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## Brief Report

# Risk of Death in Nursing Home Residents After COVID-19 Vaccination



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## A B S T R A C T

**Keywords:**  
 Nursing home  
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**Objectives:** In the first months of 2021, the Dutch COVID-19 vaccination campaign was disturbed by reports of death in Norwegian nursing homes (NHs) after vaccination. Reports predominantly concerned persons >65 years of age with 1 or more comorbidities. Also, in the Netherlands adverse events were reported after COVID-19 vaccination in this vulnerable group. Yet, it was unclear whether a causal link between vaccination and death existed. Therefore, we investigated the risk of death after COVID-19 vaccination in Dutch NH residents compared with the risk of death in NH residents prior to the COVID-19 pandemic.

**Design:** Population-based longitudinal cohort study with electronic health record data.

**Setting and Participants:** We studied Dutch NH residents from 73 NHs who received 1 or 2 COVID-19 vaccination(s) between January 13 and April 16, 2021 (n = 21,762). As a historical comparison group, we included Dutch NH residents who were registered in the same period in 2019 (n = 27,591).

**Methods:** Data on vaccination status, age, gender, type of care, comorbidities, and date of NH entry and (if applicable) discharge or date of death were extracted from electronic health records. Risk of death after 30 days was evaluated and compared between vaccinated residents and historical comparison residents with Kaplan-Meier and Cox regression analyses. Regression analyses were adjusted for age, gender, comorbidities, and length of stay.

**Results:** Risk of death in NH residents after one COVID-19 vaccination (regardless of whether a second vaccination was given) was decreased compared with historical comparison residents from 2019 (adjusted HR 0.77, 95% CI 0.69-0.86). The risk of death further decreased after 2 vaccinations compared with the historical comparison group (adjusted HR 0.57, 95% CI 0.50-0.64).

**Conclusions and Implications:** We found no indication that risk of death in NH residents is increased after COVID-19 vaccination. These results indicate that COVID-19 vaccination in NH residents is safe and could reduce fear and resistance toward vaccination.

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Since 2020 the COVID-19 pandemic impacts society worldwide. The disease affects mostly, though not exclusively, the older and most vulnerable populations.<sup>1</sup> In the Netherlands nursing home (NH)

residents were highly affected by COVID-19 and excess mortality was reported.<sup>2</sup> Therefore, in the Netherlands, NH residents were among the first to receive a COVID-19 vaccination after approval by the European Medicines Agency (EMA), even though this population was underrepresented in the safety and efficacy trials.<sup>3–8</sup>

In the first months of 2021, the Dutch COVID-19 vaccination campaign was disturbed by reports of death in Norwegian NHs after vaccination.<sup>9</sup> Reports concerned frail older people, in whom common adverse reactions potentially aggravated underlying conditions. Germany also reported deaths after vaccination, which mostly concerned seriously ill people.<sup>10</sup> In the January 2021 safety update of the

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pharmacovigilance risk assessment committee (PRAC) of the EMA, a review on the reported deaths confirmed that fatal outcomes predominantly concerned persons >65 years of age with 1 or more comorbidities.<sup>11</sup> Deaths after vaccination were therefore presumed to be caused by progression of preexisting diseases.<sup>11</sup> No safety concerns were stated and vaccinations were continued, though newly reported cases continued to be investigated thoroughly.

In the Netherlands, adverse reactions and death can be reported to the Netherlands Pharmacovigilance Centre Lareb. Similar to other countries, Lareb also received reports of death ( $n = 264$ ) after COVID-19 vaccinations.<sup>12</sup> According to the report of Lareb, in 42 of these cases, the vaccination may have contributed to decompensation of an already vulnerable state. In the large majority of these cases, adverse events of reactogenicity, such as fever and nausea, are described by reporters as clear turning points in the patients' health state and may have contributed to the prelude of the fatal outcomes. However, it remained unclear whether these events were related to COVID-19 vaccination, and studies of sufficient size evaluating this subject were lacking. Therefore, we conducted a population-based longitudinal cohort study with electronic health record data from Dutch NHs. In this study, we assessed the risk of death after COVID-19 vaccination and compared this with the risk of death in NH residents before the COVID-19 pandemic (year 2019).

## Methods

### Study Design and Setting

We performed a population-based longitudinal cohort study in Dutch NHs with routinely recorded data from the electronic health record (EHR) Ysis (managed by software developer Gerimedica). Ysis is the most widely used EHR in Dutch NHs, providing data from approximately half of the NH residents in the Netherlands. Part of NHs registered COVID-19 vaccination status in Ysis, some NHs used other systems. For the current study, it was assumed that NHs with at least 10 vaccinated residents indeed performed the registration of vaccinations in Ysis. Therefore, we only evaluated NHs when at least 10 vaccinated residents were registered in Ysis. It was not possible to define a nonvaccinated control group of NH residents in 2021, because it was unclear whether nonvaccinated residents were indeed all not vaccinated, or whether their vaccination was not registered. Instead, we evaluated a historical comparison group with residents of NHs in 2019, before the COVID-19 pandemic.

### Selection of Study Population

Dutch NH residents who received 1 or 2 COVID-19 vaccination(s) between January 13 (start of vaccinations in the first Dutch NHs) and April 16, 2021, were selected for this study. Residents or their legal representative had to give written consent for vaccination and registration of the vaccination. All residents resided on a psychogeriatric, somatic, rehabilitation, or short-term residential care ward.

The historical comparison group consisted of NH residents who resided in or entered any of the above wards between January 13 and April 16, 2019. We selected a similar period to control for any season effects.

### Data Collection

Data on vaccination status, age, gender, type of care, comorbidities, and date of NH entry and (if applicable) date of discharge or death were derived from usual care data in the EHR.

Comorbidities were extracted from free text fields in the medical history, as described previously.<sup>13</sup> The following comorbidities were extracted by an extensive automatic search using MATLAB

(The MathWorks, Natick, MA): dementia, diabetes mellitus, cerebrovascular disease, cardiovascular disease, pulmonary disease, kidney failure, and Parkinson's disease. For each comorbidity a search entry, composed of a variety of keywords, automatically searched the open text fields on medical history for presence of the addressed comorbidity.

### Ethics

The Medical Ethics Committee of the VU University Medical Centre confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study and waived the need for ethics approval.

### Statistical Analysis

Patient characteristics were compared between vaccinated residents and historical comparison residents using Pearson chi-squared, Mann-Whitney  $U$ , and independent  $t$  tests, as appropriate. Risk of death was evaluated with vaccination date as time point zero. In the historical comparison group date of NH entry, or, when date of NH entry was prior to the analyzed period, January 13 was used as time point zero. Residents were followed for a maximum of 30 days for the outcome death. Residents who did not reach the outcome were censored at 30 days, date of discharge, or April 16, whichever occurred first. Risk of death after 30 days was estimated with Kaplan-Meier curves and compared between vaccinated residents and historical comparison residents with Cox regression analyses. Regression analyses were adjusted for age, gender, comorbidities that significantly differed between vaccinated and historical comparison residents, and length of stay at baseline. Risk of death after the first vaccination was determined (regardless of whether a second vaccination was given during follow-up), as well as risk of death after 2 vaccinations. In subanalyses, results were stratified for type of care.

IBM SPSS Statistics (version 26) and MATLAB (version 9.5) were used. Because of the large sample sizes,  $P$  values  $<.01$  were considered statistically significant.

## Results

### Population

According to the EHR, a total of 21,762 residents received 1 or 2 vaccinations between January 13 and April 16, 2021. Most residents received a BioNTech/Pfizer vaccination (99%, dose: 0.3 mL); the remaining received a Moderna vaccination (dose: 0.5 mL) or the type was unknown. A smaller proportion of residents received only 1 vaccination ( $n = 3476$ , 16%), whereas most residents received 2 vaccinations ( $n = 18,286$ , 84%). The median time interval between the 2 vaccinations was 28 days (median date of first vaccination: January 29, 2021; and median date of second vaccination: February 25, 2021). The historical comparison group consisted of 27,591 residents who lived in, or newly entered, NHs between January 13 and April 16, 2019. Resident characteristics are shown in Table 1. Compared with historical comparison residents, vaccinated residents were slightly younger [mean age (SD) 83 (10) vs 84 (10)], more often resided on psychogeriatric wards (53% vs 43%), more often presented with dementia (56% vs 47%), and already resided longer at an NH at baseline [median length of stay (interquartile range) 21 (6-40) vs 10 (0-27) months]. Differences between vaccinated residents and historical comparison residents in the presence of kidney failure (13% vs 12%) and Parkinson's disease (7% vs 6%) were also statistically significant, though unlikely clinically relevant. The median follow-up time in both the vaccination and the historical comparison group was 30 days (interquartile range 30-30).

**Table 1**  
Patient Characteristics

	Vaccinated			Controls From 2019	Vaccinated (Total) vs Controls
	1 × Vaccinated (n = 3476)	2 × Vaccinated (n = 18,286)	Total (n = 21,762)	Total (n = 27,591)	P Value
Age, y, mean (SD)	82 (10)	83 (10)	83 (10)	84 (10)	<.001
Female, n (%)	2156 (62)	12,300 (67)	14,456 (66)	18,249 (66)	.51
Length of stay, mo <sup>a</sup> , median (IQR)	3 (0-23)	23 (8-42)	21 (6-40)	10 (0-27)	<.001
Type of care, n (%)					<.001
Psychogeriatric	1312 (38)	10,250 (56)	11,562 (53)	11,885 (43)	
Somatic	622 (18)	5154 (28)	5776 (27)	6779 (25)	
Rehabilitation or short-term residential care	1542 (44)	2882 (16)	4424 (20)	8927 (32)	
Comorbidities, n (%) <sup>†</sup>					
Dementia	1498 (43)	10,656 (58)	12,154 (56)	12,841 (47)	<.001
Diabetes	625 (18)	3194 (17)	3819 (18)	4786 (18)	.85
Cerebrovascular	1159 (34)	6427 (35)	7586 (35)	9548 (35)	.97
Cardiovascular	1365 (40)	6682 (37)	8047 (37)	10,145 (37)	.86
Pulmonary	623 (18)	2961 (16)	3584 (17)	4713 (17)	.03
Kidney failure	470 (14)	2383 (13)	2853 (13)	3238 (12)	<.001
Parkinson's	195 (6)	1237 (7)	1432 (7)	1615 (6)	.002

IQR, interquartile range; SD, standard deviation.

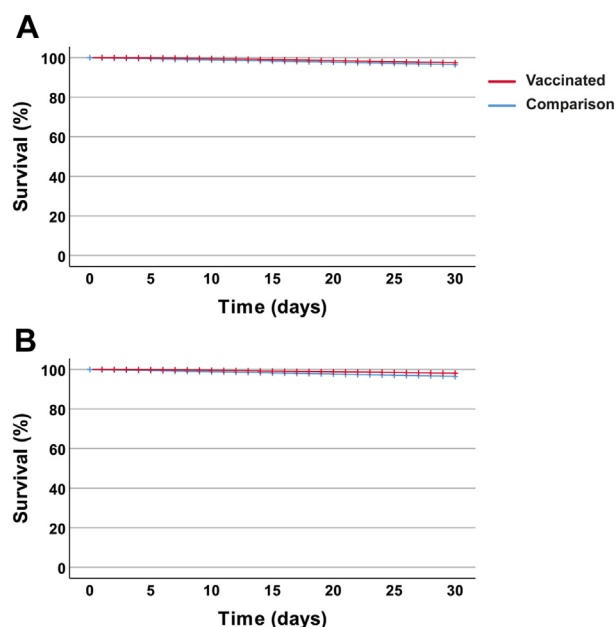
<sup>a</sup>Length of stay at baseline; baseline meaning the moment of first vaccination for vaccinated participants, for control participants baseline was January 13, 2019, or registration date for new entrants after January 13.

<sup>†</sup>Information on comorbidities was not available in 56 vaccinated and 285 control participants.

### Risk of Death

The risk of death after 30 days was 2.6% (95% CI 2.4–2.8) in residents with at least 1 vaccination, 1.9% (1.7–2.1) in residents with 2 vaccinations, and 3.6% (3.4–3.8) in historical comparison residents. The risk of death after 30 days in residents with at least 1 vaccination was 1.3 times lower compared with the historical comparison NH residents [multivariable hazard ratio (HR) 0.77 (95% CI 0.69–0.86; see Figure 1A)].

In residents who received 2 vaccinations, the risk of death was 1.8 times lower than in historical comparison residents [multivariable HR 0.57 (0.50–0.64); see Figure 1B].



**Fig. 1.** Risk of death after (A) 1 vaccination, regardless of whether a second vaccination was received during follow-up, and (B) 2 vaccinations, compared with a historical comparison group. Corresponding multivariable HRs (corrected for age, gender, dementia, kidney failure, Parkinson's, and length of stay at baseline) were as follows: (A) HR 0.77 (95% CI 0.69–0.86), (B) HR 0.57 (95% CI 0.50–0.64).

### No Differences in Risk of Death After Stratification for Type of Care

Because we observed a difference in type of care between vaccinated residents and historical comparison residents, we stratified the analyses for type of care. The risk of death after 30 days in residents with at least 1 vaccination was decreased compared with the 30-day risk of death in the historical comparison residents in all types of care, though only significantly different in psychogeriatric care, with corresponding multivariable HRs: psychogeriatric HR 0.69 (0.59–0.80), somatic HR 0.91 (0.73–1.13), and rehabilitation/short-term residential care HR 0.85 (0.67–1.07) (Supplementary Figure 1). After 2 vaccinations, the risk of death was significantly decreased compared with the 30-day risk of death in the historical comparison residents in all types of care, with corresponding multivariable HRs: psychogeriatric HR 0.55 (0.46–0.65), somatic HR 0.63 (0.49–0.82), rehabilitation/short-term residential care HR 0.57 (0.41–0.79) (Supplementary Figure 2).

### Discussion

In this study, we showed that NH residents with at least 1 vaccination had a decreased risk of death compared to risk of death in NH residents prior to the pandemic. The risk further decreased when people had received 2 vaccinations. These findings suggest that COVID-19 vaccination in NH residents is safe.

However, factors that potentially affected the results need to be addressed. First, it could be hypothesized that vaccinated residents were less vulnerable than residents in the historical comparison group, because (1) they had survived the pandemic so far, and (2) the most vulnerable residents might not have been vaccinated.<sup>14</sup> Second, because of the increased level of infection prevention and hygiene measures in NHs since the start of the COVID-19 pandemic, other infections that regularly occurred in NHs were probably less common; this could have resulted in a decreased risk of death in the vaccinated residents. To confirm these hypotheses, data on nonvaccinated NH residents from 2021 are necessary. However, such analyses were not possible with the current data. As mentioned in the Methods, because not all NHs registered the vaccination status in Ysis, and because a certain registration delay was expected, it was not possible to distinguish whether 2021 residents were not vaccinated, or whether the vaccination was not (yet) registered in the EHR. We therefore used a historical comparison group with residents from NHs in 2019 and

adjusted the analyses for differences in characteristics between the groups. However, no corrections could be made for differences in environmental factors and living conditions, although these were presumably influenced by the pandemic in 2021 as well. Finally, our results are limited to nursing home residents in the Netherlands.

Despite these limitations, an important strength of this study is the large number of residents that were included, both in the group of vaccinated residents and in the historical comparison group.

Importantly, results in this study were in line with previous publications. In response to the reported deaths in Norwegian NHs, an expert group evaluated 100 reports on a potential causal link between vaccination and death.<sup>15</sup> Although already existing processes might be accelerated in very frail patients, a clear causal relationship between vaccination and death was absent. Furthermore, a study among US NH residents reported no increase in adverse events or mortality after COVID-19 vaccination; mortality rates were lower in vaccinated than in unvaccinated residents.<sup>16</sup> Importantly, mortality rates in vaccinated residents were observed to be lower in residents with previous COVID-19 infection.<sup>17</sup> Safety of the vaccine was further confirmed in long-term care facilities in Spain, where no severe adverse reactions were observed and immunogenicity was confirmed.<sup>18</sup> Other studies additionally demonstrated immunogenicity of COVID-19 vaccines in NH residents,<sup>19,20</sup> although responses were higher in healthy control participants<sup>20</sup> and residents with previous COVID-19.<sup>18</sup> Moreover, a recent study demonstrated that the Biotech/Pfizer vaccine was well tolerated and effective in the NH population, independently of their clinical, functional, cognitive, or frailty characteristics.<sup>21</sup> Finally, a review of large-scale, controlled surveillance studies on rare adverse events associated with Biotech/Pfizer vaccine demonstrated that only myocarditis was consistently associated with the vaccine. Whether myocarditis also occurs as an adverse event in the NH population needs further investigation.<sup>22</sup>

## Conclusions and Implications

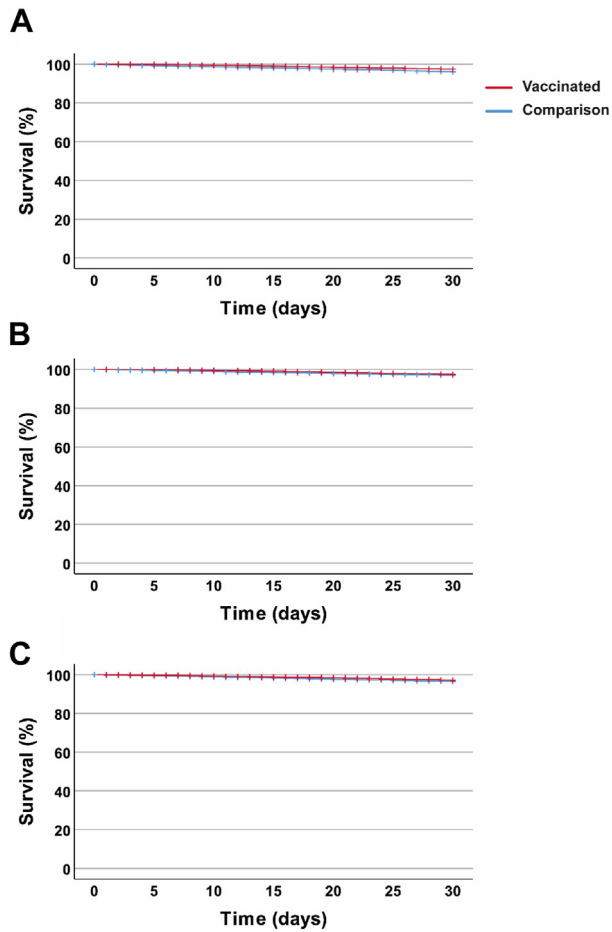
In conclusion, in this study we found no indication that risk of death in NH residents is increased after COVID-19 vaccination. These results indicate that COVID-19 vaccination in NH residents is safe and could reduce fear and resistance toward vaccination. The effectiveness of COVID-19 vaccination in NH residents is subject for further research.

## Acknowledgments

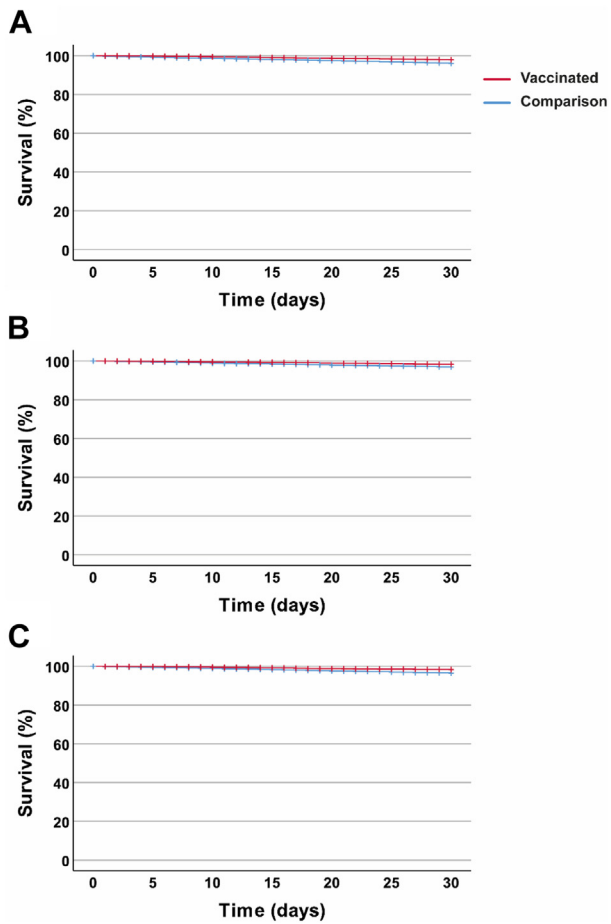
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**Supplementary Fig. 1.** Risk of death after 1 vaccination, regardless of whether a second vaccination was received during follow-up, in (A) psychogeriatric residents, (B) somatic residents, and (C) rehabilitation and short-term residential care residents. Corresponding multivariable hazard ratios (HRs) (corrected for age, gender, dementia, kidney failure, and Parkinson's) were as follows: (A) HR 0.69 (95% CI 0.59–0.80), (B) HR 0.91 (95% CI 0.73–1.13), and (C) HR 0.85 (95% CI 0.67–1.07).



**Supplementary Fig. 2.** Risk of death after 2 vaccinations in (A) psychogeriatric residents, (B) somatic residents, and (C) rehabilitation and short-term residential care residents. Corresponding multivariable hazard ratios (HRs) (corrected for age, gender, dementia, kidney failure, and Parkinson's) were as follows: (A) HR 0.55 (95% CI 0.46-0.65), (B) HR 0.63 (95% CI 0.49-0.82), and (C) HR 0.57 (95% CI 0.41-0.79).