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The effect of a prescription order requirement for pharmacist-administered vaccination on herpes zoster vaccination rates

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ABSTRACT

Objective: To determine the effect of a prescription order requirement for pharmacist-administered zoster vaccination on zoster vaccination in adults aged 60+.
Methods: A 50-state law review of statutes and regulations regarding pharmacists' ability to administer the zoster vaccine with/without a prescription order was performed. States were classified as prescription order required or not required as of January 1, 2014. Data on adults aged 60+ were obtained from the 2014 Behavioral Risk Factor Surveillance System (BRFSS). Chi-square tests and multilevel logistic regression models with and without propensity scores methods were used.
Results: Of the 50 states, 39 and the District of Columbia did not require a prescription order. After propensity score matching, zoster vaccination rates for adults ages 60 and older were significantly higher in states that did not require a prescription order (23.0% vs 21.1%, p = 0.0022). The propensity score-matched multilevel logistic regression model for adults aged 60+ found modestly higher odds of HZ vaccination for states that removed the prescription order requirement (OR 1.17, 95% CI 1.01–1.35). Similar estimates were found across other methodologies employed and age strata, although statistical significance varied.
Conclusions: Prescription order requirements are associated with HZ vaccination rates. By removing a prescription order requirement, states may be able to promote increases in HZ vaccination in adults aged 60+.

1. Introduction

Herpes zoster (HZ), also known as shingles, is a viral infection that occurs as a reactivation of the primary infection (i.e., "chicken pox") of the varicella-zoster virus (VZV) [1]. Approximately 30% of persons will experience reactivation of VZV and consequently be infected with HZ at some point in life [2]. For adults who live to age 85, their lifetime risk of developing HZ is approximately 50% [3–5].

For the prevention of HZ, the Advisory Committee on Immunization Practices (ACIP) recommended in 2008 that adults aged 60+ be vaccinated with the HZ vaccine (Zostavax®). ACIP updated these recommendations in 2018 upon the release of the new HZ vaccine (Shingrix®). In 2015, rates of HZ vaccination were approximately 30.6% in US adults aged 60+ [6], which when compared to other rates of vaccination in older adults, remain low. For example, 2015 vaccination rates for the pneumococcal vaccine (defined as ever having received a pneumonia vaccine [either the pneumococcal polysaccharide vaccine PPSV23, or the pneumococcal conjugate vaccine PCV13] among adults aged 65+) and the influenza vaccine (among adults aged 65+) were significantly higher: 63.6% and 73.5%, respectively [6]. The contrast between HZ and other vaccination rates suggest that adults aged 60+ encounter barriers specific to HZ vaccination.

A barrier that patients may encounter is lack of availability of the vaccine within their healthcare provider's office [7]. Enabling patients to obtain this vaccine in multiple locations, such as

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community pharmacies, may address this concern [8]. The US Department of Health and Human Services (HHS) identified community pharmacies as "venues for improving vaccine uptake, in addition to traditional provider sites" [9].

Currently, state laws permit pharmacists in all 50 states in the US to administer vaccines [10] with Maine being the final state to pass legislation in 2009 [10]. However, the types of vaccines pharmacists are authorized to administer, the age of the patient allowed to be vaccinated by a pharmacist, and the need for a prescription order or a patient-specific protocol from the patient's provider all vary from state to state. The American Pharmacists Association (APhA) produces a report on the legislative data regarding pharmacist authorization to administer vaccines (e.g., https://www.pharmacist.com/sites/default/files/files/IZ_Authority_012018.pdf). Data are obtained from a joint survey conducted by the APhA and National Alliance of State Pharmacy Associations. However, no formal collection of statutes and regulations, including their respective effective/enactment dates, in individual states has been published.

Previous analyses have examined the impact that authorizing pharmacist-based vaccine administration may have on influenza vaccination rates nationally and HZ vaccination rates within the Walgreens pharmacy system [8,11]. To date, however, little has been done to examine nationally the effect of laws requiring a prescription order on HZ vaccination rates.

2. Material and methods

2.1. Data source and study population

The study population consisted of adult patients surveyed in the Behavioral Risk Factor Surveillance System (BRFSS) 2014 dataset. The BRFSS was established beginning in 1984 by the Centers for Disease Control and Prevention (CDC) to monitor key health behaviors and risk factors for mortality and certain morbidities [12]. The survey has been demonstrated to be of high internal validity and quality and is representative of the US population [12].

For this analysis, we used a subset of the respondents: those who indicated to be age 60+ at the time of the survey and resided in states for which we had information on the authorization of pharmacists to vaccinate (i.e. 50 US states and District of Columbia [DC]).

2.2. Study design

To classify the exposure of subjects in the 2014 BRFSS survey data according to pharmacist authorization, a full 50-state examination on the statutes and regulations regarding pharmacist authorization to administer HZ vaccination was performed. Lexis Advance®, a legal information database, was used as a primary source of data collection (https://advance.lexis.com/). The *Healthcare Law – Medical Treatment: Immunization* compilation provided by Lexis Advance® was used as the starting point for each state search. The state statutes and regulations were searched and pertinent information regarding pharmacists and their authorization to vaccinate was collected. The effective date, approval date, enactment date, or other synonyms, were collected and collated to each change in the statutes. Once collected, the data were used to inform the immunization practices in each state as of January 1, 2014 as "Allowed" or "Rx Restricted."

This study used a cross-sectional design. Exposure was defined by state of residence of the individual at the time of the survey and the corresponding legislative landscape. Two mutually exclusive groups were created: (1) states that allowed the pharmacist to administer the HZ vaccine without requirement of a prescription order (*Allowed*); and (2) states that allowed the pharmacist to administer the HZ vaccine with requirement of a prescription order (*Rx Restricted*).

HZ vaccination rates in the study population were identified from the BRFSS survey data. A positive response to the question *"Have you ever received a shingles or zoster vaccine?"* indicated that the subject had been vaccinated. HZ vaccination rates were defined as the proportion of study patients aged 60+ with survey documentation of having previously received the HZ vaccine.

2.3. Statistical analysis

Demographic characteristics, including gender, age, race, ethnicity, income level, education level, geographic location, among others, were analyzed using descriptive statistics. Differences in vaccination rates between the exposure groups were assessed with chi-square or Student's *t*-test, as appropriate. Data were analyzed according to CDC recommendations for analysis of BRFSS data [13].

Three approaches were used to determine the effect of pharmacist authorization to administer HZ vaccines on zoster vaccination rates. The first approach was to use a complex survey-specific logistic regression model. This fixed effects model allowed for single level clustering (such as the primary sampling unit [PSU]), stratification, and weighting for selection probabilities [14]. Taking into account these three features of complex survey design was necessary in order to obtain the least biased point estimates and confidence intervals [15]. Domain analysis was performed to analyze subgroups while appropriately adjusting for standard errors [16].

In the second approach, a multilevel logistic regression model was used to examine the difference in the odds of vaccination between states with different levels of pharmacist authorization to administer vaccines. A multi-level logistic regression model allows for the inclusion of random effects that address clustering in the analysis. In this analysis, clustering occurred at the state level. That is, we expected that subjects from the same states as recorded in the survey data tended to have more similar characteristics and behaviors than those from other states. This tendency may result in the outcome of interest being subject to unobserved latent effects [17].

The third approach comprised propensity-score (PS) matched and weighted multilevel logistic regression models. The PS was generated by a complex survey logistic regression that included potential confounding variables and variables associated with the outcome variable [18]. Two additional covariate, number of pharmacies per 10,000 and primary care providers per 100,000 within a particular state, were also included. Data were obtained from National Community Pharmacists Association and Association of American Medical Colleges, respectively [19,20]. Covariates included in the propensity score were deemed balanced when standardized mean differences (SMD) were $\leq$0.10 [21]. Unbalanced covariates deemed confounders were included in the final regression model.

All results were considered statistically significant at $\alpha < 0.05$. All data analysis was performed in SAS v9.4 (SAS Institute, Cary, NC) and R Studio v1.0.136 (RStudio Team, Boston, MA). The XXX Institutional Review Board reviewed and classified this study as exempt.

3. Results

3.1. State law examination

As of January 1, 2014, 39 states allowed (*Allowed*) pharmacists to administer HZ vaccinations to patients under full prescriptive

authority or under a broad, non-patient-specific protocol (see Fig. 1). Thus, 11 states allowed pharmacists to vaccinate only under a patient-specific prescription order or protocol (*Rx Restricted*). These states were largely concentrated in the southeastern region of the US, with the exception of Ohio, New York, South Dakota, and Alaska. Of the 39 *Allowed* states, 32 permitting pharmacists to administer HZ vaccinations prior to 2012 whereas 7 began permitting HZ vaccination starting in 2012 (see supplemental Fig. A1).

3.2. BRFSS study population

In the 2014 BRFSS dataset, there were 19,426,295 adults aged 60–64 and 49,312,175 adults aged 65+ for a total of 68,738,470 adults aged 60+, after taking weighting into account. After removing individuals who did not reside in one of the 50 states or Washington DC or for whom vaccination data were missing, a total of 17,809,060 adults aged 60–64 and 42,889,170 adults aged 65+ were in the dataset. This compared well to a 2014 American Community Survey adult 65+ population estimate of 43,177,961 [22].

Although some similarities existed between the *Allowed* and *Rx Restricted* exposure groups, such as the proportions of female population ($p = 0.52$) and influenza/pneumococcal vaccination ($p = 0.08/0.80$), many differences existed. In the *Allowed* exposure group, a higher proportion of individuals indicated they were married ($p < 0.0001$), a higher proportion who identified as White ($p < 0.0001$), had higher levels of education ($p < 0.0001$), higher levels of income ($p < 0.0001$), and somewhat higher rates of other adult vaccinations (see Table 1).

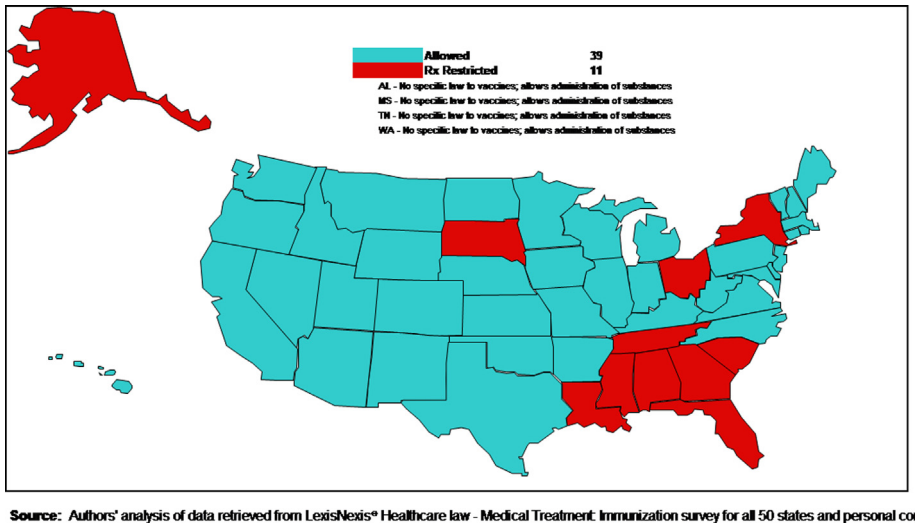

Fig. 1.

Table 1
Demographic and Clinical Characteristics of Study Population, Stratified by Rx Requirement, from Survey Respondents Aged 60+ of the Behavioral Risk Factor Surveillance System (BRFSS), 2014.

Demographic/Clinical Characteristics	Allowed	Rx Restricted	p-value
N	42,930,221	17,768,008	
Female (%)	23,657,651 (55.1%)	9,813,761 (55.2%)	0.5210
Married (%)	25,113,922 (58.5%)	10,075,422 (56.7%)	<0.0001
Race			<0.0001
White (%)	36,008,142 (83.9%)	14,343,272 (80.7%)	
Black (%)	3,450,735 (8.0%)	2,452,449 (13.8%)	
American Indian/Alaskan Native (%)	944,877 (2.2%)	203,541 (1.1%)	
Asian (%)	784,085 (1.8%)	204,798 (1.2%)	
Other (%)	1,709,509 (4.0%)	563,948 (3.2%)	
Education			<0.0001
Less than High School	5,910,510 (13.8%)	2,956,327 (16.6%)	
High School/GED	12,651,265 (29.5%)	5,671,535 (31.9%)	
Some College	13,151,101 (30.6%)	4,990,716 (28.1%)	
College Graduate	11,126,110 (25.9%)	4,080,432 (23.0%)	
Annual household income			<0.0001
Less than 25 k	10,792,636 (25.1%)	5,182,236 (29.2%)	
25 k to less than 50 k	10,836,653 (25.2%)	4,398,070 (24.8%)	
50 k to less than 75 k	5,899,283 (13.7%)	2,164,169 (12.1%)	
75 k or more	8,837,552 (20.6%)	3,016,986 (17.0%)	
Vaccinations			
Zoster Vaccine (%)	14,453,933 (33.7%)	4,861,077 (27.4%)	<0.0001
Influenza Vaccine (%)	24,310,891 (56.6%)	9,724,645 (54.7%)	0.0815
Pneumonia Vaccine (%)	24,423,182 (56.9%)	9,858,773 (55.4%)	0.8043

Table 2
Herpes Zoster Vaccination Rates between Exposure Groups among Adults Aged 60+, Stratified by Methodological Approach.

Adults Aged 60+	HZ Vaccination Rates			
	Rx Restricted	Allowed	% Difference	P-value
Unadjusted	27.4%	33.7%	6.3%	<0.0001
Inverse Probability Weighted[a]	26.7%	34.4%	7.7%	<0.0001
Matched	21.1%	23.0%	1.9%	0.0022

[a] Covariate balance after weighting, as indicated by standardized mean differences, was similar to the unadjusted but poorer for some covariates; matching produced highly balanced exposure groups.

Table 3
Logistic Regression Modeling Results Across Multiple Methodological Approaches, Stratified by Age Group.

Vaccination Law (ref: Rx Restricted)	Standard			Propensity Score	
	Simple	Multiple	Multilevel Multiple	Multilevel Matched	Multilevel Weighted
Adults Aged 60+	1.35 (1.29–1.41)	1.12 (1.07–1.17)	1.15 (0.99–1.35)	1.17 (1.01–1.35)	1.15 (1.00–1.33)
Adults Aged 60–64	1.47 (1.34–1.62)	1.18 (1.06–1.30)	1.17 (0.98–1.40)	1.06 (0.91–1.23)	1.12 (0.95–1.33)
Adults Aged 65+	1.32 (1.28–1.35)	1.12 (1.06–1.17)	1.15 (0.98–1.36)	1.26 (1.04–1.52)	1.15 (0.99–1.33)

3.3. Propensity score matching

After matching, the covariates used in the analysis were mostly balanced under our criteria of ≤ 0.10 SMD. The exceptions for adults aged 65+ were pharmacies per 10,000 and primary care providers per 100,000. Inverse probability weighting resulted in similar imbalance as the unadjusted analysis but, for some covariates, poorer balance.

3.4. Effect on vaccination rates

For adults aged 60+, the unadjusted rates of vaccination for the *Allowed* group were 33.7% vs 27.4% ($p < 0.0001$) for the *Rx Restricted* group. After weighting, the difference increased to 34.4% vs 26.7% ($p < 0.0001$) for the *Allowed* vs *Rx Restricted* groups, respectively. After matching, the difference was more modest, 23.0% vs 21.1% ($p = 0.0022$) for the *Allowed* vs *Rx Restricted* groups, respectively (see Table 2 for additional details and Tables A1 and A2 for age-stratified results). Using the age 60+ study population, these differences approximated 338,000–1,370,000 vaccinations.

For adults aged 60+, the simple weighted logistic regression resulted in an OR of 1.35 (95% CI: 1.29–1.41), indicating a 35% increase in the odds of vaccination in *Allowed* states as compared to *Rx Restricted* states. When adjusted for the potential confounders of education level, flu vaccination status, number of pharmacies in the state, and number of providers in the state, the OR decreased to 1.12 (95% CI: 1.07–1.17). The adjusted multilevel model, taking into account the random effects that may occur at the state level, retained a similar effect estimate as the adjusted model, 1.15; however, the confidence intervals were widened (0.99–1.35). The PS-matched multilevel model demonstrated a similar effect estimate as the adjusted model, 1.17 (95% CI: 1.01–1.35). The IPW model showed an OR estimate of 1.15 (95% CI: 1.00–1.33). Similar patterns were demonstrated in the subgroups of ages 60–64 and ages 65+. See Table 3 and supplemental Tables A3–A5 for more details.

4. Discussion

In this study, results indicated that where states allowed pharmacists broader authority to vaccinate (*Allowed* states), either through protocols or prescriptive authority, had modestly higher rates of vaccination as compared to *Rx Restricted* states that required a patient-specific prescription order. Each age stratum of interest (60+, 60–64 and 65+) showed a significant 6% absolute difference in the unadjusted vaccination rates between the exposure groups in favor of no Rx requirement (Tables A1 and A2). Regression results suggest that the positive effect of no Rx requirement is most consistent across all adults aged 60+ and may have led to a modestly higher odds of vaccination. In age-specific sub-analyses, the effect of the Rx requirement becomes less certain, as evidence by more non-significant regression effect estimates. However, overall, these findings support state policy decisions for broader authorization of pharmacists to administer HZ and other vaccines.

States are increasingly allowing pharmacists to perform clinical services. According to Higby, a pharmacist's role has transformed from manufacturing ingredients in the 18th and 19th Centuries, to compounding drugs in the early 20th Century, to primarily dispensing in the mid to late 20th Century [23]. Starting in the 1990s, pharmacists began to provide more patient education and counseling and perform services such as vaccination [23]. More recently, states have passed legislation to allow pharmacists to prescribe hormonal contraception [24]. These trends of novel pharmacy services typically begin in a few states and ultimately expand to the entire US as additional evidence becomes available and a movement for progressive changes develops in each state. In this study, we found that 32 states as of January 1, 2012, permitted pharmacists to administer vaccines without a patient-specific prescription order. This increased to 39 states by January 1, 2014. Since the timeframe of this analysis, additional states have passed legislation to permit pharmacists to administer vaccines.

Expanded clinical care roles in pharmacy have been shown to result in improved patient care. A Cochrane Review by Nkansah et al. concluded that involvement of pharmacists may improve clinical outcomes through enhanced medication management, patient education, and counseling [25]. This was reinforced by Haynes et al., who concluded that additional contact with patients, as may occur within the pharmacy setting, may improve medication adherence [26]. This is largely due to the higher frequency of opportunity to provide patient education, reminders, and other follow-up measures as opposed to a complex intervention [26]. The present study provides evidence that increased access to vaccination services within a pharmacy was associated with higher HZ vaccination rates. Although the results herein demonstrated a modest effect at the individual level by removing the prescription order, at the population level these differences can be significant:

increasing the vaccination rate in the *Rx Restricted* states to mirror that of the *Allowed* states could have increased the number of HZ-vaccinated individuals aged 60+ in the US by at least 338,000.

Previous research has documented the impact that state immunization laws have on vaccination rates. For example, Bradford and Mandich quantified the effect that state-allowed exemptions for childhood vaccines may have on vaccination rates and incidence of preventable diseases [27]. States that allowed for more exemptions had higher exemption rates and a higher average rate of preventable diseases [27]. Taitel et al., in their cross-sectional study using Walgreens data for adults aged 50+, found a 0.5% absolute difference in HZ vaccination rates in favor of states permitting greater authorization [8]. Steyer et al., who examined vaccination laws with respect to influenza vaccination, obtained very similar OR estimates as this study for their two age strata: 1.27 for adults aged 18–64 and 1.22 for adults aged 65+ [11]. This suggests that the effect of vaccination law may transcend individual vaccines and apply to all commonly pharmacy-administered vaccines.

This study has a number of strengths. For this analysis, we were able to use the robust survey data from the 2014 BRFSS. This data was combined with methods of causal inference to adjust for selection bias that may distort the results between the states that permit pharmacist to vaccination without a prescription and those that do not permit such practice. Results were then compared using multiple logistic regression models adjusted for potentially confounding variable and models that adjusted for random effects. The results within strata remained fairly consistent. To date, no other analysis has examined this subject so thoroughly.

The exposure groups defined in this analysis were the result of the author's analysis of state statutes and regulations. The results from this law review were mostly in accordance with the report released from the APhA (www.pharmacist.com/sites/default/files/files/Pharmacist_IZ_Authority_053114.pdf); however, some differences did exist. As opposed to previous analyses which defined exposure per APhA reports, the present analysis used the most current and up-to-date exposure definitions to examine the effect that laws may have on HZ vaccination rates.

Multiple models were developed to estimate the effect of the vaccination laws, and this robust approach was done for a number of reasons. Individuals in *Rx Restricted* states tended to be in the South, who also demonstrated, per the survey's results, lower health status and lower vaccination rates. We attempted to adjust for this through covariate adjustment and propensity scores. The overall demographics of the PS-matched sample resembled that of the entire population. Furthermore, this study attempted to account for the random effects of state residence in the multilevel model, as recommended by Steyer et al. [11] Ultimately, we were able to compare the results from these models and understand more clearly the true effect vaccination laws may have on HZ vaccination rates.

Although modest, the results of this study confirm that expanded pharmacist privileges to vaccinate may ultimately improve vaccination rates at the population level. State legislatures who have not enacted legislation to permit pharmacists to vaccinate without a prescription order should consider doing so as it may help improve the HZ vaccination rates in their state and, consequently, improve disease prevention. This holds for the current HZ vaccine and likely for any forthcoming vaccines, such as the recently approved Shingrix®. Improving vaccination rates is significant to society and to payers (both private and public) as they may reap the rewards of higher productivity and fewer medical expenditures for vaccine-preventable diseases.

4.1. Limitations

For this analysis, a number of limitations exist. This study used cross-sectional data from the 2014 BRFSS survey results. Although a robust data source, there is no temporal relationship available to determine the causal effect of the laws on vaccination rates. Moreover, th type of data may effectively bias regression estimates toward the null as misclassification of exposure is likely. For example, if someone lived in an *Allowed* state and was vaccinated but then relocated to an *Rx Restricted* state prior to the survey administration, this person would be classified as *Rx Restricted*. Future research should aim to understand the temporal relationship between vaccination laws and HZ vaccination rates.

Similarly, the exposure was defined as of January 1, 2014. This was done for simplification as no timing as to the respondent's vaccination was given. However, some states passed and enacted laws allowing HZ vaccine administration by pharmacists without a prescription order during 2014. This, under the assumption that pharmacist-administered vaccination improves vaccination rates, would bias the results toward the null. Had vaccination timing been available, the exposure periods/groups could have been more refined and the effect estimates more accurate.

Although exposure group was defined by statutes and regulations, this does not necessarily mean that all pharmacies in the state practiced as such during the time of vaccination. That is, the *de facto* practice may not follow the *de jure* authorization. For example, pharmacists have recently been authorized to begin prescribing hormonal contraception in California, Oregon, and a few other states. In a recent telephone survey of pharmacies in California conducted one year after implementation of pharmacist-prescribed HC, Gomez found that only approximately 11% of pharmacies had adopted this expanded practice [28]. This rate of adoption was consistent across pharmacy type and rural vs urban settings [28]. Therefore, the results of this analysis may be subject to the bias of state-level pharmacist-led vaccination implementation. Future research should aim to understand uptake of pharmacist-led vaccination in currently and newly authorized states and the impact this has on public health.

In the BRFSS, vaccination status is determined by self-reported measures, an inherent characteristic of the survey. Whereas with some vaccines, such as influenza and pneumococcal, self-report may be reliable, it is likely to be less-so with HZ [29,30]. In one study of patients aged 50+, the positive predictive value of self-reported zoster vaccination was 47.4% whereas the negative predictive value was 99.1% [29]. As such, patients were not able to accurately recall being vaccinated but able to accurately recall not being vaccinated. That is, given an answer of "yes" to zoster vaccination, documentation in the medical record will only be able to confirm about 47% of the time. This may be the result of either poor documentation or over-estimation on the part of patients [29]. In the present study, if overestimation trends hold for self-reported status, vaccination rates may be overestimated. This may be particularly pronounced in patients who are non-White, have a high school level of education or less, are unemployed, or who have a lower income [29]. As this would occur non-differentially, it is unlikely to affect the conclusions of the results.

5. Conclusions

Improving zoster vaccination rates remains a national goal to improve population health. In the present study, states that did not require a patient-specific prescription order appeared to have overall higher rates of HZ vaccination in adults aged 60+. These findings are less certain for specific subgroups, such as adults ages 60–64. For the remaining states that may consider removing patient-specific prescription order requirements for HZ vaccination, this research provides evidence that such action is associated with modest gains in HZ vaccination rates at the population level.

Conflicts of interest and statement of authorship

All authors declare no conflicts of interest with this work. All authors attest they meet the ICMJE criteria for authorship. CRT and KG formulated the research idea. CRT collected the data, performed data analysis, and compiled the first draft of the manuscript. CRT and JK devised the methodological approach. All authors refined the methodology, provided interpretation, and reviewed the manuscript.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2018.12.003.

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