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Recombinant Zoster Vaccine Coverage in the United States: an analysis of claims-based data

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Abstract

Recombinant zoster vaccine (RZV) is recommended for individuals ≥ 50 years of age for protection against herpes zoster (HZ). This study quantifies RZV coverage and assesses predictors for RZV vaccination using a U.S. claims database. Univariate linear regression provided annual prevalence of RZV vaccination and multivariable logistic regression provided ORs and 95% CIs for associations between predictors and RZV vaccination. A total of 4,124,315 individuals (19,080,914 person-years) were included in this study. Since receiving FDA approval for the prevention of HZ, RZV coverage (of at least one dose) has reached approximately 17% within the eligible U.S. population by January 2021, although significant disparities between demographic groups were noted. Our findings suggest that HZ vaccine coverage may be reduced below goal in the U.S. and highlights the importance of continuing to monitor RZV vaccination. Additionally, as our study found disparities in vaccine coverage, attention towards marginalized and medically underserved populations is needed.

Keywords

herpes zoster; recombinant zoster vaccine; vaccination coverage

Introduction

Nearly one in three Americans experience herpes zoster (HZ, or “shingles”) in their lifetime.¹ HZ incidence has more than doubled between 1994 to 2018.²

There are two shingles vaccines approved in the U.S., Zostavax[®] (zoster vaccine live, ZVL, Merck Sharp and Dohme Corp.) approved in 2006 and Shingrix[®] (recombinant zoster vaccine, RZV, Glaxo Smith Kline) approved in 2017. RZV is recommended for those aged

50.³ In clinical trials, RZV was more efficacious than ZVL. RZV efficacy remains >85% four years post-vaccination in individuals aged 70 while ZVL efficacy drops below 35% after six years.³

The CDC recommends RZV over ZVL and suggests individuals receive RZV even if previously vaccinated with ZVL or have a history of HZ.³ As of July 2020, sales of ZVL were suspended in the U.S.⁴

Historically, there has been slow uptake of HZ vaccination in the U.S., with estimates ranging from 7% to 35% in adults aged 60 in the last decade.⁵⁻⁷ Few studies have looked at trends in HZ vaccine coverage across demographics.⁵⁻⁸ Thus far, studies specifically quantifying RZV coverage in the U.S. have been limited.⁹

Given the significant morbidity caused by HZ, the implications of optimizing coverage of a highly effective vaccine such as RZV are significant. This study aimed to quantify RZV coverage and assess demographic, clinical, and socioeconomic predictors for RZV vaccination.

Methods

Study setting

This study utilized de-identified healthcare claims from Optum Labs Data Warehouse (OLDW; Optum Labs Inc, Minnetonka, MN, USA). Compared to the U.S. Census, OLDW demonstrates similar distributions in age, sex, and race/ethnicity with a higher proportion of enrollees in the South and Central regions. This study included individuals age 50 enrolled in commercial insurance, Medicare Advantage, and/or Medicare Part D who had insurance coverage during the study period of October 20, 2017 (the date of FDA approval of RZV) until January 26, 2021.³

Study design

This was a retrospective, observational cohort study assessing overall RZV coverage during the study period and secondarily identifying factors associated with RZV uptake.

To be included, participants were continuously enrolled in OLDW during the entire study period if aged 50 at the start of the study *or* continuously enrolled from the first day of the year that they turned 50 through the end of the study period. Gaps in enrollment coverage of <45 days were considered continuous. Vaccination status was determined by CPT and/or NDC codes indicating RZV administration.¹⁰ In the primary analysis, RZV vaccination was defined as a binary variable with two levels: “any vaccination” (one dose of RZV) or “unvaccinated” (no record of RZV). In secondary analyses, individuals were considered “fully vaccinated” with two doses of RZV, “partially vaccinated” with one dose of RZV, or “unvaccinated.”

Statistical analyses

Univariate linear regression was used to assess annual prevalence and 95% confidence intervals (CIs) of RZV vaccination in the population and subgroups. Multivariable logistic

regression was used to calculate odds ratios and 95% CIs for associations between predictors such as age, race, sex, geographic region, Charlson Comorbidity Index score (predicts 10-year mortality using comorbidities), insurance type, influenza and/or pneumococcal vaccination, and healthcare utilization and the outcome, RZV vaccination.^{5,6,11}

Results

In total, 4,124,315 eligible individuals (19,080,914 person-years) were included. Since RZV's introduction in 2017, vaccine coverage increased to nearly 17% of participants receiving at least one dose by the end of the study period. RZV coverage was greatest among those aged 65–69, Asians, females, homeowners, those with commercial insurance, and those residing in the Midwestern U.S. Coverage was similar among non-Hispanic Whites (17.0%) and Asians (18.2%); however, Blacks (10.2%) and Hispanics (10.5%) had significantly lower coverage. Among individuals in the full cohort, 50% were aged 50–69, 54% were female, and 77% were non-Hispanic Whites. Full RZV vaccination rose from 2.1% in 2018 to 12% in 2020. Prevalence of partial RZV vaccination rose from 1.9% in 2018 to 5.0% in 2020.

Multivariable logistic regression (Figure 1) revealed males were less likely to receive RZV (OR: 0.96, 95% CI 0.96–0.96). Compared to Whites, Asians were more likely (OR: 1.27, 95% CI 1.26–1.28) and Blacks (OR: 0.72, 95% CI 0.71–0.72) and Hispanics (OR: 0.78, 95% CI 0.77–0.78) were less likely to receive RZV. Individuals with pneumococcal (OR: 1.76, 95% CI 1.75–1.77) and influenza vaccination (OR: 3.90, 95% CI 3.89–3.92) were more likely to receive RZV. Compared to homeowners, renters were less likely to receive RZV (OR: 0.88, 95% CI 0.87–0.89). Those with commercial insurance were more likely to receive RZV than those using Medicare Advantage (OR: 2.27, 95% CI 2.26–2.28). In comparison to those aged 50–54, all groups were more likely to receive RZV. Vaccination was positively correlated with each increase in age interval except the 80–84 and 85 groups (Figure 1).

Odds of vaccination increased with outpatient hospital visits (OR: 1.05, 95% CI 1.05–1.06), office visits (OR: 1.10, 95% CI 1.10–1.11), and higher healthcare spending per individual (OR: 1.22, 95% CI 1.22–1.22). Odds of vaccination decreased with higher Charlson Comorbidity Index score (OR: 0.91, 95% CI 0.91–0.91), inpatient admissions (OR: 0.81, 95% CI 0.81–0.82), and ER visits (OR: 0.78, 95% CI 0.77–0.78).

Discussion

This study from a national insurance claims database found that ~17% of the eligible U.S. population has received at least one dose of RZV since FDA approval in October 2017. Females, Asians, and those aged 75–79 were most likely to receive RZV. Influenza and pneumococcal vaccinations, and more outpatient and pharmacy visits were associated with increased likelihood of vaccination while inpatient hospitalizations and ER visits were negatively associated with vaccination. Hispanic and Black participants were least likely to receive vaccination. Medicare patients were less likely to receive vaccination than those with commercial insurance.

There have been two major retrospective studies from large databases estimating HZ vaccine coverage, but not specifically RZV.^{5,6} A CDC brief using National Health Interview Survey data reported that HZ vaccination coverage increased from 6.7% in 2008 to 34.5% in 2018, however this was based on self-reported history of “shingles vaccination” with ZVL or RZV.⁷

Our results indicate that women are more likely to receive vaccinations.^{5,6} However, another recent study reported a similar likelihood of HZ vaccination between women and men at 35.4% and 33.5%, respectively.⁷ Our results confirm that there is racial/ethnic disparity regarding RZV vaccination, specifically in Black and Hispanic communities.⁷

Our findings corroborate that influenza/pneumococcal vaccination and more outpatient visits increased likelihood of RZV vaccination while higher Charlson Comorbidity Index score and more hospitalizations/ER visits decreased likelihood. This indicates sicker patients (or those without primary care) may not receive RZV as often.^{6,9}

Conclusions

Healthy People 2020 established a goal of 30% HZ vaccine coverage – a goal that was met in 2015.¹² However, this was achieved with ZVL, which is less efficacious than RZV and wanes over time. We can infer from our study’s estimate of 17% RZV coverage and the CDC’s estimate of 35% HZ vaccine coverage (ZVL or RZV) in 2018 that coverage may be effectively reduced below goal unless uptake is increased.^{3,7} This highlights a need for further studies measuring RZV coverage now that ZVL is discontinued. Finally, while meeting the Healthy People 2020 HZ vaccination goal is an accomplishment, this success was not seen across all demographics. We must continue to make concerted efforts to mitigate the disparities noted in our most marginalized and medically underserved groups.

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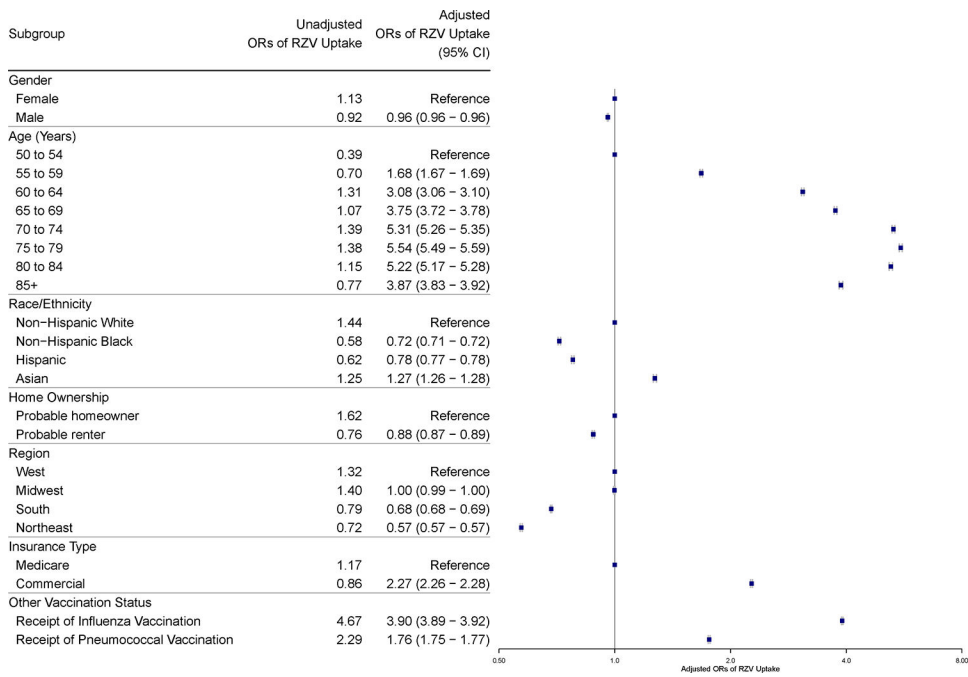


Fig. 1. Association between Demographic Characteristics and Uptake of Recombinant Zoster Vaccine.