ESSAYS ON INFECTIOUS DISEASE AND SUBSTANCE USE POLICIES

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Katherine Jia-Lin Wen

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ESSAYS ON INFECTIOUS DISEASE AND SUBSTANCE USE POLICIES

Katherine Jia-Lin Wen, Ph. D.

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This dissertation studies the impact of public policies on health outcomes related to infectious disease and substance use.

Chapter 1: Nursing home residents face both a high risk of influenza and influenza-related mortality. Influenza vaccinations can reduce these risks, but take-up remains suboptimal, in part because people may ignore the spillover benefit of positive externalities of vaccination on disease transmission. One approach that states have taken is to mandate influenza vaccination for nursing home residents and/or healthcare workers. This paper estimates the effect of such state policies on vaccination take-up and influenza-related diagnoses and deaths. I find that resident influenza vaccination requirements increase the probability of vaccination take-up by about 6% and decrease the probability of having an influenza-like illness diagnosis by roughly 20%.

Chapter 2: State policies to optimize prescriber use of Prescription Drug Monitoring Programs (PDMPs) have proliferated in recent years. Prominent policies include comprehensive mandates for prescriber use of PDMP, laws allowing delegation of PDMP access to office staff, and interstate PDMP data sharing. This study assesses the effects of three PDMP policies on adverse opioid-related hospital events among patients with prescription opioid use. Comprehensive use mandates were associated with a relative reduction in the probability of opioid-related hospital events by 28% among patients with any opioid and 21% among patients with long-term opioid use. Delegate laws and interstate data sharing were associated with limited change in the outcome.

Chapter 3: This chapter investigates the effects of Affordable Care Act facilitated Medicaid expansions on the use of pre-exposure prophylaxis (PrEP) and medications used to treat Human immunodeficiency

Virus (HIV). We exploit state-level variations in expansion status to estimate difference-in-difference models. We find a roughly 31% increase in the utilization of PrEP and a 19% increase in the utilization of therapeutic HIV medications within the Medicaid population. We do not find statistically significant evidence that the increased utilization of PrEP following these public insurance expansions had any effect on new HIV diagnoses. We also do not find evidence that the increase in utilization of therapeutic HIV medications was associated with a reduction in HIV deaths.

BIOGRAPHICAL SKETCH

Katherine Wen received a BA in economics from Bowdoin College and MPP from the University Michigan. She completed her PhD in Policy Analysis and Management at Cornell University in 2021.

Dr. Wen is a health economist and health services researcher whose research focuses on how government interventions can reduce the burden of infectious diseases and substance use to ultimately improve public health.

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CHAPTER 1

Influenza Vaccination Requirements in Nursing Homes:
Impacts on Vaccination, Illness, and Mortality

Katherine Wen, Cornell University

Abstract

Nursing home residents face both a high risk of influenza and influenza-related mortality. Influenza vaccinations can reduce these risks, but take-up remains suboptimal, in part because people may ignore the spillover benefit of positive externalities of vaccination on disease transmission. One approach that states have taken is to mandate influenza vaccination for nursing home residents and/or healthcare workers. This paper estimates the effect of such state policies on vaccination take-up and influenza-related diagnoses and deaths. Specifically, I estimate difference-in-difference models using data from the Long Term Care Minimum Data Set, Medicare claims, Nursing Home Compare data, and the National Vital Statistics System Multiple cause of death files. I find that resident influenza vaccination requirements increase the probability of vaccination take-up by about 6% and decrease the probability of having an influenza-like illness diagnosis by roughly 20%.

1 Introduction

The annual burden of influenza is large in terms of illnesses, hospitalizations, deaths, and healthcare expenditures. The Centers for Disease Control and Prevention (CDC) estimates that 9-45 million influenza-related illnesses and 140,000-810,000 influenza-related hospitalizations occur annually in the United States.[1] In 2017, influenza and pneumonia were the eighth leading cause of death in the U.S. (55,672 deaths).[2] Additionally, from 1980-2019, influenza and pneumonia mortality exceeded that of any other infectious disease in the U.S. (Hansen et al., 2016; CDC, 2017). Influenza is also very costly; the U.S. spends an estimated $10.4 billion on influenza-related medical visits each year (Molinari et al., 2007).

Older people are at greater risk of influenza and influenza-related complications.[3] Up to 70% of influenza-related hospitalizations and up to 85% of influenza-related deaths occur among people 65 years and older (CDC, 2019b) Older people are at higher risk because the immune system weakens with age. The susceptibility of older people to infectious diseases has been further highlighted in recent events; in the United States, roughly 8 out of 10 deaths caused by COVID-19 have been among adults 65 years and older (CDC, 2020a).

Furthermore, residents in long-term care facilities face an even greater risk of acquiring influenza due to their weakened immune systems, comorbidities, close living arrangements, shared caregivers, and exposure to visitors (Strausbaugh et al., 2003; Pop-Vicas and Gravenstein, 2011). Importantly, residents are in long-term care facilities because they require personal or medical assistance beyond what they can receive at home. Consequently, they are frailer than community dwelling older people. Mortality rates of nursing home residents during a seasonal influenza outbreak can exceed 5% (Kingston and Wright, 2002).

[1] Numerous factors contribute to the wide range of estimates, such as the circulating viruses, timing of the influenza season, effectiveness of influenza vaccines, and vaccination rate, among others.
[2] Influenza is infrequently documented on death certificates. Consequently, influenza deaths are typically grouped with pneumonia deaths. This is discussed further in Section 3.6.
[3] Common influenza-related complications include pneumonia, bronchitis, sinus and ear infections, sepsis, and heart attacks, among others.

This is concerning given that there are approximately 1.3 million individuals living in nursing homes and 84% of these residents are 65 years and older (CDC, 2019).

The trajectory of pandemics, epidemics, and seasonal illnesses, such as influenza, are dependent on the population's protective behavioral response to disease prevalence (Philipson, 2000; Perrings et al., 2014; Hauck, 2018). One way to reduce disease prevalence is through vaccination. The goal of widespread vaccination is to achieve a threshold of population immunity ("herd immunity") such that a disease can no longer persist. Since 2011, the CDC's Advisory Committee on Immunization Practices has recommended annual influenza vaccination for all persons who are at least six months old and who do not have contraindications.[4] However, individuals may have an incentive to ``free ride'' if they can benefit from herd immunity and the vaccination of others while avoiding the cost associated with vaccination. Since people do not fully internalize the benefit of vaccination, government interventions such as mandates and Pigouvian subsidies have been implemented to address the under-consumption of vaccines relative to the socially optimal level (Sloan, 2012).

Mandatory vaccinations are one policy tool to reduce the burden of infectious diseases. Public policy has largely focused on mandatory vaccinations for children rather than for adults.[5] Adult vaccination, however, is important because adults 65 years and older and those with weakened immune systems are at high risk of serious influenza-related complications.[6] For the 2017-18 influenza season, vaccinations prevented an estimated 7 million illnesses, 3 million outpatient medical visits, 109,000 hospitalizations, and 8,000 respiratory and circulatory deaths (Rolfes et al, 2019). Yet, nationally, only 37% of people 18 years and older and 59% of people 65 years and older received an influenza vaccination

[4] A contraindication is a condition that puts the vaccine recipient at risk for a serious adverse reaction. Such conditions include life threatening allergies to the flu vaccine or any ingredient in the vaccine, history of Guillain-Barré Syndrome, pregnancy during the first trimester, and various states of immunosuppression.

[5] For example, immunizations are required for children and adolescents to attend school. In general, state vaccination requirements for school children not only apply to children attending public schools but also to those attending private schools and day care. Additionally, programs such as the Vaccines for Children Program and Section 317 of the Public Health Services Act subsidize childhood vaccinations.

[6] High-risk groups include adults 65 years and older, pregnant women, young children, children with neurological conditions, and those with or a history of asthma, heart disease or stroke, diabetes, HIV/AIDS, and cancer.

during the 2017-18 season (CDC, 2019a). These rates fall below target vaccination rates.[7,8] Further, vaccination rates varied considerably across states, ranging from 29% in Louisiana to 46% in West Virginia (CDC, 2019c). Vaccination rates, however, are higher in nursing homes; for the 2017-18 season, an estimated 73% of nursing home residents were vaccinated, ranging from 49% in Nebraska to 89% in South Dakota (CDC, 2019d). To address the under-consumption of vaccinations, states have implemented laws requiring influenza vaccination in various settings such as hospitals, ambulatory care, and long-term care facilities. The latter are the focus of this paper.

This research provides causal estimates of the impacts of state-level influenza vaccination requirements for residents and healthcare workers in long-term care facilities on influenza vaccination take-up and health outcomes of residents (i.e., influenza-related illnesses and deaths). Ex ante, the effects of vaccination requirements on vaccination take-up may be minimal because influenza vaccination rates in long-term care setting settings are relatively high compared to those in community settings. The net effects of vaccination requirements on health outcomes are ambiguous. On the one hand, increases in vaccination take-up could decrease influenza-related diagnoses and deaths. On the other hand, vaccination may crowd out other protective behaviors such as hand washing or cause facilities to relax other infection control measures that could negatively affect health outcomes. To estimate these effects of the requirements on vaccinations and health outcomes, I use difference-in-differences methods using exogenous variation from the implementation of state-level vaccination requirements. I use administrative micro data from the Long Term Care Minimum Data Set (MDS) and claims data from Medicare fee-for-service beneficiaries, as well as Nursing Home Compare data and the National Vital Statistics System (NVSS) multiple cause of death files. These data provide detailed information surrounding the health care utilization and health outcomes of nursing home residents.

[7] In 2010, the U.S. Department of Health and Human Services launched an initiative called Healthy People 2020, which set target vaccination rates at 80% for adults 18-64 and 90% for high-risk adults 18-64 and adults 65 years and older.

[8] A survey conducted by the University of Chicago's National Opinion Research Center (NORC) found that for the 2019-20 season, 37% of adults reported that they did not intend to receive an influenza vaccination and the most

I find that resident influenza vaccination requirements increase vaccination take-up by 4-5 percentage points (about 6%) and decrease influenza-related diagnoses and deaths by 4-5 percentage points (approximately 20%) and 0.1-0.2 percentage points (about 10%), respectively. Additionally, I find that healthcare worker vaccination requirements decrease influenza-related illnesses and deaths by 2-4 percentage points (approximately 18%) and 0.1-0.2 percentage points (about 10%), respectively, though the estimated impacts of the healthcare worker vaccination requirements are only significant in models that do not control for resident requirements. These results speak broadly to the question of how government interventions can reduce the spread of infectious disease and improve public health.

This research contributes to three strands of literature. First, this paper relates to the literature on economic epidemiology and the economics of infectious disease which applies concepts from economics like behavior under uncertainty and externalities to provide insight on how people respond to the risk of infectious diseases. Vaccination is a large focus of this literature as they are an effective disease mitigation tool, but private (individual) vaccination take-up decisions are based on complex factors such as disease prevalence. Several studies find that the demand for vaccination is an increasing function of disease prevalence (Philipson, 1996; Geoffard and Philipson, 1997; Boulier et al., 2007; Oster, 2018; Schaller et al., 2019). However, beyond a certain threshold, the marginal benefit of vaccinating additional people decreases (Boulier et al., 2007; Ward, 2014) and approaches zero when herd immunity is achieved (Sloan, 2012). Importantly, the benefit accrues to both people who have been vaccinated as well as those who are not vaccinated. Additionally, this literature examines how policies like subsidies and mandates can improve public welfare (e.g. Philipson, 2000; Perrings et al., 2014; Hauck, 2018). My paper complements the current literature on vaccination take-up decisions from a policy angle by examining the extent to which vaccination requirement policies can increase vaccination take-up.

Second, this paper contributes to the emerging literature on the impacts of vaccination requirements and campaigns. Typically, these requirements and campaigns have targeted two groups:

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commonly cited reasons were concerns about the side effects from the vaccine and efficacy of the vaccine (NORC,

children and healthcare workers. For the former, vaccination requirements for children have been effective in increasing vaccination rates for hepatitis A (Lawler, 2017), varicella (Abrevaya and Mulligan, 2011), and tetanus, diphtheria, and pertussis (Carpenter and Lawler, 2019). Vaccination campaigns have also been effective in increasing influenza and tuberculosis vaccination take-up (Loeb et al, 2010; Ward, 2014; Butikofer and Salvanes, 2018). For healthcare workers, however, there is mixed evidence regarding the effectiveness of healthcare vaccination requirements on patient outcomes (De Serres et al, 2017; Thomas et al., 2016).[9] Carrera et al. (2021), however, find that laws requiring hospitals to offer influenza vaccinations to employees were associated with a reduction in the pneumonia and influenza mortality rate. Most similar to this research, White (2020) estimates the effects of county-level influenza vaccination requirements for healthcare workers in California on outcomes measured at the hospital level. White (2020) finds that these requirements increased hospital worker vaccination take-up by 10.3 percentage points and decreased influenza inpatient admissions by 20%.[10] This paper builds upon this literature by providing causal estimates of the impacts of influenza vaccination requirements for residents and healthcare workers in the context of nursing homes. This setting is of particular interest for two reasons. First, residents are at high-risk of influenza and severe influenza-related complications due to their age and health needs. Second, healthcare workers in long-term care settings have lower influenza vaccination coverage (68%) than healthcare workers in other healthcare settings such as hospitals (95%),

2019).

[9] Although studies find that healthcare worker vaccination requirements are effective in increasing vaccination rates, there is limited evidence that this translates to improvements in patient outcomes in long-term care settings. De Serres et al. (2017) and Thomas et al. (2016) review four cluster randomized controlled trials of healthcare worker influenza vaccination in long-term care facilities. They conclude that these studies find implausibly large reductions in patient risk to healthcare worker vaccination and that these studies violate the principle of dilution (reductions for less-specific outcomes such as all-cause mortality exceed reductions from influenza-like illness which exceed reductions for laboratory confirmed influenza). They also critique these studies for failing to include information about co-interventions such as handwashing, wearing face masks, and recommending sick workers to stay home when sick, among others.

[10] Prior to the implementation of vaccination requirements for healthcare workers, the mean vaccination rate for hospital workers in treatment group hospitals was 74.0%, and the mean number of influenza diagnoses in inpatient admissions (at the hospital-flu year level) was about 22. Though not discussed in the paper, I suspect the reason the vaccination rate was not 100% after the implementation of the requirement was likely due to allowable exemptions and variation in compliance.

ambulatory care or physician office (80%), and other clinical settings[11] (88%) (Black et al., 2018, CDC, 2019).

Third, this research extends the literature surrounding the economic impacts of influenza infection. People 65 years and older account for most influenza cases annually but can also spread the virus to younger people, which has health and labor market implications. In-utero exposure to both pandemic and seasonal influenza has negative impacts on childhood health such as low birth weight and premature birth (Almond, 2006; Currie and Schwandt, 2013), adult health such as kidney disease, diabetes, and respiratory problems (Almond and Mazumder, 2005; Lin and Liu, 2014), and later-life outcomes such as earnings reductions, greater welfare dependence, increased rates of disability, and lower socioeconomic status (Almond and Mazumder, 2005; Schwandt, 2018). While I do not directly examine the economic impacts of influenza infection, this existing literature suggests that the estimated benefits of vaccination requirements are likely to be a lower bound of the true benefits of these requirements. Averted diagnoses and deaths not only decrease health care spending but can also generate positive externalities related to health and labor market outcomes.

This paper proceeds as follows. Section 2 provides background information. Section 3 describes the data. Section 4 outlines the empirical strategies. Section 5 presents the results. Section 6 concludes.

2 Background

2.1 Nursing Homes

Long-term care facilities provide nursing, rehabilitative, and social services for people who are unable to live independently. In this paper, I focus on patients in nursing homes since these types of patients are observable in my data. The term ``nursing home" often includes both nursing facilities and SNFs. Commonly, facilities offer both activities of daily living assistance, which is emblematic of nursing facilities, as well as medically necessary therapy, which is associated with SNFs. The main differences

[11] E.g., dental clinic, laboratory, emergency medical services.

between the two types of facilities are the time a resident is expected to reside in the facility and the main payer (Medicare or Medicaid). In 2016, there were over 15,600 nursing homes, and these facilities provided care to over 1.3 million residents (CDC, 2019). Roughly two-thirds of nursing home residents are female, and three-quarters of residents are over age 65 (CDC, 2016).

2.2 Vaccinations

Influenza is a potentially serious illness affecting millions each year, but vaccines reduce the risk of illness. The vaccine protects against either three or four viruses: influenza A (H1N1 and H3N2) and one or two strains of the influenza B virus.[12] Containing either an inactive or weakened form of the influenza viruses, the vaccine triggers the immune system to produce antibodies that protect against influenza viruses. When a vaccinated person encounters an influenza virus, the body can quickly produce antibodies to protect against the virus.

Multiple factors influence vaccine effectiveness. First, effectiveness depends on the characteristics, such as age and health, of the person being vaccinated. The vaccine is less effective for those with weakened immune systems due to age or underlying health conditions. Despite the weakened immune response of older people, the vaccine still confers protection and reduces the severity of illness if infected.[13] Second, effectiveness can vary from season to season depending on how well matched the influenza vaccine is to the circulating influenza viruses. Prior to each flu season, researchers predict which influenza viruses are mostly likely to circulate and cause illness. The vaccine is then reformulated to adjust for genetic changes in the influenza virus. On average, the vaccine reduces the risk of influenza by 40% to 60% when the vaccine is well-matched to circulating viruses (CDC, 2020). The vaccine offers fewer protections against influenza when the vaccine is not well matched to the circulating virus. The

[12] The quadrivalent vaccine is the standard vaccine and offers broader protection (relative to trivalent vaccine) since it includes both influenza B viruses. The trivalent vaccine is a high dose vaccine that contains a higher amount of antigen to produce a stronger immune response. The trivalent vaccine is specifically designed for people 65 years and older.

[13] Some people who receive the influenza vaccine still contract the illness. Studies show, however, reductions in influenza deaths, intensive care unit admissions, length of stay, and overall duration of hospital stay for vaccinated

effectiveness of the vaccine also varies by the type of circulating virus; the vaccine is more effective in reducing illness caused by influenza A(H1N1) and influenza B while protection against influenza A(H3N2) has been less consistent (CDC, 2020).[14]

Although vaccinations are an effective protective behavior that have reduced the burden of infectious disease, they impose both private costs and benefits to the vaccinated. Private vaccination costs include monetary (e.g., potential copay, transportation) and non-monetary (e.g. inconvenience, discomfort, potential side-effects) costs.[15] The benefits of vaccination include both private and external benefits. A vaccinated person receives a private benefit in the form of reduced risk of illness and related hospitalization. In the event of illness, vaccination reduces the severity of the illness. Vaccinations also generate external benefits by protecting people who have not been vaccinated and are a textbook example of "positive externalities".[16] Such external benefit relates to the reduced risk of spreading an illness to others who have not been vaccinated. When more people are vaccinated (and are thus uninfected and resistant or immune to illness), a virus is less likely to spread and cause illness among both vaccinated and un-vaccinated people. Despite these external benefits, we assume that people make their calculation about the private benefits and costs but do not take into consideration the benefits to others. Consequently, because people do not fully internalize the benefit to others, the demand for vaccines falls below the socially optimal level absent government interventions such as subsidies and mandates.

2.3 Vaccination Requirements

Currently, 32 states have laws requiring influenza vaccination for residents and 25 states have laws requiring vaccination for healthcare workers in long-term care facilities (CDC, 2018a). The content of

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people relative to those who had not been vaccinated (CDC, 2020).

[14] footnote{Influenza A(H3N2) exhibits antigenic change more frequently than influenza A(H1N1) and influenza B viruses. As a result, the composition of the influenza A(H3N2) component of the vaccine is less likely to resemble the circulating influenza A(H3N2) virus.}

[15] Under the Affordable Care Act, health insurers are required to provide all federally recommended vaccines at no cost. Medicare Part B covers vaccination for seasonal influenza, hepatitis B, and pneumococcal disease with no copay or deductible.

[16] See Gruber (2005), Bhattacharya et al. (2013), Folland et al. (2016), and Besanko and Braeutigam (2020).

state laws was collected from the CDC Public Health Law Program's ``Menu of State Long-Term Care Facility Influenza Vaccination Laws". This document contains the legal citation of the statute or regulation documenting vaccination requirements for residents and healthcare workers in long-term care facilities. Tables 1 and 2 document the year of policy implementation for residents and healthcare workers, respectively, which were determined through a process of searching legal databases such as Nexis Uni and HeinOnline, as well as independent research.

Across states there is heterogeneity in the stringency of the vaccination requirements. Most of these requirements pertain to either all long-term care facilities or nursing homes, specifically. There are two types of vaccination requirements: administrative offer and administrative ensure. States with administrative offer requirements must offer vaccination to residents and/or healthcare workers, while states with administrative requirements to ensure vaccination must provide proof of vaccination or documentation of exemption (Lindley et al., 2007). All states with vaccination requirements allow medical exemptions, and some states also allow religious and philosophical exemptions. Additionally, the population of healthcare workers subject to vaccination requirements varies across states; some states require vaccination for all healthcare workers while others only require vaccination for workers with occupational exposure or direct patient contact. These requirement types and exemptions are also documented in Tables 1 and 2 for residents and healthcare workers, respectively.

3 Data

3.1 Long Term Care Minimum Data Set

The Long Term Care Minimum Data Set (MDS) is a federally mandated health screening and assessment tool used for all residents in Medicare and Medicaid certified nursing homes. The assessment is administered at admission, discharge, and three-month intervals during the stay (or more frequently if the resident experiences a major health status change). The MDS provides a comprehensive clinical

Table 1. Resident influenza vaccination requirements

State	Year Effective	Requirement Type			Exemptions		
		Assessment	Offer	Ensure	Medical	Religious	Philosophical
Alabama	2001			X	X	X	X
Alaska							
Arizona	2000/2013		X		X		X
Arkansas	2005			X	X	X	X
California	2005		X		X		X
Colorado							
Connecticut	2002			X	X	X	
Delaware	2005			X	X		X
District of Columbia	2002			X	X	X	X
Florida	2001			X	X	X	X
Georgia	2004/2013		X		X		
Hawaii	2011			X	X		X
Idaho							
Illinois	2003			X	X		X
Indiana	1999			X	X	X	X
Iowa							
Kansas							
Kentucky	2002			X	X	X	X
Louisiana							
Maine	2002		X		X		X
Maryland	2000			X	X	X	X
Massachusetts							
Michigan	2001		X				
Minnesota							
Mississippi							
Missouri							
Montana							
Nebraska	2012		X		X		
Nevada							
New Hampshire	2005			X	X	X	
New Jersey	2002			X	X		X
New Mexico							
New York	2000			X	X	X	X
North Carolina	2000			X	X	X	X
North Dakota							
Ohio	2006		X		X		X
Oklahoma	1999		X		X		X
Oregon							
Pennsylvania	2002			X	X	X	X
Rhode Island	2000			X	X	X	X
South Carolina	2008			X	X		X
South Dakota	1987			X	X	X	X
Tennessee	2003			X	X		X
Texas	1999			X	X		X
Utah	2002		X		X		X
Vermont							
Virginia	2004			X	X		X
Washington	2002		X				
West Virginia							
Wisconsin							
Wyoming							

Notes: Author's determination based on searches of legal databases such as Nexis Uni and HeinOnline, as well as independent research.

Table 2. Healthcare worker influenza vaccination requirements

State	Year Effective	Requirement Type			Exemptions			
		Assessment	Offer	Ensure	Surgical Mask	Medical	Religious	Philosophical
Alabama	2001			X		X	X	X
Alaska								
Arizona								
Arkansas	1999			X		X	X	
California	2010		X			X		X
Colorado	2012			X	X	X		
Connecticut								
Delaware	2018	X		X				X
District of Columbia	2002			X		X	X	X
Florida								
Georgia	2013		X					X
Hawaii								
Idaho								
Illinois	2010		X			X	X	x
Indiana								
Iowa								
Kansas								
Kentucky	2002			X		X	X	X
Louisiana								
Maine	2002			X		X	X	X
Maryland	2000			X		X	X	X
Massachusetts	2007			X		X	X	X
Michigan								
Minnesota								
Mississippi								
Missouri	2016		X			X		X
Montana								
Nebraska	2017							
Nevada								
New Hampshire	2005			X		X	X	
New Jersey								
New Mexico								
New York	2000			X		X	X	X
North Carolina	2000			X		X	X	X
North Dakota								
Ohio								
Oklahoma	1999/2001		X			X		X
Oregon	2014	X				X		X
Pennsylvania	2002			X		X	X	X
Rhode Island	2000			X		X	X	X
South Carolina	2008			X		X		X
South Dakota								
Tennessee	2007			X		X		X
Texas	2000			X		X		X
Utah	2002		X			X		X
Vermont								
Virginia								
Washington								
West Virginia								
Wisconsin								
Wyoming								

Notes: Author's determination based on searches of legal databases such as Nexis Uni and HeinOnline, as well as independent research.

assessment of each resident's functional capabilities and health conditions.[17] Importantly, the assessment documents whether a resident received an influenza vaccination in the facility and date of vaccination.

This study uses MDS data from 2011 through 2014 for a sample of Medicare fee-for-service (FFS) beneficiaries. Appendix A further discusses the sample of beneficiaries included in this data. The MDS data capture assessments for approximately 3.6 million unique individuals between 2011 and 2014 and contain approximately 7.7 to 8.5 million assessments per year.

3.2 Medicare Claims

The Medicare claims capture claims submitted by providers as well as from inpatient and outpatient facilities for Medicare FFS beneficiaries. While the primary purpose of Medicare claims is to provide reimbursement for medical services, they also provide detailed information about the diagnoses received and procedures performed on a patient.

This study uses Medicare claims from 2011 through 2014. I begin with a random sample of 20 million Medicare fee-for-service beneficiaries in 2011. This represents over 50% Medicare fee-for-service beneficiaries in 2011.[18] I then identify the subset of these beneficiaries who experienced a nursing home stay between 2011 and 2014. As a result, I have both assessment and claims for roughly 3.6 million unique beneficiaries between 2011 and 2014.

3.3 Nursing Home Compare

Nursing Home Compare contains information about every Medicare and Medicaid certified nursing home in the country. This includes information about the quality of nursing homes, which is captured by star ratings, inspection results (health, fire safety, and emergency preparedness), and penalties, as well as staffing and resident quality of care measures.[19] Among the resident quality of care measures are the

[17] For example, the data include detailed information about resource utilization group code, measures of clinical status, physical functioning, psychological status, and diagnoses and medications.
[18] In 2011, there were 35.5 million beneficiaries enrolled in original fee-for-service Medicare.
[19] Additionally, Nursing Home Compare captures whether nursing home participates in Medicare, Medicaid, or

percentage of long-stay and short-stay residents who received an influenza vaccine for the current flu season.[20,21] Long- and short-stay residents differ in their underlying health conditions and reasons for being in the nursing home. Long-stay residents typically receive residential care, and they enter a nursing home because they are no longer able to care for themselves at home. In contrast, short-stay patients typically receive post-acute or rehabilitative care, and their goal is to return to their previous setting. This study uses Nursing Home Compare data from 2006 through 2017, which captures quality measures for almost 18,000 nursing homes.[22]

3.4 National Vital Statistics System (NVSS) Multiple Cause of Death Files

These data contain individual death certificate records for the full census of U.S. deaths. The data contain detailed information about the death, including underlying cause of death, twenty additional multiple causes of death, and place of death. The restricted version additionally includes geographic identifiers such as state and county of residence. This study uses multiple cause of death files from 1999 through 2016, which capture 2.4-2.7 million death records per year.

3.5 Construction of Outcomes

The outcomes of interest include influenza related vaccination, illnesses, and deaths. Importantly, I only observe outcomes for nursing home residents. Although healthcare worker vaccination requirements are of interest, I do not observe outcomes among healthcare workers. Appendix Table A1 summarizes the data sources, years available, and level of aggregation.

3.5.1 Vaccination

The first-stage outcome - influenza vaccination - is derived at both the resident- and facility-level. At the resident-level, vaccinations are identified using both the MDS and Medicare claims. The MDS captures

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both, whether the nursing home is located within a hospital, and the type of ownership, among other information.

[20] Long-stay residents are those who had a stay of 101 days or more. Short-stay residents are those who had a stay of 100 days or less or are covered under the Medicare Part A Skilled Nursing Facility benefit.

[21] The percentage of residents who received the seasonal influenza vaccine are derived from the MDS.

whether the resident received an influenza vaccination at the facility and date of vaccination. Vaccination prior to nursing home admission or not captured in the MDS are observable in the Medicare claims. Specifically, influenza vaccination is identified using diagnosis and procedure codes from the Medicare inpatient, outpatient, and carrier files (see Appendix Table A2) for diagnosis and procedure codes and descriptions). A resident is considered to have been vaccinated if either an MDS assessment or Medicare claim indicates influenza vaccination in each calendar-quarter. Additionally, a resident is considered to have been vaccinated in all subsequent quarters within a flu season after the earliest influenza vaccination date. For example, if a resident received an influenza vaccine in November 2011 (2011 Q4), the resident is considered to be vaccinated in the remaining quarters of the 2011-12 influenza season (2012 Q1 through Q2 or Q3).[23] At the facility-level, Nursing Home Compare reports the percent of short- and long-stay residents who needed and received the influenza vaccine for the current flu season in a given calendar-quarter.[24]

3.5.2 Illnesses

Influenza and influenza-like illness (ILI) diagnoses are derived using Medicare claims at the resident-level. Although diagnostic codes specific to influenza are available in Medicare claims, these under count the occurrence of influenza, particularly in outpatient settings.[25] Consequently, I also consider the outcome of influenza-like-illness (ILI), which is defined by having a fever (temperature ≥100°F) and cough and/or sore throat with no other known cause of illness other than influenza. The outcome is a binary indicator for each influenza-related diagnosis. The variable is equal to one if a resident has a given

[22] Nursing homes may open and/or close and therefore may not consistently be in the data for all years.
[23] This measurement of vaccination assumes that vaccination protection lasts for the duration of the flu season. Typically, protection from the vaccine lasts for at least six months, so people vaccinated at the start of the flu season (which begins around October) will have protection for the duration of the flu season. Protection, however, declines over time due to decreasing antibody levels and changes in the circulating influenza viruses (Immunization Action Coalition, 2020).
[24] However, Nursing Home Compare suppresses quality measure scores for small nursing homes (<30 residents for long stay measures and <20 residents for short stay measures).
[25] An influenza diagnosis requires a lab-confirmed test for influenza, which is expensive and typically only matters for inpatient admissions since the diagnosis can affect how patients are assigned to hospital rooms.

diagnosis in any setting (inpatient admission or outpatient visit) using both primary and secondary diagnostic codes (see Appendix Table A3 for ICD codes and descriptions).

3.5.2 Deaths

At the resident-level, influenza-related deaths are identified using Medicare claims and enrollment files. Deaths are identified using date of death in the Medicare enrollment files. Deaths occurring within 30 days of an influenza or ILI event are characterized as an influenza-related death.[26]

Additionally, I supplement Medicare claims and enrollment files with the restricted-use version of the multiple cause of death mortality files from the National Vital Statistics System (NVSS) to derive state-level influenza-related mortality. Because influenza is rarely documented on death certificates, I identify influenza and pneumonia deaths since this has the highest level of specificity (rather than influenza-specific mortality.[27] However, influenza/pneumonia deaths can still exclude deaths related to influenza illness. In robustness checks, I also explore deaths with any respiratory or circulatory diagnosis.[28]

3.6 Summary Statistics

Table 3 shows summary statistics of the outcome variables, averaged across all resident-quarters and derived from the MDS and Medicare claims data. Approximately 72% of residents received an influenza vaccination. This is similar to the CDC's estimates of nursing home vaccination rates which have remained between 71% and 78% since the 2005-06 influenza season (CDC, 2020b). 1% and 23% experienced an influenza and influenza-like-illness, respectively. 2% had an influenza-related death.

[26] A 30-day window was chosen for consistency with studies of influenza-related deaths among Medicare beneficiaries, see Shay et al. (2017) and Bolge et al. (2020).

[27] The ICD-10 code used to classify influenza are 487-488. The ICD-10 codes used to document influenza/pneumonia are 480-488. There are multiple reasons why influenza is infrequently documented on death certificates. First, states are not required to report influenza illnesses or deaths among people ages 18 and older. Second, people often die of influenza-related complications rather than influenza alone, and influenza is rarely documented on death certificates in these instances. Third, many people who die of influenza are not tested for influenza or delay seeking medical care and influenza tests are most accurate within a week of the onset of illness (CDC, 2018b).

Table 3. Summary statistics for all residents

	Mean	Std Dev
Covariates		
Female	0.68	0.47
Age	80.90	11.46
Anemia	0.32	0.47
Asthma	0.23	0.42
Coronary artery disease	0.25	0.43
Diabetes mellitus	0.33	0.47
Heart failure	0.23	0.42
Any chronic condition	0.69	0.46
State median income ($)	57,744	9,309
Number of nursing home residents	26,694	26,875
Outcomes		
Influenza vaccination	0.72	0.45
Influenza diagnosis	0.01	0.07
Influenza-like illness diagnosis	0.24	0.43
Influenza-related death	0.02	0.14

Notes: Data is from the Long-Term Care Minimum Data Set, Medicare claims, Census Bureau, and U.S. Bureau of Labor Statistics

Table 4 shows summary statistics, averaged across residents in states that implemented a resident vaccination requirement before 2011, between 2011 and 2014, and after 2014 or never. Across all groups, most nursing home residents are female, the average age is about 81, and most residents have at least one underlying chronic condition.

[28] The ICD-10 codes that classify respiratory and circulatory diagnoses are 390-519.

Table 4. Summary statistics for residents by treated status

	Pre-2011 (controls)		2011-14 (treated)		Post-2014 or never (controls)	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
Covariates						
Female	0.67	0.47	0.68	0.47	0.67	0.47
Age	80.84	11.43	80.50	11.31	81.18	11.58
Anemia	0.33	0.47	0.30	0.46	0.29	0.46
Asthma	0.23	0.42	0.23	0.42	0.23	0.42
Coronary artery disease	0.25	0.43	0.23	0.42	0.22	0.42
Diabetes mellitus	0.33	0.47	0.33	0.47	0.31	0.46
Heart failure	0.23	0.42	0.22	0.41	0.23	0.42
Any chronic condition	0.70	0.46	0.68	0.47	0.67	0.469
State median income ($)	58,467	9,591	55,382	4,135	57,014	9,366
Number of nursing home residents	35,434	31,381	17,361	8,290	14,830	12,465
Outcomes	0.00	0.00	0.00	0.00	0.00	0.00
Influenza vaccination	0.70	0.46	0.73	0.45	0.76	0.43
Influenza diagnosis	0.01	0.08	0.00	0.07	0.00	0.07
Influenza-like illness diagnosis	0.53	0.43	0.22	0.41	0.21	0.41
Influenza-related death	0.02	0.14	0.02	0.13	0.02	0.13

Notes: Data is from the Long-Term Care Minimum Data Set, Medicare claims, Census Bureau, and U.S. Bureau of Labor Statistics

4 Empirical Strategy

4.1 Difference-in-differences specification

Three states (Arizona, Georgia, and Nebraska) adopted regulations regarding resident vaccination requirements and three states (Colorado, Georgia, and Oregon) adopted healthcare worker vaccination requirements during the study period (2011 and 2014).[29] Figures 1 and 2 show which states implemented requirements prior to 2011, between 2011 and 2014, and after 2014 or never, for residents and healthcare workers, respectively.

[29] Arizona and Georgia implemented *regulations* pertaining to resident vaccination requirements in 2013. Both states, however, had *laws* pertaining to resident vaccination requirements prior to 2011. In my main analyses, I use the 2013 implementation dates for Arizona and Georgia, but I also estimate additional specifications that consider implementation prior to 2011.

Figure 1. Implementation years of influenza vaccination requirements for residents

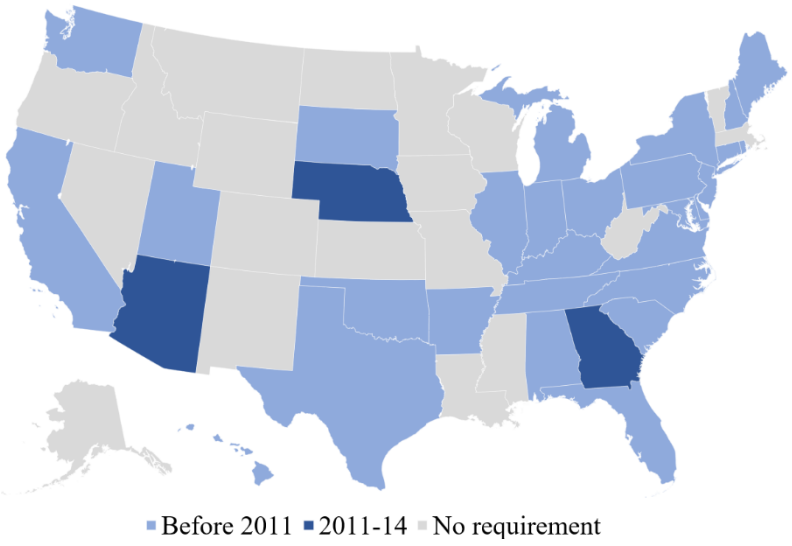
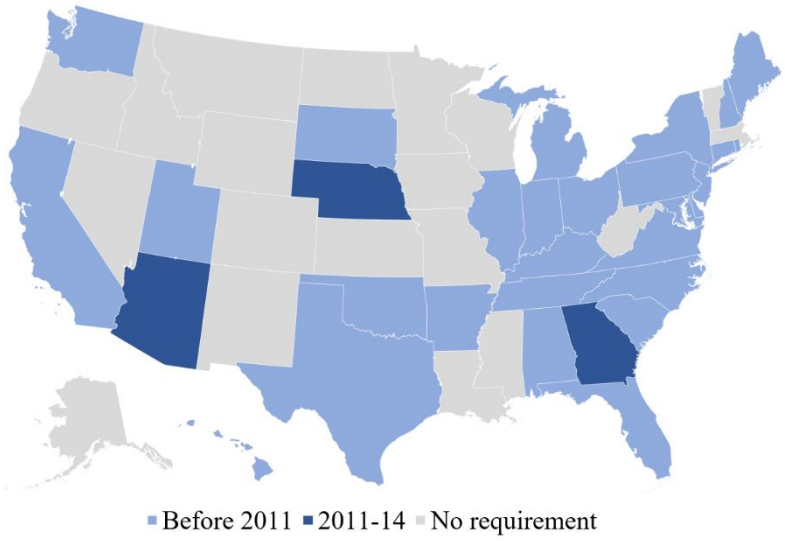


Figure 2. Implementation years of influenza vaccination requirements for healthcare workers



I exploit the quasi-experimental variation in the staggered implementation of the vaccination requirements across states and over time to estimate the impact of the requirements using difference-in-differences (DD) methods. I estimate both linear probability and logistic models to compare changes in vaccination take-up and health outcomes of nursing home residents in states that implemented a

vaccination requirement to contemporaneous changes of residents in states that did not.[30] The general estimating equation is:

$$y_{\{ist\}} = \beta_0 + \beta_1 \mathrm{Req_s} + \beta_2 \mathrm{Post_t} \times \mathrm{Req_s} + \gamma X_{it} + \eta X_{st} + \delta_s + \delta_t + \epsilon_{ist} \qquad (1)$$

where resident, state, and time are indexed by i, s, and t respectively. The outcome variable, y, is a binary variable equal to 1 if the resident received vaccination in the calendar-quarter or in an earlier calendar-quarter within the flu season. When the outcomes are influenza-related illness and mortality, the outcome variable is equal to 1 if the resident experienced the influenza-related health outcome in the specific calendar-quarter. $Treat_t$ is a binary variable set to 1 for states that implemented vaccination requirements and set to zero for states that implement a vaccination requirement after 2014 or never have a vaccination requirement.[31] $Post_{it}$ is an indicator equal to 1 if the individual's outcome occurred after policy implementation and the policy was implemented in the first quarter of the influenza season. If the policy was implemented in the second half of the influenza season, $Post_{it}$ is equal to 1 beginning the first quarter of the following influenza season. X_{it} is a vector of individual characteristics, such as demographics (age, gender), conditions suggesting weakened immune systems (anemia, HIV, AIDS, liver disorders, and heart disease), and chronic conditions known to be risk factors for influenza (asthma, diabetes, and kidney disease). X_{st} is a vector of time-varying state characteristics, such as median income and the number of nursing home residents in the state. δ_s is a vector of general state effects, which captures any between-state differences in the outcomes that did not change over time. δ_t is a vector of general time effects, which captures any national secular trend in influenza-related adverse events over time. The set of time fixed effects will also capture the effects of national policies or trends in influenza outbreaks or seasonal vaccine match rate that apply to all states.

[30] Logit models are estimated in addition to linear probability models because the latter may not be appropriate in the case of binary outcomes. Linear models with binary outcomes may produce predicted probabilities outside the 0-1 range and estimates could be biased.

[31] I estimate separate regressions for each policy of interest (resident and healthcare worker requirements). When the

I also extend Equation (1) in an alternative specification, where I consider cross-facility variation in resident influenza vaccination rates and employ a dose-response DD estimation strategy. This strategy compares changes in outcomes in nursing homes where the requirements had the potential to affect a larger percentage of residents to outcomes in nursing homes where the requirements have would have limited impact (because the nursing home already had high vaccination rate). Vaccination requirements should have larger effects in facilities with low vaccination rates, because a greater fraction of residents is exposed to the requirement.

4.2 Identification

This assumption of the DD method for β_1 to identify causal effects of vaccination requirements relies on the common shock assumption, where any shock occurring during or after the implementation of vaccination requirements should equally affect nursing home residents in both states that implemented the requirement and those that did not. Additionally, the DD method assumes that outcomes of residents in both states that implemented vaccination requirement and those that did not would have similar outcome trends absent the implementation of vaccination requirement (parallel trends assumption) (Angrist and Pischke, 2008). Systematic differences in outcomes between treatment and control states prior to mandate implementation since such differences might be indicative of policy endogeneity. Although this assumption is fundamentally untestable, I examine whether there were similar trends of outcomes prior to requirement implementation. Such parallel trends are tested using the event study specified by the following equation:

$$y_{st} = \beta_0 + \sum_{d=-6, d\neq -1}^{d=4} 1\, \delta_d (t - e^s = d) + \delta_s + \delta_t + \epsilon_{st} \qquad (2)$$

where d is the season relative to requirement implementation, t is time (influenza season), and e^s is the time of mandate implementation for state s. Due to the limited number of years for which I have MDS and Medicare data, I use Nursing Home Compare data from 2006-2017 to estimate these event studies at

outcome is influenza-related diagnoses or deaths, some models include both $Treat$ variables for the two types of

the state-influenza season level.[32] The identification in Equation (2) uses states that have not yet experienced the event to control for underlying trends. In the event study, the first post-implementation period is specified as zero and the season before requirement implementation is the reference period. The relative time dummy variables are equal to zero for all states that never implement a vaccination requirement for the entire study period. The variation in the timing of vaccination requirement implementation identifies the coefficient estimates of γ_d. Additionally, the event study specification allows me to observe whether any observed policy effects remain constant, increase, or decrease over time.

4.3 Inference

DD models typically cluster standard errors at the treatment group level (i.e., state-level for a model that exploits state-level policy variation). Robust standard errors are clustered at the state level (and facility level in robustness checks). This clustering is necessary because the default assumption of independent error terms is likely to underestimate standard errors (Cameron and Miller, 2015)

However, this approach can generate underestimates of the standard errors when the number of treated groups is small. Ferman and Pinto (2019) suggest that inference should account for imbalances in the number of observations in treatment and control groups. To address concerns about relying on residents in few states as the experimental units, I test the sensitivity of my results to inferential methods proposed by Donald and Lang (2007) In the first step, I estimate the regression-adjusted differences in outcomes between treatment and comparison group residents for each time period. The estimating equation of the first-stage regression is:

$$y_{it} = \pi_t \mathrm{Treat}_i + \gamma X_{it} + \eta X_{st} + \delta_s + \delta_t + \epsilon_{it} \qquad (3)$$

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requirements.

[32] I have four years of MDS and Medicare claims data (2011-14) and cannot estimate an event study at the resident-quarter level given the limitations of pre- and post- data.

for individual i with an assessment at year-quarter t. The vector π captures regression-adjusted differences between the treatment and comparison group residents in each time period. In the second step, I collapse the adjusted data into 16 year-quarter cells and estimate bivariate regressions of the adjusted treatment-comparison group differences on the $Post$ indicator:

$$\widehat{\pi_t} = \rho_0 + \rho_1 \mathrm{Post}_t + u_t \qquad (4)$$

where ρ_1 represents the DD effect of the vaccination requirement on the outcome of interest. A non-zero estimate implies that the difference in outcomes between the treatment and comparison group residents changed after the implementation of a vaccination requirement.

5 Results

5.1 Vaccinations

Table 5 shows the main results for the effects of resident influenza vaccination requirements on influenza vaccination (first stage). Each column represents one DD model as specified in Equation (1) and estimated at the resident-quarter level. I add control variables from left to right, starting with the most parsimonious model on the left, to the most saturated model which includes both individual and state control variables. The robustness of the main coefficient estimates to the addition of control variables suggest that it is less likely that they are correlated with unobservables that affect the outcome variable. Because the estimated marginal effects obtained from linear probability and logit models are similar, I discuss the results from linear probability models for ease of interpretation.

Columns 1-3 reveal statistically significant coefficient estimates of 4.2-4.7 percentage points. Although the effect sizes vary slightly, the estimates are not significantly different across the three models. The preferred specification in column (3) suggests that the predicted probability that a resident received an influenza vaccination increased by 4.6 percentage points following the implementation of the resident vaccination requirement. For reference, 73% of residents in states that implemented a resident vaccination requirement between 2011 and 2014 had received an influenza vaccination prior to

requirement implementation. This implies that following the implementation of the resident vaccination requirements, there was a 6% increase in the probability that a resident received an influenza vaccination.

Table 5. Effects of requirements on influenza vaccination among residents

	(1)	(2)	(3)
Panel A. OLS			
Resident requirement	0.0467***	0.0416***	0.0459***
	(0.0043)	(0.007)	(0.0075)
Panel B. Logit			
Resident requirement	0.0474***	0.0468***	0.0462***
	(0.0045)	(0.0045)	(0.0086)
Mean	0.7258	0.7258	0.7258
Observations	13,825,743	13,823,477	13,823,477
State FE	X	X	X
Time FE	X	X	X
Individual controls		X	X
State controls			X

Notes: This table reports the impact of influenza vaccination requirements on influenza vaccination take-up among residents (marginal effects reported in Panel B). This table estimates equation (1) where the policy variable of interest a binary measure of whether an influenza vaccination requirement pertaining to residents in nursing homes has been implemented. The unit of observation is resident-quarter. Estimates are calculated using data from the Long-Term Care Minimum Data Set and Medicare claims from 2011-14. Fixed effects for states and time are always included, and standard errors in parentheses are clustered at the state level. Significance levels: *p<0.1,**p<0.05,***p<0.01.

The increase in the probability of influenza vaccination among nursing home residents is small. One possible explanation for the small increase is that the states that implemented a vaccination requirement were already approaching a ceiling for vaccinations. Theoretically, the vaccination rate is unlikely to reach 100 percent because some people have health conditions that preclude them from being vaccinated and some states also allow philosophical exemptions. While vaccination requirements could increase the probability of vaccination among those who previously would have sought a philosophical exemption, it is not clear what the maximum vaccination rate could be (i.e., 100 minus the percentage of residents with medical contraindications). Another explanation for the small increase is that the requirements were weakly enforced and consequently had limited impact on the vaccination practices of nursing homes.[33] Despite the small effect size, any increase in the number of vaccinated residents

[33] However, failure to comply with regulations and meet minimum standards can have negative consequences for nursing homes. For example, nursing homes can be cited by the state's Department of Public Health which can put holds on admissions of new patients. Additionally, deficiencies could be brought to the attention of a payer or CMS. These entities can stop payments which can be disastrous for nursing homes since many already operate on very

increases the number of people who are potentially resistant or have some level of immunity, which can reduce the spread of a virus among both vaccinated and vaccinated residents as well as people they are in contact with.

5.2 Illnesses

The reduced-form estimates of vaccination requirements on influenza-like illness (ILI) are presented in Table 6.[34] Panel A reports the effects for a linear probability model and Panel B reports the marginal effects for a logit model. Columns 1-3 present estimates where the policy of interest is resident vaccination requirement, columns 4-6 present estimates where the policy of interest is healthcare worker vaccination requirement, and columns 7-9 report the estimates when both resident and healthcare worker vaccination requirements are estimated in the same model. Between 2011 and 2014, Arizona and Nebraska implement resident vaccination requirements, Colorado and Oregon implement healthcare worker vaccination requirements, and Georgia implements requirements for both residents and healthcare workers. Unlike vaccination where I do not expect healthcare worker vaccination requirements to impact resident vaccination, healthcare worker vaccination could potentially affect resident health outcomes; a vaccinated healthcare worker is less likely to contract influenza either in or outside of the nursing home and would therefore be less likely to transmit the virus to a resident.

Table 6, columns 1-3 show that resident vaccination requirements reduce the predicted probability of ILI by roughly 4.4 percentage points (20%) and the estimates are similar for both linear probability and logit models. Columns 4-6 show that healthcare worker vaccination requirements reduce the predicted probability that a resident experienced an ILI by 3.9-4.1 percentage points. This effect could operate through several channels. First, because the effectiveness of influenza vaccination depends on the vaccinated person's immune system response, vaccines tend to be more effective for healthcare workers,

slim margins. However, failure to comply with one regulation related to influenza vaccination requirements alone may be insufficient to trigger these negative consequences.

[34] As seen in Table 3 influenza diagnoses are very rare relative to the broader diagnosis of ILI. These results are presented in Table A4.

who are younger and healthier, relative to nursing home residents who are older and in worse health. Second, healthcare workers may interact with many residents while residents may interact with fewer other residents. If this is the case, the number of potential residents that a healthcare worker could infect is greater than the number of potential residents that another resident could infect. Third, a fraction of healthcare workers works across multiple facilities, which can potentially facilitate the spread of infections. The effect sizes for both resident and healthcare worker vaccination requirements decrease when both treatment indicators are included (columns 7-9), and the estimates of healthcare worker requirements are no longer significant when both policies are included in the same regression. Because the two treatment variables are highly correlated, I cannot independently estimate the effects of these requirements on influenza-related deaths. However, the results suggest that each policy may individually reduce ILI by a statistically significant and economically important amount.

5.3 Deaths

The reduced-form estimates of vaccination requirements on influenza-related deaths are presented in Table 7. Panel A reports the effects for a linear probability model and Panel B reports the effects for a logit model. Columns 1-3 present estimates where the policy of interest is resident vaccination requirement, columns 4-6 present estimates where the policy of interest is healthcare worker vaccination requirement, and columns 7-9 report the estimates when both resident and healthcare worker vaccination requirements are estimated in the same model. Resident and healthcare worker vaccination requirements individually reduce influenza-related deaths by 0.15-0.20 percentage points (9-13%). However, columns 7-9 show that when both resident and healthcare worker requirements are included in the same regression, only resident requirements are statistically significant and there is no evidence of spillovers from the healthcare worker requirements on influenza-related deaths.

Table 6. Effects of requirements on influenza-like illness among residents

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Panel A. OLS									
Resident requirement	-0.0448***	-0.0441***	-0.0439***				-0.0340**	-0.0337**	-0.0351**
	(0.0057)	(0.0052)	(0.0074)				(0.0140)	(0.0131)	(0.0155)
Healthcare worker requirement				-0.0418***	-0.0410***	-0.0387***	-0.0201	-0.0195	-0.0162
				(0.0037)	(0.0029)	(0.0056)	(0.0181)	(0.0169)	(0.0208)
Panel B. Logit									
Resident requirement	-0.0461***	-0.0451***	-0.0445***				-0.0352**	-0.0345**	-0.0359**
	(0.0063)	(0.0056)	(0.0086)				(0.0151)	(0.0140)	(0.0172)
Healthcare worker requirement				-0.0414***	-0.0405***	-0.0378***	-0.0196	-0.0191	-0.0155
							(0.0187)	(0.0174)	(0.0220)
Observations	14,183,622	13,905,698	13,905,698	14,183,622	13,905,698	13,905,69	14,183,622	13,905,698	13,905,69
State FE	X	X	X	X	X	X	X	X	X
Time FE	X	X	X	X	X	X	X	X	X
Individual controls		X	X		X	X		X	X
State controls			X			X			X

Notes: This table reports the impact of influenza vaccination requirements for nursing home residents and healthcare workers on influenza-like illness diagnoses among residents (marginal effects reported in Panel B). This table estimates equation (1) where the policy variable of interest a binary measure of whether an influenza vaccination requirement pertaining to residents (or healthcare workers) in nursing homes has been implemented. The unit of observation is resident-quarter. Estimates are calculated using data from the Long-Term Care Minimum Data Set and Medicare claims from 2011-14. Fixed effects for states and time are always included, and standard errors in parentheses are clustered at the state level. Significance levels: *p<0.1,**p<0.05,***p<0.01.

Table 7. Effects of requirements on influenza-related deaths among residents

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Panel A. OLS									
Resident requirement	-0.0017***	-0.0020***	-0.0020***				-0.0014*	-0.0015*	-0.0016
	(0.0005)	(0.0005)	(0.0006)				(0.0008)	(0.0009)	(0.0010)
Healthcare worker requirement				-0.0015***	-0.0018***	-0.0017***	-0.0005	-0.0008	-0.0007
				(0.0005)	(0.0005)	(0.0005)	(0.0011)	(0.0011)	(0.0013)
Panel B. Logit									
Resident requirement	-0.0019***	-0.0021***	-0.0021***				-0.0016*	-0.0016*	-0.0017*
	(0.0006)	(0.0005)	(0.0006)				(0.0009)	(0.0009)	(0.0010)
Healthcare worker requirement				-0.0015***	-0.0019***	-0.0018***	-0.0006	-0.0009	-0.0008
				(0.0005)	(0.0005)	(0.0006)	(0.0011)	(0.0011)	(0.0013)
Observations	14,183,622	13,905,698	13,905,698	14,183,622	13,905,698	13,905,69	14,183,622	13,905,698	13,905,69
State FE	X	X	X	X	X	X	X	X	X
Time FE	X	X	X	X	X	X	X	X	X
Individual controls		X	X		X	X		X	X
State controls			X			X			X

Notes: This table reports the impact of influenza vaccination requirements for nursing home residents and healthcare workers on influenza-related deaths among residents (marginal effects reported in Panel B). This table estimates equation (1) where the policy variable of interest a binary measure of whether an influenza vaccination requirement pertaining to residents (or healthcare workers) in nursing homes has been implemented. The unit of observation is resident-quarter. Estimates are calculated using data from the Long-Term Care Minimum Data Set and Medicare claims from 2011-14. Fixed effects for states and time are always included, and standard errors in parentheses are clustered at the state level. Significance levels: *p<0.1,**p<0.05,***p<0.01.

5.4 Heterogeneity

Next, I examine the effects of the vaccination requirements for several subgroups of interest. First, I consider whether the requirements have different effects on residents with different stay lengths (long stays of >100 days and short stays of ≤100 days). A priori, it is unclear which type of patient is at greater risk of adverse health outcomes. On the one hand, long-stay residents typically have multiple comorbidities and have chronically poorer health. On the other hand, short-stay residents are typically in the nursing home for post-acute care and are temporarily but acutely ill. Table 8 shows the effects of the requirements on vaccinations, diagnoses, and deaths by resident's length of stay. Resident vaccination requirements increase vaccination take-up by about 1.1 percentage points among long-stay residents and 2.4 percentage points among short-stay residents. Short-stay residents have a lower vaccination rate than long-stay residents and vaccinating short-stay residents, who may interact with long-stay residents, could be a way to increase the level of protection within a facility. However, the effects on ILI diagnoses are greater for long-stay residents than for short-stay residents. This might suggest that long-stay residents who have multiple comorbidities and chronically poorer health are at greater risk of infectious respiratory illnesses than short-stay residents, who are generally in the nursing home for post-acute care.

Second, I estimate the effects of the policy by age group in Table 9. Older individuals are at higher risk of influenza and influenza-related mortality because the immune system weakens with age, so I expect larger reductions in adverse health outcomes among the oldest residents. However, older people can also be less responsive to the vaccine relative to other age groups so vaccinating other residents and staff in the nursing home is one strategy to protect a very vulnerable population from influenza. Although the effect sizes vary slightly, the estimates on vaccination are not statistically different across age groups, which suggests that facilities are vaccinating all residents regardless of age. Additionally, ILI illnesses are not significantly different across age groups. While the estimates of the requirements on influenza-related deaths are also similar across age group, they are only statistically significant for the oldest age group (85+ years). This suggests that the requirements may be effective at reducing the most severe outcome

(death) for the group most likely to have the weakest immune systems as a result of age (residents ages 85+).

Table 8. Effects of requirements on outcomes by resident length of stay

	Long-stay			Short-stay		
	(1)	(2)	(3)	(4)	(5)	(6)
Panel A. Vaccinations						
Resident requirement	0.0106***			0.0236***		
	(0.0025)			(0.0068)		
Panel B. Diagnoses						
Resident requirement	-0.0158***		-0.0106	-0.0066***		-0.0066***
	(0.0036)		(0.0090)	(0.0021)		(0.0022)
Healthcare worker requirement		-0.0161***	-0.0089		-0.0037*	-0.0000
		(0.0054)	(0.0118)		(0.0019)	(0.0018)
Panel C. Deaths						
Resident requirement	0.0004		0.0002	0.0030***		0.0025**
	(0.0003)		(0.0005)	(0.0008)		(0.0012)
Healthcare worker requirement		0.0004	0.0003		0.0024***	0.0010
		(0.0003)	(0.0004)		(0.0006)	(0.0012)
Observations	8,907,829	8,907,829	8,907,829	4,997,869	4,997,869	4,997,869
State FE	X	X	X	X	X	X
Time FE	X	X	X	X	X	X
Individual controls	X	X	X	X	X	X
State controls	X	X	X	X	X	X

Notes: This table reports the impact of influenza vaccination requirements on influenza-related outcomes among residents. This table estimates equation (1) where the policy variable of interest a binary measure of whether an influenza vaccination requirement pertaining to residents in nursing homes has been implemented. The unit of observation is resident-quarter. Estimates are calculated using data from the Long-Term Care Minimum Data Set and Medicare claims from 2011-14. Fixed effects for states and time are always included, and standard errors in parentheses are clustered at the state level. Significance levels: *p<0.1,**p<0.05,***p<0.01.

Third, Table 10 shows the effects separately for peak (October-December and January-March) and non-peak quarters (April-June and July-September). Ex-ante, the size of the effects are ambiguous. On the one hand, effect sizes might be larger during peak quarters because vaccinations are typically administered beginning in October and influenza-related diagnoses and deaths typically occur during winter months. On the other hand, vaccinations during non-peak quarters may increase for residents arriving in the spring or summer if nursing homes are concerned with compliance. In this case, vaccination requirements for residents, particularly short-stay residents, would be inframarginal for

people during the typical flu season since they would have received the vaccine regardless of the requirement. In the off-season, however, requirements may push more residents to get vaccinated.

5.5 Parallel Trends

Figures 3 and 4 show the estimates produced by Equation (2) for long- and short-stay residents, respectively. These events studies, which are estimated at the state-flu season level using data from Nursing Home Compare, produce estimates in both the pre- and post-period that are not statistically different from zero. While this suggests that the parallel trends assumption is valid, the noisy post-period estimates differ from the statistically significant and positively signed estimates produced at the resident-quarter level using MDS and Medicare claims data (in Table 5). However, the wide confidence intervals in the event studies appear to contain the effects estimated at the individual-level.

Table 9. Effects of requirements on outcomes by resident age

	Under 65			65-74		
	(1)	(2)	(3)	(4)	(5)	(6)
Panel A. Vaccinations						
Resident requirement	0.0383***			0.0468***		
	(0.0102)			(0.0089)		
Panel B. Diagnoses						
Resident requirement	-0.0454***		-0.0341*	-0.0414***		-0.0315*
	(0.0084)		(0.0183)	(0.0080)		(0.0172)
Healthcare worker requirement		-0.0497***	-0.0180		-0.0379***	-0.0169
		(0.0038)	(0.0204)		(0.0041)	(0.0192)
Panel C. Deaths						
Resident requirement	-0.0010		-0.0017	-0.0007		-0.0008
	(0.0008)		(0.0010)	(0.0007)		(0.0009)
Healthcare worker requirement		-0.0001	0.0010		-0.0005	0.0000
		(0.0004)	(0.0012)		(0.0006)	(0.0010)
Observations	1,247,433	1,247,433	1,247,433	2,159,999	2,159,999	2,159,999

	75-84			85+		
	(7)	(8)	(9)	(10)	(11)	(12)
Panel A. Vaccinations						
Resident requirement	0.0483***			0.0434***		
	(0.0058)			(0.0079)		
Panel B. Diagnoses						
Resident requirement	-0.0375***		-0.0287*	-0.0468***		-0.0391**
	(0.0063)		(0.0145)	(0.0082)		(0.0152)
Healthcare worker requirement		-0.0350***	-0.0164		-0.0394***	-0.0154
		(0.0069)	(0.0199)		(0.0058)	(0.0217)
Panel C. Deaths						
Resident requirement	-0.0004		-0.0003	-0.0037***		-0.0027***
	(0.0008)		(0.0011)	(0.0003)		(0.0008)
Healthcare worker requirement		-0.0004	-0.0002		-0.0035***	-0.0019*
		(0.0010)	(0.0014)		(0.0002)	(0.0011)
Observations	4,319,452	4,319,452	4,319,452	6,178,814	6,178,814	6,178,814
State FE	X	X	X	X	X	X
Time FE	X	X	X	X	X	X
Individual controls	X	X	X	X	X	X
State controls	X	X	X	X	X	X

Notes: This table reports the impact of influenza vaccination requirements for nursing home residents and healthcare workers on influenza-like illness diagnoses among residents. This table estimates equation (1) where the policy variable of interest a binary measure of whether an influenza vaccination requirement pertaining to residents (or healthcare workers) in nursing homes has been implemented. The unit of observation is resident-quarter. Peak quarters are defined calendar quarters 1 (January to March) and 4 (October to December), and non-peak quarters are defined as quarters 2 (March to June) and 3 (July to September). Estimates are calculated using data from the Long-Term Care Minimum Data Set and Medicare claims from 2011-14. Fixed effects for states and time are always included, and standard errors in parentheses are clustered at the state level. Significance levels: *p<0.1,**p<0.05,***p<0.01.

Table 10. Effects of requirements on outcomes by peak and non-peak quarters

	Peak			Non-peak		
	(1)	(2)	(3)	(4)	(5)	(6)
Panel A. Vaccinations						
Resident requirement	-0.0052			0.0746***		
	(0.0036)			(0.0216)		
Panel B. Diagnoses						
Resident requirement	-0.0400***		-0.0293*	-0.0498***		-0.0411***
	(0.0086)		(0.0172)	(0.0070)		(0.0153)
Healthcare worker requirement		-0.0381***	-0.0190		-0.0427***	-0.0170
		(0.0072)	(0.0202)		(0.0044)	(0.0220)
Panel C. Deaths						
Resident requirement	-0.0017***		-0.0013	-0.0027***		-0.0020*
	(0.0006)		(0.0010)	(0.0006)		(0.0012)
Healthcare worker requirement		-0.0016***	-0.0007		-0.0026***	-0.0013
		(0.0066)	(0.0011)		(0.0007)	(0.0016)
Observations	6,973,073	6,973,073	6,973,073	6,932,625	6,932,625	6,932,625
State FE	X	X	X	X	X	X
Time FE	X	X	X	X	X	X
Individual controls	X	X	X	X	X	X
State controls	X	X	X	X	X	X

Notes: This table reports the impact of influenza vaccination requirements on influenz-related outcomes among residents. This table estimates equation (1) where the policy variable of interest a binary measure of whether an influenza vaccination requirement pertaining to residents in nursing homes has been implemented. The unit of observation is resident-quarter. Estimates are calculated using data from the Long-Term Care Minimum Data Set and Medicare claims from 2011-14. Fixed effects for states and time are always included, and standard errors in parentheses are clustered at the state level. Significance levels: *p<0.1,**p<0.05,***p<0.01.

Figure 3. Event study, long-stay resident vaccination rate

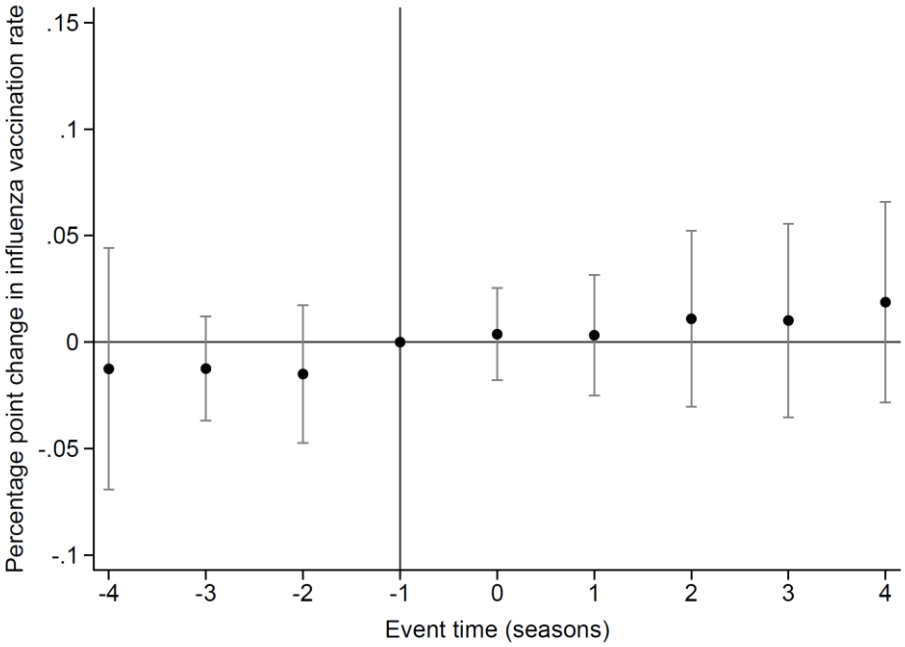
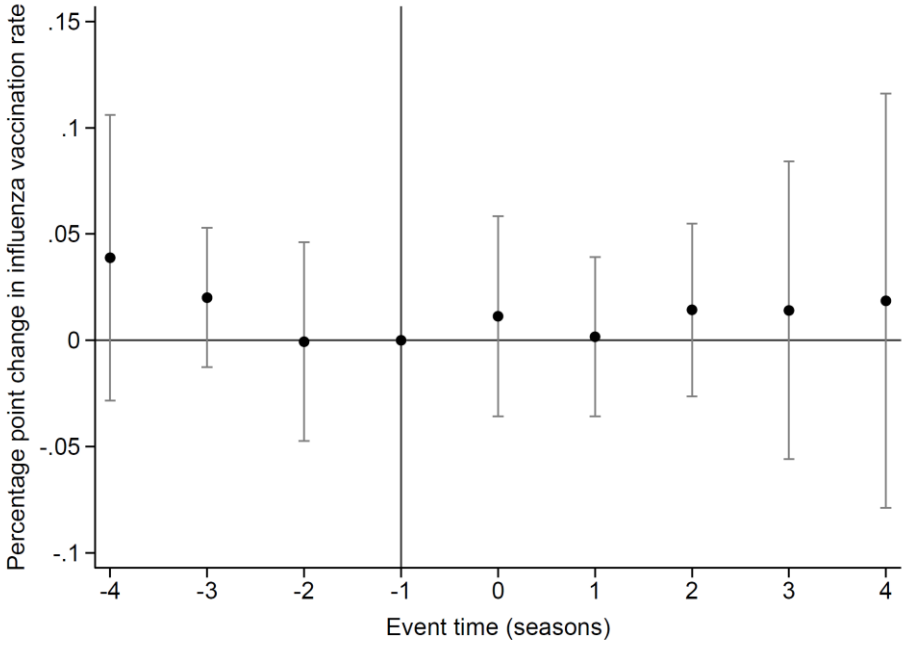


Figure 4. Event study, short-stay resident vaccination rate



6 Discussion

The goal of this research is to better understand how vaccination requirements can reduce the spread of infectious diseases and improve public health. In this paper, I estimate the effects of resident and healthcare worker influenza vaccination requirements on influenza vaccination, and influenza-related illnesses and deaths among nursing home residents. I find that resident vaccination requirements increase the predicted probability of vaccination by about 6% and decrease ILI diagnoses by about 20%. I do not find evidence of spillovers from healthcare worker vaccination requirements on influenza-related illnesses or deaths. These results apply to nursing home residents with Medicare fee-for-service and dual enrollment in both Medicare and Medicaid. A back-of-the-envelope calculation suggests that the resident vaccination requirements implemented by three states translates to 226 fewer influenza-related hospitalizations, though this is likely a much lower bound estimate of the true reduction in influenza-related hospitalizations.[35]

These findings are consistent with the literature on the impact of vaccination requirements on vaccination take-up. In this literature, which has largely focused on requirements for children, Carpenter and Lawler (2019) find that mandates increase take-up by roughly 14 percentage points for the Tdap booster, Lawler (2017) finds an 8-percentage point increase for hepatitis A vaccine, and \cite{abrevaya2011} find a 5 percentage point increase for the varicella vaccine. I find that resident vaccination requirements increase influenza vaccination take-up among nursing home residents by approximately 5 percentage points. While White (2020) finds evidence of external benefits of hospital

[35] For the 2018-19 flu season, there were an estimated 279,384 influenza-related hospitalizations among people 65 years and older (CDC, 2020c). Adults living in nursing homes account for 4.5% of all adults 65 and older in the U.S, suggesting that 12,572 hospitalizations occurred among people 65 and older and in nursing homes (279,384*0.045). However, this is likely a lower bound estimate since older adults in nursing homes are frailer than community dwelling older people so older adults from nursing homes likely account for more than 4.5% of hospitalizations among the 65+ population. If resident vaccination requirements decrease the predicted probability of ILI diagnosis by about 20% and an estimated 9% of symptomatic influenza illnesses result in hospitalization among the 65+ population (279,384 hospitalizations / 3,073,337 symptomatic influenza illnesses), then the percent change in influenza-related hospitalization because of the resident requirements is about 1.8% (0.20*0.09). Again, however, because the 65+ nursing home population is frailer than the community dwelling 65+ population, the percentage of influenza illness that require hospitalization among nursing home residents likely exceeds 9%. The resulting lower

worker vaccination (20% reduction in influenza inpatient admissions), I do not find evidence of spillover benefits of healthcare worker vaccination requirements in nursing homes.

There are several limitations of this paper. First, while this paper is interested in the effects of both resident and healthcare worker vaccination requirements, I do not have data on healthcare worker vaccination and consequently cannot observe whether vaccination take up increases following the implementation of healthcare worker vaccination requirements. Second, I cannot distinguish between state- and facility-level vaccination policies, and there are several scenarios that may suggest that my estimates have upward or downward bias. My results will overstate the effects of the vaccination requirements if individual facilities in states with state-wide requirements have stricter policies beyond those of state regulations. Additionally, facilities in states that implemented requirements could also have had their own vaccination policies prior to the laws and regulations. Alternatively, states without state-wide vaccination requirements may have facilities that implement their own vaccination policies. If these policies appeared more often in states without state laws or regulations, my results would understate the effects of these requirements. However, if nursing homes were more likely to require residents and workers to be vaccinated after states passed laws or regulations, then spurring change in nursing homes policies may be an important pathway through which the laws and regulations increase vaccination take-up and reduce ILI diagnoses.

In future work, I will estimate event study models for my various outcomes for each subgroup of interest. Additionally, DD analyses rely on the assumption that the outcomes in treatment and control groups would have followed parallel trends in the absence of policy implementation. Synthetic controls are an alternative method for causal inference with few treated units and many control units. As a robustness exercise, I will implement the synthetic control approach proposed by Abadie et al. (2010) in analyses at the state-level. This method selects control states that exhibit similar pre-treatment characteristics and dynamics as those in the treatment states and calculates treatment effects by comparing

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bound estimate of the reduction in the number of hospitalizations is 226 (12,572*0.018).

treatment states to their synthetic counterpart. By selecting a weighted subset of states as the control group, this method identifies states that are a more ideal control group for each state that experienced treatment. To implement this synthetic control method, I will generate state outcomes, and states are then weighted using the pre-policy trend in outcomes. The final vector of state weights sums to one, such that each synthetic treated state is the weighted average of the selected control states. I will then compare outcomes in each treated state and synthetic treated state graphically, where the treatment effect is represented by the difference in outcomes between the two groups over time.

Future research will also examine the effects of these vaccination requirements in more detail. First, I will also consider other facility level analyses that include controls such percent of contract staff (who could introduce infections), facility composition of short versus long-stay patients. Second, I will estimate the external benefits of vaccination by comparing outcomes of residents who were vaccinated to those who were not vaccinated. Third, I will also examine racial disparities in vaccination take-up and whether these requirements reduce documented racial disparities in vaccination receipt. Finally, I will also explore the variation in policy stringency (offer versus ensure requirements) using earlier years of data.

Nursing home residents are a particularly vulnerable population, which has been highlighted by the COVID-19 pandemic. Although only 0.6% of the population resides in long-term care facilities which include nursing homes, an estimated 45% of COVID-19 deaths have occurred in these facilities (Kaiser Family Foundation, 2020). The current pandemic has highlighted concern about the spread of communicable diseases within nursing homes and the importance of infection control policies in these settings. Effective policies to reduce the spread of infectious disease among nursing homes not only benefits the nursing home residents but also generates social benefits.

Although COVID-19 and the flu vaccinations differ in important ways, this paper may help to inform future policies that consider COVID-19 vaccination requirements, particularly for older adults and healthcare workers in nursing homes. While there have been high vaccination rates of residents across

states, there are emerging issues related to vaccination take-up among healthcare workers; in the first month of SNFs participating in the Pharmacy Partnership for Long-Term Care Program, an estimated 78% of residents had received at least one vaccine dose compared to 38% of staff (Ghapure et al., 2021). Some facility chains have begun requiring COVID vaccination for their workers, though this raises questions about the impact of these requirements on labor supply, who responds to incentive, and the mistrust of political and health care systems across different racial and socioeconomic groups. In a *Nature* poll of immunologists, infectious disease researchers, and virologists working on the coronavirus, 89% of respondents said it is very likely or likely that the coronavirus will become an endemic virus (Phillips, 2021). While we do not yet know how long COVID vaccine protection lasts and whether people will be need annual COVID vaccination as we do for influenza, findings from this paper and others show that vaccination requirements can be an effective policy tool for increasing vaccination rates and reducing illnesses.

Appendix A. Data and Variable Construction

Summary of data sources used

Table A1. Summary of data sources and levels of analysis

Unit of analysis	Vaccination	Illnesses	Deaths
Resident	MDS, 2011-14 Medicare claims, 2011-14	Medicare claims, 2011-14	Medicare claims, 2011-14
Facility	Nursing Home Compare, 2006-17	Medicare claims, 2011-14	Medicare claims, 2011-14
State			NVSS mortality files, 1999-2016

Details on Medicare and MDS sample

I begin with a random sample of 20 million Medicare fee-for-service beneficiaries in 2011. This represents over 50% Medicare fee-for-service beneficiaries in 2011.[36] I then identify the subset of these beneficiaries who experienced a nursing home stay between 2011 and 2014. As a result, I have both assessment and claims for roughly 3.6 million unique beneficiaries between 2011 and 2014.

[36] In 2011, there were 35.5 million beneficiaries enrolled in original fee-for-service Medicare.

Diagnoses and Procedure Codes

Table A2. ICD-9 and CPT codes for influenza vaccination

ICD-9 or CPT Code	Description
V04.81	Vaccine for influenza
90655	Influenza virus vaccine, split virus, preservative free, for children 6-35 months of age, for intramuscular use
90656	Influenza virus vaccine, split virus, preservative free, for use in individuals 3 years and above, for intramuscular use
90657	Influenza virus vaccine, split virus, for children 6-35 months of age, for intramuscular use
90658	Influenza virus vaccine, split virus, for use in individuals 3 years and above, for intramuscular use
90660	Influenza virus vaccine, live, for intranasal use
90662	Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use
Q2034	Influenza virus vaccine, split virus, for intramuscular use (agriflu)
Q2035	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (afluria)
Q2036	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (flulaval)
Q2037	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (fluvirin)
Q2038	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use (fluzone)
Q2039	Influenza virus vaccine, not otherwise specified
G0008	Administration of influenza virus vaccine

Table A3. ICD-9 and CPT codes for influenza and influenza-like illness

ICD-9 Code	Description
Influenza	
487	Influenza with pneumonia
487.1	Influenza with other respiratory manifestations
487.8	Influenza with other manifestations
Influenza-like-illness	
079.89	Viral infection NEC
079.99	Viral infection NOS
460	Nasopharyngitis, acute
462	Pharyngitis, acute
464.00	Laryngitis, acute without obstruction
464.10	Tracheitis, acute without obstruction
464.20	Laryngotracheitis, acute without obstruction
465.0	Larynogopharyngitis, acute
465.8	Infectious upper respiratory, multiple sites, acute NEC
465.9	Infectious upper respiratory, multiple sites, acute NOS
466.0	Bronchitis, acute
466.11	Bronchiolitis due to respiratory syncytial virus
466.19	Bronchiolitis, acute due to other infectious organism
478.9	Disease, uper respiratory NEC/NOS
480.0	Pneumonia due to adenovirus
480.1	Pneumonia due to respiratory syncytial virus
480.2	Pneumonia due to parainfluenza
480.8	Pneumonia due to virus NEC
480.9	Viral pneumonia unspecified
484.8	Pneumonia in other infectious disease NEC
485	Brochopneumonia, organism NOS
486	Pneumonia, organism NOS
487	Influenza with pneumonia
487.1	Influenza with other respiratory manifestations NEC
487.8	Influenza with other manifestations NEC
490	Bronchitis NOS
780.6	Fever
484.1	Pain, throat
786.2	Cough

Appendix B

Table A4. Effects of requirements on influenza diagnoses among residents

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Panel A. OLS									
Resident requirement	-0.0010***	-0.0010***	0.0010***				-0.0012***	-0.0012***	-0.0011***
	(0.0003)	(0.0003)	(0.0003)				(0.0004)	(0.0004)	(0.0004)
Healthcare worker requirement				-0.0005	-0.0005	-0.0005	0.0003	0.0003	0.0002
				(0.0005)	(0.0006)	(0.0005)	(0.0003)	(0.0004)	(0.0003)
Panel B. Logit									
Resident requirement	-0.0009**	-0.0009**	-0.0008**				-0.0013*	-0.0014*	-0.0012*
	(0.0004)	(0.0004)	(0.0004)				(0.0007)	(0.0008)	(0.0007)
Healthcare worker requirement				-0.0002	-0.0002	-0.0003	0.0006	0.0007	0.0006
				(0.0007)	(0.00008)	(0.0007)	(0.0006)	(0.0007)	(0.0006)
Observations	14,183,622	13,905,698	13,905,698	14,183,622	13,905,698	13,905,69	14,183,622	13,905,698	13,905,69
State FE	X	X	X	X	X	X	X	X	X
Time FE	X	X	X	X	X	X	X	X	X
Individual controls		X	X		X	X		X	X
State controls			X			X			X

Notes: This table reports the impact of influenza vaccination requirements for nursing home residents and healthcare workers on influenza-like illness diagnoses among residents. This table estimates equation (1) where the policy variable of interest a binary measure of whether an influenza vaccination requirement pertaining to residents (or healthcare workers) in nursing homes has been implemented. The unit of observation is resident-quarter. Estimates are calculated using data from the Long-Term Care Minimum Data Set and Medicare claims from 2011-14. Fixed effects for states and time are always included, and standard errors in parentheses are clustered at the state level. Significance levels: $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$.

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CHAPTER 2

State Policies for Prescription Drug Monitoring Programs and Adverse Opioid-Related Hospital Events

Katherine Wen, Cornell University
Phyllis Johnson, Weill Cornell Medical College
Philip J. Jeng, Weill Cornell Medical College
Bruce R. Schackman, Weill Cornell Medical College
Yuhua Bao, Weill Cornell Medical College

Background: State policies to optimize prescriber use of Prescription Drug Monitoring Programs (PDMPs) have proliferated in recent years. Prominent policies include comprehensive mandates for prescriber use of PDMP, laws allowing delegation of PDMP access to office staff, and interstate PDMP data sharing. Evidence is limited regarding the effects of these policies on adverse opioid related hospital events.

Objective: The objective of this study was to assess the effects of 3 PDMP policies on adverse opioid-related hospital events among patients with prescription opioid use.

Research Design: We examined 2011–2015 data from a large national commercial insurance database of privately insured and Medicare Advantage patients from 28 states with fully operating PDMPs by the end of 2010. We used a difference-in-differences framework to assess the probabilities of opioid-related hospital events and association with the implementation of PDMP policies. The analysis was conducted for adult patients with any prescription opioid use, a subsample of patients with long-term prescription opioid use, and stratified by older (65+) versus younger patients.

Results: Comprehensive use mandates were associated with a relative reduction in the probability of opioid-related hospital events by 28% among patients with any opioid and 21% among patients with long-term opioid use. Such reduction was greater (in relative terms) among older patients despite the lower rate of these events among older than younger patients. Delegate laws and interstate data sharing were associated with limited change in the outcome.

Conclusion: Comprehensive PDMP use mandates were associated with meaningful reductions in opioid-related hospital events among privately insured and Medicare Advantage adults with prescription opioid use.

1 Introduction

Between 1999 and 2015, drug overdose deaths involving prescription or illicit opioids increased nearly 6-fold.[1] The Centers for Disease Control and Prevention estimated annual health and social costs of prescription opioid misuse at $55 billion, of which $20 billion was spent on emergency department (ED) and inpatient care for opioid poisonings.[2] Despite the general perception that the opioid crisis has shifted from prescription opioids to heroin and other synthetic opioids (e.g., fentanyl), in 2017, prescription opioids still accounted for over 40% of opioid overdose deaths, and 11.4 million Americans reportedly misused prescription opioids.[3]

Prescription Drug Monitoring Programs (PDMPs) are a prominent strategy taken by states to address the opioid crisis. PDMPs are statewide electronic databases of controlled substances dispensed at retail pharmacies. PDMPs provide information to prescribers about controlled substances received by a patient and thus can assist prescribers with identifying possible misuse among patients while ensuring legitimate use for pain management. In recent years, states have implemented policies to address low prescriber participation in PDMPs.[4,5] One prominent type of policy is legislative mandates that prescribers use the PDMP at the point of care. Evidence is accumulating that comprehensive use mandates that apply to all prescribers in all settings and do not rely on prescriber discretion were associated with reductions in opioid prescriptions presenting a high risk of misuse and overdose among the privately insured populations[6,7] and Medicare.[8] Other PDMP policies have been implemented to lower the prescriber burden when using the PDMP (e.g., legislations allowing prescriber delegation of PDMP use to office staff) or to make information more complete or useful (e.g., enabling interstate PDMP data sharing). There is some evidence that PDMP delegation laws were associated with reductions in high-risk opioid prescriptions.[6]

Policies designed to increase prescriber PDMP use may lead to decreases in opioid-related hospital events as a result of reductions in high-risk prescription opioid use. In contrast, one major unintended consequence of these policies (and of comprehensive use mandates in particular) may be

reduced or discontinued opioid prescribing regardless of patient need or risk. Concerns are mounting that patients whose opioid therapy gets terminated abruptly without effective alternative pain management strategies are being "pushed" to illicit opioids, which, in turn, may lead to adverse events associated with illicit opioid use and overdose.[9,10] Because claims-based diagnoses may offer low specificity to differentiate prescription opioid-related events from illicit opioid-related events, our analysis assessed the net effects of PDMP policies on adverse opioid-related hospital events.

Our study makes several contributions to the literature. First, we examined the effects of 3 prominent policies designed to improve prescriber take-up and use of PDMP on adverse opioid related hospital events including ED visits and inpatient admissions. Earlier studies largely focused on the implementation of PDMPs and opioid overdose deaths using vital statistics; they generated mixed findings regarding PDMP implementation and fatal or nonfatal drug overdoses.[11–20] Other studies examining features of PDMPs (e.g., prescriber mandates, interstate data sharing) found that prescriber mandates were associated with decreased fatal drug overdoses.[18,20] Second, we estimated such effects for younger versus older patients. National statistics between 2002 and 2014 suggest differentially evolving epidemics by age; although the rate of opioid misuse remained much lower among people ages 50+ compared with the younger population, the rate almost doubled among those 50+ in contrast with a decline among those ages 18–25 and relative stability among those ages 26–49.[21] Given that PDMP policies are intended to reduce high-risk prescription opioid use, it is important to examine how PDMP policies have impacted younger and older patients differently. Third, we focused on the implications of PDMP policies for privately insured and Medicare Advantage adults, 2 populations that have been less studied despite bearing the large absolute burden of pain and prescription opioid misuse.[22]

2 Methods

2.1 Data

We used 2011–2015 data from the Health Care Cost Institute (HCCI), a large commercial insurance claims database that covers about 50 million individuals per year enrolled in a health insurance plan offered or administered (i.e., self-insured plans) by Aetna, Humana, or UnitedHealthcare, including employers Sponsored, individual market, and Medicare Advantage plans.[23] The data contain beneficiary enrollment information, inpatient facility, outpatient, physician, and pharmacy claims. We ended the study period on December 31, 2015, due to data availability.

2.2 Subjects

Our study population was adults (ages 18+) with private or Medicare Advantage insurance who had filled at least 1 opioid prescription during 2011–2015, a target population of PDMP policies. The HCCI data capture prescriptions dispensed by pharmacies and covered by the patient's pharmacy or prescription drug benefit. We further considered a subpopulation of patients with at least 1 episode of long-term opioid use (thus at heightened risk of opioid misuse or overdose) during the study years.[24] Long-term opioid use was defined as the continuous use of prescription opioids for ≥90 days; a gap of ≥30 days with no opioids determined the end of an episode.[24–29] Our unit of analysis was patient half-year. We thus required patients to be continuously enrolled in a half-year (January–June, or, July–December, during 2011–2015) to be included in the analysis. In addition, we excluded patient half-years in which the patient had a diagnosis of cancer or sickle cell disease to focus on patients receiving opioids for non–cancer-related and non–sickle cell disease-related pain.

2.3 Measures

We focused on 3 types of policies increasingly implemented by states during our study years to enhance prescriber PDMP use. Comprehensive use mandates are legislations that require all prescribers to use the PDMP at the point of care when prescribing opioids/controlled substances for the first time and at least annually thereafter. Delegate laws allow the prescriber delegation of PDMP access to office staff. Interstate data sharing enables prescriber access to PDMP information from other states. These policies

were selected because of their potential to increase prescriber use of PDMPs and change prescribing behaviors, implementation by a sufficient number of states during our study years, the relative homogeneity of policies implemented across states, and the availability of reliable data on implementation dates.

Implementation of PDMP comprehensive use mandates and of delegate laws was determined based on the effective date of the legislation. The National Alliance for Model State Drug Laws[30] provided effective dates of pertinent state legislations. During our study period, the most robust way of enabling interstate data sharing was through state participation in PMP InterConnect, provided by the National Association of Boards of Pharmacy (NABP).[31] Participating states sign a memo of understanding and develop an interface to connect their PDMP with PMP Inter- Connect. Each state controls access to its data via a dashboard within PMP InterConnect, allowing selected states to share the data. The "go-live" date provided by NABP for each state defined the implementation of interstate data sharing.

We restricted our analysis to patients in states with a fully operating PDMP by the end of 2010. By the end of our study period (2015), 7 states had implemented comprehensive use mandates, 23 had allowed prescribers to delegate PDMP to use an office staff member, and 22 participated in interstate data sharing via PMP InterConnect (Table 1). For each of the 3 policies, we set the policy indicator to 1 for each full half-year post the effective date of the policy in a given state, and 0 otherwise.

Table 1. PDMP policy implementation dates

State	PDMP accessible	Comprehensive Use Mandate	Delegate Access	Interstate Data Sharing
Alabama	2007		2013	
Arizona	2008		2014	2012
California	2009			
Colorado	2008		2014	2013
Connecticut	2008	2015	2015	2012
Idaho	1998			2014
Illinois	2008		2015	2013
Indiana	2007		2007	2011
Iowa	2009		2012	2015
Kentucky	1999	2012	2012	2013
Louisiana	2009		2013	2013
Maine	2005		2011	
Michigan	2003			2012
Minnesota	2010		2010	2013
Mississippi	2005		2005	2013
Nebraska	2009			
Nevada	1997	2015		2014
New Mexico	2005		2005	2012
North Carolina	2007		2013	
North Dakota	2007		2008	2012
Ohio	2006	2015	2011	2011
Oklahoma	2006	2015	2015	2015
South Carolina	2008		2014	2012
Tennessee	2007	2013	2012	2013
Utah	1997		2012	2014
Vermont	2009		2013	
Virginia	2006		2009	2011
West Virginia	2004	2012	2011	2014

Notes: The PDMP implementation dates were collected from the National Alliance for Model State Drug Laws (NAMSDL), correspondence with program administrators, and additional searches of state legislation websites. Comprehensive use mandate effective dates were collected from the Pew Charitable Trusts, NAMSDL, and additional searches of state legislation websites. Delegation law effective dates were collected from NAMSDL and additional searches of state legislation websites. Inter-state data-sharing effective dates were provided by the National Association of Boards of Pharmacy.

Our primary outcome of interest was an indicator of having any opioid-related hospital event (ED visit or inpatient admission), defined as those with a diagnosis of opioid dependence, opioid abuse, or opioid poisoning in any of the observed (primary and secondary) diagnostic codes (Appendix Table 1, Supplemental Digital Content 1, http://links.lww.com/MLR/B996). We focused on the dichotomous

outcome of having at least one such event in a half-year rather than the count of events because the majority of patients (77%) whoever experienced any event had only 1 event. We took this inclusive approach in defining our outcome given the serious under-coding of opioid poisonings in claims data.[32,33] In several sensitivity analyses, we adopted more restrictive definitions including using primary diagnoses only and using poisoning codes only.

2.4 Analyses

We exploited staggered implementation of PDMP policies across states to estimate difference-in-differences models, using patients in states that had not implemented the policies as controls. We conducted an event study analysis to assess the assumption that the outcome in states implementing a given policy followed a parallel trend with what was seen in states that did not implement the policy. Violation of the parallel trend assumption could be suggestive of policy endogeneity. To produce an event study, we replaced the binary policy indicators with categorical indicators capturing 6-month intervals (0–6, 7–12, 13–18, 19+ months) before and after policy implementation. The reference point was the half-year before the policy implementation. The event study produces a visual representation of the differences between implementing and non-implementing states in time intervals before (as a test of the parallel trend assumption) and after (as an estimate of time variant policy effect) policy implementation. We restricted our analysis to the 28 states with a fully operating PDMP (with user access) by the end of 2010. States that launched a PDMP more recently were more likely to have implemented PDMP enhancing policies at the same time as they launched PDMPs, making it challenging to isolate the effects of the PDMP policies from those of launching a PDMP.

In addition, for both the population of all opioid users and a subpopulation of patients with long-term opioid use, we estimated the models separately for patients ages 18–64 and patients aged 65 or older. While prescription opioid misuse, illicit opioid use, and opioid-related adverse events were lower among older compared with younger adults,[21,34] older adults suffer from more pain conditions and were more

likely to experience long-term opioid use (Appendix Table 3, Supplemental Digital Content 1, http://links.lww.com/MLR/B996).

We estimated linear probability models of the probability of having at least 1 opioid-related hospital event during a defined half-year, among patients who were ever dispensed an opioid during our study period. Each model included the 3 dichotomous PDMP policy indicators, dichotomous state indicators to control for differences among states that did not change over time, and dichotomous indicators of half-years to control for nationwide trends in the outcome. Each model controlled for patient sex and age, indicators for pain-related diagnoses (back, neck, arthritis-related, or other), an indicator for any mental health condition, and indicators of alcohol use disorder, drug use disorder, and tobacco use, based on claims based diagnostic codes in a given half-year (Appendix Table 2, Supplemental Digital Content 1, http://links.lww.com/MLR/B996). The clinical conditions were identified if any claim (inpatient, outpatient, or physician) during the half-year had any diagnosis (primary and secondary) suggesting the condition. Because patients may contribute multiple half years to the analysis, we derived robust standard errors clustered at the patient-level.

3 Results

3.1 Patients With Any Prescription Opioid Use

Our sample included 31,482,222 half-years from 6,423,416 unique patients who had filled at least 1 opioid prescription during the study years. Of all patients' half-years, 0.10% experienced at least 1 opioid-related hospital event, 0.04% experienced at least 1 opioid-related ED visit, and 0.07% experienced at least 1 opioid-related inpatient admission (Table 2).

Table 2. Summary statistics of study outcomes and sample characteristics

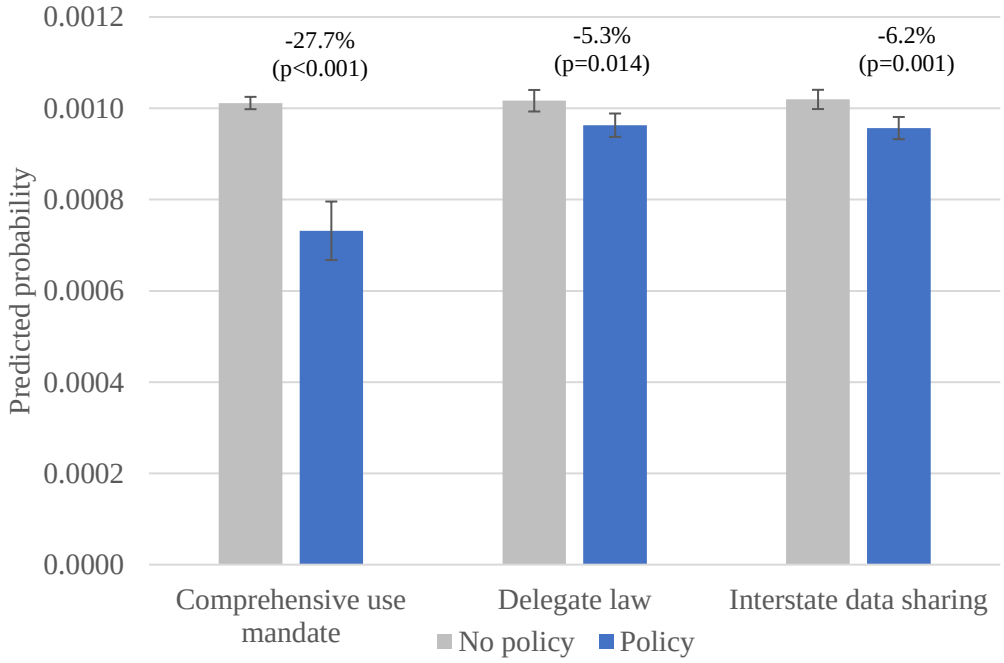
	Full sample Mean	Long-term use sample Mean
Opioid-related events (%)		
Any ED or inpatient	0.099	0.373
ED visit	0.040	0.145
Inpatient admission	0.067	0.255
Opioid poisoning events (%)		
Any ED or inpatient	0.027	0.102
ED visit	0.014	0.046
Inpatient admission	0.014	0.059
Characteristics (%)		
Insurance		
Employer based	69.64	43.00
Individual market	3.75	1.93
Medicare Advantage	26.62	55.08
Age group		
18-24 years	9.09	1.27
25-34 years	14.04	5.03
35-44 years	16.35	9.97
45-54 years	18.98	18.30
55-64 years	17.56	23.74
65-74 years	14.62	23.42
75-84 years	7.08	13.39
85+ years	2.28	4.86
Female	54.69	58.64
Any mental health condition	13.83	24.63
Alcohol use disorder	0.62	1.19
Drug use disorder	0.88	2.78
Tobacco use	2.63	4.81
Back pain	15.60	34.95
Neck pain	6.13	12.39
Arthritis pain	28.61	51.42
Other pain	13.81	25.11
Number of observations	31,482,222	2,088,000
Number of unique patients	6,423,416	358,940

Notes: Full sample are adults (ages 18+) with private insurance or Medicare Advantage who had filled at least one opioid prescription during study years, did not have a diagnosis of cancer or sickle cell, and were living in states that had an operational PDMP by December 2010. Long-term use sample are patients with at least one long-term episode during study years. A long-term opioid episode was defined as continuous use of prescription opioids for 90 days or longer; a gap of 30 days or more with no opioid use was used to determine the end of a long-term opioid use episode. The unit of analysis was patient half-year.

The event study analysis indicated that implementing and non-implementing states largely followed parallel trends in our primary outcome in the 4 half-years leading to policy implementation (Appendix Figs. 1, 2, Supplemental Digital Content 1, http://links.lww.com/MLR/B996).

Implementation of comprehensive use mandates was associated with a reduction in the probability of any opioid-related hospital event from 0.101% [95% confidence interval (CI): 0.100, 0.103] to 0.073% (95% CI: 0.067, 0.080), amounting to a relative reduction of 27.7%. Delegate laws were associated with a 5.3% reduction, from 0.102% (95% CI: 0.099, 0.104) to 0.096% (95% CI: 0.094, 0.099). Interstate data sharing was associated with a 6.2% reduction, from 0.102% (95% CI: 0.100, 0.104) to 0.096% (95% CI: 0.093, 0.098) (Fig. 1).

Figure 1. Changes in the probability of any opioid-related hospital event among patients with any opioid use, 2011-2015



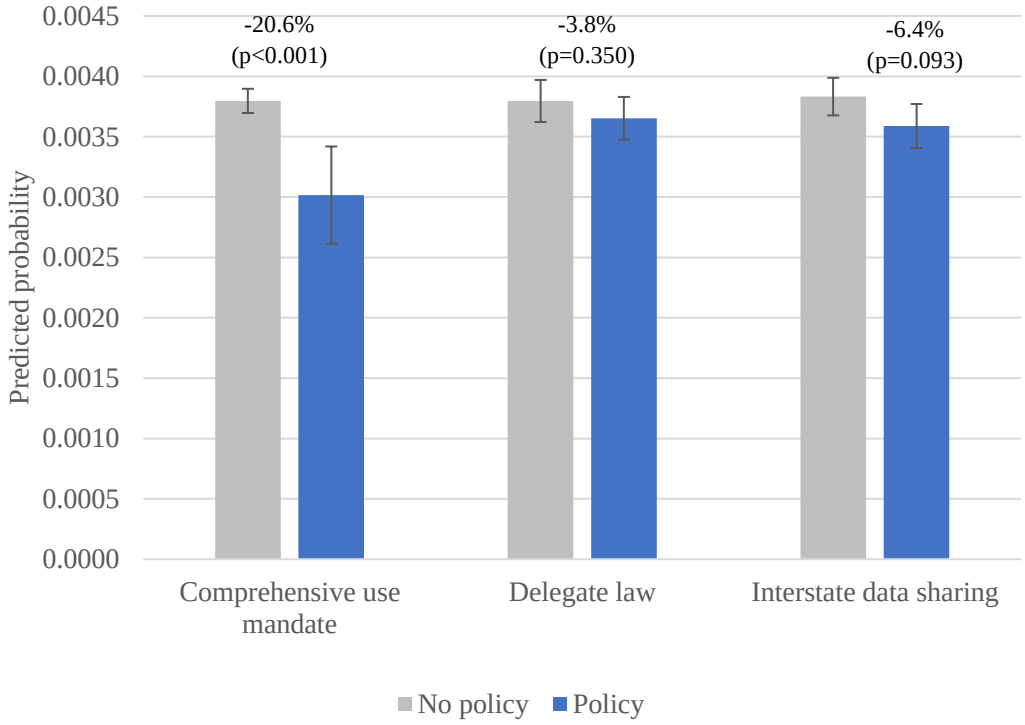
Notes: The exhibit shows the predicted changes in the probabilities of outcomes associated with implementation of Prescription Drug Monitoring Program policies among privately insured or Medicare Advantage adults who were ages 18+, had at least 1 opioid prescription in the study period, did not have a diagnosis of cancer or sickle cell, and lived in the 28 states that had an operating program by December 2010. The unit of analysis was patient half-year. The whiskers indicate 95% confidence intervals. The percentages (relative effects) indicate the difference between probabilities with and without a mandate. Source: Author's analysis of data for 2011–2015 from the Health Care Cost Institute's insurance claims database.

3.2 Patients With Long-term Opioid Use

Our sample included 2,088,000 half-years from 358,940 unique patients with at least 1 episode of long-term opioid use. Of these half-years, 0.37% experienced an opioid-related hospital event, 0.15% experienced an opioid-related ED visit, and 0.26% experienced an opioid-related inpatient admission (Table 1).

In this subsample, comprehensive use mandates were associated with a 20.6% reduction in the probability of any opioid-related hospital event, from 0.380% without a mandate (95% CI: 0.370, 0.390) to 0.302% with a mandate (95% CI: 0.261, 0.342). Neither delegate laws nor interstate data sharing were associated with a statistically significant change in the probability of such an event (Fig. 2).

Figure 2. Changes in the probability of any opioid-related hospital event among patients with long-term opioid use, 2011-2015



Notes: The exhibit shows the predicted changes in the probabilities of outcomes associated with implementation of Prescription Drug Monitoring Program policies among privately insured or Medicare Advantage adults who were ages 18+, had at least 1 opioid prescription in the study period, did not have a diagnosis of cancer or sickle cell, and lived in the 28 states that had an operating program by December 2010. Long-term use sample are patients with at least 1 long-term episode during study years. A long-term opioid episode was defined as continuous use of prescription opioids for ≥90 days; a gap of ≥30 days with no opioid use was used to determine the end of a long-term opioid use episode. The unit of analysis was patient half-year. The whiskers indicate 95% confidence intervals. The percentages (relative effects) indicate the difference between probabilities with and

without a mandate. Source: Author's analysis of data for 2011–2015 from the Health Care Cost Institute's insurance claims database.

3.3 Sensitivity Analyses

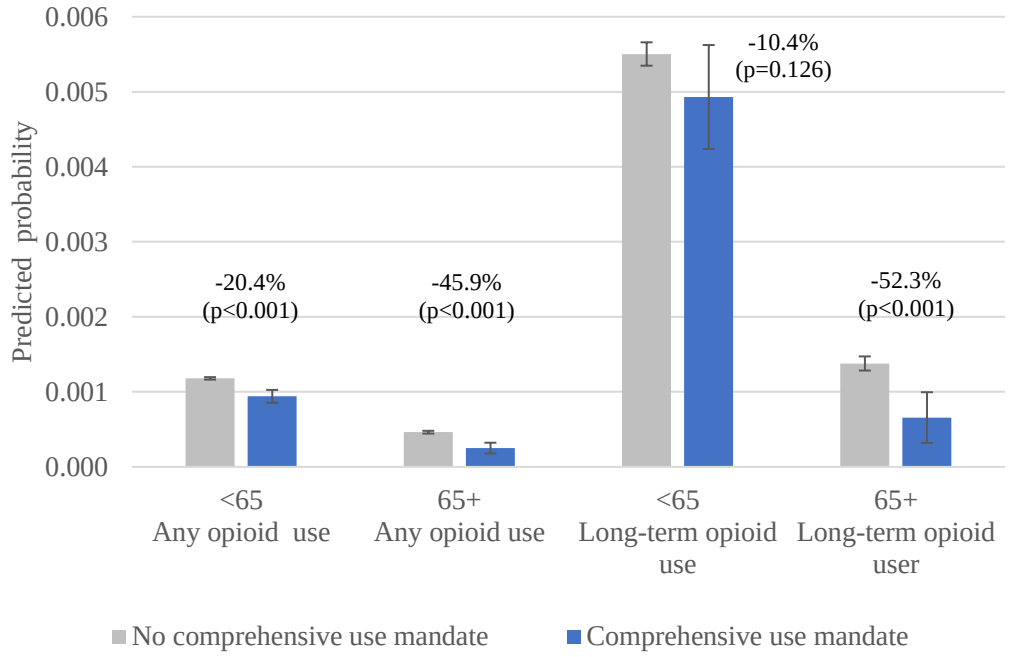
Our results are robust across multiple sensitivity analyses. First, we ended our study period on June 30, 2015, to avoid any implication of the transition from International Classification of Diseases (ICD)-9 to ICD-10 codes starting in October 2015 (Appendix Figs. 3A, B, Supplemental Digital Content 1, http://links.lww.com/MLR/B996). Second, we defined our outcome of opioid-related hospital events based on the primary diagnosis only (rather than using primary and secondary diagnoses) (Appendix Figs. 4A, B, Supplemental Digital Content 1, http://links.lww.com/MLR/B996). Results based on these 2 analyses (in terms of relative changes in outcomes) were similar to those of the main analysis. Lastly, we defined our outcome as hospital events involving opioid poisonings only (Appendix Figs. 5A, B, Supplemental Digital Content 1, http://links.lww.com/MLR/B996). Poisoning events, however, were rare and were known to be seriously underreported. While comprehensive use mandates were associated with reduced opioid poisoning events among patients with any opioid use, the policy was not associated with significant changes among patients with long-term opioid use.

3.4 Policy Effects for Older Versus Younger Patients

Among patients with any opioid use, the rate of opioid-related events among patients 65 or older was about one third of that of younger patients (0.0004 vs. 0.0012). Among patients with long-term opioid use, the rate of opioid-related events for older patients was about one fifth of that of younger patients (0.001 vs. 0.005) (Appendix Table 3, Supplemental Digital Content 1, http://links.lww.com/MLR/B996). As shown in Figure 3, although the rate of opioid-related hospital events was much lower among older patients, the relative reduction associated with a comprehensive use mandate was substantially higher (46%–52%) among older patients compared with younger patients (10%–20%). Delegate laws were associated with reductions in opioid-related hospital events for patients of all ages (5%–13%); the estimates did not achieve statistical significance among patients with long-term opioid use. Interstate

data sharing was associated with reductions in opioid-related hospital events for patients ages 65 or older (6%–22%).

Figure 3. Changes in the probability of any opioid-related hospital event associated with a state's implementation of comprehensive PDMP use mandates, 2011-2015



Notes: The exhibit shows the predicted changes in the probabilities of outcomes associated with implementation of comprehensive use mandates among privately insured or Medicare Advantage adults who were ages 18+, had at least 1 opioid prescription in the study period, did not have a diagnosis of cancer or sickle cell, and lived in the 28 states that had an operating program by December 2010. Long-term use sample are patients with at least 1 long-term episode during study years. A long-term opioid episode was defined as continuous use of prescription opioids for ≥ 90 days; a gap of ≥ 30 days with no opioid use was used to determine the end of a long-term opioid use episode. The unit of analysis was patient half-year. The whiskers indicate 95% confidence intervals. The percentages (relative effects) indicate the difference between probabilities with and without a mandate. Source: Author's analysis of data for 2011–2015 from the Health Care Cost Institute's insurance claims database.

4 Discussion

Using a large national commercial insurance database, we found that state policies designed to enhance prescriber PDMP use and, in particular, comprehensive use mandates for prescriber use of PDMP at the point of care, were associated with as much as 28% reduction in the probability of a hospital event related to opioid dependence, abuse, or overdose over a half-year. This finding suggests that 27,486 fewer individuals with private insurance or Medicare would have experienced opioid-related hospital events in the second half of 2015 alone if comprehensive use mandates had been implemented in every state

(Appendix Table 4, Supplemental Digital Content 1, http://links.lww.com/MLR/B996). Delegate laws and interstate data sharing were associated with limited reduction (5%–6%) in the probability of an opioid-related hospital event among patients receiving at least 1 opioid prescription and no significant change among patients with long-term prescription opioid use. Despite a much lower rate of such events, patients 65 or older saw a much larger relative reduction in the probability of having these events in response to a comprehensive use mandate compared with younger patients. Our findings provide strong evidence that comprehensive use mandates contributed to reductions in prescription opioid misuse and overdose.

One mechanism by which PDMP policies might affect opioid-related hospital events is through reduced prescription opioid use that puts patients at high risk of opioid misuse or overdose. Our analysis of HCCI data pertaining to the same study population indicated that comprehensive use mandates were associated with a 10%–11% reduction in the probability of having overlapping opioid prescriptions and a more modest reduction in the probability of having opioid prescriptions from ≥3 prescribers, 2 prominent measures of high-risk opioid prescriptions (Appendix Fig. 6, Supplemental Digital Content 1, http://links.lww.com/MLR/B996), thus providing support for this mechanism.

Our findings are also consistent with those of a recently published study that found comprehensive use mandates were associated with a 4.2% reduction in opioid-related inpatient discharges and 17.8% reduction in opioid-related ED discharges among Medicaid patients.35 Our estimated effect on the composite outcome of opioid-related inpatient or ED events was slightly larger (28% overall and 20% and 46% reduction for younger and older patients, respectively). This likely reflects differences in the study populations; while people with private insurance or Medicare Advantage—the focus of our study—had a lower likelihood of opioid misuse and overdose compared with Medicaid enrollees,36 we restricted our population to patients with at least 1 opioid prescription during the study years (and thus a heightened risk of opioid misuse or overdose) compared with the general Medicaid population in the other study.

Our (and other recent) findings may alleviate concerns regarding potential unintended consequences of PDMP policies, for example, by increasing harmful illicit opioid use among patients whose use of prescription opioids were curtailed or discontinued abruptly. Increased illicit opioid use associated with a higher and rapidly increasing rate of overdose may counteract the (intended) effects of the PDMP policies on adverse events related to prescription opioid misuse and overdose. Although we were not able to separately assess the effects of PDMP policies for prescription opioid- and illicit opioid-related events, the sizable reduction in all opioid-related hospital events suggests that it was unlikely that comprehensive use mandates were associated with a large unintended shift to harmful illicit opioid use in the study population.

Our findings of large relative effects for older patients are consistent with age differences in the evolving epidemic of prescription opioid misuse over 2002–2014.[21] Specifically, the rate of prescription opioid misuse doubled among people 50 or older compared with a decline among individuals 18–24 and stability among those 25–49. In contrast, the rate of illicit opioid use (and illicit opioid-related overdoses[37]) increased much more rapidly among younger than older adults. While comprehensive use mandates seemed associated with similar or smaller relative reduction in high-risk opioid prescriptions among older versus younger patients (Appendix Fig. 6, Supplemental Digital Content 1, http://links.lww.com/MLR/B996), these policies, by addressing prescription opioid misuse, may have been more effective in reducing opioid-related hospital events among older patients since prescription opioid misuse (rather than illicit opioid use) may have more dominantly accounted for hospital events among older patients. Our study had several limitations. First, whether a state implemented a PDMP policy and the timing of implementation may be correlated with the development of the opioid crisis in the state, leading to potential biases in our estimates.

Our event study analysis, however, indicated that implementing and non-implementing states exhibited parallel trends in study outcomes before policy implementation. Second, in addition to implementing PDMP policies, states may have concurrently engaged in other actions to publicize and

prioritize strategies to address the opioid epidemic. We cannot disentangle the effects of PDMP policies of interest from these other activities. Third, many states implemented multiple PDMP-enhancing policies. In particular, 6 of the 7 states with comprehensive use mandates in our analysis had implemented delegate laws before or at the same time as their comprehensive use mandates took effect. The estimated effects pertaining to comprehensive use mandates thus more closely reflect the combined effects of comprehensive use mandates and delegate laws. Meanwhile, 17 of the 23 states with delegate laws did not implement comprehensive use mandates. The estimated effects of delegate laws thus captured their effects independent of the effects of comprehensive use mandates. Fourth, we did not include non-PDMP policies that might bear implications for prescription opioid use. Previous studies did not find state laws governing pain clinics to be associated with a reduction in opioid prescribing or opioid overdose death rates.18 Although several studies had found medical marijuana legalizations (MMLs) to be associated with reductions in population rates of prescription opioid overdose deaths or opioid-related hospitalizations,[38–40] these MMLs largely took effect before 2011 or after 2015,[41] and, thus had little overlap with the implementation of PDMP policies examined in this study. Importantly, of the 7 states that implemented comprehensive PDMP use mandates in our study, 3 (Kentucky, Oklahoma, and Tennessee) never had MML, 1 (Nevada) had MML in 2001, and 2 (Ohio, West Virginia) did not have MML effective until 2016 and 2017, respectively; in only 1 state (Connecticut), MML took effect during our study years (2012), 3 years before their comprehensive use mandate took effect.[42] It is thus unlikely that the association we found between comprehensive use mandates and opioid-related hospital events was confounded by the MML. Fifth, although the HCCI data cover approximately one third of those with private insurance and one half of those with Medicare Advantage nationwide,[43] the generalizability of our findings to the privately insured and Medicare Advantage populations is unknown and may vary across states. Our analysis of national data of privately insured and Medicare Advantage adults provides evidence that state implementation of comprehensive mandates for prescriber use of PDMP was associated with large relative reductions in hospital events related to opioid dependence, abuse, and

overdose. In relative terms, such mandates seemed more beneficial for older adults who used prescription opioids.

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CHAPTER 3

The Impact of Public Health Insurance Expansions on Access and Use of Medications for HIV Treatment and Prevention: Evidence from the Affordable Care Act

Shyam Raman, Cornell University
Katherine Wen, Cornell University
Dan Sacks, Indiana University
Alex Hollingsworth, Indiana University

Objectives: To investigate the effects of Affordable Care Act (ACA) facilitated Medicaid expansions on the use of pre-exposure prophylaxis (PrEP) and medications used to treat Human Immunodeficiency Virus (HIV).

Methods: This study uses Medicaid State Drug Utilization and AIDSVu data from 2008 to 2018 to identify drugs prescribed for PrEP and HIV treatment. We exploit state-level variations in expansion status to estimate difference-in-difference models, where we compare changes in the use of PrEP and HIV treatment medications between Medicaid expansion and non-expansion states.

Results: We find a roughly 31% increase in the utilization of PrEP and a 19% increase in the utilization of therapeutic HIV medications within the Medicaid population. We do not find statistically significant evidence that the increased utilization of PrEP following these public insurance expansions had any effect on new HIV diagnoses. We also do not find evidence that the increase in utilization of therapeutic HIV medications was associated with a reduction in HIV deaths.

Conclusion: These results suggest that the Medicaid expansions were associated with increased access to and use of HIV prevention and treatment medications. Expanding public insurance access may be a tool to end the HIV epidemic.

Introduction

The HIV epidemic in the United States continues to plague its most vulnerable communities. More than 36,000 new HIV infections and 15,000 HIV deaths occurred in 2018 (US Department of Health and Human Services, 2020). Though still without a cure, prophylactic and therapeutic antiviral medications are now prescribed to decrease the transmission and virulence of some of these infections. Pre-exposure prophylaxis (PrEP) are antivirals that dramatically reduce the likelihood of contracting HIV conditional on exposure. Truvada and Descovy, two trugs approved by the FDA for PrEP, have an efficacy rate of over 90% in preventing new infections (Underhill et al., 2016). If infection cannot be prevented, antiviral medications can be prescribed to reduce a patient's viral load, the amount of measured virus, to an undetectable level.

Despite its high efficacy, only 0.85% of people at risk of HIV use PrEP. One barrier is cost; an annual prescription costs $24,000 and an annual prescription of therapeutic antivirals can cost up to $25,000. Private insurers and Medicare Part D cover the cost of PrEP and therapeutic HIV antivirals. Medicaid generally covers these prescriptions without copayment. Thus, insurance access is strongly associated with PrEP use and insured individuals are 400% more likely to adhere to a regimen than the uninsured (Patel et al., 2017).

HIV prevention relates to the literature surrounding the demand for health care in response to health insurance. Specifically, this research relates to the literature on ex ante moral hazard, which reflects the effect of health insurance on investments in disease prevention and risky health behaviors. On one hand, health insurance decreases the cost of preventive care. Although we know that heath care consumption is sensitive to health insurance and cost from experimental and quasi-experimental settings (e.g., RAND Health Insurance Experiment, Oregon Health Insurance Experiment, and Affordable Care Act), there is mixed empirical evidence of ex ante moral hazard. Barbaresco et al. (2015), however, do not find evidence that the ACA increased preventive care utilization among people ages 23–25 while Dave and Kaestner (2009) find some evidence that gaining access to Medicare coverage at age 65

increases the number of doctor visits. Other studies have documented some changes in consumer demand for preventive, routine care such as well-patient visits, pap smear and mammogram tests, and cancer screening among others (Finkelstein et al., 2012; Kolstad and Kowalski, 2012; Soni et al., 2017; Courtemanche et al., 2018). Studies of the RAND Health Insurance Experiment estimate the price elasticity of demand for preventive care to be -0.17 to -0.43 (Simon et al., 2017). On the other hand, health insurance also decreases the cost of engaging in risky health behaviors because it lowers the cost of treatment. Risky behaviors such as smoking, alcohol consumption, poor diet, lack of exercise, and unprotected sex are a major source of preventable deaths (Cawley and Ruhm, 2011). There is limited evidence that health insurance increases engagement in risk health behaviors, such as drinking (Barbaresco et al., 2015), alcohol consumption, and less physical activity (Dave and Kaestner 2009). Similarly, Simon et al. (2017) find no evidence that ACA increased heavy drinking, binge drinking, exercise, BMI, or obesity.

Additionally, laws, policies, and biomedical research advances may change the cost of and demand for risky sex. For example, stricter abortion laws and minimum drinking ages have been found to reduce the demand for risky sex (Chesson, 2012). Biomedical research advances such as highly active anti-retroviral therapy (HAART) to treat HIV effectively reduced the price of risky sex (Chan et al., 2015), which could increase the demand for risky sex. Although the introduction of HAART decreased HIV mortality, it coincided with an increase in HIV incidence (Lakdawalla et al., 2006). These studies also find that HIV positive individuals living in states with more generous Medicaid eligibility rules (and therefore more likely to get HAART) were also more likely to engage in risky sex. Additionally, Willage (2019) finds that while the zero-cost sharing mandate of the ACA decreased prescription contraception prices, it also decreased condom use and increased sexually transmitted infections.

This study evaluates the effect of state Medicaid expansions, facilitated by ACA, on the utilization of prophylactic and therapeutic treatment for HIV. Between 2014 and 2018, 36 states opted to expand Medicaid eligibility to nearly all people with household incomes below 138% of the federal

poverty line. Our study finds that states which expanded Medicaid following the ACA saw greater increases in PrEP utilization when compared to non-expansion states.

Data and Methods

Our primary data source is the Medicaid State Drug Utilization Data (SDUD), which records outpatient drugs paid for by state Medicaid agencies. We retrieved these data from the NBER archive at the yearly level from 2008 to 2018. The data contain aggregate prescribing data for each national drug code (NDC) at the state-quarter level, including the number of prescriptions filled and paid for by Medicaid. Additionally, we are also interested in the utilization of therapeutic HIV drugs, which are used after diagnosis to mitigate disease spread and reduce the HIV viral load in the body. These drugs were identified from the FDA recommended therapeutics portal for HIV and can also be identified in the SDUD.

A limitation of the SDUD data, however, is that it does not provide patient-level demographics to further stratify our analyses by gender, age, ethnicity, or other socioeconomic factors. Additionally, these data do not contain information on non-Medicaid prescriptions. Thus, if we find evidence of an increase in utilization using only the SDUD data, this should not be taken on its own as evidence that Medicaid expansion increased the use of HIV medications per capita, regardless of health insurance coverage. It may be that Medicaid is crowding out private insurance or self-purchased prescriptions. Given this limitation, the SDUD may overstate the impact of Medicaid expansion on total medication use.

Consequently, we supplement the SDUD with PrEP utilization measures captured by AIDSVu, a website which provides resources for visualizing the AIDS epidemic, which is available from 2012-2018. AIDSVu contains a database of the count of PrEP users at the state-year level. These counts are derived from prescription data compiled by Source Healthcare Analytics, a market research firm, and are estimates from a validated algorithm assessing counts of PrEP. Although these counts are not meant to be representative of the total population of each state, they do represent a consistent sample across time. This

sample includes data from over 50,000 pharmacies, 1,000 hospitals, 80,000 physician practices, and 800 outpatient centers. The data capture PrEP users covered by private insurance, Medicare, Medicaid, self-paying patients, and pharmaceutical cash assistance programs.

We obtain data on new HIV diagnoses and the rate of new sexually transmitted infections (STIs) from the CDC annual surveillance reports and AtlasPlus, which are also available from 2008-2018. These data contain aggregate cases at the state-year level for new HIV diagnoses and each of the additional infectious diseases we use in our analysis: gonorrhea, chlamydia, and syphilis. HIV mortality data were retrieved from the CDC Wonder for ICD-10 codes [B20-24] which represented HIV-related deaths.

We adjust for changes in population by dividing total prescription unit amounts by state-year population data obtained from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER). Population data sourced from SEER was retrieved from the NBER data archive at the county-year level and aggregated to a state-year level. Additionally, to adjust for economic conditions that may have separate effects on Medicaid enrollment, we add state-level unemployment rates from the Bureau of Labor Statistics (BLS) Local Area Unemployment Statistics (LAUS).

We use the coding and dating of Medicaid expansions in Simon, et al (2017), updated for 2016 and 2017 expansions using the definitions in Carey, et al (2020). We define states as having expanded if they had complete, substantial, or mild expansions. We test separately whether effects are strongest in the full expansion states and find no evidence of this difference.

We fit difference-in-difference models to estimate the effect of Medicaid expansion on our outcomes of interest. Our model for the conditional mean of an outcome y_{st} in state *s* and period *t* takes the form

$$\mathrm{y_{st}} = \alpha \mathrm{Post_t} * \mathrm{Treat_s} + \beta \mathrm{X_{st}} + \mu_s + \theta_t + \epsilon_{st}$$

α is identified by state variation in Medicaid expansion status over time. $\mathrm{Post_t} * \mathrm{Treat}_s$ is an indicator for post Medicaid expansion, X_{st} is a vector of controls indexed at state-time, and μ_s and θ_t are state and

time fixed effects. In some models we control for census region-year fixed effects (rather than year fixed effects) to ensure that regional trends are not confounding our results since prior work has shown that regional disparities in prior authorization can be a barrier for PrEP access (McManus, 2020). As our outcome variables are logged rates, we perform a delta method expansion of our coefficients to produce a percent change value represented in our results.

We also consider event study models to examine the impacts of the expansions over time:

$$E[y_{st}|x_{st}, t, s] = \exp\left(\sum_{\tau=-6,\tau\neq-1}^{\tau=4} \alpha post_{st,\tau} + X_{st}\beta + \mu_s + \theta_t\right)$$

Here, $post_{st,\tau}$ is an indicator for τ years since Medicaid expansion. We include four post-period indicators because most expansion states have four years of post-data (2015-2018); we also include a dummy for greater than four years post expansion, for early expanders.

We do not expect Medicaid expansions to have an immediate effect on PrEP utilization or HIV diagnoses, for several reasons. First, to obtain a PrEP prescription, a person must demonstrate that they have been HIV-free for six months, meaning there can be a delay between seeking PrEP and obtaining it. Second, HIV transmission and diagnoses both take time to occur. Third, many Medicaid expansions took place mid-year, but our data are annual, and this can attenuate their first-year impact.

Results

Table 1 provides summary statistics on our key variables as well as the underlying sources. Although the two PrEP measures appear to give very different amounts, we note that they are measuring different things – PrEP *prescriptions* in the Medicaid SDUD and PrEP *users* in AIDSVu data. If every PrEP user generates 12 prescriptions per year, then we would expect about 172 (~14.3 x 12) prescriptions per 100,000. As we only observe Medicaid prescriptions, we do not expect the PrEP prescription count to be this high. Thus, the measures derived from different sources are roughly in alignment.

Table 1. Summary statistics

Variable	Source	Mean	Std Dev
PrEP prescriptions per 100,000 people	SDUD	120.5	176.0
PrEP users per 100,000 people	AIDSVu	14.3	24.0
New HIV diagnoses per 100,000 people	CDC	13.6	17.1
Ever expanded	See note	0.65	0.48

Notes: The sample consists of 41 full-expansion and non-expansions states. This table reports the equal-weighted sample average and standard deviation of the variables.

Table 2 shows the estimated percent change for each outcome in the Medicaid expansion states compared to non-expansion states. Column 1 includes state and year fixed effects and column 2 includes state and year fixed effects as well as control variables. Column 3, which includes state and region-by-year fixed effects as well as control variables, is the most robust and our preferred specification.

We are interested, first, in the impact of ACA-facilitated Medicaid expansions on PrEP prescriptions within the Medicaid population. Using the SDUD, in Table 2 column 3, we find that expansions were associated with a 31% increase in PrEP prescriptions in states which expanded Medicaid compared to states that did not. Using the AIDSVu data, we find that the Medicaid expansions were also associated with a 16% increase in PrEP users from those with private and public insurance as well as self-pay and cash-assistance users. The distinction in users captured by SDUD and AIDSVu is important because the SDUD more accurately captures Medicaid-enrolled PrEP users, the population that saw an increase in insurance access with the Medicaid expansions.

Table 2. Impact of Medicaid expansions on PrEP use and prescriptions, STI diagnoses, and HIV testing

	(1)	(2)	(3)
Main Results			
SDUD PrEP Prescriptions	42.70**	43.11**	31.19*
	(16.05)	(17.10)	(17.88)
SDUD Therapeutic HIV Prescriptions	26.62**	26.19**	18.96
	(11.92)	(12.60)	(11.37)
SDUD PrEP Users	80.35***	80.07***	63.12***
	(20.74)	(22.06)	(22.16)
Years Included	2008-2018	2008-2018	2008-2018
AIDSVu Prescriptions	13.29*	14.59*	15.54*
	(7.27)	(7.29)	(8.21)
Years Included	2012-2018	2012-2018	2012-2018
STD Results			
Chlamydia Diagnoses	2.47	2.31	-1.42
	(2.14)	(1.97)	(1.54)
Gonorrhea Diagnoses	12.14	12.18	-16.65***
	(10.30)	(9.77)	(5.12)
HIV Diagnoses	-1.13	-1.60	-1.64
	(2.90)	(2.99)	(4.27)
HIV Mortality	4.20	3.75	-0.57
	(2.57)	(2.56)	(2.66)
Syphilis Diagnoses	17.51*	17.88*	-7.03
	(9.11)	(9.12)	(7.97)
Years Included	2008-2018	2008-2018	2008-2018
BRFSS Results			
HIV Test [Ever]	1.22	0.98	0.61
	(1.27)	(1.45)	(1.69)
HIV Test [Past 3mo]	3.76	1.26	1.97
	(7.06)	(6.62)	(5.91)
HIV Test [Past 6mo]	3.62	2.22	2.90
	(4.54)	(4.43)	(5.30)
Same sex households per capita	-2.85**	-2.66**	0.65
	(1.41)	(1.28)	(1.63)
HIV Test [Past 12mo]	2.65	2.02	1.93
	(2.36)	(2.46)	(3.21)
Years Included	2011-2018	2011-2018	2011-2018

Notes: Our outcome variables are logged rates, so we perform a delta method expansion of our coefficients to produce a percent change values, reported in this table. Column 1 includes state and year fixed effects, column 2 includes state and year fixed effects and controls for state unemployment, and column 3 includes state and region-by-year fixed effects and controls for state unemployment. Robust standard errors are clustered at the state level in parentheses. Regressions use a log transformation of the raw data. * p<0.1, ** p<0.05, ***p<0.001.

We illustrate our difference-in-differences model visually in Figure 1. The top panel shows the number of Medicaid PrEP prescriptions per 100,000 people and the middle panel shows the number of PrEP users per 100,000. In both plots we see a clear increase in PrEP prescriptions and users the expansion states relative to the non-expansion states, post expansion. In these figures, we plot 2014 full expansion states against non-expansion states, so that calendar time and event time align. In the bottom panel, we plot therapeutic HIV prescriptions. While rates of therapeutic HIV prescriptions are similar for both expansion and non-expansion states through 2013, these rates begin to decline for non-expansion states in 2014 and for expansion states in 2015.

Figure 2 demonstrates the importance of capturing both Truvada and Descovy prescriptions, both which are manufactured by Gilead Sciences. During the time captured in our study, Truvada was the only FDA-approved drug for PrEP through 2018, though Descovy entered the market in 2016 and was allowed to be prescribed off-label as PrEP and received FDA approval for PrEP in 2019. Descovy is reported to have fewer bone and kidney related side-effects compared to Truvada, and Descovy prescriptions have been increasing since 2016 while Truvada prescriptions have been decreasing.

We then explore the effects of the Medicaid expansions in an event-study framework in Figure 3, which shows that PrEP prescriptions and PrEP users have increased following the implementation of the Medicaid expansion. Graphical illustration of this framework also allows us to validate the "parallel trends assumption" of our research design, which assumes pre-period trends between groups to be parallel with variation only after treatment.

Additionally, because quarterly HIV testing is a requirement for a PrEP prescription, we expect to see increases in recent HIV testing among new PrEP users. However, we do not find a statistically significant increase in HIV testing in the last 3 months, last 6 months, last 12 months, or ever (Table 2 and Figure 4).

Figure 1. Time trends for SDUD and AIDSVu PrEP prescriptions

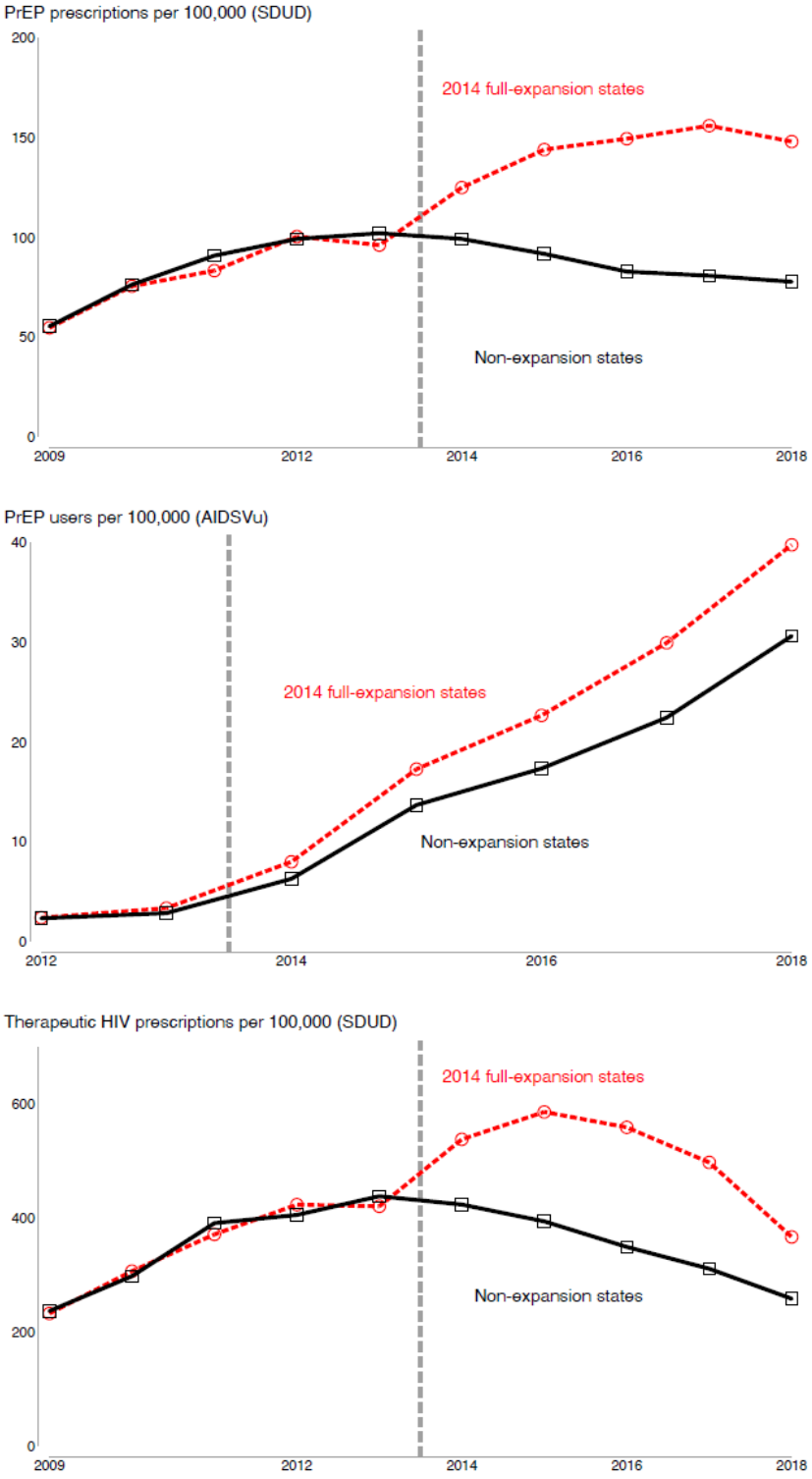
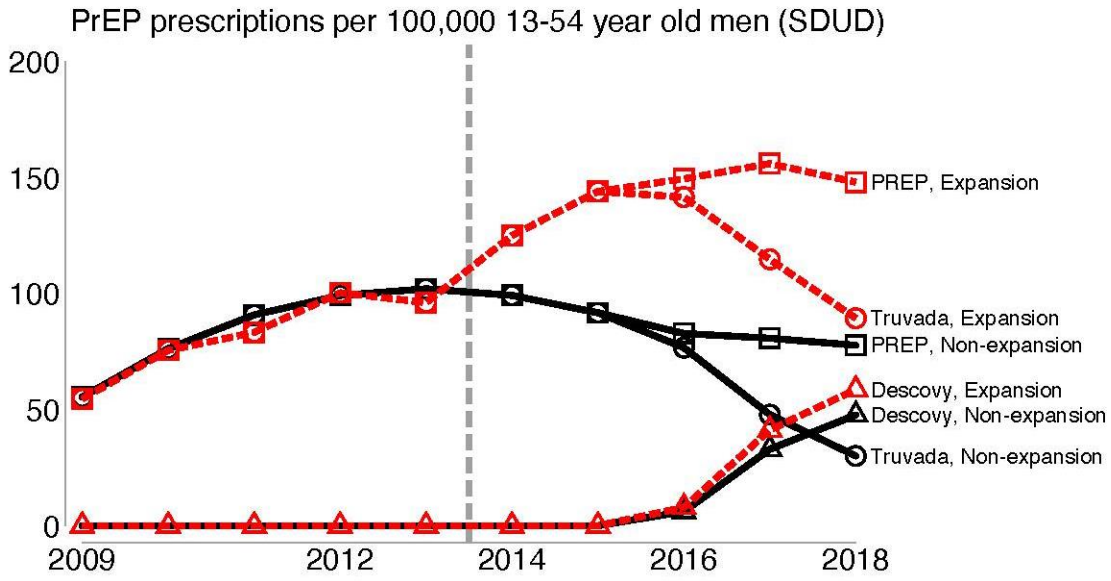


Figure 2. Truvada and Descovy prescriptions in expansion and non-expansion states



Notes: Calculated using Medicaid State Drug and Utilization Data, 2009-18. Late expansion states are not included in this graph. Descovy entered the market in 2016 and is reported to have fewer bone and kidney related side effects relative to Truvada. Descovy could be prescribed for off-label PrEP use beginning in 2016, after which Descovy prescriptions increased while Truvada prescriptions decreased.

One concern may be that populations at risk of HIV were moving to states that expanded Medicaid access to receive PrEP following the Medicaid expansions. In the United States, gay, bisexual, and other men who have sex with men (MSM) are most affected by HIV, but we do not have annual state estimates for this population. However, the American Community Survey does allow us to estimate the number of same-sex households in each state over time. In Figure 5, we estimate an event study to examine the change in same-sex households and find no significant changes in the number of same-sex households in Medicaid expansion states.

Discussion

Preventing the spread of infectious diseases is a textbook justification for health care and health insurance interventions. Despite this, there is limited evidence on whether government induced increases in insurance coverage reduces the spread of infectious disease. In this paper, we estimate the effect of insurance expansions on the use of medications designed to prevent and treat HIV infections.

The Medicaid expansions represent a recent variation in access to HIV-related medications. Specifically, we see a significant increase in the use of PrEP and therapeutic HIV medications in states that expanded Medicaid compared to those that did not. While significant increases were shown in the utilization of PrEP, we do not find evidence that this increase in use lead to any risk compensating behaviors. Specifically, we do not find statistically significant effects of Medicaid expansion on the rates of diagnosis for chlamydia, gonorrhea, or syphilis. Our findings are consistent with the existing literature that documents mixed evidence about the change in demand for preventive care and limited change in engaging in risky behaviors in response to gaining access to health insurance. Similarly, Gai and Marthinsen (2019) find that the Medicaid expansions were not associated with increases in HIV risk behaviors.

Additionally, we use both SDUD and AIDSVu data to measure PrEP prescriptions and utilization. The AIDSVu captures PrEP users among those with private, public, self-pay and cash-assistance users, while the SDUD captures PrEP prescriptions among Medicaid enrollees, the population that actually saw an increase in insurance access due to the expansions. This is an important distinction. First, our results will better inform policymakers seeking to direct resources and reduce the cost of publicly provided HIV-related care; estimates using the entire population of PrEP users may understate the effect of Medicaid expansions since they include data on PrEP use for the non-Medicaid population, which has been rapidly growing across this time in both expansion and non-expansion states. Second, Medicaid-specific estimates of PrEP use are important since this group represents a vulnerable population at greater risk of HIV, who--if positive--are more likely to require public assistance for treatment. In addition to reducing community spread of HIV, PrEP is significantly less costly than HIV treatment (Schackman et al., 2015). Medicaid covers 42% of adults with HIV in comparison to 13% of the general adult population (Kaiser Family Foundation, 2019). The Medicaid expansions were associated with increased access to and use of HIV prevention and treatment medications and expanding public insurance access may be one tool to end the HIV epidemic.

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