Investigation of A SARS-CoV-2 Delta (B.1.617.2) Variant Outbreak Among Residents of a Skilled Nursing Facility and Vaccine Effectiveness Analysis — Maricopa County, Arizona, June–July 2021

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Summary: A SARS-CoV-2 Delta variant outbreak investigation in a short-term rehabilitation unit found a low vaccination rate and a medically complex resident population. Estimated VE against symptomatic infection was the highest in non-immunocompromised residents primary-vaccine series with an mRNA vaccine.

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Abstract

Background: Short-term rehabilitation units present unique infection control challenges due to high turnover and medically complex residents. In June 2021, Maricopa County Department of Public Health (MCDPH) was notified of a SARS-CoV-2 Delta outbreak in a skilled nursing facility short-term rehabilitation unit. We describe the outbreak and assess vaccine effectiveness (VE).

Methods: Facility electronic medical records were reviewed for residents who spent ≥1 night on the affected unit between June 10–July 23, 2021, to collect demographics, SARS-CoV-2 test results, underlying medical conditions, vaccination status, and clinical outcomes. COVID-19 VE estimates using Cox proportional hazards models were calculated.

Results: Forty (37%) of 109 short-stay rehabilitation unit residents who met inclusion criteria tested positive for SARS-CoV-2. SARS-CoV-2 positive case-patients were mostly male (58%) and white (78%) with a median age of 65 (range: 27-92) years; 11 (27%) were immunocompromised. Of residents, 39% (10 cases; 32 non-cases) received 2-doses and 9% (4 cases, 6 non-cases) received 1-dose of mRNA vaccine. Among non-immunocompromised residents, adjusted 2-dose primary-series mRNA VE against symptomatic infection was 80% (95% CI: 15, 95). More cases were hospitalized (33%) or died (38%) than non-cases (10% hospitalized; 16% died).

Conclusions: In this large SARS-CoV-2 Delta outbreak in a high-turnover short term rehabilitation unit, a low vaccination rate and medically complex resident population were noted alongside severe outcomes. VE of 2-dose primary-series mRNA vaccine against symptomatic infection was the highest in non-immunocompromised residents. Health departments can use vaccine coverage data to prioritize facilities for assistance in preventing outbreaks.

Keywords: COVID-19, skilled nursing facility, delta variant, outbreak, local public health

Background

Skilled nursing facility (SNF) residents are at increased risk of contracting SARS-CoV-2 compared to non-congregate living persons and were prioritized for early vaccination [1]. Outbreaks have been previously described in long-term care facilities [2,3] but data on the impact of the Delta(B.1.617.2) variant in these settings are only now emerging. Within SNFs, short-term rehabilitation unit residents are unique due to varying disease acuity; outbreaks in this population have not been well characterized. Additionally, real-world vaccine effectiveness (VE) estimates against the Delta variant among rehabilitation unit residents are limited and can help inform state and local health department response.

In June 2021, Maricopa County Department of Public Health (MCDPH) was notified of a SARS-CoV-2 outbreak in a SNF short-term rehabilitation unit. Weekly SARS-CoV-2 antigen testing was initiated for staff and residents following notification to MCDPH [4]. Our primary objective is to describe the extent of a Delta variant outbreak in a short-term rehabilitation unit in addition to assessing estimated VE against significant clinical endpoints.

Methods

MCDPH was notified June 18, 2021, of a positive SARS-CoV-2 result from a SNF resident upon admission for respiratory symptoms to a local acute care on June 17, 2021. Facility-wide testing of residents was initiated the same day using the Abbott BinaxNOW antigen test; staff had been completing weekly testing in accordance with moderate community transmission levels [4,5]. Weekly antigen testing was provided to all staff and residents, and all positive antigen tests were confirmed by reverse-transcriptase polymerase chain reaction (RT-PCR). Available specimens were sequenced at their respective laboratories.

Additionally, trained data abstractors reviewed facility electronic medical records (EMR) for residents who spent \geq 1 night in the affected unit during June 10–July 23, 2021. Abstracted data

included demographic information, admission and discharge dates, underlying conditions associated with severe COVID-19 outcomes [6], SARS-CoV-2 test results, vaccination history, COVID-19 symptoms, and hospitalization and death outcomes. Testing, vaccination, and death certificate information were supplemented with data received from the Arizona Department of Health Services.

The facility admitted SARS-CoV-2 positive individuals during their isolation periods; these persons were excluded from the outbreak analysis. A case patient was defined as a resident with a SARS-CoV-2 positive RT-PCR test while at the facility. Additionally, residents who were transferred to another healthcare facility and tested positive within 24 hours or died <24 hours after discharge and tested positive on autopsy were considered cases. Resident and staff vaccination status was categorized as 1) unvaccinated (no documented COVID-19 vaccination); 2) vaccinated (completion of a 2-dose primary series of the COMIRNATY (Pfizer-BioNTech) or SPIKEVAX (Moderna) mRNA vaccines or one dose of the Johnson & Johnson (Janssen) vaccine; all doses received \geq 14 days before the risk period or positive SARS-CoV-2 test) and 3) partially vaccinated (at least one dose of an mRNA vaccine; \geq 14 days before the risk period or positive SARS-CoV-2 test.

An epi curve was created using specimen collection dates comparing cases and non-cases by demographic and clinical characteristics. We calculated attack rates by vaccination status; however, given limitations in interpreting simple attack rates by vaccination status with varying resident lengths of stay, we used more rigorous methods to calculate VE. VE estimates were calculated using a time-to-event analysis. Person-time began on the facility admission date or June 10, 2021 (one week prior to index case), whichever occurred later, and ended on the date of first positive test, discharge, death, or July 23, 2021, whichever occurred earliest. Days between facility readmissions were excluded for residents readmitted during the investigation period. Residents were included in the VE analysis if they received ≥1 SARS-CoV-2 test at the facility and were not positive for SARS-CoV-2 within 90 days prior to admission.

Cox proportional hazards models were used to calculate primary series VE and 95% confidence intervals (CI) as (1-hazard ratio) X 100%. Our modeling strategy was informed by literature describing COVID-19 VE and disease severity [6,7]; possible confounders were systematically added to develop adjusted models (Supplementary Table 1). Our primary analysis was to assess mRNA VE in nonimmunocompromised persons by excluding severely immunocompromised residents (e.g., having current cancer, solid organ transplant, HIV, or immunosuppressive condition/therapy) [8]. Secondary VE analyses were conducted to include those vaccinated with Janssen and to other clinical endpoints including infection, symptomatic infection, hospitalization, and death, and to exclude those with a documented history of SARS-COV-2 infection. All analyses were conducted using SAS statistical software (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy [9].

Results

The outbreak was limited to one unit at the SNF. For 68 available beds in this unit of the SNF, 161 residents spent ≥1 night during June 10–July 23, 2021. EMR abstractions were conducted for 161 residents; 109 residents met inclusion criteria for additional analysis (supplementary Figure 1). Fifty-two residents were excluded from the epi curve and additional analyses because they were admitted to the facility with COVID-19, spent less than 24 hours in the facility, or had not received a SARS-CoV-2 test during their stay.

Facility-wide testing revealed transmission was limited to residents of a short-term rehabilitation unit (one of four units). Forty (37%) of 161 residents were SARS-CoV-2 positive during the outbreak period (Figure 1). No staff tested positive during weekly outbreak testing June 18 – July 23; 39% (53/135) were fully vaccinated and 16% (21/135) were partially vaccinated. Of ten outbreak specimens available for sequencing, all were the Delta variant (B.1.617.2) and the remaining were epidemiologically linked to the sequenced cases (Supplementary Figure 2). Among 109 residents included in the VE analysis, most residents were male (n=60; 55%) and of white race (n=76; 70%). Age range was 27–92 years for case patients (median=65) and 32–97 years for non-cases (median=69). Among all residents meeting inclusion criteria, the median number of underlying conditions associated with risk of severe COVID-19 illness was 4 (range 1–8) (Table 1). Heart conditions (case patients: 48%; non-cases: 64%), diabetes (case patients: 40%; non-cases: 43%), and neurological conditions excluding stroke (cases: 55%, non-cases: 48%) were the most common. Twenty-eight percent (n=11) of case patients and 12% (n=8) of non-cases were immunocompromised. Additionally, 28% (n=31 residents) had documented substance use disorder and 7% (n=8 residents) were noted to be experiencing homelessness, although this was not systematically documented and may be an underestimate. A higher proportion of cases were hospitalized (33%) or died (38%) than non-cases (10% hospitalized; 16% died). Case patient median length of stay (LOS) in the SNF was 27.5 days (range: 5–145) and 14 days for non-cases (range: 1-51). Of 40 case patients, 24 (60%) had cough, shortness of breath, or loss of taste or smell and 8 (20%) had other COVID-19 symptoms (Table 1).

Overall, 39% (42/109; 10 case patients; 32 non-cases) of residents received 2-doses of the primary mRNA COVID-19 vaccine series, 9% (10/109; 4 case patients, 6 non-cases) were partially vaccinated with an mRNA vaccine, and 45% (49/109; 19 case patients, 30 non-cases) were unvaccinated (Table 1); additionally, 6% (7/109; 6 case patients, 1 non-case) were vaccinated with 1-dose of the Johnson & Johnson (Janssen) vaccine. A total of 2,032 person-days were observed during the investigation period. Case median person-time was 8.5 (range: 4–27) days and 14 (range: 1–43) days for non-cases (Table 1). Ten residents (4 case-patients and 6 non-cases) were only partially vaccinated and thus excluded from the final VE analysis; therefore 99 residents were included in the overall VE calculations prior to excluding immunocompromised residents.

Among 74 non-immunocompromised residents (22 case-patients, 52 non-cases) series, adjusted 2dose primary-series mRNA COVID-19 VE against SARS-CoV-2 symptomatic infection was 80% albeit with a wide confidence interval (CI; 95% CI: 15, 95%) (Figure 1). Primary-series VE (13 case-patients, 69 non-cases) with any vaccine against hospitalization was 48% (95%CI: -118, 87%) and increased to 69% (95%CI: -20, 92%) against death (Figure 1). Two-dose primary mRNA vaccine series VE (27 case-patients, 59 non-cases) against SARS-CoV-2 infection was 51% (95%CI: -27, 81%) and increased to 80% (95%CI: -10, 96%) against death, following a similar pattern of increasing VE against increasingly severe endpoints such as hospitalization or death. Additionally, two-dose primary mRNA vaccine series VE estimates were higher than VE with any vaccine. There was no substantial difference when excluding those with a previous SARS-COV-2 infection (data not shown). Additional VE estimates are presented in supplementary material including variables used in model adjustment.

Discussion

MCDPH investigated a large outbreak of SARS-CoV-2 within a 68-bed short-term rehabilitation unit during June 10–July 23, 2021, at the emergence of the Delta variant within the United States and presents findings of an early outbreak investigation. During the outbreak period in this unit, the average LOS within the facility regardless of COVID-19 test result was 17 days and less than half (46%) of the residents completed COVID-19 vaccination primary series. Despite widely available and effective COVID-19 vaccines, this outbreak was extensive with many adverse outcomes. One factor that likely led to rapid disease spread was the low vaccination coverage among residents (45% unvaccinated) despite vaccines being available since December of 2020. In addition to the higher risk associated with congregate living, facilities with short average LOS units are likely at increased risk of a COVID-19 outbreak (compared to long-stay SNF facilities) due to more potential exposures from higher turnover of residents, especially if the resident vaccination rate is low. Surveillance of vaccination coverage, including in short-stay rehabilitation units, might assist health departments in prioritizing both prevention, through high vaccination coverage and layered mitigation, and outbreak support, as SNFs/rehabilitation units with lower vaccination coverage are likely to have higher transmission risk. Additionally, facility-wide staff vaccination coverage at the time of the

outbreak as reported to the Centers for Medicare and Medicaid Services was 39% which may have contributed to facility transmission; however, no staff cases were identified through weekly serial testing. Healthcare facilities and health departments should work closely to develop strategies to increase vaccination prior to and upon admission to rehabilitation units, particularly in units with high turnover rates or those accepting SARS-CoV-2 positive patients prior to end of isolation period, in conjunction with careful review of infection prevention and control measures.

This large SARS-CoV-2 Delta variant outbreak within the SNF short-term rehabilitation unit occurred as the Delta variant was emerging in Arizona [10]. While COVID-19 SNF outbreaks and the increased risk for severe disease and outcomes among residents has been well-documented [2,3,11], fewer data are available on Delta variant outbreaks in these settings, particularly in the unique setting of a short-stay rehabilitation unit. The cohort described here had a wide age range (27-97 years) and included many residents with complex underlying conditions and other risk factors associated with poor outcomes, including high proportions of substance use disorders and/or experiencing homelessness [12]. Widespread presence of the highly contagious Delta variant in the United States [10] makes it more critical to identify opportunities for infection prevention (such as complete vaccination of residents and staff and layered mitigation measures) before an outbreak is identified in such high-risk settings.

VE modeling for non-immunocompromised residents with 2-dose mRNA COVID-19 vaccine primary series demonstrated high effectiveness (80%) against symptomatic SARS-CoV-2 infection when adjusting for age and number of comorbidities associated with increased risk for severe COVID-19 outcomes [6]. This outbreak occurred prior to the August 13, 2021 ACIP recommendation to provide a third dose of mRNA vaccine to moderate and severely immunocompromised individuals [8], which is why we excluded this group in a sensitivity analysis. In the months following this recommendation, the CDC expanded the third dose recommendation to include all persons greater than 6 months from completion of primary series of vaccination, as underscored by the recent emergence of the

Omicron variant.[14] Additional studies are needed to understand the impact of this recommendation on protection against severe outcomes of SARS-COV-2 in this highly susceptible population. Strategies for prevention of SARS-CoV-2 transmission within SNFs and short-stay rehabilitation units should include increasing overall vaccination rates in residents and staff according to the current recommendations.

Real-world VE estimates can guide health departments to prioritize distribution of resources and support outbreak response to mitigate COVID-19 spread. Although this outbreak was large, the sample size was too small to be able to draw substantive conclusions about VE. However, increasing trends in the VE point estimates with outcome severity is consistent with other studies [13]. The use of a real-world COVID-19 outbreak to calculate vaccine effectiveness estimates has a strong purpose; it characterizes vaccine performance in a unique setting and helps translate what might otherwise be considered technical epidemiologic methods into real-world context that is more easily appreciated by nursing home staff, residents, and others.

This analysis is subject to several limitations. First, EMR abstraction did not adequately capture timing or initiation of a do-not-resuscitate order or hospice care, which limited our understanding of death outcomes. Second, due to changes in commercial laboratory processes and specimen retention times, only ten of 40 samples were sequenced (all Delta). However, it is less likely that another variant contributed to this outbreak given the prevalence of Delta variant circulating during the outbreak period and bioinformatic analyses showing multiple introductions into the facility [10]. Finally, we were unable to quantify the impact that COVID-19-positive admissions or compassionate care visitation had on intra-facility transmission, information which may help in SNF administration decision-making. Because of admissions policies at this facility, additional sequencing would not help determine the number or source of introductions in this outbreak. This report documents a large SARS-CoV-2 outbreak within a high-turnover short term rehabilitation unit. Understanding the extent of a Delta variant outbreak and VE in real world conditions where those at higher risk for severe disease and outcomes reside, may help health departments prioritize support. This investigation lends further evidence that vaccination remains a critical tool in preventing SARS-CoV-2 outbreaks and severe outcomes in high-risk congregate settings.

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Disclaimer

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Disclosures

JC reports investing \$299.99 in 7.1 shares of Pfizer stock, purchased on 12/10/2020; no profit (have not sold); investing \$303.99 in 2.8 shares of BioNTech stock, purchased on 12/9/2020, 12/10/2020, & 12/21/2020; no profit (have not sold); and investing \$1,253.80 in 9.3 shares of Moderna stock, purchased on 12/10/2020, 12/17/2020, 12/22/2020, and 12/30/2020; no profit (have not sold). RS reports being member at large in Coccidioidomycosis Study Group. SS reports sponsorship to attend the 2022 CSTE Annual Conference (travel, lodging, meals) from CSTE and sponsorship to attend the 2022 Annual Conference (lodging) from AZ Infectious Diseases Society. All other authors indicate that they have no conflicts of interest relevant to this article to disclose.

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Table 1. Demographic characteristics, COVID-19 vaccination status, SARS-CoV-2 symptoms and
outcome data among residents included in a vaccine effectiveness analysis from a skilled nursing
facility outbreak — Maricopa County, Arizona, June 10–July 23, 2021.

Characteristics	N (%)		
	All Residents	Case Patient	Non-Cases
Total	109 (100.0%)	40 (100.0%)	69 (100.0%)
Sex			
Male	60 (55.0%)	23 (57.5%)	37 (53.6%)
Female	49 (45.0%)	17 (42.5%)	32 (46.3%)
Race and Ethnicity		5	
White	76 (69.7%)	31 (77.5%)	45 (65.2%)
Black/African American	9 (8.3%)	4 (10.0%)	5 (7.2%)
American Indian/Alaska Native	12 (11.0%)	2 (5.0%)	10 (14.4%)
Asian	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hispanic or Latino	10 (9.2%)	3 (7.5%)	7 (10.1%)
Native Hawaiian / Pacific Islander	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unknown	2 (1.8%)	0 (0.0%)	2 (2.8%)
Age (years)			
Median age (range)	69 (27-97)	65 (27-92)	69 (32-97)
18-54	22 (20.2%)	9 (22.5%)	13 (18.8%)
55-64	25 (22.9%)	11 (27.5%)	14 (20.2%)
65-74	32 (29.4%)	14 (35.0%)	18 (26.0%)
≥ 75	30 (27.5%)	6 (15.0%)	24 (34.7%)
Presence of underlying conditions/risk factors			
19 ¹			
Obesity (BMI>30 kg/m2)	31 (28.4%)	11 (27.5%)	20 (28.9%)
Overweight (BMI 25-29 kg/m2)	15 (13.8%)	5 (12.5%)	10 (14.4%)
Chronic Lung Disease (Asthma, COPD, etc.)	41 (37.6%)	14 (35.0%)	27 (39.1%)
Smoking current or former	24 (22.0%)	9 (22.5%)	15 (21.7%)
Diabetes mellitus	46 (42.2%)	16 (40.0%)	30 (43.4%)
End stage renal disease (w/dialysis)	12 (11.0%)	3 (7.5%)	9 (13.0%)
Chronic kidney disease	24 (22.0%)	8 (20.0%)	16 (23.1%)
Heart conditions	63 (57.8%)	19 (47.5%)	44 (63.7%)
Hypertension	43 (39.4%)	19 (47.5%)	24 (34.7%)
Substance use disorder	31 (28.4%)	9 (22.5%)	22 (31.8%)
Cancer (not in remission)	16 (14.7%)	8 (20.0%)	8 (11.5%)
Autoimmune condition	3 (2.8%)	0 (0.0%)	3 (4.3%)

Other Immunocompromising Conditions ²	3 (2.8%)	3 (7.5%)	0 (0.0%)
History of ischemic/hemorrhagic stroke	7 (6.4%)	0 (0.0%)	7 (10.1%)
Neurologic Conditions (minus stroke)	55 (50.5%)	22 (55.0%)	33 (47.8%)
Total Count of Underlying Conditions			
Median count (range)	4 (1-8)	4 (1-7)	4 (1-8)
1-2	27 (24.8%)	13 (32.5%)	14 (20.2%)
3-4	39 (35.8%)	12 (30.0%)	27 (39.1%)
5-6	36 (33.0%)	12 (30.0%)	24 (34.7%)
≥7	7 (6.4%)	3 (7.5%)	4 (5.7%)
Symptomatic Status (Cases Only)			
No symptoms	8 (7.3%)	8 (20.0%)	NA
CSTE definition one ³	24 (22.0%)	24 (60.0%)	NA
Any Non-CSTE symptoms	8 (7.3%)	8 (20.0%)	NA
COVID-19 Vaccination Status			
Primary-Series Vaccinated ⁴	50 (45.9%)	17 (42.5%)	33 (47.8%)
COMIRNATY (Pfizer-BioNTech)	20 (18.3%)	5 (29.4%)	15 (45.4%)
SPIKEVAX (Moderna)	22 (20.2%)	5 (29.4%)	17 (51.5%)
Jansen (Johnson & Johnson)	7 (6.4%)	6 (35.2%)	1 (3.0%)
Mixed product ⁵	1 (0.9%)	1 (5.8%)	0 (0.0%)
Partially Vaccinated	10 (9.2%)	4 (10.0%)	6 (8.6%)
Unvaccinated	49 (45.0%)	19 (47.5%)	30 (43.4%)
mRNA COVID-19 Vaccination Status & Non- immunocompromised ⁹			
Primary Series Vaccinated ^₄	35	7	28
Unvaccinated	39	15	24
Month of Vaccine Series Completion ⁶			
Jan-Mar	28 (25.7%)	11 (64.7%)	17 (51.5%)
Apr-June	22 (20.2%)	6 (35.2%)	16 (48.5%)
Previously COVID Positive ⁷	10 (9.2%)	1 (2.5%)	9 (13.0%)
Outcome			
Hospitalized	20 (18.3%)	13 (32.5%)	7 (10.1%)
Died	26 (23.9%)	15 (37.5%)	11 (15.9%)
Median days (range) person-time ⁸	11 (1-43)	8.5 (4-27)	14 (1-43)
Median days (range) length of stay	17 (1-145)	27.5 (5-145)	14 (1-51)

¹There were no documented report of pregnancy status (among female residents), sickle cell disease/thalassemia, or down syndrome.

² Includes the following: any immunosuppressive condition/therapy, solid organ/blood stem cell transplant, or HIV.

³ CSTE definition one was defined as presence of cough, shortness of breath, or new loss of taste or smell. Any non-CSTE symptoms was defined as having ≥1 of the following: fever, chills, myalgias, headache, sore throat, rhinorrhea, nasal congestion, abdominal pain, nausea, vomiting, diarrhea, falls, confusion, anorexia, lethargy ⁴ Primary-series vaccinated includes those having received the second dose of Pfizer-BioNTech

or Moderna mRNA vaccines or one dose of the Janssen (Johnson & Johnson) vaccine ≥14 days prior to the risk period or positive SARS-CoV-2 test date. Partially vaccinated includes those who received at least one dose of

an mRNA vaccine (Pfizer-BioNTech or Moderna) ≥14 days prior to the risk period or positive SARS-CoV-2 test date.

⁵ Includes one person who received one dose of Pfizer and one dose of Janssen (Johnson & Johnson) vaccine ⁶ Excludes one person whose vaccination dates could not be confirmed.

⁷ Excludes the 90 days prior to positive test at facility or admission to facility

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⁸ Person-time was defined as the total number of days in facility from admission or June 10 (whichever later) until positive test, death, discharge, or July 23 (whichever earliest). If discharged and readmitted, time away from the facility was subtracted

⁹ Persons who were non-immunocompromised did not have any of the following medical conditions: current cancer, solid organ transplant, HIV, or immunosuppressive condition/therapy

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FIGURE LEGEND

Figure 1. Crude and adjusted primary-series vaccine effectiveness (VE) of any COVID-19 vaccine series and mRNA COVID-19 primary vaccine series only against a range of outcomes in a skilled nursing facility — Maricopa County, Arizona, June–July 2021

VE: Vaccine effectiveness

¹ Includes the Janssen (Johnson & Johnson) or mRNA-based Pfizer-BioNTech or Moderna SARS-CoV-2 vaccines ² Includes the Pfizer-BioNTech or Moderna mRNA SARS-CoV-2 vaccines

³ Models including vaccination with any vaccine currently authorized for use in the United States were adjusted for the following: Any infection: age, cancer, neurological conditions; Symptomatic (≥ 1

symptom): neurological conditions, cancer, age; Hospitalization: age, sex, cancer, neurological conditions, heart conditions; and Death: age, cancer, neurological conditions

⁴ Models including 2-dose primary-series vaccination with mRNA vaccines only were adjusted for the following: Any infection: Total count of comorbidities, age; Symptomatic (\geq 1) infection: total count of comorbidities, age; Hospitalization: cancer, age, neurological comorbidities; Death: age, cancer, obesity

⁵Immunocompromised was defined as having current cancer, solid organ transplant, HIV, or

immunosuppressive condition/therapy

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