



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

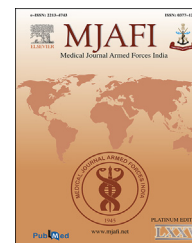
Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



ELSEVIER

Available online at [www.sciencedirect.com](http://www.sciencedirect.com)

ScienceDirect

journal homepage: [www.elsevier.com/locate/mjafi](http://www.elsevier.com/locate/mjafi)

## Original Article

# Disease profile and patient outcomes in vaccinated COVID-19 patients at a tertiary care Indian hospital: An observational, real-world study

Manu Chopra <sup>a,\*</sup>, Abhyam Gupta <sup>b</sup>, Shafin Babu P.S. <sup>c</sup>, Rajan Kapoor <sup>d</sup>,  
Yadvendra Singh Sirohi <sup>e</sup>, Ajith Nilakantan <sup>f</sup>

<sup>a</sup> Classified Specialist (Pulmonary Medicine), Command Hospital (Eastern Command), Kolkata, India

<sup>b</sup> Intern, Command Hospital (Eastern Command), Kolkata, India

<sup>c</sup> Pulmonologist, Command Hospital (Eastern Command), Kolkata, India

<sup>d</sup> Head (Medicine), Command Hospital (Eastern Command), Kolkata, India

<sup>e</sup> Deputy Commandant, Command Hospital (Eastern Command), Kolkata, India

<sup>f</sup> Commandant, Command Hospital (Eastern Command), Kolkata, India

## ARTICLE INFO

## Article history:

Received 15 December 2021

Accepted 3 April 2022

Available online xxx

## Keywords:

COVID 19

SARS-CoV-2

Vaccination

Pneumonia

## ABSTRACT

**Background:** There is a lack of real-world evidence evaluating the disease outcomes and patient features in vaccinated coronavirus disease (COVID-19) cases. This study aimed to address this scientific need gap and also compare characteristics between the partially vaccinated and fully vaccinated COVID-19 patients in India.

**Methods:** This observational cross-sectional study included data of adult patients diagnosed with COVID-19 at a tertiary care Indian hospital with a history of at least single-dose COVID-19 vaccination. Overall evaluation of patient features and disease characteristics was done. Patients were segregated into two groups based on vaccination status (partial or fully vaccinated), and characteristics were compared between these two groups along with COVID-19 outcomes.

**Results:** Data of 403 vaccinated patients treated for breakthrough COVID-19 infection postvaccination was evaluated. The mean age was  $47.7 \pm 15.3$  years (range: 19–87 years), with the majority being males (73.94%); 54.1% of evaluated cases were fully vaccinated; 74.93% of cases were asymptomatic. The majority of the symptomatic cases (60.39%) suffered from only mild-moderate symptoms; 72.7% of cases needed only home isolation, while only 1.99% died. A significantly higher number of partially vaccinated COVID-19 patients had severe COVID-19 pneumonia vs. fully vaccinated ones (14.59% vs. 5.96%,  $p < 0.05$ ). The relative risk (RR) for the development of severe COVID-19 infection was 0.32 for the fully vaccinated subgroup, which was a significant finding (CI: 0.19–0.55,  $p < 0.05$ ). **Conclusion:** The majority of vaccinated COVID-19 patients are asymptomatic or suffer from mild clinical features, which can be managed with home isolation. Fully vaccinated

\* Corresponding author.

E-mail address: [drmanuchopra@gmail.com](mailto:drmanuchopra@gmail.com) (M. Chopra).

<https://doi.org/10.1016/j.mjafi.2022.04.004>

0377-1237/© 2022 Director General, Armed Forces Medical Services. Published by Elsevier, a division of RELX India Pvt. Ltd. All rights reserved.

patients have a lower risk of developing severe COVID-19 infection in comparison to partially vaccinated cases.

© 2022 Director General, Armed Forces Medical Services. Published by Elsevier, a division of RELX India Pvt. Ltd. All rights reserved.

## Introduction

The pandemic caused by severe acute respiratory syndrome coronavirus—2 (SARS-CoV-2) strain, also known globally now as the “COVID-19 pandemic,” has affected all the nations across the globe. Till November 2021, there have been at least 255 million cases of COVID-19 cases confirmed globally, which led to more than 5.1 million deaths.<sup>1</sup> Since the time COVID-19 disease was declared a “pandemic” by World Health Organization (WHO), efforts had begun to develop therapeutic agents and vaccines to tackle this global menace. Under normal circumstances, the identification of a vaccine candidate itself can take approximately 10 years, following which the human trials are initiated, which may take a few more additional years.<sup>2</sup> However, seeing the unprecedented need for a COVID-19 vaccine, processes were fast-tracked, and the world saw approvals to various vaccines over late 2020.<sup>3</sup>

Currently, India is home to an astounding 17.7% of the world’s population, and hence it was not surprising that the country was also impacted by the COVID-19 waves in a major way. As of November 2021, India had three vaccines approved against COVID-19 (Covishield [ChAdOx1 nCoV-19; Oxford–AstraZeneca; manufactured by Serum Institute of India], Covaxin [BBV152; Bharat Biotech], and Sputnik V [Gam-COVID-Vac; Gamaleya Research Institute of Epidemiology and Microbiology]) approved for emergency utilization.<sup>4</sup> India’s vaccination drive picked up well from early 2021, mainly after the “second wave” of the pandemic in the country. India was hit by two major surges of COVID-19 cases, and the so-called “second wave” occurred from April to May 2021, wreaking havoc on the nation. As of early May 2021, the rolling average of COVID-19 cases per day was more than a staggering 3,50,000 per day.<sup>5</sup> After this surge, the vaccination drive gained momentum, and even the vaccine hesitancy among the public decreased. This has led to more than 116 crores of COVID-19 vaccination doses being administered across India as of November 21, 2021, the highest number compared to any nation in the world.<sup>6</sup>

Vaccination against COVID-19 does not mean that the vaccinated cannot contract the infection. In addition, different virus variants have evolved, which can have augmented transmissibility as well (as noted with B.1.1.7—the alpha variant).<sup>7</sup> There is ample evidence to show that COVID-19 is generally milder in nature in vaccinated individuals in comparison to those unvaccinated, but the impact on mortality rates requires to be studied further.<sup>8,9</sup> In addition, different individuals may have varied clinical features of COVID-19, and it is important to identify the disease features and outcomes in vaccinated COVID-19 patients as well so that

the medical resource requirements can be predicted in this increasing group of patients.<sup>10</sup>

The currently available vaccines in India require double-dosing for the individual to be labeled as “fully vaccinated.” However, because of the vast Indian population, it will take some time before all the people in the country can get both the jabs. There have been clinical trials, which have shown the utility of two doses of the vaccines, but real-world studies are limited, which have compared the patient features and disease outcomes of COVID-19 infection between single-dose or partially vaccinated, and fully vaccinated groups of patients. A recent study conducted in India evaluated the COVID-19 infection postvaccination in healthcare staff and found that numerically the fully vaccinated individuals had lower chances of infection in comparison to partially vaccinated staff (9.6% versus 10.6%). However, this study particularly evaluated only healthcare staff and not the general population.<sup>11</sup>

Hence, we planned this study to evaluate the disease and patient features along with the COVID-19 outcomes in vaccinated cases at an Indian tertiary care hospital, in a real-world scenario. We also aimed to make a comparison of these characteristics between the partially vaccinated and fully vaccinated groups of COVID-19 patients to understand the difference between these two subgroups.

## Material and methods

This was an observational cross-sectional study conducted at a 970-bedded tertiary care hospital in India. The study included data of patients over the age of 18 years, diagnosed with COVID-19 at the hospital, with a history of at least single dose COVID-19 vaccination. The patients were screened irrespective of their clinical characteristics, hospitalization status, or patient outcomes. Data of any patient diagnosed with COVID-19 in the year 2021 (January 2021 to September 2021) at the hospital and whose details were in the hospital database were screened. A convenience sampling technique was used in the study. No sample size was calculated and all patients fulfilling the screening criteria were considered for study enrolment.

The baseline data of the enrolled patients were noted down, which included demographic details like age and gender, as well as the COVID-19 vaccination history. The patients were characterized clinically as asymptomatic and symptomatic. Based on the requirement, the treating physician at the hospital advised the patient either to be under home isolation or hospitalization. The clinical manifestations of the COVID-19 patients were also noted as mild-to-moderate and severe pneumonia. The recovery or mortality

status was also noted for all enrolled cases. Based on the vaccination status (partially vaccinated or fully vaccinated), the patients were segregated into two groups, following which the patient and disease features were compared between these two groups along with the final COVID-19 outcomes.

Collected data were entered in Microsoft Excel and analyzed using SPSS (Version 26.0). Age was represented as mean  $\pm$  standard deviation (SD), while the other variables were discrete in nature. The comparison of mean age between the single-dose vaccinated or fully vaccinated groups was done using an unpaired T-test, while the comparison of other case features, disease characteristics, and patient outcomes was made using the chi-square test. A P-value of less than 0.05 was considered significant wherever applicable.

Flowchart 1 below shows the enrollment and methodology utilized.

## Results

Data of 403 vaccinated patients treated for breakthrough COVID-19 infection postvaccination was evaluated. Table 1 below gives the patient characteristics and outcomes of vaccinated COVID-19 patients.

The majority of the vaccinated COVID-19 patients, almost three-fourths of them, were asymptomatic. Of the symptomatic cases, more than 60% of cases were suffering from only mild-moderate cases, while overall, around 10% of cases suffered from severe COVID pneumonia. Out of all the 403 cases, nearly three-fourths of cases required only home isolation for recovery, while only eight cases (1.99%) died. Of the eight cases in the study that expired, two were obese and hypertensive, one had hypothyroidism with diabetes mellitus, and one was suffering from chronic obstructive pulmonary disease. All were aged over 60 years.

A comparison between the baseline characteristics and COVID-19 outcomes was conducted between partially vaccinated and fully vaccinated COVID-19 patient subgroups. The mean age was found to be statistically comparable between the two subgroups ( $p > 0.05$ ), but it was noted that the number of fully vaccinated males with COVID-19 infection was significantly higher than partially vaccinated COVID-19 male patients ( $p < 0.05$ ). In comparison between the two subgroups, the number of symptomatic and asymptomatic cases was

**Table 1 – Patient characteristics and outcomes of vaccinated COVID-19 patients (n = 403).**

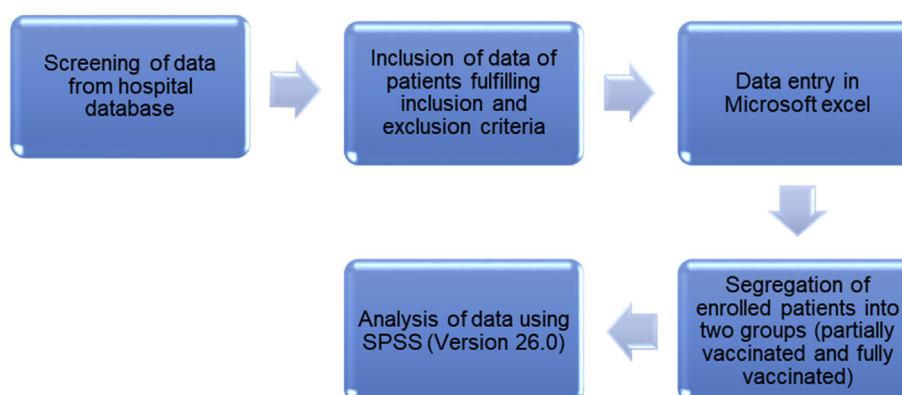
Parameter assessed	Calculated value
Mean age (years)	47.7 $\pm$ 15.3
Age range (years)	19–87
Number of males	298 (73.94%)
Number of females	105 (26.06%)
Number of patients partially vaccinated with COVID-19 vaccine	185 (45.9%)
Number of patients fully vaccinated with COVID-19 vaccine	218 (54.1%)
<i>Clinical characteristics of COVID-19 patients</i>	
Asymptomatic	302 (74.93%)
Symptomatic	101 (25.07%)
<i>Clinical manifestations of symptomatic COVID-19 cases (n = 101)</i>	
Mild to moderate symptoms	61 (60.39%)
Severe COVID-19 pneumonia (recovered)	32 (31.68%)
Severe COVID-19 pneumonia (died)	8 (7.92%)
<i>Patient outcomes of vaccinated COVID-19 patients</i>	
Home isolation only	293 (72.7%)
Hospitalized and discharged to home	102 (25.31%)
Hospitalized but died	8 (1.99%)

noted to be statistically comparable ( $p < 0.05$ ). However, it was noted that a significantly higher number of partially vaccinated COVID-19 patients had severe COVID-19 pneumonia ( $p < 0.05$ ). In addition, a significantly higher number of fully vaccinated COVID-19 patients were hospitalized but discharged to home ( $p < 0.05$ ). The proportion of deaths in the partially vaccinated COVID-19 subgroup was numerically higher, but this was not a significant finding ( $p > 0.05$ ). The relative risk (RR) for the development of severe COVID-19 infection was noted to be 0.32 for the fully vaccinated subgroup, which was a significant finding (CI: 0.19–0.55,  $p < 0.05$ ).

Table 2 below summarizes the comparison findings between partially vaccinated and fully vaccinated COVID-19 patient subgroups.

## Discussion

Despite the expedited approvals of COVID-19 vaccines globally, there are cases of postvaccination breakthrough COVID-19 infections being reported. The surge of infections



**Flowchart 1 – Enrolment and Methodology utilized in Study.**

**Table 2 – Comparison of clinical characteristics and patient outcomes between partially vaccinated and fully vaccinated COVID-19 patient subgroups.**

	Partially vaccinated COVID-19 patients (n = 185)	Fully vaccinated COVID-19 patients (n = 218)	P value
Mean age (years)	48.47 ± 13.08	47.80 ± 15.37	0.61
Gender distribution			
Number of males	117 (63.24%)	181 (83.02%)	<0.01*
Number of females	68 (36.76%)	37 (16.98%)	
Clinical characteristics of COVID-19 patients			
Asymptomatic	144 (77.84%)	158 (72.47%)	0.25
Symptomatic	41 (22.16%)	60 (27.53%)	
Clinical manifestations of symptomatic COVID-19 cases (n = 101)			
Mild to moderate symptoms	14 (7.56%)	47 (21.55%)	<0.01*
Severe COVID-19 pneumonia (recovered or died)	27 (14.59%)	13 (5.96%)	
Patient outcomes of vaccinated COVID-19 patients			
Home isolation only	140 (75.67%)	153 (70.18%)	0.06
Hospitalized and discharged to home	39 (21.08%)	63 (28.89%)	
Hospitalized but died	6 (3.24%)	2 (0.93%)	

Mean age compared by unpaired t-test, other parameters compared using chi-square analysis, p < 0.05 considered significant.

attributed to the SARS-CoV-2 Delta variant shows that vaccinated individuals can be at risk of infections even after vaccination.<sup>12</sup> A new Omicron SARS-CoV-2 variant has also emerged from South Africa, and several cases of the new strain have been found globally. Although data with regards to vaccine protection against this new strain is limited, early laboratory results indicate that existing vaccines could be less effective against the fast-spreading coronavirus variant, but boosters should lead to improved immunity.<sup>13</sup> According to the dashboard entry in October 2021 by the Massachusetts Department of Public Health in the United States of America (USA), 35% of the admitted COVID-19 cases at the Massachusetts hospital were fully vaccinated.<sup>14</sup> Since it has not been long since the general population has got access to their second dose of vaccine, especially in India, the real-world data related to postvaccination breakthrough COVID-19 infections is less. In addition, evaluating the patients and disease profiles of breakthrough COVID-19 infections in a vaccinated population can help in understanding the people at risk of such infections.

In the present study, the hospital database for vaccinated COVID-19 patients was analyzed, and the data of 403 patients were evaluated. The majority of cases were males, and the age range of patients was varied (19–87 years). The reason for the higher number of males in the study is probably due to a greater proportion of males getting jabbed compared to females, based on media reports and COWIN portal data.<sup>15</sup> There was a near-equal distribution of partially vaccinated and fully vaccinated patients. However, three-fourths of the cases were asymptomatic, which points toward the benefit of vaccination. These are records of people who came forth for RT-PCR testing; there may be many more vaccinated individuals in the society who may not undergo the COVID-19 tests due to lack of symptoms. Only a quarter of the cases were hospitalized, as the majority of them were without clinical manifestation and can recover on oral medications under home isolation. For a highly populated country like India, triaging of COVID-19

cases is important because of the low hospital-bed-to-population ratio, and hospitalization should be restricted to only those who need it.

There is published evidence to show that vaccinated individuals with breakthrough COVID-19 infections are less likely to suffer from clinical manifestations or undergo hospitalization.<sup>16</sup> According to the US data from August 2021, the age-adjusted rate of hospitalization among US adults aged 18 years or older was 4.5 per 100 000 for fully vaccinated persons, which was much lesser in comparison to 83.6 per 100 000 for unvaccinated persons.<sup>17</sup>

A recently published study from India assessed the protective effect of the COVID-19 vaccine among healthcare professionals in the real world. The study found that the infection risk among the vaccinated was low (RR: 0.35), and the protective effect of vaccination was noted in preventing infection (65%), hospitalization (77%), and need for oxygen (92%).<sup>11</sup> There have been studies from other parts of the world as well, which corroborate with our findings, indicating the protective nature of COVID-19 vaccination in the real-world.<sup>18–20</sup> However, most of these studies have evaluated the HCWs and not the general population.

Studies of viral dynamics propose that while viral loads in breakthrough COVID-19 infections may be as high in vaccinated population as they are in unvaccinated people, viral loads in vaccinated individuals reduce more rapidly in comparison, and the shed virus is less expected to be culture-positive than virus shed by unvaccinated patients.<sup>12</sup> This indicates that fully vaccinated individuals are less likely to become infected and if infected, will be transmissible for shorter time-periods in comparison to unvaccinated people. This is reinforced by transmission study findings and also includes data of Delta variant.<sup>21</sup>

Based on the literature search, it can be noted that the real-world comparison of patient profiles between partially and fully vaccinated COVID-19 patients has not been explored much. The Indian study by Victor et al found that the breakthrough COVID-19 infection rate was lower in the fully

vaccinated group vs. partially vaccinated (9.6% vs. 10.6%), and the protective effect of two doses of vaccine was 65%.<sup>11</sup> In the present study, there were comparable proportions of symptomatic patients in both, partially and fully vaccinated subgroups. In present study, the higher number of fully vaccinated COVID-19 patients found with COVID-19 infection or who were admitted might be because of a single-center study design bias. However, severe infection was noted only in 5.96% of the cases in the fully vaccinated group, vs. 14.59% in the partially vaccinated group. The RR for the development of severe COVID-19 infection for the fully vaccinated group indicated a 68% risk reduction in comparison to the partially vaccinated group. In addition, the proportion of patients who died was numerically higher in the partially vaccinated group. An assessment by the Centers for Disease Control and Prevention (CDC) in April 2021 had shown that the elderly, fully vaccinated COVID-19 patients had 94% lower risk of hospitalization than unvaccinated ones, while the partially vaccinated patients were 64% less likely to be hospitalized post-COVID.<sup>22</sup>

The present study is one of the first real-world studies that has tried to evaluate disease and patient profiles in the vaccinated COVID-19 cases in India. However, since this was a database analysis done at only one hospital over a limited period and with a small sample size, there were some limitations. There was no control arm in the study to compare the characteristics with nonvaccinated patients. Antibody titers for the patients were not evaluated, and long-term patient outcomes in the vaccinated COVID-19 cases could not be assessed.

Vaccination is clearly effective against COVID-19 in the real world, but some patients still being hospitalized after vaccination is a matter to ponder upon. The efficacy of vaccines against new strains like Delta variant and the newly found Omicron variant is still under evaluation, and hence, it is important that the general population are consistently reminded about the importance of wearing masks and social distancing. In addition, considering the vast Indian population, full vaccination of the people will still take some time. Studies evaluating booster doses of vaccines are on, but to meet the massive Indian requirements, the manufacturing will need to be scaled up.

## Conclusion

Majority of vaccinated COVID-19 patients are asymptomatic or suffer from mild clinical manifestations, which can be managed with home isolation. Fully vaccinated patients have a significantly lower risk of developing severe COVID-19 infection in comparison to partially vaccinated cases. Maintenance of the current vaccination pace can lead to the quicker achievement of complete vaccination in the Indian population.

## Disclosure of competing interest

All authors have none to declare.

## Acknowledgments

The authors would like to appreciate front-line medical and nursing teams who showed selfless and heroic devotion to duty amidst the COVID-19 outbreak.

## REFERENCES

1. World Health Organization. WHO Coronavirus (COVID-19) Dashboard. Available online at: <https://covid19.who.int/>. Accessed on November 5th, 2021.
2. Bregu M, Draper SJ, Hill AVS, Greenwood BM. Accelerating vaccine development and deployment: report of a Royal Society satellite meeting. *Philos Trans R Soc B Biol Sci.* 2011;366:2841–2849.
3. World Health Organization. COVID-19 vaccines. Available online at: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines>. Accessed on November 7th, 2021.
4. Choudhary OP, Choudhary P, Singh I. India's COVID-19 vaccination drive: key challenges and resolutions. *Lancet Infect Dis.* 2021;21(11):1483–1484.
5. The Lancet. India's COVID-19 emergency. *Lancet.* 2021;397:1683.
6. Government of India. COVID-19. Vaccination dose status. Available from: <https://www.mygov.in/covid-19>. Accessed on 21st November 2021.
7. Graham MS, Sudre CH, May A, et al. Changes in symptomatology, reinfection, and transmissibility associated with the SARS-CoV-2 variant B.1.1.7: an ecological study. *Lancet Public Health.* 2021;6:e335–e345.
8. Egan C, Knight S, Baillie K, Harrison E, Docherty A, Semple C. Hospitalised Vaccinated Patients during the Second Wave, Update April '21; April, 2021. Available from [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/982499/S1208\\_CO-CIN\\_report\\_on\\_impact\\_of\\_vaccination\\_Apr\\_21.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982499/S1208_CO-CIN_report_on_impact_of_vaccination_Apr_21.pdf). Accessed November 15, 2021.
9. Docherty AB, Mulholland RH, Lone NI, et al. Changes in in-hospital mortality in the first wave of COVID-19: a multicentre prospective observational cohort study using the WHO Clinical Characterisation Protocol UK. *Lancet Respir Med.* 2021;9:773–785.
10. Sudre CH, Lee KA, Lochlainn MN, et al. Symptom clusters in COVID-19: a potential clinical prediction tool from the COVID Symptom Study app. *Sci Adv.* 2021;7, eabd4177.
11. Victor PJ, Mathews KP, Paul H, Mammen JJ, Murugesan M. Protective effect of COVID-19 vaccine among health care workers during the second wave of the pandemic in India. *Mayo Clin Proc.* 2021;96(9):2493–2494.
12. Klompas M. Understanding breakthrough infections following mRNA SARS-CoV-2 vaccination. *JAMA.* 2021;326(20):2018–2020.
13. Callaway E. Omicron likely to weaken COVID vaccine protection. *Nature.* Accessed from <https://www.nature.com/articles/d41586-021-03672-3> on 9th December 2021.
14. Massachusetts Department of Public Health. COVID-19 Interactive Data Dashboard. Accessed from <https://www.mass.gov/info-details/covid-19-response-reporting# covid-19-interactive-data-dashboard->. Accessed on November 24, 2021.
15. The Indian Express. *Metros Show Gender Gap in Covid-19 Vaccination, More Men Get Jabbed*; January 20, 2022. Accessed from <https://indianexpress.com/article/india/india-covid-vaccination-gender-gap-metros-7732512/>. Accessed January 22, 2022.

16. Tartof SY, Slezak JM, Fischer H, et al. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. *Lancet*. 2021;398(10309):1407–1416.
17. Centers for Disease Control and Prevention. COVID Data Tracker. Rates of laboratory-confirmed COVID-19 hospitalizations by vaccination status. Accessed from <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination>. Accessed on November 24, 2021.
18. Hall VJ, Foulkes S, Saei A, et al. COVID-19 vaccine coverage in health-care workers in England and effectiveness of BNT162b2 mRNA vaccine against infection (SIREN): a prospective, multicentre, cohort study. *Lancet*. 2021;397:1725–1735.
19. Benenson S, Oster Y, Cohen MJ, Nir-Paz R. BNT162b2 mRNA Covid-19 vaccine effectiveness among health care workers. *N Engl J Med*. 2021;384(18):1775–1777.
20. Keehner J, Horton LE, Pfeffer MA, et al. SARS-CoV-2 infection after vaccination in health care workers in California. *N Engl J Med*. 2021;384(18):1774–1775.
21. Shah ASV, Gribben C, Bishop J, et al. Effect of vaccination on transmission of SARS-CoV-2. *N Engl J Med*. 2021;385(18):1718–1720.
22. CDC Newsroom. Fully Vaccinated Adults 65 and Older are 94% Less Likely to be Hospitalized with COVID-19. Accessed from <https://www.cdc.gov/media/releases/2021/p0428-vaccinated-adults-less-hospitalized.html>. Accessed on November 25th 2021.