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Introduction of the BNT162b2 vaccine during a COVID-19 nursing home outbreak



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A B S T R A C T

Background: Coronavirus disease 2019 (COVID-19) outbreaks often occur in nursing homes and prompt frequent surveillance testing for SARS-CoV-2. A single dose of the BNT162b2 vaccine reduces viral load and transmission. In this study, we describe the real-world efficacy of BNT162b2 single-dose vaccination during a COVID-19 outbreak at a Veterans Affairs Community Living Center (CLC).

Methods: From 12/2/20 to 5/14/21, twice weekly antigen testing was used to detect COVID-19 among 146 residents at the CLC. Residents without a prior history of COVID-19 who agreed to immunization were vaccinated with the BNT162b2 vaccine on 12/16/20 and 1/6/21. Single-dose vaccine efficacy was determined for days 1–21 and days 14–21 after the first vaccine dose.

Results: The outbreak occurred from 12/2/20 to 1/7/21 with an attack rate of 30.8% (45/146); 46.7% (21/45) of the cases were due to asymptomatic COVID-19. One unit accounted for 77.8% (35/45) of the cases. In the vaccine analysis, 116 residents were a median age of 74.5 years and 93.1% (108/116) had ≥ 1 comorbid condition. Between the first and second dose, 15.5% (15/97) of vaccinated residents, and 21.2% (4/19) of unvaccinated residents developed COVID-19 ($P = .81$). One week after the second dose, no cases of COVID-19 occurred.

Conclusions: Albeit limited by the small numbers, a single dose of the BNT162b2 vaccine was not efficacious at preventing COVID-19 during this nursing home outbreak.

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INTRODUCTION

Of those with coronavirus disease 2019 (COVID-19) in the United States, approximately 50% of the hospitalizations, 50% of the intensive care unit admissions, and 80% of the deaths occurred in adults \geq

65 years of age, with the highest fatality being among those ≥ 85 years of age.¹ Nursing home residents, in particular, are at high risk of hospitalization and death.² Given the high mortality rate, the United States Centers for Disease Control and Prevention (CDC) recommended in December 2020 that nursing home residents and health care workers (HCW) be the first to be vaccinated with a mRNA COVID-19 vaccine.³ The real-world vaccine efficacy 14–20 days after the first dose of the BNT162b2 vaccine against symptomatic COVID-19 in a nationwide vaccination program was 57% (95% confidence interval [CI], 50%–63%) overall, 44% (95% CI, 19%–64%) among individuals ≥ 70 years of age, and 62% (CI, 43%–77%) among those with at least 3 co-morbid conditions.⁴ Among those who developed asymptomatic COVID-19 despite a single dose of the BNT162b2 vaccine, a 2.4 mean log₁₀ lower nasopharyngeal viral load was observed in

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vaccinated compared to unvaccinated nursing home residents.⁵ Moreover, single-dose vaccination with either the BNT162b2 vaccine or the ChAdOx1 nCoV-19 vaccine reduced transmission by 40%–50%.⁶

Interrupting transmission is a key method of controlling outbreaks, and the CDC recommends surveillance SARS-CoV-2 testing of all nursing home residents and HCW every 3–7 days if a case of COVID-19 is detected.⁷ The BD Veritor rapid antigen test has a sensitivity of ~80% for detecting symptomatic disease, especially in those with a high viral load⁸; however, antigen tests have been shown to have a sensitivity of only ~40% for asymptomatic disease.⁹ Moreover, given relatively low specificity in detecting asymptomatic infections, the CDC recommends that a positive antigen test result in an asymptomatic person without a known COVID-19 exposure be confirmed with a RT-PCR test.¹⁰ COVID-19 nursing home outbreak models suggest that a point-of-care (POC) test with a 50% sensitivity that is completed every 3 days will prevent 80% of the cases.¹¹ One real-world outbreak also demonstrated the effectiveness of POC testing every 3–5 days, with an outbreak of 27 residents lasting less than 2 weeks in duration.¹²

While vaccine efficacy trials¹³ and active surveillance with POC antigen testing models¹¹ suggest that each will be instrumental in controlling nursing home COVID-19 outbreaks, the effectiveness of combining these interventions are not well described. A real-world outbreak where the individuals are older and sicker¹⁴ than patients evaluated in the BNT162b2 randomized controlled vaccine trial¹³ is a practical method of evaluating efficacy under real-world conditions. One study reported an efficacy of 66% of the BNT162b2 vaccine from 15 days after the first dose through 7 days after the second dose during two 4-to 5-week-long nursing home outbreaks with attack rates ranging from 17.8% to 28.2%; however, the 95% CIs of efficacy were wide ranging from 29% to 83%.¹⁵ In this study, we describe the only COVID-19 outbreak at our Community Living Center (CLC) nursing facility from 12/2/20 to 2/4/21 and the efficacy of a single dose of the BNT162b2 vaccine between 12/16/20 and 1/6/21 among residents who had not previously had documented COVID-19. By February 4, 2021, 49.1% of HCW had received at least one dose of the BNT162b2 vaccine.

METHODS

Infection prevention and control interventions to prevent SARS-CoV-2 spread

Health care workers and visitors

Starting in April 2020, universal masking, respirators for aerosol-generating procedures, eye protection for patient care, and frequent hand hygiene were enforced for all HCW. Prior to each shift, the HCW were screened for COVID-19 by a series of questions and a temperature check. A positive screen, including a temperature of 100.4°F, led to a SARS-CoV-2 RT-PCR test from one of the following manufacturers: BD-Max (BD Diagnostic Systems, Franklin Lakes, NJ),¹⁶ Cepheid Xpert Xpress System (Cepheid, Sunnyvale, CA),¹⁷ and Aries SARS-CoV-2 Assay (Luminex, Austin, TX). If the SARS-CoV-2 test was positive, the employee isolated at home for 14 days. Visitors were not allowed inside the facility except for those visiting dying residents; those visitors must have passed a COVID-19 symptom screen and temperature of check as described above.

Residents

Starting on 12/2/20, the residents were screened at least daily by nursing staff for COVID-19 by a series of questions and a temperature check. A positive screen, including a temp of $\geq 99.0^\circ\text{F}$, led to SARS-CoV-2 testing with the antigen test, with RT-PCR confirmation of a positive antigen test. While awaiting RT-PCR confirmation, residents were quarantined in their room with contact/droplet isolation in place. Residents with a positive SARS-CoV-2 RT-PCR test were moved to a separate unit comprised of solely SARS-CoV-2 positive

individuals for 20 days after symptom onset, assuming resolution of fever for at least 24 hours without the use of fever-reducing medications and improvement of other symptoms. In addition, residents who returned from an inpatient hospitalization, emergency department visit, or outpatient clinic appointment were observed on a separate, isolated unit for 14 days.¹⁸ Residents who refused PCR confirmation were considered to be infected and isolated.

Twice weekly surveillance SARS-CoV-2 testing

Between 12/02/2020 and 12/03/2020, all CLC residents had a nasopharyngeal swab tested for SARS-CoV-2 with the RT-PCR test completed in Palo Alto, CA¹⁹; the turnaround time was 7–8 days. Between 12/3/20 and 12/7/20, symptomatic residents were tested for SARS-CoV-2 with an in-house RT-PCR test with a 1- to 3-hour turnaround. Starting on 12/8/20 and continuing through 5/14/21, all residents were tested for SARS-CoV-2 twice weekly using the BD-Veritor POC antigen test with an approximate 1-hour turnaround. Except for 3 cases detected on 12/10/20, 12/11/20, and 12/14/20, one of which was symptomatic, a positive antigen test was confirmed with a RT-PCR test.

BNT162b2 vaccine analysis

Residents without a prior history of COVID-19 who agreed to immunization were vaccinated with the BNT162b2 vaccine on 12/16/20. On 1/6/21, 3 weeks after the first dose, eligible and willing residents received the second dose of the BNT162b2 vaccine. These residents were compared to residents who declined BNT162b2 immunization. Residents who had at least one of the following comorbid conditions were considered at increased risk of severe COVID-19: active cancer, chronic kidney disease, chronic obstructive pulmonary disease, diabetes, coronary artery disease, congestive heart failure, transplant, and/or body mass index $\geq 30 \text{ kg/m}^2$. Symptomatic disease was defined per the BNT162b2 vaccine randomized controlled trial,¹³ with COVID-19-related symptoms and/or a temperature $\geq 100.4^\circ\text{F}$ within 4 days of a nares or nasopharyngeal sample positive for SARS-CoV-2. Symptoms included new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, or vomiting.¹³ Residents in the vaccine analysis were censored if they developed asymptomatic or symptomatic COVID-19 confirmed with an RT-PCR test for SARS-CoV-2 or declined the second dose of the BNT162b2 vaccine. Residents were also censored if they were hospitalized at an acute care hospital on 1/6/21. As well, residents were censored if they either were discharged to home or died between 12/16/20 and 1/6/21. The hazard ratio of cumulative incidence of asymptomatic and symptomatic cases of COVID-19 from days 1–21 and days 14–21 were calculated using the log-rank test to determine the 95% CI and *P* values.

RESULTS

COVID-19 outbreak

The Veterans Affairs (VA) Pittsburgh CLC has 175-beds on 7 units located on 4 floors. During the outbreak, 146 residents were living at the CLC, an occupancy rate of 83.4%. From 12/2/20 to 1/7/21, 45 residents had a positive-SARS-CoV-2 test, for an attack rate of 30.8% (45/146); 46.7% (21/45) of the cases were asymptomatic (Fig 1). Seventy-eight percent (35/45) of the residents were located on Unit 1. The remaining 10 cases were located on 4 different units; the cases were temporally linked and consisted of 1–4 residents each (Fig 1). No additional cases of COVID-19 were detected between 1/8/21 and 5/14/21.

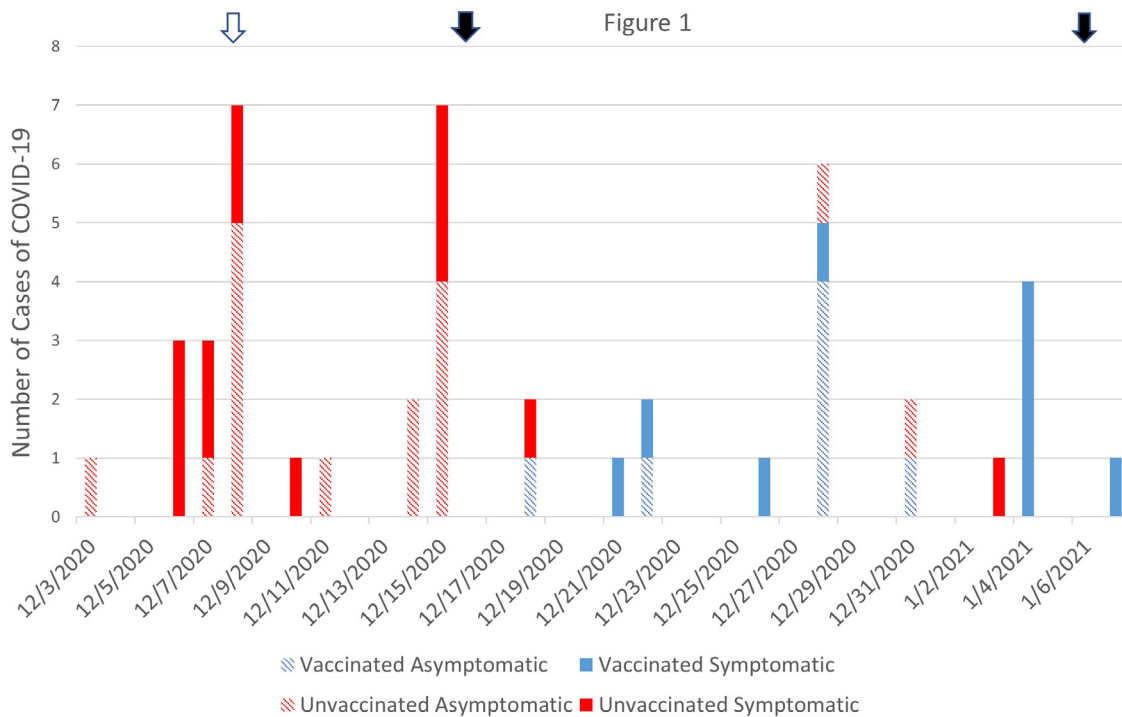


Fig 1. Timeline of cases of COVID-19 among vaccinated and unvaccinated residents. Unfilled arrow indicates start of twice weekly COVID-19 surveillance testing. Filled arrows indicate first and second dose vaccine dates. All cases located on Unit 1 except for 10 cases on 4 other units. Units 2 and 3 with one case each; Unit 4 with 4 cases between 12/10 and 12/15; Unit 5 with 4 cases between 12/15 and 12/26. All cases had same day testing except for 12/3/20; testing returned on 12/11/20.

BNT162b2 vaccine demographics

Among the 146 residents, 22 residents had a prior history of COVID-19; 8 residents agreed to immunization after 12/16/21. These 30 residents were excluded. Of the remaining 116 residents, 97 residents were immunized with the first dose of the BNT162b2 vaccine on 12/16/20, and 19 repeatedly declined immunization (Fig 2). Among the 116 residents, the median age was 74.5 years, 93.1% (108/116) had at least one comorbid condition, and 42.2% (49/116) of the residents had at least 3 comorbid conditions associated with severe COVID-19 (Table 1). The median age, the proportion who were ≥ 65 years of age, the proportion who had at least one comorbid condition, and the proportion who had at least 3 comorbid conditions associated with severe disease did not differ between vaccinated and unvaccinated residents (Table 1). In contrast, none (0/19) of the unvaccinated compared to 9.3% (9/97) of the vaccinated residents were female ($P = 0.001$; Table 1). On 1/6/21, 77.3% (75/97) of those who received the first dose received the second dose of the BNT162b2 vaccine. Among the 22 residents who did not receive the second dose at our facility per the protocol schedule, 15 developed COVID-19, 3 declined the second dose, 1 was discharged home, 1 was hospitalized, and 2 died from non-COVID causes.

BNT162b2 vaccine efficacy

Between the first dose and the second dose of the BNT162b2 vaccine, 8.3% (8/97) of the vaccinated residents and 10.5% (2/19) of the unvaccinated residents developed symptomatic COVID-19. Inclusion of asymptomatic and symptomatic cases increased the frequency of COVID-19 to 15.5% (15/97) in the vaccinated group, and 21.2% (4/19) in the unvaccinated group (Fig 2). The hazard ratio of cumulative incidence of all cases of COVID-19 from days 1 to 21 did not significantly differ between single-dose vaccinated compared to unvaccinated residents (hazard ratio [HR] 0.88, 95% CI 0.28–2.7, $P = 0.81$). Inclusion of

only symptomatic cases from days 1 to 21 resulted in similar findings (Table 1).

An analysis of days 14–21 after the first vaccine dose included 84 vaccinated and 17 unvaccinated residents due to censoring prior to day 14. Between 14 and 21 days after the first dose, 4.8% (4/84) of the vaccinated residents and 5.9% (1/17) of the unvaccinated residents developed symptomatic COVID-19. Inclusion of asymptomatic and symptomatic cases increased the frequency of COVID-19 to 6.0% (5/84) in the vaccinated group, and 11.8% (2/17) in the unvaccinated group. The hazard ratio of cumulative incidence of symptomatic cases and all cases of COVID-19 from days 14 to 21 did not significantly differ (Table 1). Between the second dose of the BNT162b2 vaccine on 1/6/21 and 2/28/21, only one case of COVID-19 was detected in the vaccinated group; this case was detected on 1/7/21.

Among those in the vaccine analysis who were diagnosed with COVID-19, 25% (1/4) of the unvaccinated and 25% (4/16) of the vaccinated residents developed severe disease. All were treated with dexamethasone and remdesivir; none required intubation or died. None of the cases of COVID-19 diagnosed solely by the POC antigen test were included in the vaccine analysis.

BNT162b2 vaccine safety

The residents were assessed at least daily for fever and could voluntarily report a local or systemic reaction. Only 8.2% (8/97) of the residents had a known adverse reaction: 75% (6/8) had a documented fever and 25% (2/8) reported a sore arm.

DISCUSSION

In this study, a single dose of the BNT162b2 vaccine did not confer protection against COVID-19 during an approximately 5-week-long outbreak at our nursing home. The lack of efficacy of a single dose of the BNT162b2 vaccine detected could have been due to a type II error

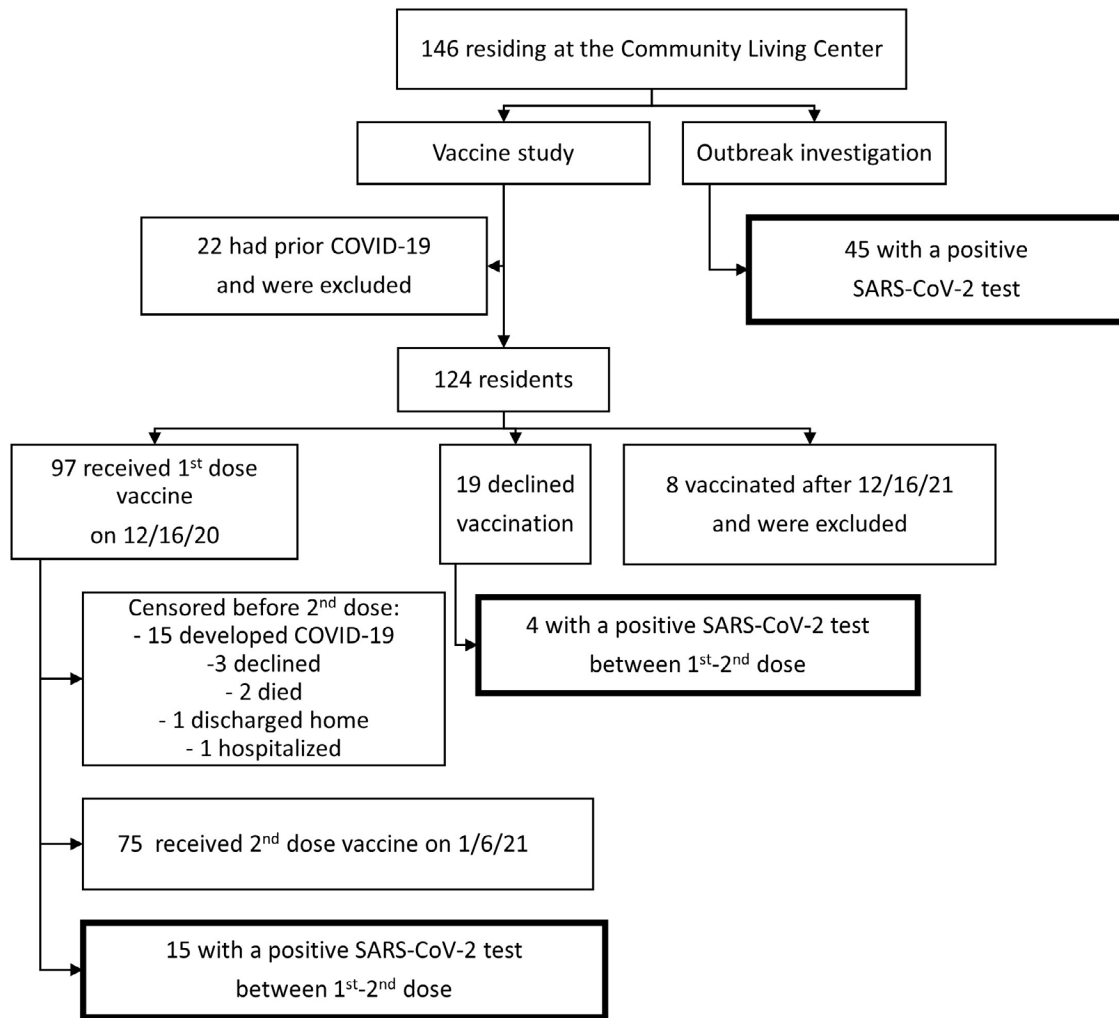


Fig 2. Residents included in the vaccine analysis and COVID-19 outbreak.

as only 19 residents remained unvaccinated during the study period. Larger studies have shown that a single dose of the BNT162b2 vaccine has lower efficacy among nursing home residents,¹⁵ and older people with multiple co-morbidities compared to healthier individuals⁴; thus, the ability to detect a difference, should it be present, might require a larger sample size.

The arrest of the outbreak, with an attack rate of 30.8%, was likely achieved by reducing transmission among residents and among HCW. Given strict visitations restrictions during the study period, the HCW were the main source of community contact for the residents. Among residents, the facility-wide twice weekly surveillance POC testing for SARS-CoV-2 detected cases of COVID-19 early in the

Table 1
Demographic characteristics and BNT162b2 vaccine efficacy between first and second dose

Variable (No.)	Vaccinated (97)	Unvaccinated (19)	P value
Median age (IQR)	74.0 (70.0-80.0)	78.0 (72.0-86.5)	.175
≥65 years No., %	85 (87.6)	16 (84.2)	.710
Male, No. %	88 (90.7)	19 (100)	.001
≥1 co-morbid condition	90 (92.8)	18 (94.7)	1.0
≥3 co-morbid conditions	43 (44.3)	6 (31.6)	.45
All COVID-19	15 (15.5)	4 (21.2)	HR = 0.88, 95% CI 0.28-2.7, P = .81
days 1-21 after first dose, No., %			
Symptomatic COVID-19	8 (8.3)	2 (10.5)	HR = 0.76,
days 1-21 after first dose, No., %			95% CI 0.14-4.1, P = .72
All COVID-19	5 (6.0)	2 (11.8)	HR = 0.47,
14-21 days after the first dose, No., %*			95% CI 0.06-3.6, P = .36
Symptomatic COVID-19	4 (4.8)	1 (5.9)	HR = 0.76,
14-21 days after the first dose, No., %*			95% CI 0.07-8.3, P = .80

CI, Confidence interval; HR, Hazard ratio; IQR, Interquartile range; No, Number.

*Denominator: Vaccinated = 84 residents, Unvaccinated = 17 residents.

disease,¹¹ nearly 50% of which were asymptomatic. Moreover, the rapid transfer of residents with a positive SARS-CoV-2 test to a separate unit comprised of solely SARS-CoV-2 positive individuals further reduced exposure to uninfected residents. While a single dose of the BNT162b2 vaccine was not efficacious at preventing COVID-19 during this nursing home outbreak, one dose of this vaccine likely reduced transmission.^{5,6} Among HCW, nearly 50% received at least one dose of the BNT162b2 vaccine during the study period, which has a real-world efficacy of 80% against COVID-19 in this population.²⁰ Moreover, some HCW likely had immunity through prior COVID-19 as seroprevalence studies have shown that between 3.7%²¹ and 11.1%²² of Pennsylvania residents had immunity by September 2020, 3 months before this outbreak began. Taken together, HCW immunity to SARS-CoV-2 at the CLC may have reached ~67% during the study period, a level associated with potential herd immunity of SARS-CoV-2.²³

Although a previous study with similar attack rates touted partial BNT162b2 vaccination as the primary mechanism for controlling a nursing home outbreak, the analysis included cases from day 15 after the first dose through 7 days after the second dose, a timeframe that included full vaccination,¹⁵ moreover, the reported efficacy was associated with wide confidence intervals.¹⁵ In addition, the previous study also performed active surveillance 1–2 times weekly,¹⁵ and likely immunized their HCW; both of these interventions also likely reduced transmission and curbed the outbreak.

While the lack of efficacy of a single dose of the BNT162b2 vaccine could have been due to a type II error, another explanation was considered. The unvaccinated residents were more likely to be male than the vaccinated residents; however, gender has not been linked to acquisition of COVID-19. In addition to the limitations associated with the vaccine analysis, the HCW immunity data were lacking in 2 important respects. First, HCW immunization rates from December 2020 to January 2021 were not available. Second, the seroprevalence rates of COVID-19 among HCW in this study were inferred from published data of Pennsylvania residents that was collected 3 months prior to this outbreak.^{21,22} While local reactivity to the vaccine was uncommon, the study was not designed or powered to formally evaluate for side effects potentially leading to an underestimation of these events.

Limitations associated with the outbreak focus around SARS-CoV-2 testing. The 2 asymptomatic residents with a positive POC antigen test should have undergone RT-PCR testing to reduce the risk of false-positive results based on the CDC guidelines.¹⁰ The lack of confirmation of negative POC antigen tests, albeit endorsed by the CDC and unfeasible given limited testing resources during the outbreak, could have led to inadvertent transmission thereby potentially lengthening the outbreak duration. Notably, despite continued twice weekly POC antigen screening testing for months after the outbreak, no further positive antigen tests were detected, suggesting a remarkably low rate of false positives.

CONCLUSIONS

Notwithstanding these limitations, most notably the small numbers, the data indicate that a single dose of the BNT162b2 vaccine was not efficacious at preventing COVID-19 during this nursing home outbreak.

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