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A national examination of pharmacy-based immunization statutes and their association with influenza vaccinations and preventive health

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ABSTRACT

Background: A series of state-level statute changes have allowed pharmacists to provide influenza vaccinations in community pharmacies. The study aim was to estimate the effects of pharmacy-based immunization statutes changes on per capita influenza vaccine prescriptions, adult vaccination rates, and the utilization of other preventive health services.
Methods: A quasi-experimental study that compares vaccination outcomes over time before and after states allowed pharmacy-based immunization. Measures of per capita pharmacy prescriptions for influenza vaccines in each state came from a proprietary pharmacy prescription database. Data on adult vaccination rates and preventive health utilization were studied using multiple waves of the Behavioral Risk Factor Surveillance System (BRFSS). The primary outcomes were changes in per capita influenza vaccine pharmacy prescriptions, adult vaccination rates, and preventive health interventions following changes.
Results: Between 2007 and 2013, the number of influenza vaccinations dispensed in community pharmacies increased from 3.2 to 20.9 million. After one year, adopting pharmacist immunization statutes increased per capita influenza vaccine prescriptions by an absolute difference (AD) of 2.6% (95% CI: 1.1–4.2). Adopting statutes did not lead to a significant absolute increase in adult vaccination rates (AD 0.9%, 95% CI: −0.3, 2.2). There also was no observed difference in adult vaccination rates among adults at high-risk of influenza complications (AD 0.8%, 95% CI: −0.2, 1.8) or among standard demographic subgroups. There also was no observed difference in the receipt of preventive health services, including routine physician office visits (AD −1.9%, 95% CI: −4.9, 1.1).
Conclusions: Pharmacists are providing millions of influenza vaccines as a consequence of immunization statutes, but we do not observe significant differences in adult influenza vaccination rates. The main gains from pharmacy-based immunization may be in providing a more convenient way to obtain an important health service.

1. Introduction

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Increasing the rate of influenza vaccination is an important public health goal in the United States [1]. One way to promote access to basic health services is to expand the scope of practice afforded to non-physician health occupations which affect wages, prices, and utilization of health services [2–8]. Starting in the 1990s, state governments have expanded the pharmacist scope of practice laws to allow pharmacists to provide vaccinations [9]. By 2010, pharmacists were allowed to provide influenza vaccines to adults in every state, the District of Columbia, and Puerto Rico. Pharmacy associations, schools, and community practitioners have encouraged these changes and trained pharmacists to provide vaccines [9,10]. When pharmacist scope of practice is restricted, pharmacies can still offer vaccinations in a limited way by hosting clinics staffed by nurses or other providers [11]. However directly allowing pharmacists to vaccinate may be beneficial because pharmacies are located in rural and urban areas, provide vaccinations without appointment, accept insurance plans or cash, and operate on expanded hours relative to primary care clinics or other vaccinators [12]. This convenience

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could increase adult vaccination rates by reaching individuals not vaccinated in traditional settings. The CDC estimates that 20% of all influenza vaccinations in the 2010–2011 influenza season were administered by pharmacists [13].

The rise of pharmacy-based immunization could also come from a re-allocation of market share (i.e. some patients may go to a pharmacy rather than alternative vaccination providers). Re-allocation could occur without increasing the number of people who are vaccinated and may have unintended negative effects. If influenza vaccination gives patients a reason to schedule physician appointments and physicians tend to bundle vaccinations with other preventive health services, then pharmacy-based immunization may result in fewer physician office visits and preventive services. Despite the possible advantages and disadvantages offered by a pharmacy delivery model, there is no nationwide study evaluating the effects of pharmacy-based immunization regulations.

The main objectives of this study were to examine the effects of pharmacy-based immunization statutes on: (1) Per capita pharmacy influenza vaccine prescriptions, (2) adult influenza vaccination rates, (3) preventive health interventions.

2. Methods

2.1. Study design

This study employs a quasi-experimental difference-in-differences (DID) design that exploits the differential timing of pharmacy-based immunization adoption across states to study the pharmacy-based immunization effects [14]. In the simplest version of DID, treatment and comparison groups are observed at two time points. Between periods, the treatment group is exposed to treatment and the control group is not. In our analysis, control groups are states and years where pharmacy-based immunization was not allowed or allowed by individual physician prescription only.

Treatment effects are estimated by subtracting the change in the control group from the change in the treatment group. This "double-differencing" adjusts for biases from time varying confounders that affect both groups, and permanent pre-existing differences between the two groups. We apply this framework to include multiple states and time periods that adjusts for fixed pre-existing differences between the states, and from time-varying "trend" factors that affect all of the states.

2.2. Measures

2.2.1. Pharmacy-based Immunization statutes

Data on state level changes in pharmacy laws related to pharmacy-based immunization that occurred between 1996 and 2013 were compiled. The American Pharmacist Association's reports, legislative databases, state boards of pharmacy, and other secondary sources were used to corroborate the timing of the policy changes [9,15,16]. Appendix A contains more detailed information about these resources. In this manuscript we evaluate all 50 U.S. states, Puerto Rico and the District of Columbia referred to collectively as states. States have used four approaches to allow pharmacy-based immunization: (i) physician prescription requirements, (ii) state-wide protocol agreements, (iii) independent pharmacist authority, or (iv) pharmacist-physician collaborative practice agreements. In the analysis, we defined flexible statutes as those that allow pharmacy-based immunization through statewide protocol agreements, independent pharmacist authority, or pharmacist-physician collaborative practice agreements. In comparison, statutes that did not permit pharmacy-based immunization at all or that allowed pharmacy-based immunization only with an individual prescription from a physician were considered restrictive. We study the effects of adopting a flexible pharmacy-based immunization policy relative to a restrictive policy.

2.2.2. Per capita pharmacy prescriptions

We estimated the number of influenza vaccines dispensed in community pharmacies using a pharmaceutical prescription sales database called the Pharmaceutical Audit Monthly Suite (PHAST). The PHAST data includes ~82% of all prescriptions filled in community pharmacies [17,18]. Influenza vaccines administered in other settings are not routinely sent as prescriptions to pharmacies, therefore this was considered a reasonable measure of vaccinations occurring by pharmacists themselves. Prescriptions for influenza vaccinations were identified in the PHAST using Uniform System of Classification Code (USC4) 027210. The counts included both intranasal and injectable influenza vaccine forms, and both single- and multiple-dose vials (high-dose vaccines were not available in the time periods studied). Previous work suggests that influenza antiviral prescriptions follow trends in influenza-like illness [19]. Pharmacy-based immunization statute changes should not directly affect antivirals and if they do then it seems likely that the statutes are correlated with unmeasured state trends in influenza related illnesses. Using PHAST data, we computed the number of influenza antiviral prescriptions dispensed in community pharmacies in each state and year. The antiviral prescriptions were identified using USC4 code 82230, which includes oseltamivir, zanamivir, rimantidine and amantadine. Adamantanes were then excluded by NDC code because they are used for other indications [2]. Raw prescription counts were changed to per capita rates using population data from the U.S. Census Bureau [19]. Data were only available from 2007 to 2013, and restricted to 2010 for models to match the vaccination rate timeframe.

2.2.3. Adult influenza vaccination rates

The Behavioral Risk Factor Surveillance System (BRFSS) was used to study the effects of pharmacy-based immunization statutes on the broader population [19]. The BRFSS is a large, annual, nationally representative cross-sectional survey that includes survey questions about influenza vaccination from all sources and receipt of a range of preventive health services. We pooled data from the 1996 to 2010 waves of BRFSS with all available states, D.C. and Puerto Rico. All of our analyses of the BRFSS data used sampling weights to account for the survey design. The BRFSS sampling design changed for the 2011 survey year so 2010 was the last year included. In addition, our main analysis is based on an unbalanced panel because some states did not fully participate in the survey in every year from 1996 to 2001. Appendix B presents estimates using only a balanced panel data from 2001 to 2010. We measured influenza vaccination status for the calendar year at the individual level in repeated cross sectional samples using the BRFSS. The survey items across years were combined to a binary variable indicating whether a person received an injection or nasal spray influenza vaccination in the previous 12 months.

We examined the effects of pharmacy-based immunization in sub-populations defined by gender, age, health insurance status, and employment status. To examine the effects of pharmacy-based immunization on people who are at increased risk of complications from influenza, we also examined a high risk sub-population consisting of pregnant women, American Indians/Alaskan Natives, people aged 65 or older, and/or people with a past medical history of asthma, stroke/myocardial infarction or angina, diabetes, or body mass index ≥40 [21]. We also fit versions of the core regression models that included controls for basic demographic characteristics including: age, gender, education, health insurance status and racial/ethnic background.

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