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# Adverse events following mRNA SARS-CoV-2 vaccination among U.S. nursing home residents

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ABSTRACT

*Background:* The devastating impact of the SARS-CoV-2 pandemic prompted the development and emergency use authorization of two mRNA vaccines in early 2020. Vaccine trials excluded nursing home (NH) residents, limiting adverse event data that directly apply to this population.
*Methods:* To prospectively monitor for potential adverse events associated with vaccination, we used Electronic Health Record (EHR) data from Genesis HealthCare, the largest NH provider in the United States. EHR data on vaccinations and pre-specified adverse events were updated daily and monitored for signal detection among residents of 147 facilities who received the first dose of vaccine between December 18, 2020 and January 3, 2021. For comparison, unvaccinated residents during the same time period were included from 137 facilities that started vaccinating at least 15 days after the vaccinating-facilities.
*Results:* As of January 3, 2021, 8553 NH residents had received one dose of SARS-CoV-2 vaccine and by February 20, 2021, 8371 residents had received their second dose of vaccine; 11,072 were included in the unvaccinated comparator group. No significant associations were noted for neurologic outcomes, anaphylaxis, or cardiac events.
*Conclusions:* No major safety problems were detected following the first or second dose of the vaccine to prevent COVID-19 in the study cohort from December 18, 2020 through March 7, 2021.
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## 1. Introduction

The SARS-CoV-2 pandemic has had a devastating impact on the nursing home (NH) and residential care population in the United States and globally. Less than 1% of the U.S. population lives in long-term care facilities, but by March 2021, 34% of US SARS-CoV-2 deaths occurred in the long-term care population [1]. Accordingly, frail older adults living in congregate settings ranked in the top priority group for distribution of the vaccine [2]. However, both the Pfizer-BioNTech and Moderna vaccine trials excluded NH residents [3,4]. Because considerable evidence indicates immune system responsiveness declines with age and frailty, and such individuals were excluded from vaccine trials on which these vaccines were tested [5], we especially need safety monitoring after vaccination for this population.

By March 10, 2021, over 2.7 million long-term care facility residents and staff were fully vaccinated against SARS-CoV-2 [6]. Reports of fatal adverse events following mRNA-based vaccination (Pfizer-BioNTech) for SARS-CoV-2 in Norwegian NH residents raised concern regarding vaccine safety in very old and frail persons [7]. Those reports lacked contemporaneous control groups, a significant limitation given the high baseline mortality in this population. Moreover, no studies assessed adverse events of special interest following immunization in the NH population such as Guillain-Barre syndrome or Bell's Palsy, as distinguished by the Brighton Collaboration [8]. Prior to the SARS-CoV-2 pandemic, only passive surveillance captured suspected adverse events after vaccination among the NH population [9]. To address this gap, Brown

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University partnered with Genesis HealthCare, a large NH provider spanning 24 U.S. states, to conduct active, prospective surveillance of adverse events after vaccination of NH residents. Herein, we report results of active surveillance for signal detection after vaccination of NH residents from December 18, 2020 through March 7, 2021.

## 2. Methods

Our study population included 21,222 NH residents of 284 facilities within Genesis Healthcare, a large NH provider spanning 24 U. S. states. One of two long-term care pharmacy chains administered SARS-CoV-2 vaccine at these NHs on specific days or "clinics" temporally spaced according to the recommended vaccination schedule. Genesis coordinated with pharmacy chains to offer vaccine to residents and staff during three vaccine clinics over a three-month period.

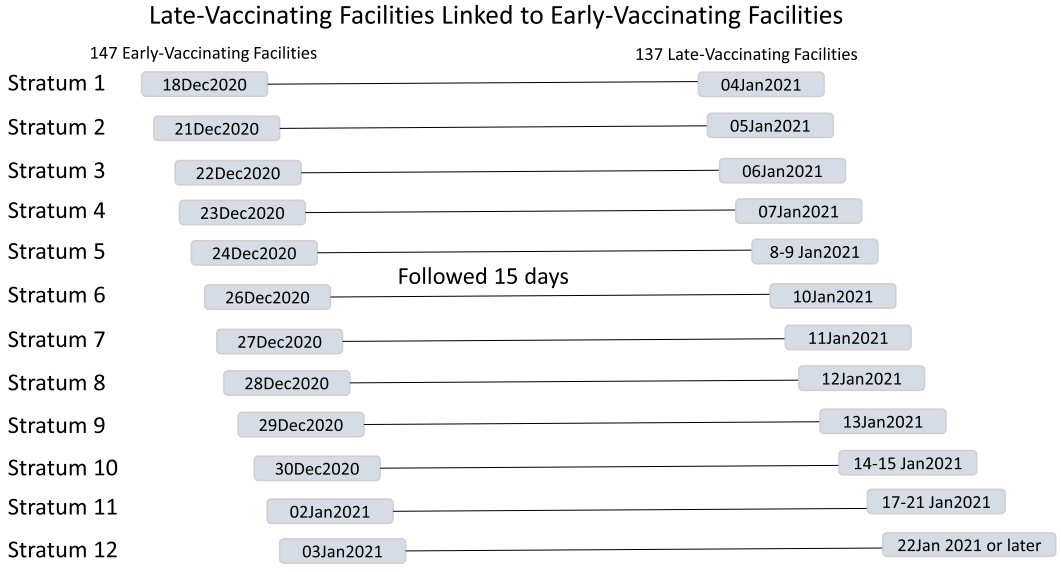
### 2.1. Study design

Genesis HealthCare transferred daily electronic health record (EHR) data to Brown for analysis. These data included the Minimum Data Set (MDS), daily resident census, vital signs, diagnoses, immunizations, SARS-CoV-2 testing records, nursing documentation, medication records and other core EHR elements. To ensure comparison in rates of adverse events during the same time period and with the same duration of follow-up, we identified late-vaccinating facilities based on the date of their first vaccination clinic (e.g., at least 15 days after early-vaccinating facilities). Between December 18, 2020 and January 3, 2021 147 NHs ('early-vaccinating facilities') administered the first dose of vaccine and between January 8 through February 20, 2021 those facilities held 2nd clinics, administering the 2nd dose of vaccine. The vaccine received (e.g., Moderna or Pfizer-BioNTech) varied by state. The comparison group included residents from the 137 Genesis facilities that did not start vaccinating until January 4, 2021 ('late-vaccinating facilities) [Fig. 1]. Early- and late-vaccinating facilities were partitioned into 12 strata by the date of their first vaccination clinic. This ensured that residents in the late-vaccinating facilities were vaccinated at least 15 days after the early vaccinating facilities. Residents included in the analysis were present in the facility on the day the vaccinating facility had its first vaccination clinic. Follow-up for the first dose and the unvaccinated groups was between December 18, 2020 and January 18, 2021, and follow-up for the second dose was between January 8 and March 7, 2021. For example, in the first stratum, residents of facilities that vaccinated on December 18, 2020 were included and unvaccinated residents of NHs that held their first vaccination clinic on January 4, 2021 who were present in those NHs on December 18, 2020 were included as the comparator group. All in stratum 1 were followed from December 18, 2020 through January 2, 2021.

Consistent with CDC guidelines, we excluded residents with a laboratory confirmed SARS-CoV-2 infection in the 20 days prior to the vaccine clinic, as well as those who had received monoclonal antibody treatment for their SARS-CoV-2 infection during the 90 days prior to the vaccine clinic.

### 2.2. Outcomes

Serious outcomes such as mortality and hospital transfers post-vaccination were monitored for 7 days. If a resident died in the




Vaccination began at 147 facilities between December 18, 2020 and January 3, 2021. They were matched to 137 facilities in which vaccination began at least 15 days later. Those 137 facilities in which vaccination began January 4 or later were the unvaccinated comparator group, including residents who were in those facilities on the date of their matched vaccinating facilities. For example, in stratum 1, vaccinated residents were in the facility in which vaccination began on December 18, 2020 and unvaccinated residents were in the facilities in which vaccination began on January 4, 2021 *who were in those facilities* on December 18, 2020 and all were followed for 15 days, from December 18-January 3. This ensured the comparator group was unvaccinated and followed during the same time period as the vaccinated residents.

**Fig. 1.** Vaccination began at 147 facilities between December 18, 2020 and January 3, 2021. They were matched to 137 facilities in which vaccination began at least 15 days later. Those 137 facilities in which vaccination began January 4 or later were the unvaccinated comparator group, including residents who were in those facilities on the date of their matched vaccinating facilities. For example, in stratum 1, vaccinated residents were in the facility in which vaccination began on December 18, 2020 and unvaccinated residents were in the facilities in which vaccination began on January 4, 2021 who were in those facilities on December 18, 2020 and all were followed for 15 days, from December 18-January 3. This ensured the comparator group was unvaccinated and followed during the same time period as the vaccinated residents.

hospital shortly after transfer or they were expected to return to the Genesis facility, Genesis was notified of the death, and the outcome was therefore captured in this analysis. Other serious outcomes that could manifest somewhat longer post-vaccination were monitored for 15 days. We monitored for events identified by the Brighton Collaboration [8] using ICD-10-CM codes for diagnoses and exclusions from the Center for Disease Control and Prevention's Vaccine Safety Datalink [10]. For most events, we excluded prevalent cases to ensure capturing only incident cases.

### 2.3. Medical record reviews

We prospectively conducted an EHR record review on each case with a potential adverse event identified in the 15-day risk interval after SARS-CoV-2 vaccination. These reviews parsed potential adverse events between an incident (new onset) condition, a recent prevalent condition (duration varied by event) or incorrectly coded diagnosis within a 2-week period after identification. In order to estimate comparable unvaccinated rates, we also conducted record reviews on cases among the unvaccinated for the risk interval period identified by the vaccination date of their respective stratum.

### 2.4. Statistical analysis

We used SAS version 9.4 software for data management and to compute frequencies, and used chi-squared tests to assess statistical differences in baseline characteristics of residents. Adverse event rates and 95% Wilson's confidence intervals (CI) were calculated per 100,000 residents [11]. To identify the risk ratios of adverse events between vaccinated and unvaccinated residents, we estimated average treatment effects (presented as risk ratios) weighted by the conditional inverse probability of vaccination (or not if not given) (IPW). The weights were estimated with logistic regression and included the following variables: age, sex, race/ethnicity, diabetes, chronic obstructive pulmonary disease (COPD), chronic kidney disease, congestive heart failure, coronary artery disease, dementia, hypertension, and MDS measures of physical and cognitive function. Physical function was measured using the Morris Activities of Daily Living (ADL) scale, which ranges from 0 to 28, with higher scores indicating more impairment [12]. Cognitive function was measured using the Cognitive Function Scale which classifies residents as cognitively intact; or has having mild, moderate, or severe cognitive impairment [13]. Standard errors were estimated using a Huber-White covariance (''sandwich'') estimator clustered by strata. STATA version 16 (StataCorp, College Station, TX) software was used for the IPW-adjusted analysis [14,15].

The Brown University Institutional Review Board approved this study.

## 3. Results

In the 147 early-vaccinating facilities, 8553 residents received the first dose of vaccine and 8371 residents received the second dose of vaccine. Of the 8275 vaccinated for whom the vaccine manufacturer was known, 70.6% received Pfizer vaccine. Among the 137 late-vaccinating facilities, 11,072 residents were followed to assess for background event rates among the unvaccinated. There were no baseline significant differences among the vaccinated

**Table 1**
Demographic and clinical characteristics of nursing home residents by vaccination status.

| | 284 Facilities | | 147 Facilities | | | | 137 Facilities | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | 1 dose | | 2 doses | | Unvaccinated | | $p^*$ |
| | N (%) | | N (%) | | N (%) | | N (%) | | |
| **Gender** | | | | | | | | | 0.41 |
| Male | 8092 | (38.1) | 3191 | (37.6) | 3072 | (37.3) | 4128 | (38.0) | |
| Female | 13,123 | (61.9) | 5301 | (62.4) | 5161 | (62.7) | 6731 | (62.0) | |
| **Age Group (years)** | | | | | | | | | 0.98 |
| <65 | 4001 | (18.8) | 1611 | (19.0) | 1593 | (19.3) | 2041 | (18.8) | |
| 65–74 | 4981 | (23.5) | 1988 | (23.4) | 1916 | (23.3) | 2571 | (23.7) | |
| 75–84 | 5912 | (27.9) | 2341 | (27.6) | 2281 | (27.7) | 3006 | (27.7) | |
| ≥85 | 6328 | (29.8) | 2552 | (30.1) | 2443 | (29.7) | 3241 | (29.8) | |
| **Race/Ethnicity** | | | | | | | | | |
| African-American | 2768 | (13.1) | 952 | (11.2) | 969 | (11.8) | 1600 | (14.7) | <0.01 |
| Latinx | 1027 | (4.9) | 333 | (3.9) | 311 | (3.8) | 614 | (5.7) | <0.01 |
| **Comorbidities** | | | | | | | | | |
| COPD | 5503 | (26.3) | 2309 | (27.2) | 2251 | (27.3) | 2742 | (25.3) | <0.01 |
| Dementia | 9203 | (43.9) | 3884 | (45.7) | 3836 | (46.6) | 4667 | (43.0) | <0.01 |
| Coronary artery disease | 5315 | (25.4) | 2247 | (26.5) | 2171 | (26.4) | 2650 | (24.4) | <0.01 |
| Diabetes | 8056 | (38.3) | 3222 | (37.9) | 3096 | (37.6) | 4173 | (38.4) | 0.49 |
| Congestive heart failure | 4779 | (22.8) | 1984 | (23.4) | 1897 | (23.0) | 2433 | (22.4) | 0.20 |
| Chronic kidney disease | 5629 | (26.9) | 2254 | (26.5) | 2157 | (26.2) | 2903 | (26.7) | 0.72 |
| Hypertension | 16,529 | (78.9) | 6755 | (79.5) | 6519 | (79.2) | 8521 | (78.5) | 0.15 |
| **Cognitive Function Scale** | | | | | | | | | <0.01 |
| Cognitively Intact | 6372 | (29.6) | 2435 | (28.7) | 2300 | (27.9) | 3433 | (31.6) | |
| Mildly Impaired | 5003 | (23.9) | 2058 | (24.2) | 1987 | (24.1) | 2563 | (23.6) | |
| Moderately Impaired | 6775 | (33.3) | 2874 | (33.8) | 2883 | (35.0) | 3415 | (31.4) | |
| Severely Impaired | 2748 | (13.2) | 1125 | (13.2) | 1063 | (12.9) | 1448 | (13.3) | |
| **ADL score, mean (SD)** | 18.9 | (5.7) | 19.1 | (5.6) | 19.1 | (5.6) | 18.7 | (5.8) | |
| **ADL dependency quartile** | | | | | | | | | <0.01 |
| 0–17 | 5917 | (28.1) | 2334 | (27.5) | 2215 | (26.9) | 3153 | (29.0) | |
| 18–20 | 5798 | (27.5) | 2255 | (26.6) | 2211 | (26.9) | 3016 | (27.8) | |
| 21–22 | 4219 | (20.1) | 1762 | (20.7) | 1709 | (20.8) | 2124 | (19.6) | |
| 23–28 | 5106 | (24.3) | 2141 | (25.2) | 2098 | (25.5) | 2566 | (23.6) | |

Note: Residents who received two doses vaccine are among those who received the first dose of vaccine in the same 147 facilities.
* Indicates chi-squared test p-value.

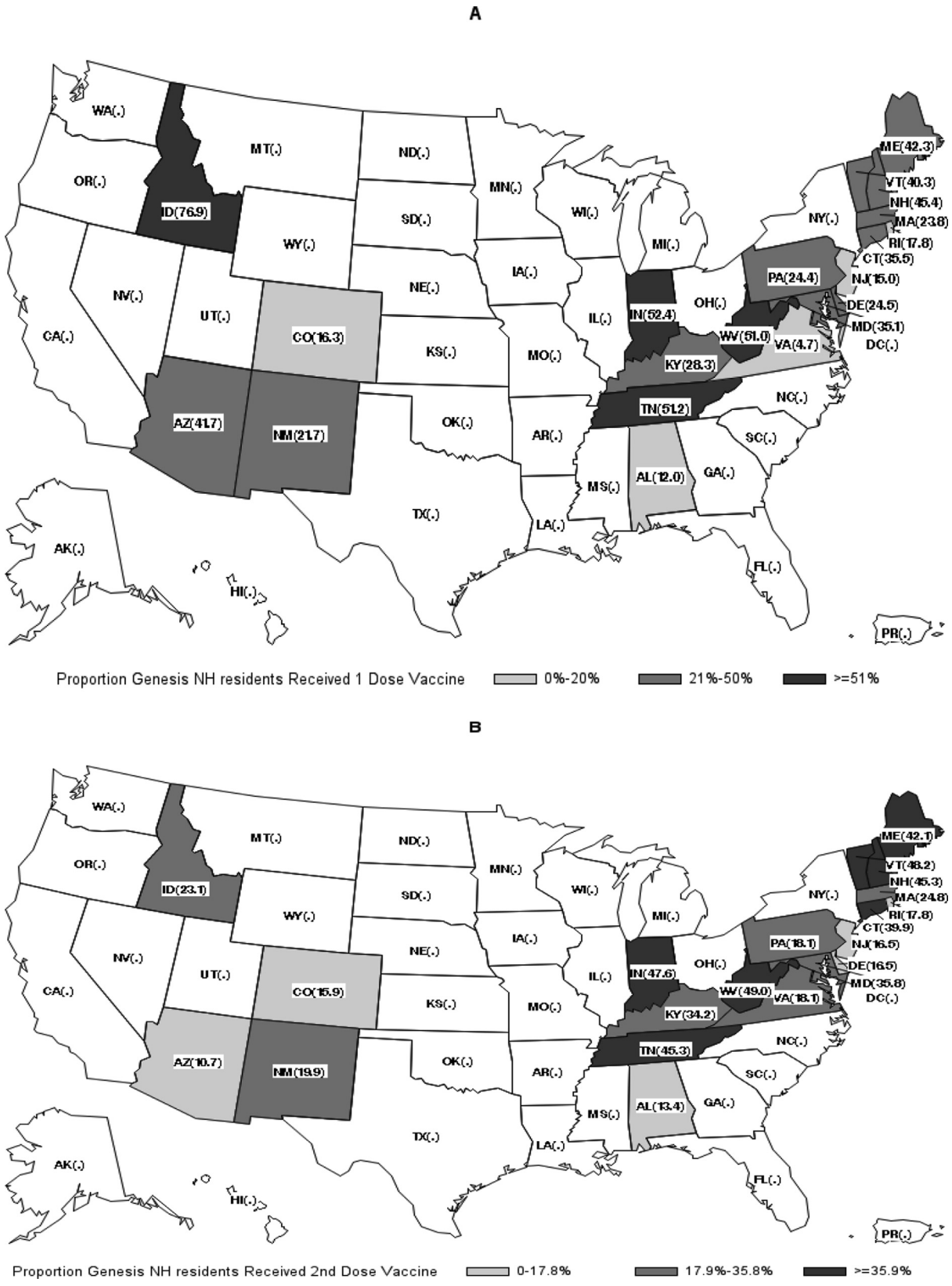



**Fig. 2.** A, Proportion of study participants in the 147 early vaccinating facilities in the state who received one dose of COVID-19 vaccine from December 18, 2020 through January 3, 2021. B, Proportion of study participants in the 147 early vaccinating facilities in the state who received the second dose of COVID-19 vaccine from January 8-February 20, 2021. C, Proportion of study participants in the 137 late vaccinating facilities in the state who were not vaccinated from December 18, 2020 through January 3, 2021 by state.

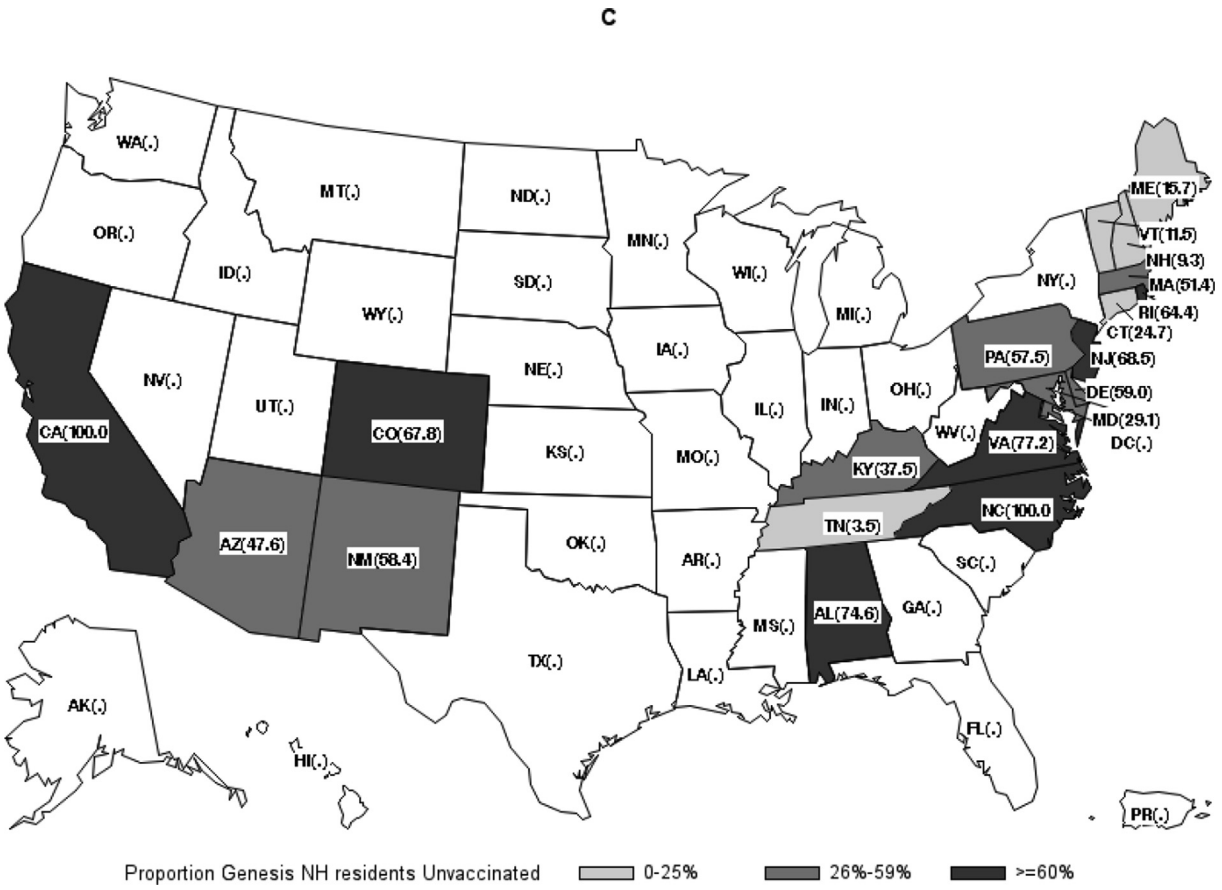



**Fig. 2** (*continued*)

and unvaccinated groups by age, sex, concurrent diabetes, history of congestive heart failure or chronic kidney disease [Table 1]. However, vaccinated residents were less likely than unvaccinated comparator group residents to identify as Black/African-American (one dose: 11.2%, two doses: 11.8%, unvaccinated 14.7%), or Hispanic/Latinx residents (one dose: 3.9%, two doses: 3.8%, unvaccinated 5.7%). Vaccinated residents were also more likely than unvaccinated residents to have COPD (one dose: 27.2%, two doses: 27.3%, unvaccinated 25.3%). Coronary artery disease, cognitive impairment and dementia were also more frequent among the vaccinated than among the unvaccinated ($p < 0.01$). In addition, the proportion vaccinated and unvaccinated residents varied by the state in which the facility was located. ($p < 0.01$) [Fig. 2 a-c].

### 3.1. Adverse events

Chart reviews were conducted to verify events identified using ICD-10-CM codes. Among the vaccinated, five events were verified during the 15-day risk interval post-vaccination; and among the unvaccinated, two events were verified during the 15-day risk interval [Tables 2a and 2b].

Unadjusted 15-day rates of adverse events per 100,000 residents following the first dose of vaccine were the same for Bell's Palsy, ischemic stroke, and pulmonary embolism (12 (95% CI: 2, 66)); the rate for venous thromboembolism was 23 (95% CI: 6, 85). The unadjusted 7-day rate of mortality per 100,000 residents following first dose of vaccine was 374 (95% CI: 265, 528) and of hospital transfer was 1,497 (95% CI: 1,260, 1,777). The unadjusted rate of mortality was similar following the second dose of vaccine, though the rate of hospital transfers per 100,000 residents was lower (1,003 95% CI: 811, 1,241) than after the first dose (see Table 3).

Among the unvaccinated, unadjusted event rates for venous thromboembolism and pulmonary embolism were similar to those observed in the vaccinated. Unlike the vaccinated, no occurrences of Bell's Palsy, acute myocardial infarction, or ischemic stroke were observed among the unvaccinated during the 15-day period.

In the adjusted analyses, 7-day mortality rates post-vaccination were lower among those who were vaccinated than unvaccinated (one dose: risk ratio (RR) 0.34 (95%CI: 0.22, 0.54); second dose: RR 0.49 (95%CI: 0.34, 0.71)) [Table 2]. Hospital transfers within 7 days post-vaccination were less frequent among those after the second dose of vaccine when compared with residents after the first dose (RR 0.66 (95%CI: 0.51, 0.86) or when compared with the unvaccinated (RR 0.57 (95%CI: 0.43, 0.75).

## 4. Discussion

We conducted active, prospective surveillance for adverse events following SARS-CoV-2 mRNA vaccinations under Emergency Use Authorization in a large multi-state cohort of NH residents. Our analyses did not detect statistically significant safety signals for the pre-specified outcomes including demyelinating disease, Guillain-Barre Syndrome, peripheral nervous system disorders, seizures, encephalomyelitis, ataxis, anaphylaxis, allergic reactions, cranial nerve disorders, or myocarditis. Rates of thromboembolic events were also similar between vaccinated and unvaccinated NH residents. Although cases of anaphylaxis have been reported in adults after the first dose of mRNA SARS-CoV-2 vaccines [16], none were observed in this NH population. Unlike

**Table 2a**
Selected clinical findings of adverse events after mRNA COVID-19 vaccine among nursing home residents.

| Adverse Event | Age (yr) sex | Vaccine | Onset after vaccination (days) | Clinical verification of event | PMH | Illness/other in 4 wks prior to onset |
|---|---|---|---|---|---|---|
| **Bell's Palsy** | Over 90F | First dose, Pfizer | 11 | Verified diagnosis with physician note | VascDem, AF, COPD, ICH, TIA/CVA, SZ, MDD, HL, HTN, PVD, OP, GERD, HypoT | |
| **Acute MI** | 56 M | Second dose, Pfizer | 2 | Verified diagnosis by in-hospital cardiac cath showing extensive disease | CAD (2015), CABG, DM, HTN, HL, AKI, HypoT | |
| **Venous thromboembolism** | 80F | First dose, Pfizer | 8 | Verified diagnosis with US | Breast and uterine CA, ThAoAn, ITP, TKR, CHF, AF, CKD, prior DVT/PE, HTN, HL, HypoT, FTT, Obesity | Previously Dx'd extensive DVT sent out for tachy r/o PE, returned no PE by CTA |
| **Venous thromboembolism (*same patient as below)** | 60F | First dose, Pfizer | 12 | Verified diagnosis at hospital with CTA + bil PE | MS, DM, HTN, HLD, PAF, IBS , Anx/Dep, Migraine | Sent out for acute CP, SOB, hypoxia |
| **Pulmonary Embolism** | 60F | First dose, Pfizer | 12 | Verified diagnosis at hospital with CTA + bil PE | MS, DM, HTN, HLD, PAF, IBS , Anx/Dep, Migraine | Sent out for acute CP, SOB, hypoxia |

VascDem - Vascular dementia; AF - Atrial fibrillation; COPD - Chronic obstructive pulmonary disease; ICH - intracranial hemorrhage; TIA - transient ischemic attack; CVA - cerebral vascular accident; SZ - seizure; MDD - major depressive disorder; HL - hyperlipidemia; HTN - Hypertension; PVD - Peripheral vascular disease; OP - Osteoporosis; GERD - Gastroesophageal reflux disease; HypoT - Hypothyroidism; CAD - Coronary artery disease; CABG - Coronary artery bypass graft; DM - Diabetes mellitus; AKI - Acute kidney injury; CA - Cancer; ThAoAn - Thoracic aortic aneurysm; ITP - Idiopathic thrombocytopenia purpura; TKR - Total knee replacement; CHF - Congestive heart failure; Chronic kidney disease; DVT - Deep venous thrombosis; PE - Pulmonary embolism; FTT - Failure to thrive; MS - Multiple Sclerosis; PAF, - Paroxysmal atrial fibrillation; IBS - Irritable bowel syndrome; Anx - Anxiety; PD - Parkinson's disease; AD - Alzheimer's disease.

the Norwegian reports [7], we found lower 7-day mortality rates in vaccinated versus unvaccinated adults; however, it is unlikely that the vaccine protected against mortality due to SARS-CoV-2 in such a short time-period, and this may represent residual confounding. Although we did not collect information on reasons for or against vaccination, residents near-death may differ from others in how vaccine is offered to them or their proxies, how they understand the risk:benefit proposition to vaccinate, and whether they decline vaccination for other reasons.

This short-term safety monitoring project demonstrates the feasibility of real time adverse event reporting using NH EHR data as a complement to the Vaccine Safety Datalink (VSD) which was established in 1990 [17]. Though some older adults are in the large linked databases, the VSD has primarily been used to evaluate adverse events on childhood vaccines and for vaccinations in pregnant women [17]. Moreover, only passive surveillance through the Vaccine Adverse Event Reporting System (VAERS) has been used to date to assess adverse events following residents' vaccination in long-term care facilities [18]. VAERS is limited in that only cases are reported with no information on persons at risk to be able to estimate the proportion of events in the population, or to have a comparison group to determine if events are occurring more or less frequently among vaccinated than among unvaccinated individuals. Furthermore, the ability to follow-up on individual cases reported to VAERS is limited. Thus, the prospect for using this monitoring system for future pandemics, novel adult vaccines or solely for annual influenza vaccination safety monitoring offers considerable promise.

Our study had a number of limitations. To conduct timely analyses, adverse events were only included if they were diagnosed by the medical provider. For example, some events such as Bell's Palsy were identified in nurses' notes but were not formally diagnosed by a physician or advanced practice provider with a corresponding ICD-10 code. Also, NH residents were vaccinated quickly, in a short period of time so our unbiased follow-up period had to be restricted to 15 days or our unvaccinated comparator group would have been compromised. We determined that we could not use a comparator group from the pre-vaccination period because it included many of the same residents who were later in the vaccinated group. Further, because of the rapid decline in health of some residents, a self-controlled study design was not feasible. Another limitation of this study was the relatively small sample size to assess rare adverse events resulting in an inability to generate sufficiently precise estimates or to determine whether risk of events was increased due to vaccination. On the other hand, the absolutely low number of suspected adverse events was reassuring and the most important finding of the study.

Our findings reveal no significant safety issues for NH residents after SARS-CoV-2 vaccination, including no impact on short term mortality rates which should dispel concerns raised by the Norwegian reports [7]. Nor was the occurrence of serious anticipated adverse events any greater in this frail, older population than was reported in the original randomized trials of these vaccines. Rather, the mRNA-based vaccines appear to be safe, and offer the prospect of being life-saving for NH residents who have borne a disproportionate share of morbidity and mortality from COVID-19. This study underscores the value of having an analytic infrastructure to support near real-time monitoring of adverse events, safety and efficacy during rapid vaccine deployment in this vulnerable population.

## Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: BHB reports conflicts with vaccine manufacturers Sanofi

**Table 2b**
Selected clinical findings of adverse events among unvaccinated nursing home residents.

| Event | Age(yr) sex | Onset after start date (days) | Current event | PMH | Illness/other in 4 wks prior to onset |
|---|---|---|---|---|---|
| **Venous thromboembolism** | 69 F | 12 | Verified | VascDem, DM, HTN, HL, anemia, sickle trait, DVT, COVID and pressure ulcers | |
| **Pulmonary Embolism** | 67 F | 4 | Verified, clot likely due to fracture and repair | | Fall hip fracture, PE by CTA in hospital |

VascDem - Vascular dementia; AF - Atrial fibrillation; COPD - Chronic obstructive pulmonary disease; ICH - intracranial hemorrhage; TIA - transient ischemic attack; CVA - cerebral vascular accident; SZ - seizure; MDD - major depressive disorder; HL - hyperlipidemia; HTN - Hypertension; PVD - Peripheral vascular disease; OP - Osteoporosis; GERD - Gastroesophageal reflux disease; HypoT - Hypothyroidism; CAD - Coronary artery disease; CABG - Coronary artery bypass graft; DM - Diabetes mellitus; AKI - Acute kidney injury; CA - Cancer; ThAoAn - Thoracic aortic aneurysm; ITP - Idiopathic thrombocytopenia purpura; TKR - Total knee replacement; CHF - Congestive heart failure; Chronic kidney disease; DVT - Deep venous thrombosis; PE - Pulmonary embolism; FTT - Failure to thrive; MS - Multiple Sclerosis; PAF, - Paroxysmal atrial fibrillation; IBS - Irritable bowel syndrome; Anx - Anxiety; PD - Parkinson's disease; AD - Alzheimer's disease.

**Table 3**
Adverse events diagnosed after vaccinated and unvaccinated nursing home residents.

| | **147 Facilities** | | | | | | | **137 Facilities** | |
|---|---|---|---|---|---|---|---|---|---|
| | **Vaccinated Residents (first dose) n = 8553** | | | **Vaccinated Residents (second dose) n = 8371** | | | | **Unvaccinated Residents n = 11,072** | |
| | **n** | **Unadjusted Per 100,000[1]** | **First dose vs unvaccinated Adjusted Risk Ratio 95%CI** | **n** | **Unadjusted Per 100,000[1]** | **Second dose vs first dose Adjusted Risk Ratio** | **Second dose vs unvaccinated Adjusted Risk Ratio** | **n** | **Unadjusted Per 100,000[1]** |
| **15-day event rates** | | | | | | | | | |
| Acute Myocardial Infarction (AMI) | 0 | | | 1 | 12 (2, 68) | | | 0 | |
| Bell's Palsy | 1 | 12 (2, 66) | | 0 | | | | 0 | |
| Stroke, ischemic | 1 | 12 (2, 66) | | 0 | | | | 0 | |
| Venous thromboembolism (VTE) | 2 | 23 (6, 85) | 2.41 (0.22, 26.3) | 0 | | | | 1 | 9 (2,51) |
| Pulmonary Embolism (PE) | 1 | 12 (2, 66) | 1.14 (0.07, 18.0) | 0 | | | | 1 | 9 (2,51) |
| **7-day event rates** | | | | | | | | | |
| Death | 32 | 374 (265, 528) | 0.34 (0.22, 0.54) | 44 | 526 (392, 705) | 1.51 (0.96, 2.38) | 0.49 (0.34, 0.71) | 126 | 1138 (957, 1353) |
| Hospital Transfer | 128 | 1497 (1260, 1777) | 0.95 (0.72, 1.24) | 84 | 1003 (811, 1241) | 0.66 (0.51, 0.86) | 0.57 (0.43, 0.75) | 179 | 1617 (1398, 1869) |

First dose of vaccine rates of adverse events were among those vaccinated between December 18, 2020 and January 3, 2021 followed 15 days through January 18, 2021 (except mortality and hospital transfers were within 7 days).
Second dose of vaccine rates of adverse events are among those vaccinated January 8, 2021 through February 20, 2021.
Unvaccinated rates of adverse events are during the period before vaccination, including residents in the SNFs that began vaccinating after January 3, 2015, followed for 15 days through January 18, 2021 (except mortality and hospital transfers were followed for 7 days).
Adjusted risk ratios: Inverse probability weighting was used to adjust the probability of vaccination by age, gender, race/ethnicity, diabetes, COPD, renal disease, hypertension, congestive heart failure, coronary heart disease, dementia, cognitive function and physical function.
Note: Residents with a positive COVID-19 test within 20 days of vaccination (since they should not have been vaccinated) or start date, or who were on monoclonal antibodies within 90 days of vaccination or start date were excluded.
[1] Wilson's 95% Confidence Intervals.

and Pfizer related with grants. RAF and CB are employed by Genesis HealthCare. S. G. reports conflicts with vaccine manufacturers Sanofi, Seqirus, Pfizer related to grants, consulting, and speaking engagements. S. G. also consults with other pharmaceutical companies including Janssen, and Merck and has grants with Sunovion. KM reports conflicts with vaccine manufacturers Sanofi, Pfizer, and Sequiris related with grants. RG has served as an expert witness to Johnson & Johnson/Janssen in the opioid litigation. EMW, AN, VM, and INS have no conflicts.

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## Disclaimer

The content and views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

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