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Beneficiary characteristics and vaccinations in the end-stage renal disease Medicare beneficiary population, an analysis of claims data 2006–2015

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ABSTRACT

Background: The Advisory Committee on Immunization Practices (ACIP) routinely recommends three vaccines – influenza, hepatitis B, and pneumococcal vaccines – for End-Stage Renal Disease (ESRD) dialysis patients.
Methods: We sought to assess vaccination coverage among fee-for-service (FFS) Medicare beneficiaries with ESRD who received Part B dialysis services at any point from January 1, 2006 through December 31, 2015 (through June 30, 2016 for influenza). To assess influenza vaccination rates in a given influenza season, we restricted the population to beneficiaries who were continuously enrolled in Medicare Parts A and B throughout all twelve months of that season. To assess hepatitis B and pneumococcal vaccine coverage following dialysis initiation, we developed a Kaplan-Meier curve for all patients who began dialysis between 2006 and 2015.
Results: For influenza vaccination, we identified an average of approximately 325,000 ESRD dialysis beneficiaries enrolled through each influenza season from 2006–2015. Seasonal influenza vaccination rates steadily increased during the 10-year period, from 52% in 2006–2007 to 71% in 2015–2016. The greatest increases in influenza vaccination appear in non-white beneficiaries with overall utilization in non-whites higher than in whites ($p < .001$). For the hepatitis B and pneumococcal vaccinations, we identified over 350,000 ESRD dialysis beneficiaries who began dialysis over the 10-year study window. The probability of receiving a hepatitis B vaccine within the first three years of entering into the ESRD program was higher (77%) than the probability of receiving any pneumococcal vaccine (53%). 45% of ESRD patients completed at least one dose of the two hepatitis B series (three-dose or four-dose) at any time during the study period.
Conclusions: Opportunities exist at regional and facility levels to improve vaccination coverage. Compliance to ACIP recommendations may directly affect risk for ESRD dialysis patients for complications from diseases that can be mitigated by vaccination.

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1. Introduction

Chronic kidney disease is a progressive loss of kidney function over a period of time, months or years, leading in some cases to end-stage renal disease (ESRD), the most severe stage of chronic kidney disease. At this stage of chronic kidney disease, patients require renal replacement therapy in the form of dialysis or kidney transplant. Dialysis treatment is used primarily as an artificial replacement for lost kidney function and requires treatments three times a week. ESRD patients are inherently immunocompromised from the uremic toxicity that characterizes their disease. These patients represent a high-risk group for developing infectious diseases [1]. Infection is common and is the second leading cause of death and contributor to hospitalizations in this population. [1–4]. Co-morbidities such as diabetes mellitus and the inherent process of dialysis, where patients are frequently exposed to multiple pathogenic agents and potential cross-contamination

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from dialysis equipment in the health care environment, adds to the susceptibility of this population [5–6].

The Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP) routinely recommends three vaccines – inactivated influenza, hepatitis B, and pneumococcal vaccines – for patients with ESRD [1]. Previous studies and recent outbreaks indicate low compliance to these specific recommendations, particularly among non-white patients [7–9]. Moreover, *Healthy People* targets for immunization seek to increase vaccine utilization across the lifespan and in special and vulnerable populations while eliminating health disparities. *Healthy People* are a set of science-based, 10-year national objectives with the goal of improving the health of Americans [10].

ACIP recommends a routine annual influenza vaccination with no preference indicated for any influenza product. One influenza product is licensed with four-fold increased antigen, designed for older adults (age 65 years and older) with weaker immune systems, and not specified for the ESRD population. ACIP also recommends a three- or four-dose series of hepatitis B vaccinations for dialysis patients as early as possible and preferably before the patient requires dialysis for a better immune response [1]. The pneumococcal vaccination recommendations involve two different vaccine products: a 13-valent pneumococcal conjugate vaccine (PCV13) and a 23-valent pneumococcal polysaccharide vaccine (PPSV23) [1,11–12]. The recommended intervals between PCV13 and PPSV23 differ by age, risk group and the order in which the two different vaccines are given. Adults aged ≥65 years with immunocompromising conditions are recommended to receive PCV13 first, followed by PPSV23 ≥8 weeks later. In June 2014, ACIP also recommended that all adults aged ≥65 years who already received PPSV23 should receive a dose of PCV13 ≥1 year after receipt of PPSV23 [12].

1.1. Medicare coverage

ESRD is a medical condition that confers eligibility to Medicare, a federal health insurance program that provides coverage for over 50 million Americans [13]. Medicare's ESRD Program was created in 1972 and covers dialysis in addition to all other services related to kidney failure. Medicare Part A enrollment is the hospital insurance coverage a beneficiary receives upon enrollment in Medicare. Medicare Part B is medical insurance that includes coverage for preventive services such as wellness visits, screening tests and vaccinations. The purpose of this population-based study is to describe the ESRD dialysis beneficiary population and explore differences in utilization of ACIP-recommended vaccines.

2. Methods

2.1. Database and patient selection

Our study cohort was composed of fee-for-service (FFS) Medicare beneficiaries who received Part B dialysis services at any point from January 1, 2006 through December 31, 2015 (through June 30, 2016 for influenza when the vaccine product expires). To assess influenza rates in a given influenza vaccine season (July - June), we restricted the population to ESRD dialysis beneficiaries who were continuously enrolled in Medicare Parts A and B throughout all twelve months of that season, recognizing the majority of vaccinations are observed between October and March, during the height of circulating viruses. To design Kaplan-Meier curves that calculate the probability of pneumococcal and hepatitis B vaccination following dialysis initiation, the population was subset to those who began dialysis during the study's observation period (2006–2015).

2.2. Outcomes

The study outcome measures were influenza, hepatitis B, and pneumococcal (PPSV23 and PCV13) vaccinations. Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Codes for these vaccines were extracted from Medicare Part B claims submitted during the study period. The influenza vaccination is one dose recommended annually. There are currently two formulations of the hepatitis B vaccine recommended for hemodialysis patients and other immunocompromised adults ages ≥20 years. One contains an increased dosage and is administered in a three-dose schedule (Recombivax HB, 40 μg/mL, Merck & Co., Inc, Whitehouse Station, New Jersey); the other is administered at a double standard dosage in a four-dose schedule (two Engerix-B, 20ug [1.0 mL doses] administered in one or two injections, GlaxoSmithKline Biologicals, Rixensart, Belgium). The dosing schedule for these vaccines is one and six months after the initial dose; and one, two, and six months after the initial dose, respectively.

The ACIP also recommends serologic testing after hepatitis B vaccination to determine response to the vaccine. Testing is recommended 1–2 months after administration of the last dose of the vaccine series. Persons found to have anti-HB levels of <10 mIU/mL after the primary vaccine series should be revaccinated with a second hepatitis B vaccination series [1]. We explored serological testing compliance after series completion as well as re-vaccination rates. For pneumococcal vaccines, we documented the first dose of PPSV23 and capture the 2012 introduction of PCV13 vaccine in this population.

2.3. Covariates

Demographic variables were obtained from the CMS Enrollment Database. Age was categorized into the following groups: children (0–17 years), adults who did not "age into" Medicare (18–64 years), and older adults (age 65+ years, partitioned into five-year intervals). Race was classified as white, black, Asian, Hispanic, or other. Patients were also grouped according to their Medicaid dual eligibility status. State of residence was grouped into the following geographic regions: North, Midwest, South, West, and other, with other representing beneficiaries outside the fifty states and the District of Columbia (e.g. Puerto Rico, Guam). Rural status was defined based on core based statistical area codes, as defined by the United States Census Bureau [14].

2.4. Statistical analysis

We calculated descriptive statistics to compare the annual demographic makeup of the ESRD population to the overall Medicare population. Since the influenza vaccine is distributed seasonally, we calculated vaccination rates among ESRD patients who are enrolled in Medicare throughout a given influenza season. We also calculated vaccination coverage for "any" pneumococcal vaccination, for at least one dose of PPSV23 (regardless of PCV13) status, claims of one dose of PCV13 (regardless of PPSV23 status) and one dose of hepatitis B vaccination from 2006–2015.

However, for the hepatitis B and pneumococcal vaccines, ACIP recommendations indicate that many patients receive only one vaccine (or vaccine series) per lifetime. Therefore, it was not feasible to calculate vaccination rates in the same way as the annual influenza recommendations as a patient could have been vaccinated prior to enrolling in Medicare. Therefore, we identified 357,297 ESRD patients who began dialysis on or after January 1, 2006 and designed a Kaplan-Meier survival analysis calculating the probability of receiving each vaccine following their start of dialysis. The Kaplan-Meier estimates the probability of receiving

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