I dati scientifici non sono opinioni

I vaccini Covid sono sperimentali?

Si.

Table 2 Timing of release of individual participant data from COVID-19 vaccine trials

Phase 3 trial	Protocol released before results released?	Pledge to share IPD	Estimated date of availability (based on data sharing statement in protocol or publication)
Pfizer phase 2/3; 43 998 participants (NCT04368728)	Yes	Yes	April 2025, based on statement in trial protocol that data will be made available '24 months after study completion'
Moderna phase 3; 30 420 participants (NCT04470427)	Yes	Unclear	October 2022, based on statement in trial publication that data "may be available ... once the trial is complete"
Oxford/AstraZeneca phase 3; 10 300 participants (ISRCTN89951424)	No	Yes	December 2021, based on statement in trial publication that trial data 'will be made available when the trials are complete'
Janssen (Johnson & Johnson) phase 3; 44 325 participants (NCT04505722)	Yes	Yes	Unclear. April 2021 publication suggested data availability will begin 'with publication,' but as of June, still not listed on Yale Open Data Access Project website.
Novavax phase 3; 30 000 participants (NCT04611802)	Yes	No*	We could not locate any other written statement regarding patient-level data sharing. It is not discussed in the trial protocol or publication.
Gamaleya Research Institute phase 3; 33 758 participants (NCT04530396)	No	Yes*	May 2021, based on statement in trial publication that data will be made available 'on completion of clinical trials'
Sinopharm phase 3; 45 000 participants (NCT04510207)	No	Yes	December 2022, based on statement in trial publication that data will be available between December 2022 and December 2027, with reasonable request to the sponsor and principal investigator.
Sinovac phase 3; 13 000 participants (NCT04582344)	Yes	No*	We could not locate any other written statement regarding patient-level data sharing. It is not discussed in the full-length study protocol. Also, a structured summary of study protocol states 'Not applicable' under the availability of data and material.

EBM analysis

Transparency of COVID-19 vaccine trials: decisions without data

Sarah Tanveer [1], Anisa Rowhani-Farid [1], Kyungwan Hong,[1] Tom Jefferson [2], Peter Doshi [1]

10.1136/bmjebm-2021-111735

Protective immunity after recovery from SARS-CoV-2 infection

Panel: **Biological, epidemiological, and clinical evidence that previous COVID-19 infection reduces the risk for reinfection**

Biological studies

- Dan et al (2021):[1] about 95% of participants tested retained immune memory at about 6 months after having COVID-19; more than 90% of participants had $CD4^+$ T-cell memory at 1 month and 6–8 months after having COVID-19
- Wang et al (2021):[2] participants with a previous SARS-CoV-2 infection with an ancestral variant produce antibodies that cross-neutralise emerging variants of concern with high potency

Epidemiological studies

- Hansen et al (2021):[3] in a population-level observational study, people who had had COVID-19 previously were around 80·5% protected against reinfection
- Pilz et al (2021):[4] in a retrospective observational study using national Austrian SARS-CoV-2 infection data, people who had had COVID-19 previously were around 91% protected against reinfection
- Sheehan et al (2021):[5] in a retrospective cohort study in the USA, people who had had COVID-19 previously were 81·8% protected against reinfection
- Shrestha et al (2021):[6] in a retrospective cohort study in the USA, people who had had COVID-19 previously were 100% protected against reinfection
- Gazit et al (2021):[7] in a retrospective observational study in Israel, SARS-CoV-2-naive vaccinees had a 13·06-times increased risk for breakthrough infection with the delta (B.1.617.2) variant compared with those who had had COVID-19 previously; evidence of waning natural immunity was also shown
- Kojima et al (2021):[8] in a retrospective observational cohort of laboratory staff routinely screened for SARS-CoV-2, people who had had COVID-19 previously were 100% protected against reinfection

Clinical studies

- Hall et al (2021):[9] in a large, multicentre, prospective cohort study, having had COVID-19 previously was associated with an 84% decreased risk of infection
- Letizia et al (2021):[10] in a prospective cohort of US Marines, seropositive young adults were 82% protected against reinfection

I guariti da Covid sono immunizzati?

Si.

80-100%

Protetti dopo infezione primaria

Lancet Infect Dis 2021

Published Online
November 8, 2021
https://doi.org/10.1016/
S1473-3099(21)00676-9

Le reinfezioni sono severe? No.

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Severity of SARS-CoV-2 Reinfections as Compared with Primary Infections

Table 1. Severity of SARS-CoV-2 Reinfections as Compared with Primary Infections in the Population of Qatar.

Disease Outcome*	Reinfection†	Primary Infection†	Odds Ratio (95% CI)
	no. of persons with outcome/no. of persons with infection that was not severe, critical, or fatal		
Severe disease	4/1300	158/6095	0.12 (0.03–0.31)
Critical disease	0/1300	28/6095	0.00 (0.00–0.64)
Fatal disease	0/1300	7/6095	0.00 (0.00–2.57)
Severe, critical, or fatal disease	4/1300	193/6095	0.10 (0.03–0.25)

Cite this as: *BMJ* 2021;375:e067873

Elapsed time since BNT162b2 vaccine and risk of SARS-CoV-2 infection: test negative design study

Ariel Israel,[1] Eugene Merzon,[1,3] Alejandro A Schäffer,[2] Yotam Shenhar,[1] Ilan Green,[1,4] Avivit Golan-Cohen,[1,4] Eytan Ruppin,[2] Eli Magen,[1,5] Shlomo Vinker[1,4]

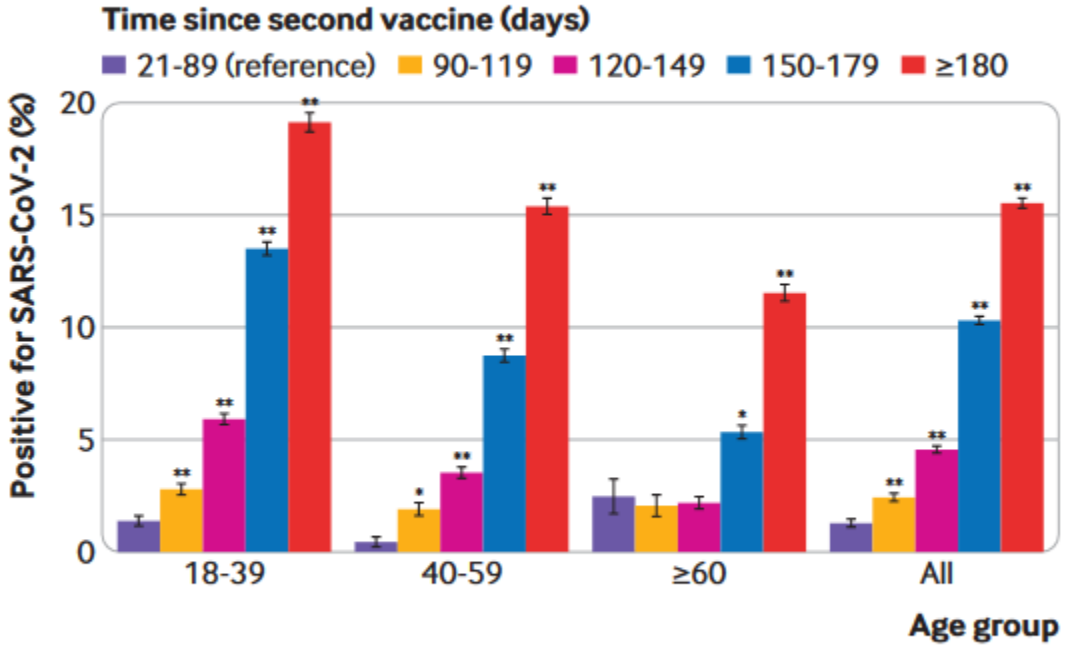

Fig 2 | Comparison of percentage of positive results, according to time elapsed since second vaccine dose, in pre-matched cohort. Error bars=standard error of the proportion. *P<0.01, **P<0.001

La protezione cala nel tempo?

Si.

Problemi con dati su 2 mesi di sperimentazione, durasse 3 anni…

"ART. 4

(Obblighi vaccinali per gli esercenti le professioni sanitarie e gli operatori di interesse sanitario)

1. Al fine di tutelare la salute pubblica e mantenere adeguate condizioni di sicurezza nell'erogazione delle prestazioni di cura e assistenza, in attuazione del piano di cui all'articolo 1, comma 457 della legge 30 dicembre 2020, n. 178, gli esercenti le professioni sanitarie, per la prevenzione dell'infezione da SARS-CoV-2 sono obbligati a sottoporsi a vaccinazione gratuita, comprensiva, a far data dal 15 dicembre 2021, della somministrazione della dose di richiamo del ciclo vaccinale primario, nel rispetto delle indicazioni e dei termini previsti con circolare del Ministero della salute. La vaccinazione costituisce requisito essenziale per l'esercizio della professione e per lo svolgimento delle prestazioni lavorative dei soggetti obbligati. La vaccinazione è somministrata altresì nel rispetto delle indicazioni fornite dalle regioni e dalle province autonome in conformità alle previsioni contenute nel predetto piano.

Ensuring COVID-19 Vaccines Work

Updated Nov. 10, 2021 Languages Print

COVID-19 Vaccines Work

- Research provides evidence that COVID-19 vaccines are **effective** at preventing COVID-19.
- COVID-19 vaccination is an important tool to help stop the COVID-19 pandemic.
- COVID-19 vaccination helps protect adults and children ages 5 years and older from getting sick or severely ill with COVID-19 and helps protect those around them.

Morbidity and Mortality Weekly Report (*MMWR*)

CDC

Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021

Weekly / August 6, 2021 / 70(31);1059-1062

On July 30, 2021, this report was posted online as an MMWR *Early Release.*

Catherine M. Brown, DVM[1]; Johanna Vostok, MPH[1]; Hillary Johnson, MHS[1]; Meagan Burns, MPH[1]; Radhika Gharpure, DVM[2]; Samira Sami, DrPH[2]; Rebecca T. Sabo, MPH[2]; Noemi Hall, PhD[2]; Anne Foreman, PhD[2]; Petra L. Schubert, MPH[1]; Glen R. Gallagher, PhD[1]; Timelia Fink[1]; Lawrence C. Madoff, MD[1]; Stacey B. Gabriel, PhD[3]; Bronwyn MacInnis, PhD[3]; Daniel J. Park, PhD[3]; Katherine J. Siddle, PhD[3]; Vaira Harik, MS[4]; Deirdre Arvidson, MSN[4]; Taylor Brock-Fisher, MSc[5]; Molly Dunn, DVM[5]; Amanda Kearns[5]; A. Scott Laney, PhD[2] (View author affiliations)

What is added by this report?

In July 2021, following multiple large public events in a Barnstable County, Massachusetts, town, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town during July 3–17; 346 (74%) occurred in fully vaccinated persons. Testing identified the Delta variant in 90% of specimens from 133 patients. Cycle threshold values were similar among specimens from patients who were fully vaccinated and those who were not.

Contents lists available at ScienceDirect

The Lancet Regional Health - Europe

journal homepage: www.elsevier.com/lanepe

Letter

The epidemiological relevance of the COVID-19-vaccinated population is increasing

Günter Kampf*

University Medicine Greifswald, Institute for Hygiene and Environmental Medicine, Greifswald, Germany

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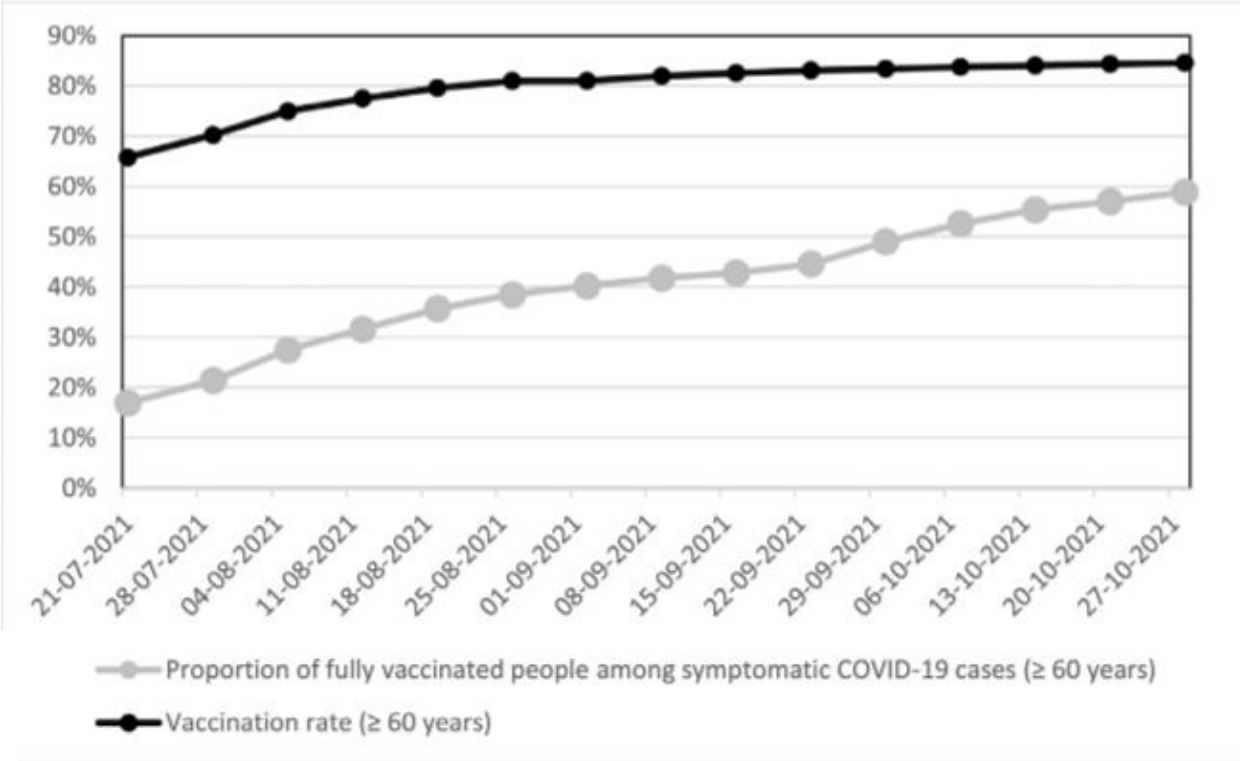
High COVID-19 vaccination rates were expected to reduce transmission of SARS-CoV-2 in populations by reducing the number of possible sources for transmission and thereby to reduce the burden of COVID-19 disease. Recent data, however, indicate that the epidemiological relevance of COVID-19 vaccinated individuals is increasing. In the UK it was described that secondary attack rates among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% for vaccinated vs 23% for unvaccinated). 12 of 31 infections in fully vaccinated household contacts (39%) arose from fully vaccinated epidemiologically linked index cases. Peak viral load did not differ by vaccination status or variant type [1]. In Germany, the rate of symptomatic COVID-19 cases among the fully vaccinated ("breakthrough infections") is reported weekly since 21. July 2021 and was 16.9% at that time among patients of 60 years and older [2]. This proportion is increasing week by week and was 58.9% on 27. October 2021 (Figure 1) providing clear evidence of the increasing relevance of the fully vaccinated as a possible source of transmission. A similar situation was described for the UK. Between week 39 and 42, a total of 100.160 COVID-19 cases were reported among citizens of 60 years or older. 89.821 occurred among the fully vaccinated (89.7%), 3.395 among the unvaccinated (3.4%) [3]. One week before, the COVID-19 case rate per 100.000 was higher among the subgroup of the vaccinated compared to the subgroup of the unvaccinated in all age groups of 30 years or more. In Israel a nosocomial outbreak was reported involving 16 healthcare workers, 23 exposed patients and two family members. The source was a fully vaccinated COVID-19 patient. The vaccination rate was 96.2% among all exposed individuals (151 healthcare workers and 97 patients). Fourteen fully vaccinated patients became severely ill or died, the two unvaccinated patients developed mild disease [4]. The US Centres for Disease Control and Prevention (CDC) identifies four of the top five counties with the highest percentage of fully vaccinated population (99.9–84.3%) as "high" transmission counties [5]. Many decisionmakers assume that the vaccinated can be excluded as a source of transmission. It appears to be grossly negligent to ignore the vaccinated population as a possible and relevant source of transmission when deciding about public health control measures.



COVID-19: stigmatising the unvaccinated is not justified

“People who are vaccinated have a lower risk of severe disease but are still a relevant part of the pandemic. It is therefore wrong and dangerous to speak of a pandemic of the unvaccinated. Historically, both the USA and Germany have engendered negative experiences by stigmatising parts of the population for their skin colour or religion. I call on high-level officials and scientists to stop the inappropriate stigmatisation of unvaccinated people, who include our patients, colleagues, and other fellow citizens, and to put extra effort into bringing society together.”

I declare no competing interests.

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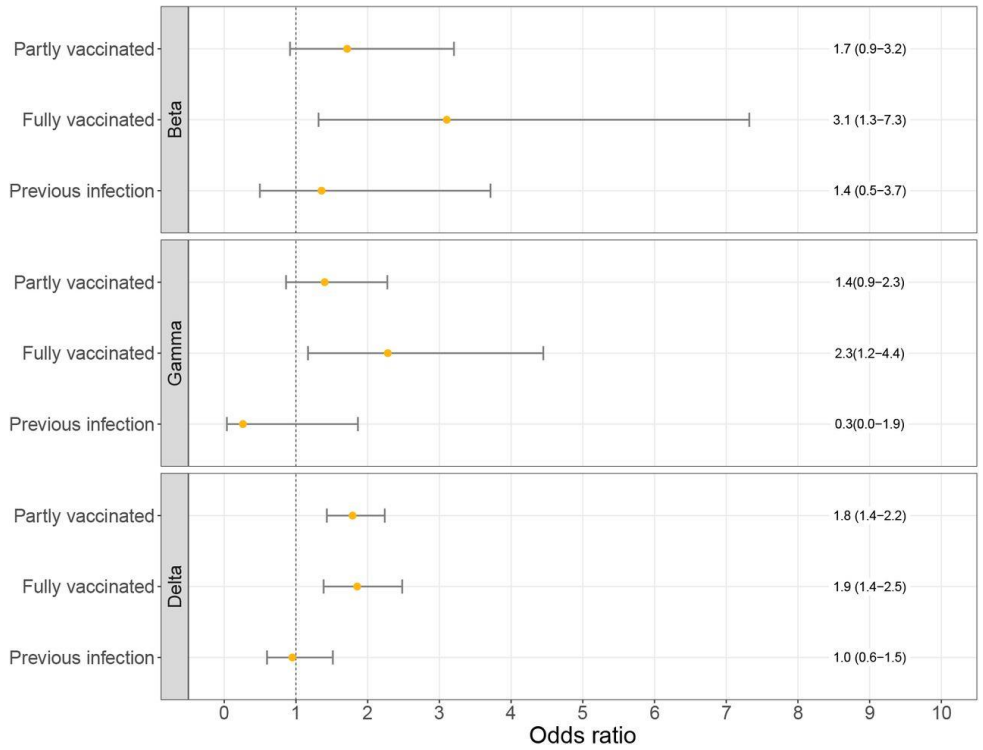
1 Goldman E. How the unvaccinated threaten the vaccinated for COVID-19: a Darwinian perspective. *Proc Natl Acad Sci USA* 2021; **118:** e2114279118.

2 Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings—Barnstable County, Massachusetts, July 2021. *MMWR Morb Mortal Wkly Rep* 2021; **70:** 1059–62.

3 US Centers for Disease Control and Prevention COVID-19 Vaccine Breakthrough Case Investigations Team. COVID-19 vaccine breakthrough infections reported to CDC—United States, January 1–April 30, 2021. *MMWR Morb Mortal Wkly Rep* 2021; **70:** 792–93.

4 Robert Koch Institut. Wöchentlicher Lagebericht des RKI zur Coronavirus-Krankheit-2019 (COVID-19)—14·10·2021—aktualisierter Stand für Deutschland. Oct 14, 2021. https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Wochenbericht/Wochenbericht_2021-10-14.pdf?__blob=publicationFile (accessed Oct 18, 2021).

5 Von Dolle F. Münster: Inzwischen 85 Infizierte nach 2G-Party im Club. Sept 20, 2021. https://www1.wdr.de/nachrichten/westfalen-lippe/corona-infektionen-clubbesuch-muenster-100.html (accessed Sept 23, 2021).



Comments (2)

Increased risk of infection with SARS-CoV-2 Beta, Gamma, and Delta variant compared to Alpha variant in vaccinated individuals

Stijn P. Andeweg, Harry Vennema, Irene Veldhuijzen, Naomi Smorenburg, Dennis Schmitz, Florian Zwagemaker, SeqNeth Molecular surveillance group, RIVM COVID-19 Molecular epidemiology group, Arianne B. van Gageldonk-Lafeber, Susan J.M. Hahné, Chantal Reusken, Mirjam J. Knol, Dirk Eggink

doi: https://doi.org/10.1101/2021.11.24.21266735

Comments (2)
Previous
Next

Patient trajectories among hospitalised COVID-19 patients vaccinated with an mRNA vaccine in Norway: a register-based cohort study

Robert Whittaker, Anja Bråthen Kristofferson, Beatriz Valcarcel Salamanca, Elina Seppälä, Karan Golestani, Reidar Kvåle, Sara Viksmoen Watle, Eirik Alnes Buanes

doi: https://doi.org/10.1101/2021.11.05.21265958

Posted November 09, 2021.

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Results We included 2,361 patients, including 70 (3%) partially vaccinated and 183 (8%) fully vaccinated. Fully vaccinated patients 18–79 years had a shorter LoS in hospital overall (adjusted hazard ratio for discharge: 1.35, 95%CI: 1.07–1.72), and lower odds of ICU admission (adjusted odds ratio: 0.57, 95%CI: 0.33–0.96). Similar estimates were observed when collectively analysing partially and fully vaccinated patients. We observed no difference in the LoS for patients not admitted to ICU, nor odds of in-hospital death between vaccinated and unvaccinated patients.

Age group	Outcome	Vaccination status									
		Unvaccinated		Fully vaccinated				Partially and fully vaccinated			
		No (%)	Yes (%)	No (%)	Yes (%)	Crude odds ratio compared to unvaccinated (95%CI)	Adjusted [b] odds ratio compared to unvaccinated (95%CI)	No (%)	Yes (%)	Crude odds ratio compared to unvaccinated (95%CI)	Adjusted [b] odds ratio compared to unvaccinated (95%CI)
18–64 years	Admission to ICU	1401 (83%)	277 (17%)	40 (80%)	10 (20%)	1.264 (0.625–2.559)	0.946 (0.412–1.975)	80 (86%)	13 (14%)	0.822 (0.451–1.498)	0.717 (0.360–1.323)
	Death in hospital [a]	1641 (98%)	31 (2%)	42 (87.5%)	6 (12.5%)	**7.562 (2.995–19.095)**	2.568 (0.760–7.433)	83 (92%)	7 (8%)	**4.464 (1.909–10.438)**	1.599 (0.512–4.316)
65–79 years	Admission to ICU	271 (71.5%)	108 (28.5%)	49 (83%)	10 (17%)	0.512 (0.250–1.048)	0.512 (0.237–1.007)	68 (83%)	14 (17%)	**0.517 (0.279–0.957)**	**0.455 (0.201–0.988)**
	Death in hospital [a]	335 (90%)	37 (10%)	50 (88%)	7 (12%)	1.268 (0.536–2.998)	1.297 (0.505–2.928)	69 (86%)	11 (14%)	1.443 (0.702–2.969)	1.480 (0.685–2.982)
18–79 years	Admission to ICU	1672 (81%)	385 (19%)	89 (82%)	20 (18%)	0.976 (0.593–1.605)	**0.571 (0.326–0.955)**	148 (85%)	27 (15%)	0.792 (0.518–1.212)	**0.516 (0.321–0.802)**
	Death in hospital [a]	1976 (97%)	68 (3%)	92 (88%)	13 (12%)	**4.106 (2.189–7.702)**	1.234 (0.596–2.393)	152 (89%)	18 (11%)	**3.441 (1.995–5.935)**	1.174 (0.621–2.124)
≥80 years	Admission to ICU	48 (94%)	3 (6%)	69 (93%)	5 (7%)	1.159 (0.264–5.083)	1.889 (0.366–12.300)	72 (92%)	6 (8%)	1.333 (0.318–5.590)	2.156 (0.453–13.475)
	Death in hospital [a]	41 (80%)	10 (20%)	65 (88%)	9 (12%)	0.568 (0.213–1.515)	0.588 (0.206–1.658)	67 (86%)	11 (14%)	0.673 (0.263–1.724)	0.720 (0.269–1.948)
≥18 years	Admission to ICU	1720 (81%)	388 (18%)	158 (86%)	25 (14%)	0.701 (0.454–1.085)	**0.497 (0.281–0.857)**	220 (87%)	33 (13%)	**0.665 (0.454–0.974)**	**0.600 (0.387–0.908)**
	Death in hospital [a]	2017 (96%)	78 (4%)	157 (88%)	22 (12%)	**3.624 (2.197–5.976)**	0.741 (0.402–1.322)	219 (88%)	29 (12%)	**3.424 (2.187–5.362)**	0.842 (0.488–1.422)

ICU: Intensive care unit; 95%CI: 95% confidence interval. Bold text = statistically significant results.

[a] Excludes patients who were still admitted to hospital at the end of the study period.

[b] Adjusted for age, sex, county of residence, regional health authority, date of admission, country of birth, virus variant and underlying risk factors. The variables included in the final multivariable model were obtained by forward model selection and AIC comparison (see supplementary materials D).