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Influenza vaccine delivery and effectiveness in end-stage renal disease

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Influenza vaccine delivery and effectiveness in end-stage renal disease.

Background. Influenza vaccination rates in the general population have been associated with improved outcomes, yet high-risk populations, such as end-stage renal disease (ESRD) patients, have received little attention in determining the potential benefits. This report assessed the frequency and effectiveness of influenza vaccination, while also assessing disparities in vaccination rates in the ESRD population.

Methods. Using the United States Renal Data System research files containing claims for all Medicare ESRD patients, vaccination rates and outcomes among vaccinated and unvaccinated persons for the 1997 to 1998 and 1998 to 1999 influenza seasons were compared after adjustment for baseline demographic factors and health characteristics.

Results. Vaccination rates in the ESRD population were less than 50% for each season. Influenza vaccination rates were lower in non-whites, women, younger patients, and peritoneal dialysis patients. Influenza vaccination was associated with a lower risk for hospitalization and death.

Conclusions. Despite universal coverage of free influenza vaccination, the ESRD population had a less than 50% vaccination rate for the years 1997 to 1998 and 1998 to 1999 as demonstrated by Medicare billing data. Substantial differences were found in vaccination rates among non-whites and peritoneal dialysis patients. This study confirms that the ESRD populations benefit from influenza vaccination, suggesting that dialysis providers should take advantage of all opportunities to immunize this high-risk group.

Influenza causes a significant burden of morbidity and mortality in the general population with an average of 20,000 deaths annually [1]. Patients with end-stage renal disease (ESRD) are likely at high risk for influenza infection and complications given their altered immune status; infectious disease is the second leading cause of death among ESRD patients and pulmonary infectious mortality is tenfold higher in the ESRD population than in the general population [2]. Especially among the aged [3], and those with increased comorbidity [4], influenza vaccination decreases the likelihood of hospitalization, mortality, and costs [4–7]. A goal of the "Healthy People 2000" program was to immunize 60% of the elderly and other high-risk individuals against influenza. For "Healthy People 2010" the goal has been increased to 90% [8, 9]. Despite the recommendations for annual vaccination in patients with ESRD [10], little is known about influenza vaccination frequency and outcomes in this high risk population.

The efficacy of influenza vaccination depends upon an intact B cell and T cell response, and studies have shown a decrease in both the number of B cells and the IgG production among patients undergoing hemodialysis [11]. However, previous studies suggest that hemodialysis patients' response rates to influenza vaccination were similar to controls [12]. It is unclear whether uncertainty about the benefits of influenza vaccination may lead to a lower rate of influenza vaccination among patients with kidney failure. In addition, little is known regarding differences between hemodialysis and peritoneal dialysis patients in vaccination practices and effectiveness.

Thus, we undertook this study to determine the frequency and outcomes associated with influenza vaccination in this high-risk population. Influenza vaccination rates and association of influenza vaccination with morbidity and mortality were determined in patients receiving either peritoneal dialysis or hemodialysis during two influenza seasons, 1997 to 1998 and 1998 to 1999, using Medicare claims data.

METHODS

Study cohorts

Our sample included all Medicare fee-for service (non-HMO, non-Medicare as secondary payer) ESRD pa-

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tients receiving dialysis in two influenza epidemic years: 1997 to 1998, and 1998 to 1999. The cohort of patients included in 1997 to 1998 consisted of patients who initiated therapy for ESRD prior to October 1, 1996. The October 1 date was chosen to ensure that complete data would be available for patients after January 1, 1997. The period from January 1, 1997 through August 31, 1997 was used to characterize patient comorbidities. The period from September 1 through December 31, 1997 was used to identify patients who received influenza vaccination, and then the period from January 1, 1998 through February 28, 1998 was used to assess hospitalization and mortality [13]. Treatment modality (hemodialysis or peritoneal dialysis) was determined on September 1, 1997 and switching between renal replacement therapies following this date was ignored.

The cohort for the subsequent influenza season epidemic year initiated prior to October 1, 1997. The periods for characterizing comorbidity and classifying influenza vaccination status were similar. The outcome assessment period for the 1998 to 1999 influenza season was January 17, 1999 through March 20, 1999 [14]. The Centers for Medicare and Medicaid Services (CMS) Medical Evidence Form 2728 was used to determine age, gender, race, first ESRD service date, and cause of renal failure.

Vaccination status

Billing codes were used to classify vaccination status from the Medicare Part B Physician/supplier and Part A hospital outpatient claims files that were searched for Current Procedural Terminology (CPT) codes 90724, 90657, 90658, 90659, or HCFA Common Procedure Coding System (HCPCS) G0008, during September 1 through December 31 of 1997 or September 1 through December 31 of 1998 [15].

Comorbidity index

A comorbidity index was calculated using the method of Charlson et al [16], which was later adapted for use with claims data by Deyo, Cherkin and Ciol [17]. The time periods from January 1, through August 31 of 1997 or January 1, through August 31 of 1998 were used as characterization periods, where Medicare Part A inpatient claims from these periods were searched for each patient, and total hospital days for each patient were calculated, as well as the total Charlson score. This score provides a single number as a measure of the overall comorbidity burden for that patient for inclusion in subsequent analyses. All 10 ICD-9-CM diagnosis fields were searched for codes as previously described in Deyo et al [17]. The total score for an individual was calculated as the sum of the weights accumulated during the eight-month period. This comorbidity index has been applied to ESRD populations previously and found to be strongly associated with mortality and costs [19].

Hospitalization and mortality outcomes

Principal discharge diagnoses for hospitalizations were examined to categorize cause of hospitalization. Hospitalization causes included in the analyses were any-cause, influenza/pneumonia (P&I; ICD-9-CM 480.xx-487.xx), bacteremia/viremia/septicemia (ICD-9-CM 038.xx, 790.7, 790.8), and respiratory infection (ICD-9-CM 472.xx-474.0x, 475.xx-477.9, 478.22-478.24, 480.xx-491.xx, 494, 510.x-511.x, 513.0, 518.6). CMS form 2746, the ESRD Death Notification form, was used to classify cause-specific mortality. Three categories were created: cardiac (myocardial infarction, pericarditis, atherosclerotic heart disease, cardiomyopathy, cardiac arrhythmia, cardiac arrest, valvular heart disease, pulmonary edema), infection (septicemia, pulmonary infection, viral infection, tuberculosis, hepatitis B, other viral hepatitis, fungal peritonitis, other infections), and all other causes.

Statistical analysis

Baseline demographics and comorbid illness in vaccinated and unvaccinated persons were compared using the Student *t* test and chi-square test. Unadjusted vaccination rates were calculated overall and by age, gender, race, ethnicity, vintage (time on dialysis), diabetic status, and mode of dialysis. The denominator included those patients that initiated prior to October 1 of the previous year and survived to the beginning of the influenza season examined. Chi-square tests were used to compare differences in vaccination rates between hemodialysis and peritoneal dialysis patients. Influenza vaccination rates were also adjusted using multiple logistic regression models for age, gender, race, prior length of time with ESRD, and cause of renal failure (diabetes vs. other).

To determine the association between influenza vaccination and the risk for hospitalization and mortality, multiple logistic regression models were performed adjusting for age, gender, race, ethnicity, ESRD network, length of time with ESRD, cause of renal failure, Charlson comorbidity index and a severity of disease measure of hospital days during the eight-month entry period from January 1, through August 31.

We hypothesized that the relationship between vaccination and outcomes may be different at different ages and with different degrees of comorbidity, since we reasoned that older, sicker patients might benefit more from influenza vaccination. In order to test this hypothesis, separate logistic models were performed by four age groups: 0 to 17, 18 to 39, 40 to 65, and greater than 65 years old. We also performed separate multiple logistic regression models for patients with each comorbidity included in the Charlson index. This was performed for both influenza seasons and for the outcomes of any-cause death, cause-specific death, death or hospitalization, and cause-specific hospitalization. We then looked for consis-

Table 1. Patient characteristics and vaccination rates (September 1–December 31, 1998)

	Hemodialysis, 112,409 (48.8%)		Peritoneal dialysis, 13,091 (39.2%)		
N (*% vaccinated*)	% of Population	% Vaccinated	% of Population	% Vaccinated	*P*
Age					
<18	0.2	19.3[a]	1.7	14.2[a]	NS
18–39	11.6	39.3	20.6	27.5	<0.001[d]
40–64	43.1	46.2	48.8	36.3	<0.001[d]
65+	45.0	53.9	28.9	53.8	NS
Gender					
Female	47.8	48.2[a]	50.8	38.1[b]	<0.001[d]
Male	52.2	49.3	49.2	40.3	<0.001[d]
Race					
White	48.2	54.2[a]	61.6	44.3[a]	<0.001[d]
Black	45.2	43.5	30.1	30.0	<0.001[d]
Native American	1.9	45.9	1.8	25.3	<0.001[d]
Asian	3.3	45.4	4.7	41.4	NS
Other	1.4	43.4	1.8	25.3	<0.001[d]
Ethnicity					
Hispanic	9.9	49.1[c]	10.3	30.5[a]	<0.001[d]
Non-hispanic	90.1	48.8	89.7	40.1	<0.001[d]
Prior ESRD time					
<1 year	2.3	49.8[a]	2.4	43.1[a]	<0.005[e]
1–2 years	22.6	49.2	24.6	42.0	<0.001[d]
2–4 years	32.2	50.7	35.2	40.3	<0.001[d]
>4 years	42.9	47.0	37.7	35.9	<0.001[d]
Cause of renal failure					
Diabetes	34.8	51.2[a]	27.8	42.4[a]	<0.001[d]
Other	65.2	47.5	72.2	37.9	<0.001[d]

NS is not significant.
[a] Statistical test of difference in vaccination rates <0.001, for example, the *P* value for a difference in vaccination rates by age, within HD, is less than 0.001
[b] Statistical test of difference in vaccination rates <0.01
[c] Not significant
[d] Statistical test of HD vaccination rate vs. PD vaccination rate, $P < 0.001$
[e] Statistical test of HD vaccination rate vs. PD vaccination rate, $P < 0.05$

tency of the size and sign of the parameter estimates for vaccination across models. In order to test the generalizability of the impact of influenza vaccination, we performed similar stratified multiple logistic regression analyses by race (white, black, Native American, Asian, other).

RESULTS

The hemodialysis and peritoneal dialysis population's combined vaccination rate was 47.8% in epidemic year 1998–1999. Patient characteristics and vaccination rates for that year are presented in Table 1 by dialysis modality. The rate of vaccination among the 112,409 hemodialysis patients was significantly greater (48.8%) than the rate among the 13,091 peritoneal dialysis patients (39.2%). This was true in virtually every demographic category. Compared to hemodialysis, patients on peritoneal dialysis were younger, included a higher percentage of whites, and had diabetes as a cause of renal failure less frequently. Blacks were less likely to be immunized than whites, especially among persons on peritoneal dialysis: 30.0% of blacks versus 44.3% of whites. Results for the 1997 to 1998 epidemic year were similar, and are not shown.

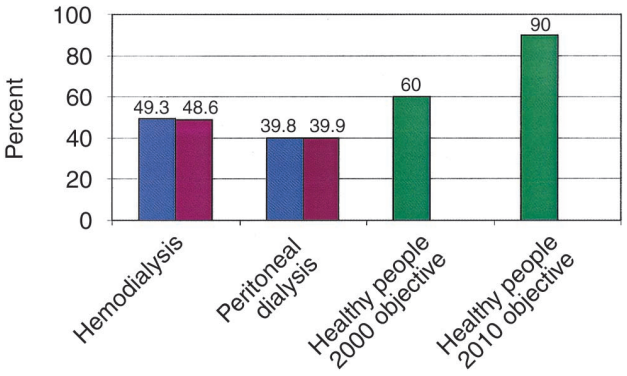

Fig. 1. Influenza vaccination rates for hemodialysis versus peritoneal dialysis compared to the Health People 2000 and 2010 objectives in the two cohorts. Symbols are: (▒) 1997 to 1998; (■) 1998 to 1999.

Figure 1 shows the adjusted vaccination rates for hemodialysis and peritoneal dialysis patients, along with Healthy People 2000 and Healthy People 2010 target vaccination rates. Even after adjustment for age, gender, race, and ethnicity, the ESRD patients receiving peritoneal dialysis had significantly lower influenza vaccination rates compared to patients receiving hemodialysis (39.9 vs. 48.6% for 1998 to 1999, $P < 0.0001$). Both groups

Table 2. Odds ratios for the impact of vaccinations on mortality and morbidity

	Hemodialysis		Peritoneal dialysis	
	1997–1998	1998–1999	1997–1998	1998–1999
Hospitalization				
Any-cause	0.95 (0.92, 0.98)	0.93 (0.90, 0.95)	0.90 (0.83, 0.98)	1.01 (0.93, 1.11)
Influenza/pneumonia	0.88 (0.80, 0.97)	0.84 (0.77, 0.92)	0.95 (0.67, 1.37)	0.85 (0.59, 1.21)
Bacteremia/viremia/septicemia	0.83 (0.73, 0.94)	0.76 (0.67, 0.87)	0.48 (0.27, 0.86)	1.12 (0.62, 2.01)
Respiratory infection	0.93 (0.85, 1.01)	0.88 (0.81, 0.95)	0.88 (0.64, 1.21)	0.86 (0.62, 1.18)
Death				
Any-cause	0.75 (0.71, 0.80)	0.77 (0.73, 0.81)	0.70 (0.59, 0.82)	0.83 (0.71, 0.97)
Cardiac	0.84 (0.77, 0.92)	0.82 (0.76, 0.88)	0.77 (0.61, 0.98)	0.90 (0.72, 1.13)
Infection	0.75 (0.64, 0.88)	0.64 (0.56, 0.72)	0.80 (0.56, 1.15)	0.85 (0.62, 1.17)
Other	0.69 (0.62, 0.75)	0.81 (0.75, 0.88)	0.58 (0.44, 0.78)	0.78 (0.61, 1.00)
Hospitalization or death	0.91 (0.89, 0.94)	0.89 (0.86, 0.91)	0.86 (0.79, 0.93)	0.96 (0.89, 1.05)

had substantially lower rates than the 2000 goal of 60% and the 2010 goal of 90%.

Table 2 displays odds ratios (vaccinated vs. not vaccinated) and 95% confidence intervals for overall and cause-specific hospitalization and mortality, for peritoneal dialysis and hemodialysis patients, for both influenza seasons, adjusted for age, gender, race, ethnicity, ESRD network, length of time with ESRD, cause of renal failure, Charlson comorbidity index and hospital days. Among hemodialysis patients, influenza vaccination was associated with a decreased risk of hospitalization for any cause, P&I, and bacteremia/viremia/septicemia in both cohorts, and respiratory infection in the 1998 to 1999 cohort. Among peritoneal dialysis patients, only in the 1997 to 1998 cohort were there statistically significant associations between influenza vaccination and hospitalization for any cause and bacteremia/viremia/septicemia, although most of the other odds ratios were below one. Vaccination was significantly associated with a decreased risk for any-cause death and cause-specific death in hemodialysis patients in both years. Among peritoneal dialysis patients, vaccination was associated with a decreased risk for any-cause and other cause death for both years, with a decreased risk of cardiac death in the 1997 to 1998 cohort only, and not associated with infectious death. The relationship between vaccination and the combined outcome of any-cause hospitalization or death was statistically significant for both cohorts of hemodialysis patients, but only for the 1997 to 1998 cohort of peritoneal dialysis patients. Odds ratio estimates from the two influenza seasons were relatively consistent, except for the change in the direction of association noted for hospitalizations for bacteremia/virema/septicemia among peritoneal dialysis patients: lower odds in the 1997 to 1998 cohort and higher odds (but not significant) for the 1998 to 1999 cohort.

There were no consistent differences in the parameter estimates of influenza vaccination in the analyses stratified by age, comorbidity, and race in the outcomes of death, hospitalization, and cause-specific hospitalization, indicating a consistent effect of vaccination on outcomes (data not shown).

DISCUSSION

This nationally representative study of influenza vaccination in both hemodialysis and peritoneal dialysis patients provides new information regarding the vaccination rates and effectiveness of this preventive health care measure in this population. Overall, fewer than half of the patients received influenza vaccination. There was a demonstrated association of vaccination with a lower likelihood of death and hospitalization, which was more consistent among hemodialysis patients.

The vaccination rate in the ESRD population falls well below targets for the general population and is consistent with influenza rates previously reported in the United States Renal Data System 2000 and 2001 Annual Data Report [20, 21], while vaccination rates have been climbing in the general population [9]. The low rates of vaccination among dialysis patients are difficult to explain, given that cost and access to care, which are commonly thought to contribute to lower utilization of recommended medical interventions, should not be an issue. This is despite the access to influenza vaccination without a co-payment and without meeting the annual deductible as part of their Medicare benefits. The findings are even more striking since hemodialysis patients encounter the medical system three times per week and peritoneal dialysis patients are generally seen every month by their dialysis providers. However, it may be that the lower rates of vaccination in the peritoneal dialysis population reflect the reduced frequency of medical encounters relative to the hemodialysis population. Other potential reasons for low influenza vaccination rates that have been previously reported include: the subject did not know that it was needed, thought it caused the influenza, believed the shot could have adverse effects, did not think that it would prevent the flu, and did not think about it [22]. The design of the current study precludes investigation of rea-

sons for low vaccination rates, and whether non-Medicare dialysis patients receive influenza vaccinations more or less frequently than Medicare patients. Previous studies have demonstrated improvements in influenza vaccination from 27 to 77% and corresponding decreases in hospital admissions for pneumonia (abstract, Steinman et al, *J Am Soc Nephrol* 12:347A, 2001). A strategy for improving vaccination rates may be to add this intervention to the CMS Clinical Performance Measures project for quality of care of the dialysis population. These efforts by CMS and others have been associated with improvements in anemia management, dialysis adequacy, and increased utilization of simple fistulas [23].

Although influenza vaccination has been recommended for all ESRD patients, this report demonstrates marked disparities in vaccination rates, with non-whites less likely to receive influenza vaccination. This is consistent with previously reported information on influenza vaccination among Medicare recipients over 65 and in other populations [9, 24]. In addition, ESRD patients receiving peritoneal dialysis who were members of minority groups were even less likely to be immunized against influenza than minority group patients on hemodialysis. Of note, our analyses did not show a difference in the benefits of vaccination by racial group. Cost and access to care are not likely explanations for the discrepancy for the reasons cited above. Some investigators have suggested reasons for racial disparity in vaccination may include limited access to primary care, failure of clinicians to vaccinate during health care visits, limited awareness among minority patients of the need for vaccination, or misconceptions about the costs, adverse effects, risks, and benefits of vaccination [25]. In addition, racial differences have been reported for a variety of other medical interventions [26–28], and may relate to discriminatory practices, ethnic variations in risk aversion and different beliefs about treatment effectiveness that may influence decision making, and previous negative experiences with health care [29, 30]. The current study is unable to investigate reasons for these racial disparities.

This study shows the effectiveness of influenza vaccination, particularly in the associated decreased mortality risk in both peritoneal dialysis and hemodialysis patients and decreased rates of hospitalization among hemodialysis patients. These findings agree with other studies that have demonstrated that vaccination may improve survival among the elderly and chronically ill, and possibly decrease costs [4–6]. In addition, influenza vaccination has been shown to decrease the likelihood of an acute myocardial infarction [31], an important consideration given the high risk for cardiac events in the ESRD population [32]. Although we cannot demonstrate causality, the likelihood of a true association of influenza vaccination with decreased mortality is strengthened by the beneficial impact on cause-specific hospitalization, and the consistency of results over the two influenza seasons. Our findings are supported by numerous studies that have shown a protective effect of influenza vaccination against hospitalization for respiratory-related illnesses and other causes, including cardiopulmonary complications [5, 33], a relationship shown in healthy populations as well as populations with chronic conditions. The reduction in mortality and hospitalization strongly support the recommendations that all dialysis patients should receive this preventive health care measure.

Several points should be considered when interpreting our results. First, similar to any observational study, there may be baseline differences between the vaccinated and unvaccinated that cannot be adjusted in a model of observed differences. Although we cannot rule out a bias, the reductions in mortality and hospitalization from influenza vaccination are biologically plausible and the data were adjusted for important confounders such as age, race and comorbidity in our multiple logistic regression models. Second, only variables that were recorded in administrative databases were studied, and important variables like tobacco use and socioeconomic status were unavailable. Third, the low vaccination rates may reflect a low sensitivity of billing data, or ambivalence to immunize on the part of patients and providers possibly related to perceptions about lack of effectiveness in dialysis patients [34]. In a survey from a single network, facility-reported influenza vaccination rates were 74.6%, compared to rates of 40 to 50% from HCFA billing data [35]. CMS billing data may underestimate the actual rates since some patients could receive vaccinations that are not billed to Medicare, either because they are billed to another primary payor or are not billed at all. However, since the Rodgers study did not have a validation of the vaccination reports, it is difficult to interpret their results as the gold standard [35]. Moreover, assuming that the impact of vaccination would be in the same direction among those who received the vaccine but were not recorded in the data as such, then the significant findings of decreased hospitalizations and death reported herein may actually represent the minimum associations. In order to more accurately quantify vaccination rates, and more precisely determine association with outcomes, primary data collection is needed.

This study highlights the existence of a ready opportunity to improve the care of patients on dialysis, and more specifically, to focus attention on non-white and peritoneal dialysis patients. To this end it appears that quality improvement programs focused on influenza vaccination rates are needed to address this vulnerable population. The implementation of these programs could be expected to have similar success as prior efforts focused on quality of dialysis and anemia care. Further monitoring of the di-

alysis population is needed to determine if providers are addressing this important preventive health care measure.

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