patients as vaccination candidates. Unlike previous predictive analyses, increasing age did not increase the odds of having received either vaccination. Adherence to influenza vaccination recommendations was consistent across comorbid disease burden. This, in conjunction with lower mean BMI and A1C levels in adherent patients, suggests that influenza vaccination may be associated with other positive health management decisions.

The most noteworthy result of this study is the failure to immunize patients with diabetes with the hepatitis B vaccine. This indicates that many providers may be unaware of the 2011 ACIP hepatitis B vaccination recommendation for this population. Expanding coverage for the influenza and pneumococcal vac-

cines has been a nationwide health goal since the original *Healthy People* initiative began in 1979 (29). Annual increases in pneumococcal and influenza vaccination rates were sustained throughout much of the past few decades (30,31) but have slowed in recent years (23,32). Drivers of the increase in vaccination coverage include the use of health information technology for identification of unvaccinated patients, protocols for screening and administration, and extension of access to larger patient populations by increasing the number of immunizing providers and locations where vaccination services are available. Increased coverage of preventive services under the Affordable Care Act also promises to reduce the cost-associated barriers to vaccination. Health plans created after 23 September 2010 must provide full reimbursement without a patient copayment for ACIP-recommended immunizations (33).

Pharmacists in all 50 states are now permitted to administer vaccinations (34,35). Limitations differ among states regarding which vaccinations may be administered, whether a prescription or protocol is required, and the age of eligible patients. The influenza vaccination may be administered to patients  $\geq 19$  years of age by pharmacists in all 50 states. All states, with the exception of South Dakota, allow pharmacist administration of the pneumococcal vaccine. In 45 states, any vaccination, including the hepatitis B vaccine, may be administered by pharmacists. Pharmacy interns who have completed the immunization certificate training program and who are operating under the supervision of a pharmacist may administer vaccinations in 38 states (34,35). Thus, using pharmacists to screen, educate, and immunize patients is an intervention amenable to multiple care settings.

The results of this study underscore the need for continued expansion of vaccination efforts to attain national goals for immuni-

zation coverage for the influenza, pneumococcal, and hepatitis B vaccines. This study is believed to be the first to examine rates of hepatitis B vaccination in patients with diabetes since the release of the ACIP recommendation in October 2011. Further research is required to assess changes in national coverage for the vaccination since that time. The use of data from an EMR in this study enabled the evaluation of a multitude of potential demographic and health-related predictors of vaccination. Access to outpatient pharmacy claims records contributed to the completeness of the immunization history.

Previous investigations have evaluated immunization rates in patient populations presenting to an emergency department (ED) and confirmed the feasibility of immunizing eligible patients during emergency visits (36,37). One prospective, cross-sectional study (37) conducted in an urban ED found that only 16 and 18% of presenting high-risk patients were up to date on influenza and pneumococcal vaccinations, respectively. Eligible patients were offered vaccinations during the ED visit, and the percentage of patients who were adherent on leaving the ED was improved to 83% for the influenza vaccine and 84% for the pneumococcal vaccine.

In contrast to ED interventions, our study evaluated immunization histories obtained at hospital admission, which would prompt subsequent offers for influenza or pneumococcal vaccination in eligible populations through a standing order protocol. Other studies have demonstrated the effectiveness of standing order protocols involving nurse, physician, and pharmacy practitioners in institutional settings for both the pneumococcal and influenza vaccines (38). Prioritizing screening and administration of vaccinations during all points of patient contact can increase immunization coverage for ACIP-recommended vaccines in patients with diabetes and is an attain-

able goal for emergency, inpatient, and outpatient health care providers.

### Limitations

One limitation of this study was the unavailability of comprehensive outpatient immunization records. Immunization history was ascertained from hospital records and patient self-reports. Self-reported immunization history is subject to recall bias, with the potential for interviewer bias also to be present because of variability among practitioners in the meticulousness of their questioning of patients regarding past vaccinations. As a result, there is a possibility that some patients who were uncertain of or misrepresented their vaccination history were misclassified. The generalizability of this study is limited by its single-hospital design and lack of ethnic and geographic diversity in the patient population. Although the results are comparable to studies examining immunization rates and predictors of vaccination in nationally representative populations, vaccination procedures may differ markedly among regions and institutions.

### Conclusion

In this study, rates of adherence to ACIP recommendations for influenza, pneumococcal, and hepatitis B immunization of patients with diabetes were all below national coverage estimates. Increasing burden of comorbid disease predicted pneumococcal vaccination, whereas no significant predictors of influenza vaccination were identified. Allocation of health care resources to increase vaccine coverage should remain a priority, with a focus on spreading awareness of the ACIP hepatitis B vaccine recommendation for people with diabetes.

### Duality of Interest

No potential conflicts of interest relevant to this article were reported.

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