

Risk of myocarditis and pericarditis following BNT162b2 and ChAdOx1 COVID-19 vaccinations

Sample size

Dose 1

analysis_product	sample	N
BNT162b2	Exposed	13216259
BNT162b2	Total	49786346
ChAdOx1-S	Exposed	19366909
ChAdOx1-S	Total	49786346

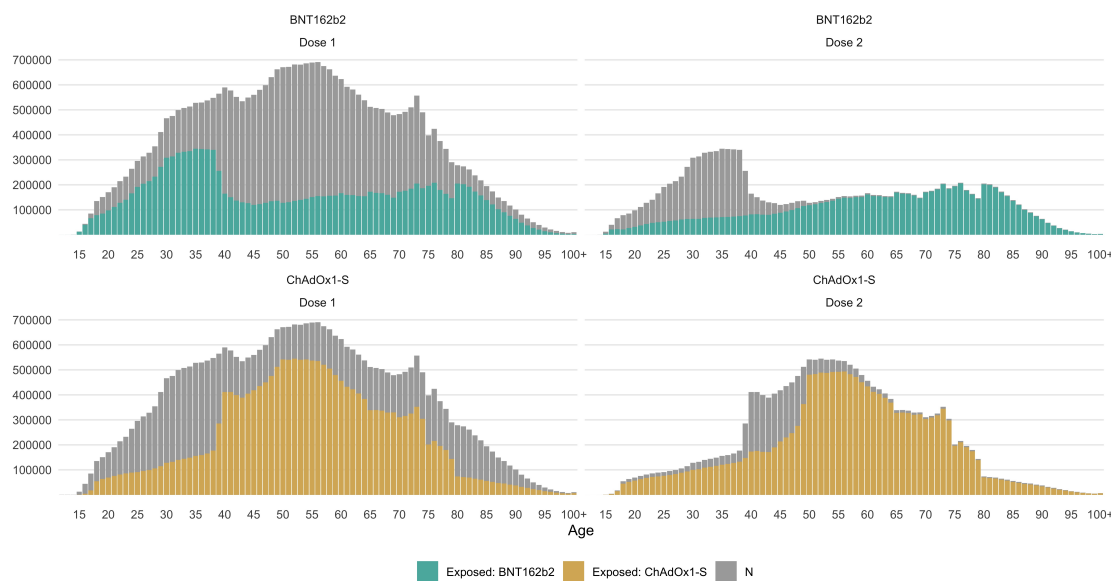
Dose 2

analysis_product	sample	N
BNT162b2	Exposed	8614934
BNT162b2	Total	13216259
ChAdOx1-S	Exposed	15925122
ChAdOx1-S	Total	19366909

Patient characteristics

Category	Sub-category	BNT162b2			ChAdOx1		
Age Group		<40	40-69	70+	<40	40-69	70+
N		5285006	4412060	3519193	2683141	13368016	3315752
Sex	Male	2487435	1900760	1594618	1135001	6833559	1478295
Sex	Female	2797571	2511300	1924575	1548140	6534457	1837457
Ethnicity	Asian or Asian British	549040	386154	108015	308781	908142	98539
Ethnicity	Black or Black British	111271	141237	33590	76271	367260	39489
Ethnicity	Mixed	94880	50062	11442	50015	134397	12033
Ethnicity	Other Ethnic Groups	171014	86458	26778	69486	268767	26373
Ethnicity	White	4190348	3670391	3294163	2129790	11350894	3089673
Ethnicity	Unknown Or Missing	168453	77758	45205	48798	338556	49645
Deprivation	Quintile 1 (most deprived)	881344	790045	443962	572438	2207082	461548
Deprivation	Quintile 2	981813	835141	581166	534701	2419578	556935
Deprivation	Quintile 3	961616	881695	731166	477660	2615004	678834
Deprivation	Quintile 4	927203	887068	817091	436929	2739606	736807
Deprivation	Quintile 5 (least deprived)	871970	867543	863689	390149	2857595	759426
History	Coronavirus Infection	81731	160404	59623	92381	285426	77470
History	Myocarditis/pericarditis	3434	5551	4046	2975	13069	3843
Region	North West	617093	608345	468799	345748	1646966	396372
Region	Missing	950906	438841	331880	412244	1431009	385804
Region	London	782420	624630	361282	389359	1682984	248603
Region	South East	685750	623726	560464	332962	2092038	537598
Region	East Of England	428282	376427	355180	221443	1284366	324343
Region	South West	372983	377451	333654	165922	1104950	331338
Region	East Midlands	357990	314067	282392	195491	989434	249357
Region	Yorkshire And The Humber	461281	419032	326902	257455	1299522	351528
Region	West Midlands	452944	446357	369992	266374	1315953	346754
Region	North East	175357	183184	128648	96143	520794	144055

Patient age distribution



Estimates, overall

Dose 1

exposure	days_post_vaccination	estimate	conf.low	conf.high	p.value
BNT162b2	0-13	0.58	0.39	0.84	0.00
BNT162b2	14+	0.80	0.65	0.97	0.03
ChAdOx1-S	0-13	0.67	0.50	0.89	0.01
ChAdOx1-S	14+	0.75	0.63	0.90	0.00

Dose 2

exposure	days_post_vaccination	estimate	conf.low	conf.high	p.value
BNT162b2	0-13	0.77	0.50	1.18	0.23
BNT162b2	14+	1.11	0.79	1.55	0.56
ChAdOx1-S	0-13	1.33	0.84	2.10	0.23
ChAdOx1-S	14+	1.38	0.85	2.24	0.20

Estimates, by sex

Dose 1

exposure	days_post_vaccination	sex	estimate	conf.low	conf.high	p.value
BNT162b2	0-13	Male	0.38	0.21	0.70	0.01
BNT162b2	0-13	Female	0.84	0.52	1.35	0.92
BNT162b2	14+	Male	0.81	0.63	1.03	0.30
BNT162b2	14+	Female	0.78	0.60	1.03	0.29
ChAdOx1-S	0-13	Male	0.79	0.56	1.10	0.49
ChAdOx1-S	0-13	Female	0.48	0.29	0.81	0.02
ChAdOx1-S	14+	Male	0.83	0.68	1.02	0.25
ChAdOx1-S	14+	Female	0.63	0.48	0.82	0.00

Dose 2

exposure	days_post_vaccination	sex	estimate	conf.low	conf.high	p.value
BNT162b2	0-13	Male	0.75	0.42	1.35	0.80
BNT162b2	0-13	Female	0.78	0.43	1.41	0.88
BNT162b2	14+	Male	1.18	0.77	1.79	0.90
BNT162b2	14+	Female	1.03	0.66	1.60	1.00
ChAdOx1-S	0-13	Male	1.17	0.66	2.08	0.97
ChAdOx1-S	0-13	Female	1.62	0.83	3.13	0.48
ChAdOx1-S	14+	Male	0.99	0.51	1.92	1.00
ChAdOx1-S	14+	Female	2.05	1.07	3.91	0.12

Estimates, by age group

Dose 1

exposure	days_post_vaccination	age_group	estimate	conf.low	conf.high	p.value
BNT162b2	0-13	<40	1.56	0.64	3.78	0.90
BNT162b2	0-13	40-69	0.81	0.48	1.39	0.97
BNT162b2	0-13	70+	0.29	0.15	0.55	0.00
BNT162b2	14+	<40	1.44	0.89	2.32	0.58
BNT162b2	14+	40-69	1.13	0.88	1.45	0.91
BNT162b2	14+	70+	0.47	0.36	0.63	0.00
ChAdOx1-S	0-13	<40	1.64	0.85	3.18	0.60
ChAdOx1-S	0-13	40-69	0.73	0.51	1.05	0.42
ChAdOx1-S	0-13	70+	0.33	0.18	0.60	0.00
ChAdOx1-S	14+	<40	1.42	0.94	2.15	0.47
ChAdOx1-S	14+	40-69	0.92	0.74	1.13	0.96
ChAdOx1-S	14+	70+	0.43	0.32	0.57	0.00

Dose 2

exposure	days_post_vaccination	age_group	estimate	conf.low	conf.high	p.value
BNT162b2	0-13	<40	1.52	0.62	3.76	0.93
BNT162b2	0-13	40-69	0.37	0.15	0.92	0.18
BNT162b2	0-13	70+	0.93	0.53	1.65	1.00
BNT162b2	14+	<40	1.24	0.56	2.72	1.00
BNT162b2	14+	40-69	0.79	0.44	1.41	0.96
BNT162b2	14+	70+	1.29	0.85	1.96	0.77
ChAdOx1-S	0-13	<40	1.11	0.26	4.66	1.00
ChAdOx1-S	0-13	40-69	2.05	1.19	3.54	0.06
ChAdOx1-S	0-13	70+	0.77	0.36	1.68	0.99
ChAdOx1-S	14+	<40	0.69	0.10	5.00	1.00
ChAdOx1-S	14+	40-69	1.25	0.54	2.89	1.00
ChAdOx1-S	14+	70+	1.52	0.83	2.80	0.69

Heterogeneity p-values

Dose 1

Sex

exposure	days_post_vaccination	p.value
BNT162b2	0-13	0.06
BNT162b2	0-13	<0.005
BNT162b2	0-13	0.04
BNT162b2	14+	0.80
BNT162b2	14+	0.62
BNT162b2	14+	0.87
ChAdOx1-S	0-13	0.15
ChAdOx1-S	0-13	0.46
ChAdOx1-S	0-13	0.11
ChAdOx1-S	14+	0.06
ChAdOx1-S	14+	0.65
ChAdOx1-S	14+	0.08

Age group

exposure	days_post_vaccination	p.value
BNT162b2	0-13	<0.005
BNT162b2	0-13	<0.005
BNT162b2	0-13	<0.005
BNT162b2	14+	<0.005
BNT162b2	14+	<0.005
BNT162b2	14+	<0.005
ChAdOx1-S	0-13	<0.005
ChAdOx1-S	0-13	<0.005
ChAdOx1-S	0-13	<0.005
ChAdOx1-S	14+	<0.005
ChAdOx1-S	14+	0.45
ChAdOx1-S	14+	<0.005

Dose 2

Sex

exposure	days_post_vaccination	p.value
BNT162b2	0-13	0.89
BNT162b2	0-13	0.89
BNT162b2	0-13	0.90
BNT162b2	14+	0.94
BNT162b2	14+	0.94
BNT162b2	14+	0.62
ChAdOx1-S	0-13	0.55
ChAdOx1-S	0-13	0.55
ChAdOx1-S	0-13	0.44
ChAdOx1-S	14+	0.23
ChAdOx1-S	14+	0.23
ChAdOx1-S	14+	0.11

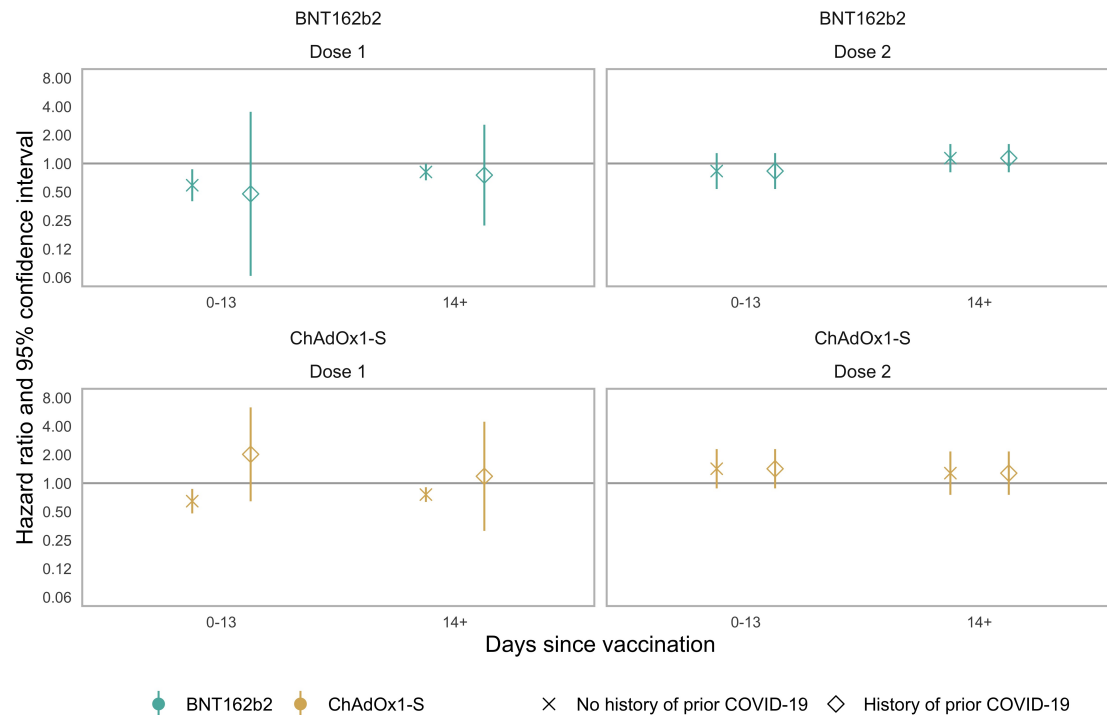
Age group

exposure	days_post_vaccination	p.value
BNT162b2	0-13	0.07
BNT162b2	0-13	0.07
BNT162b2	0-13	0.09
BNT162b2	14+	0.27
BNT162b2	14+	0.27
BNT162b2	14+	0.34
ChAdOx1-S	0-13	0.11
ChAdOx1-S	0-13	0.11
ChAdOx1-S	0-13	0.10
ChAdOx1-S	14+	0.51
ChAdOx1-S	14+	0.51
ChAdOx1-S	14+	0.76

Estimated excess risk 90 days post vaccination

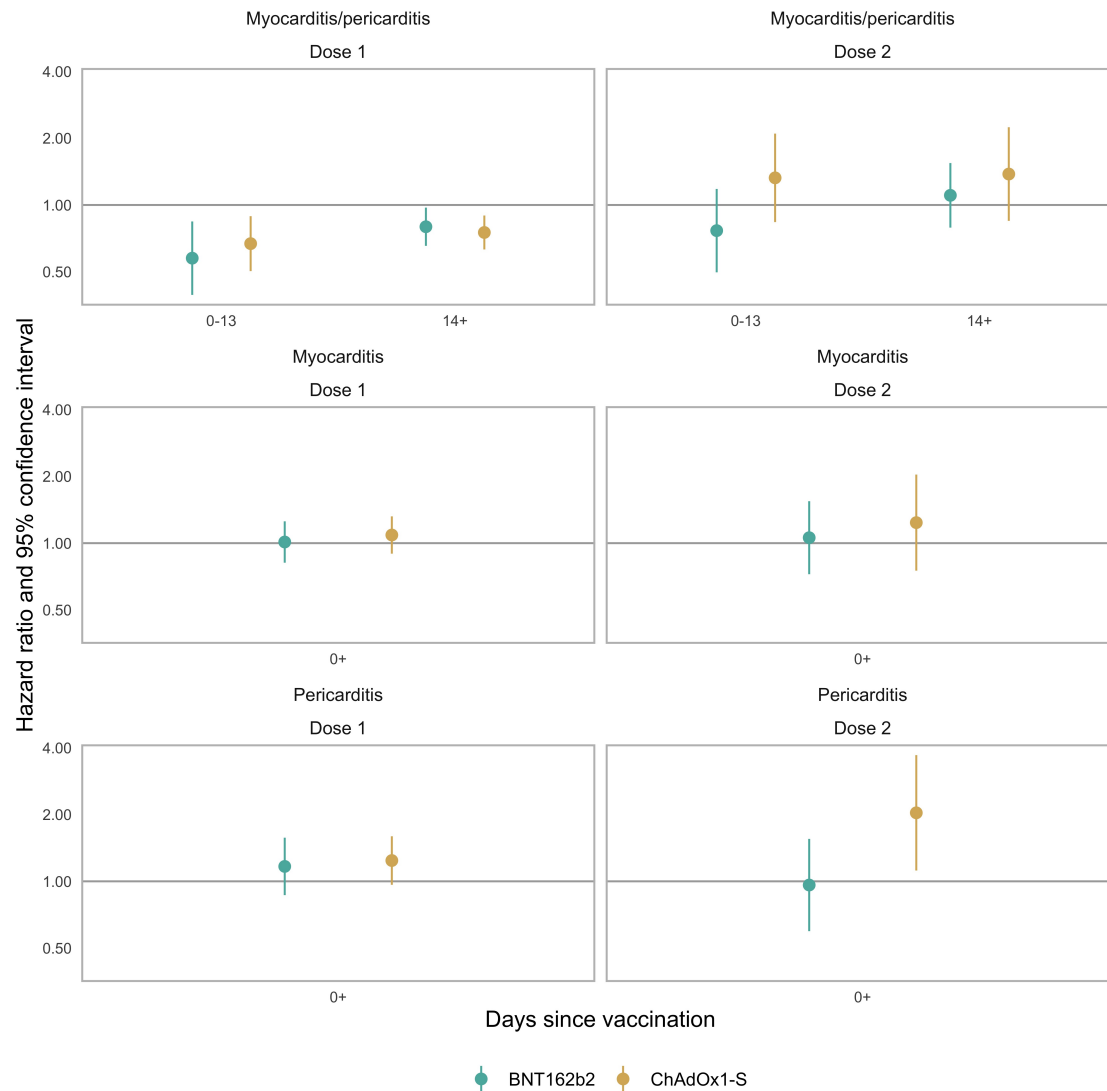
exposure	dose1	dose2
BNT162b2	-55	6
ChAdOx1	-122	42

Estimates, by prior history



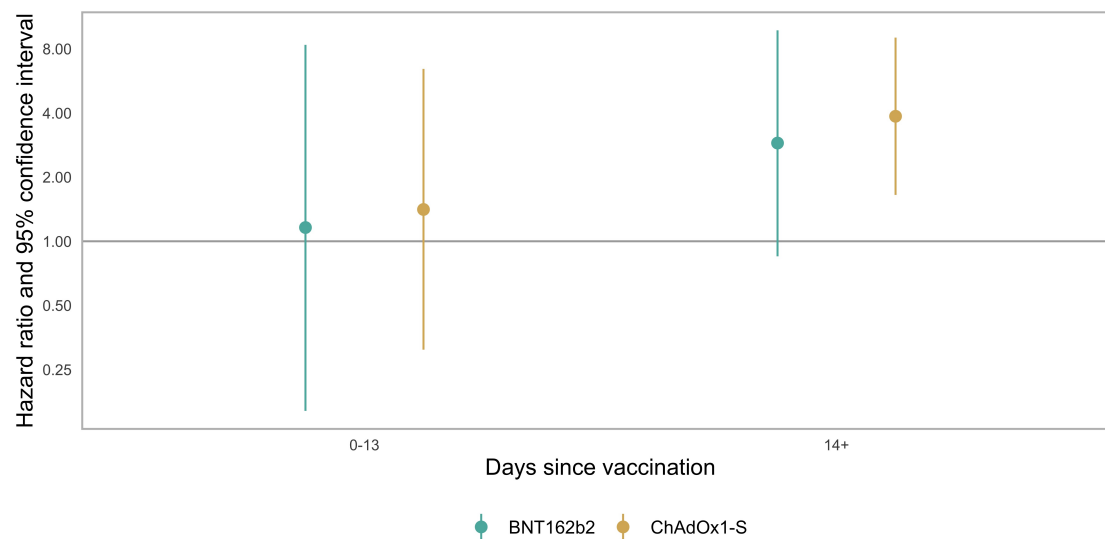
prior_covid	dose	exposure	estimate	conf.low	conf.high	p.value
No	Dose 1	BNT162b2	0.59	0.40	0.87	0.01
No	Dose 1	BNT162b2	0.81	0.66	1.00	0.05
No	Dose 1	ChAdOx1-S	0.65	0.48	0.87	0.00
No	Dose 1	ChAdOx1-S	0.76	0.63	0.91	0.00
No	Dose 2	BNT162b2	0.83	0.54	1.29	0.41
No	Dose 2	BNT162b2	1.14	0.81	1.61	0.46
No	Dose 2	ChAdOx1-S	1.42	0.88	2.29	0.15
No	Dose 2	ChAdOx1-S	1.28	0.75	2.16	0.36
Yes	Dose 1	BNT162b2	0.48	0.06	3.52	0.47
Yes	Dose 1	BNT162b2	0.75	0.22	2.57	0.65
Yes	Dose 1	ChAdOx1-S	2.02	0.64	6.33	0.23
Yes	Dose 1	ChAdOx1-S	1.18	0.31	4.46	0.80
Yes	Dose 2	BNT162b2	0.83	0.54	1.29	0.41
Yes	Dose 2	BNT162b2	1.14	0.81	1.61	0.46
Yes	Dose 2	ChAdOx1-S	1.42	0.88	2.29	0.15
Yes	Dose 2	ChAdOx1-S	1.28	0.75	2.16	0.36

Estimates, by individual outcome



outcome	dose	exposure	estimate	conf.low	conf.high	p.value
myocarditis	Dose 1	BNT162b2	1.01	0.82	1.25	0.91
myocarditis	Dose 1	ChAdOx1-S	1.09	0.90	1.32	0.39
myocarditis	Dose 2	BNT162b2	1.06	0.72	1.55	0.77
myocarditis	Dose 2	ChAdOx1-S	1.24	0.75	2.04	0.40
pericarditis	Dose 1	BNT162b2	1.17	0.87	1.57	0.31
pericarditis	Dose 1	ChAdOx1-S	1.24	0.96	1.60	0.09
pericarditis	Dose 2	BNT162b2	0.96	0.60	1.55	0.88
pericarditis	Dose 2	ChAdOx1-S	2.04	1.12	3.70	0.02

Dose 1 replication in Wales



Events

outcome	dose	exposure	days_post_vaccination	events
myocarditis/pericarditis	Dose 1	BNT162b2	Before	43
myocarditis/pericarditis	Dose 1	BNT162b2	0-13	<5
myocarditis/pericarditis	Dose 1	BNT162b2	14+	14
myocarditis/pericarditis	Dose 1	ChAdOx1-S	Before	43
myocarditis/pericarditis	Dose 1	ChAdOx1-S	0-13	<5
myocarditis/pericarditis	Dose 1	ChAdOx1-S	14+	14

Estimates

outcome	dose	exposure	days_post_vaccination	estimate	conf.low	conf.high
myocarditis/pericarditis	Dose 1	BNT162b2	0-13	1.16	0.16	8.35
myocarditis/pericarditis	Dose 1	BNT162b2	14+	2.89	0.85	9.77
myocarditis/pericarditis	Dose 1	ChAdOx1-S	0-13	1.41	0.31	6.44
myocarditis/pericarditis	Dose 1	ChAdOx1-S	14+	3.86	1.65	9.03

Contributions to this work

This work was conducted on behalf of the BHF Data Science Centre (Health Data Research UK) CVD-COVID-UK/COVID-IMPACT Consortium and the Longitudinal Health and Wellbeing and Data and Connectivity UK COVID-19 National Core Studies. Samantha Ip developed the analysis code and implemented the analysis in England; Fatemeh Torabi derived the dataset for Wales and implemented the analysis in Wales; and Venexia Walker derived the dataset for England, combined and visualised the results from both nations, and drafted the report. The work relied on the support of the CCU002 project group, members of which include: Angela Wood (University of Cambridge), Arun Karthikeyan Suseeladevi (University of Bristol), Ashley Akbari (Swansea University), Cathie Sudlow (BHF Data Science Centre), Emanuele Di Angelantonio (University of Cambridge), Efosa Omigie (NHS Digital), Fatemeh Torabi (Swansea University), Hoda Abbasizanjani (Swansea University), Jennifer Cooper (University of Bristol), Jonathan Sterne (University of Bristol), Rachel Denholm (University of Bristol), Rochelle Knight (University of Bristol), Sam Hollings (NHS Digital), Samantha Ip (University of Cambridge), Spencer Keene (University of Cambridge), Spiros Denaxas (University College London), Teri-Louise North (University of Bristol), Thomas Bolton (BHF Data Science Centre), Venexia Walker (University of Bristol) and William Whiteley (University of Edinburgh). The project was conceived by this group, all members of which contributed to the development of the protocol (https://github.com/BHFDSC/CCU002_03/blob/main/protocol/COVID%20vaccination%20and%20myocarditis%20and%20pericarditis.pdf). Members of the group also reviewed and discussed analysis results and their interpretation, including in the context of other relevant published studies.

Funding

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Other acknowledgements

This work makes use of de-identified data held in NHS Digital's TRE for England and the SAIL Databank for Wales, made available via the BHF Data Science Centre's CVD-COVID-UK/COVID-IMPACT consortium. This work uses data provided by patients and collected by the NHS as part of their care and support. We would like to acknowledge all data providers who make health relevant data available for research.

This study makes use of anonymised data held in the Secure Anonymised Information Linkage (SAIL) Databank. This work uses data provided by patients and collected by the NHS as part of their care and support. We would also like to acknowledge all data providers who make anonymised data available for research. We wish to acknowledge the collaborative partnership that enabled acquisition and access to the de-identified data, which led to this output. The collaboration was led by the Swansea University Health Data Research UK team under the direction of the Welsh Government Technical Advisory Cell (TAC) and includes the following groups and organisations: the SAIL Databank, Administrative Data Research (ADR) Wales, Digital Health and Care Wales (DHCW), Public Health Wales, NHS Shared Services Partnership (NWSSP) and the Welsh Ambulance Service Trust (WAST). All research conducted has been completed under the permission and approval of the SAIL independent Information Governance Review Panel (IGRP) project number 0911.

Data availability

The data used in this study are available in NHS Digital's TRE for England, but as restrictions apply they are not publicly available (<https://digital.nhs.uk/coronavirus/coronavirus-data-services-updates/trusted-research-environment-service-for-england>). The CVD-COVID-UK/COVID-IMPACT programme led by the BHF Data Science Centre (<https://www.hdruc.ac.uk/helping-with-health-data/bhf-data-science-centre/>) received approval to access data in NHS Digital's TRE for England from the Independent Group Advising on the Release of Data (IGARD) (<https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data>) via an application made in the Data Access Request Service (DARS) Online system (ref. DARS-NIC-381078-Y9C5K) (<https://digital.nhs.uk/service-s/data-access-request-service-dars/dars-products-and-services>). The CVD-COVID-UK/COVID-IMPACT Approvals & Oversight Board (<https://www.hdruc.ac.uk/projects/cvd-covid-uk-project/>) subsequently granted approval to this project to access the data within the TRE for England and the Secure Anonymised Information Linkage (SAIL) Databank. The de-identified data used in this study was made available to accredited researchers only.

The data used in this study are available in the SAIL Databank at Swansea University, Swansea, UK, but as restrictions apply they are not publicly available. All proposals to use SAIL data are subject to review by an independent Information Governance Review Panel (IGRP). Before any data can be accessed, approval must be given by the IGRP. The IGRP gives careful consideration to each project to ensure proper and appropriate use of SAIL data. When access has been granted, it is gained through a privacy protecting safe haven and remote access system referred to as the SAIL Gateway. SAIL has established an application process to be followed by anyone who would like to access data via SAIL at <https://www.saildatabank.com/application-process>

Ethical approval

The North East-Newcastle and North Tyneside 2 research ethics committee provided ethical approval for the CVD-COVID-UK/COVID-IMPACT research programme (REC No 20/NE/0161).