

# THE LANCET

## Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

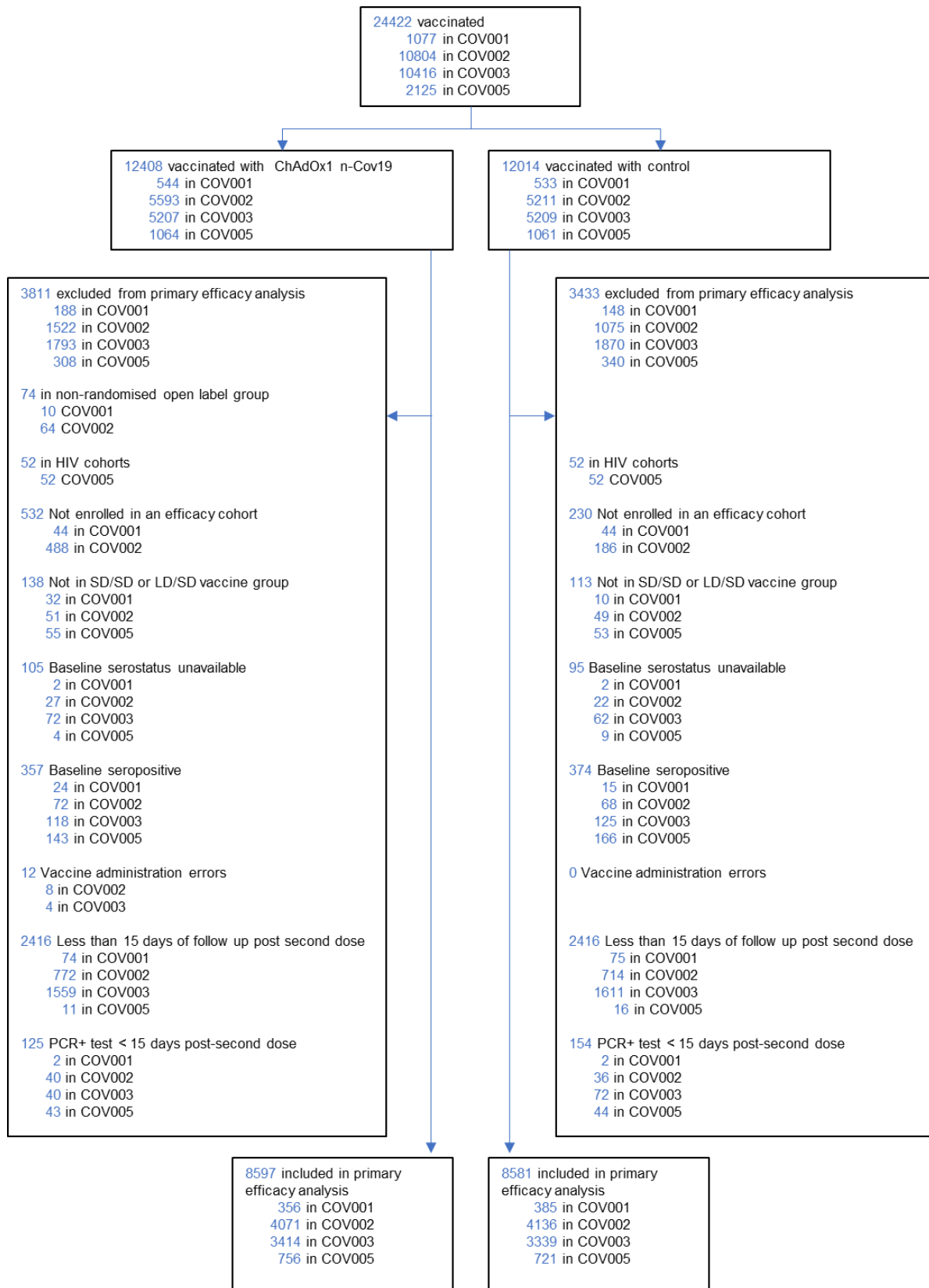
Supplement to: Voysey M, Clemens SAC, Madhi SA, et al. Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a pooled analysis of four randomised trials. *Lancet* 2021; published online Feb 19. [http://dx.doi.org/10.1016/S0140-6736\(21\)00432-3](http://dx.doi.org/10.1016/S0140-6736(21)00432-3).

## Supplementary File

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**Figure S1 CONSORT diagram**



**Table S1 Baseline characteristics of primary efficacy analysis two-dose cohort**

Characteristics	COV001 (UK)		COV002 (UK)		COV003 (Brazil)		COV005 (South Africa)	
	ChAdOx1 nCoV-19 (n=356)	Control (n=385)	ChAdOx1 nCoV-19 (n=4071)	Control (n=4136)	ChAdOx1 nCoV-19 (n=3414)	Control (n=3339)	ChAdOx1 nCoV-19 (n=756)	Control (n=721)
Age								
18-55 years	356 (100.0%)	385 (100.0%)	3282 (80.6%)	3334 (80.6%)	2850 (83.5%)	2808 (84.1%)	719 (95.1%)	679 (94.2%)
56-69 years	0 (0.0%)	0 (0.0%)	377 (9.3%)	378 (9.1%)	492 (14.4%)	466 (14.0%)	37 (4.9%)	42 (5.8%)
≥70 years	0 (0.0%)	0 (0.0%)	412 (10.1%)	424 (10.3%)	72 (2.1%)	65 (1.9%)	0 (0.0%)£	0 (0.0%)£
missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sex (female) n%	174 (48.9%)	201 (52.2%)	2395 (58.8%)	2521 (61.0%)	1936 (56.7%)	1839 (55.1%)	311 (41.1%)	319 (44.2%)
BMI (kg/m <sup>2</sup> ) median [IQR]	24.1 [22.3- 26.7]	24.4 [21.9- 26.9]	25.4 [22.9- 28.7]	25.4 [22.9- 29.0]	25.8 [23.2-29.2]	25.9 [23.2-29.4]	23.4 [20.4- 27.7]	23.5 [20.8-28.3]
Ethnicity								
White	323 (90.7%)	355 (92.2%)	3725 (91.5%)	3815 (92.2%)	2273 (66.6%)	2249 (67.4%)	114 (15.1%)	121 (16.8%)
Black	3 (0.8%)	1 (0.3%)	23 (0.6%)	17 (0.4%)	337 (9.9%)	336 (10.1%)	510 (67.5%)	466 (64.6%)
Asian†	17 (4.8%)	16 (4.2%)	220 (5.4%)	203 (4.9%)	83 (2.4%)	66 (2.0%)		
Mixed	6 (1.7%)	7 (1.8%)	70 (1.7%)	66 (1.6%)	704 (20.6%)	670 (20.1%)	113 (14.9%)€	117 (16.2%)€
Other	7 (2.0%)	6 (1.6%)	33 (0.8%)	35 (0.8%)	17 (0.5%)	18 (0.5%)	19 (2.5%)	17 (2.4%)
missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Health and social care setting workers n%	67 (18.8%)	63 (16.4%)	2731 (67.1%)	2825 (68.3%)	2526 (74.0%)	2425 (72.6%)	64 (8.5%)	79 (11.0%)
Co-morbidities								
Cardiovascular disease	0 (0.0%)	0 (0.0%)	476 (11.7%)	468 (11.3%)	540 (15.8%)	511 (15.3%)	24 (3.2%)	20 (2.8%)
Respiratory disease	0 (0.0%)	0 (0.0%)	489 (12.0%)	525 (12.7%)	354 (10.4%)	321 (9.6%)	29 (3.8%)	20 (2.8%)
Diabetes	0 (0.0%)	0 (0.0%)	93 (2.3%)	86 (2.1%)	141 (4.1%)	113 (3.4%)	3 (0.4%)	4 (0.6%)

† Asian not recorded as a category in South Africa. £ Maximum age at enrolment for eligibility was 65 years in South Africa. € This category recorded as 'Coloured' in original data.

**Table S2 Follow-up time (days) after 14 days post-booster dose in primary efficacy cohort, by country**

<b>Pooled data</b>		<b>ChAdOx1 nCoV-19</b>	<b>Control</b>
Time between prime-boost SD/SD	<6 weeks	54.0 [18.0, 81.0]	53.0 [17.0, 80.0]
	6-8 weeks	83.0 [53.0, 97.0]	82.0 [52.0, 95.0]
	9-11 weeks	83.0 [67.0, 91.8]	84.0 [66.0, 92.0]
	≥12 weeks	61.0 [54.0, 69.0]	62.0 [53.8, 69.0]
Time between prime-boost SD/SD or LD/SD	<6 weeks	54.0 [18.0, 81.0]	53.0 [17.0, 80.0]
	6-8 weeks	83.0 [53.0, 97.0]	83.0 [52.0, 95.0]
	9-11 weeks	90.0 [81.0, 96.0]	90.0 [80.0, 96.0]
	≥12 weeks	67.0 [59.0, 82.0]	67.0 [56.0, 82.0]
<b>UK</b>		<b>ChAdOx1 nCoV-19</b>	<b>Control</b>
Time between prime-boost SD/SD	<6 weeks	35.0 [21.0, 63.0]	35.0 [21.0, 63.0]
	6-8 weeks	97.0 [89.0, 102.0]	95.0 [59.0, 101.0]
	9-11 weeks	89.0 [83.0, 95.0]	89.0 [82.0, 95.0]
	≥12 weeks	63.0 [56.0, 69.2]	63.0 [55.0, 70.0]
Time between prime-boost SD/SD or LD/SD	<6 weeks	35.0 [21.0, 63.0]	35.0 [21.0, 63.0]
	6-8 weeks	97.0 [90.0, 102.0]	95.0 [67.0, 101.0]
	9-11 weeks	94.0 [88.0, 98.0]	92.0 [88.0, 97.0]
	≥12 weeks	68.0 [59.0, 82.0]	68.0 [59.0, 82.0]
<b>Brazil</b>		<b>ChAdOx1 nCoV-19</b>	<b>Control</b>
Time between prime-boost SD/SD	<6 weeks	35.0 [13.0, 80.0]	35.0 [13.0, 70.0]
	6-8 weeks	68.0 [45.0, 83.0]	69.0 [47.0, 84.0]
	9-11 weeks	63.0 [53.0, 69.0]	61.0 [53.0, 69.0]
	≥12 weeks	46.0 [39.0, 53.0]	45.0 [33.5, 52.0]
<b>South Africa</b>		<b>ChAdOx1 nCoV-19</b>	<b>Control</b>
Time between prime-boost SD/SD	<6 weeks	81.0 [63.0, 91.0]	80.0 [63.0, 90.0]
	6-8 weeks	62.0 [52.0, 62.0]	61.0 [53.0, 63.0]
	9-11 weeks	30.5 [23.8, 33.5]	55.0 [46.0, 55.0]
	≥12 weeks	-	-
Time between prime-boost SD/SD or LD/SD	<6 weeks	81.0 [63.0, 91.0]	80.0 [63.0, 90.0]
	6-8 weeks	62.0 [52.0, 62.0]	61.0 [52.0, 63.0]
	9-11 weeks	30.5 [23.8, 33.5]	55.0 [46.0, 55.0]
	≥12 weeks	-	-

Follow-up time presented as median [IQR] in days from 15 days after booster dose until the first occurrence of either withdrawal, PCR+ event, or date of data lock.

**Table S3 Hospitalisation for COVID-19 (Any dose efficacy population)**

	<b>N cases</b>	<b>ChAdOx1 nCoV-19 N=11794</b>	<b>Control N=11776</b>
< 22 days after a single dose	9	2	7
>= 22 days after the first dose and < 15 days post booster dose	6	0	6
>= 15 days post booster dose	9	0	9

\*>=22 days after first dose, 0 vs 15 cases, VE: 100%, (97.5% one-sided CI 72.2%, NE). Estimate determined from stratified Poisson regression with Exact Conditional Method. NE: Not evaluated.

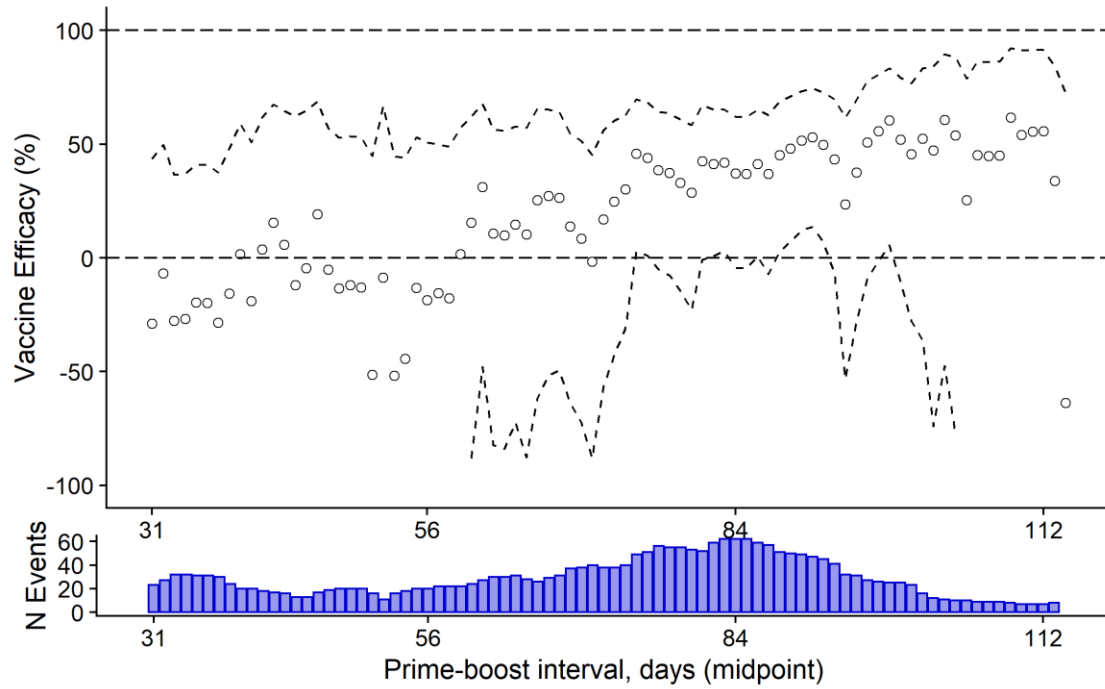
**Table S4 Factors related to receipt of a booster dose**

	<b>Participants who received booster N=19150</b>	<b>Participants who were not boosted N=2752</b>	<b>P value*</b>
Age, median [IQR]	40.0 [30.1, 52.0]	36.3 [28.0, 48.0]	<0.001
18 – 55 years, n (%)	15841/19150 (82.7%)	2377/2752 (86.4%)	<0.001
56 – 69 years, n (%)	2218/19150 (11.6%)	247/2752 (9.0%)	
≥70 years, n (%)	1091/19150 (5.7%)	128/2752 (4.7%)	
<b>Sex</b>			
Female, n (%)	10679/19150 (55.8%)	1680/2752 (61.0%)	<0.001
Male, n (%)	8471/19150 (44.2%)	1072/2752 (39.0%)	
<b>Health or social care worker, n (%)</b>	11518/19150 (60.1%)	1809/2752 (65.7%)	<0.001
<b>Dose group (COV002 only)</b>			
SD, n (%)	5782/8676 (66.6%)	693/1173 (59.1%)	<0.001
LD, n (%)	2894/8676 (33.4%)	480/1173 (40.9%)	
<b>Country (single SD cohort only)</b>			
UK (SD), n (%)	6566/16222 (40.5%)	838/2272 (36.9%)	<0.001
Brazil (SD), n (%)	8194/16222 (50.5%)	1389/2272 (61.1%)	
South Africa (SD), n (%)	1462/16222 (9.0%)	45/2272 (2.0%)	
<b>Ethnicity</b>			
White, n (%)	14532/19150 (75.9%)	2180/2751 (79.2%)	<0.001
Non-white, n (%)	4615/19150 (24.1%)	571/2751 (20.8%)	
<b>Follow-up time from 21 days after prime vaccination, days, median [IQR]</b>	20.0 [10.0, 58.0]	90.0 [23.0, 157.0]	<0.001

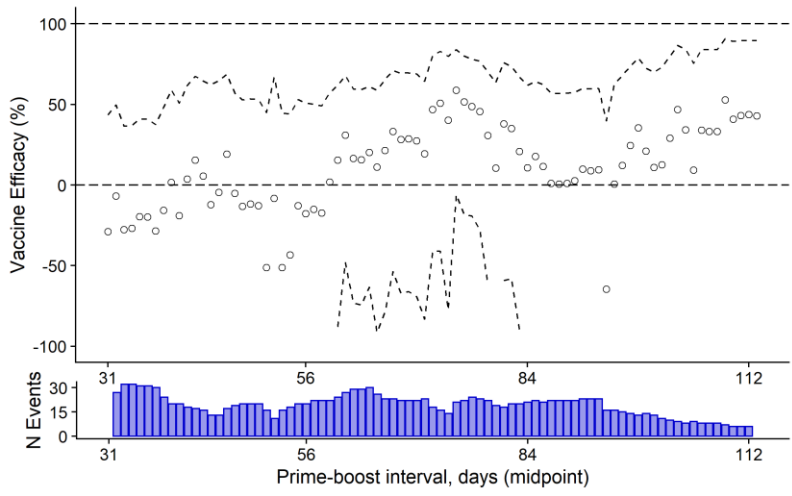
\*p-values from Chi-squared tests, Wilcoxon Rank Sum tests (continuous age and follow-up time) and Cochran-Armitage tests (ordinal age groups).

**Figure S2 Vaccine efficacy against asymptomatic/unknown infection by interval between first and second dose after, A) SD/SD or LD/SD, B) SD/SD, C) LD/SD administration**

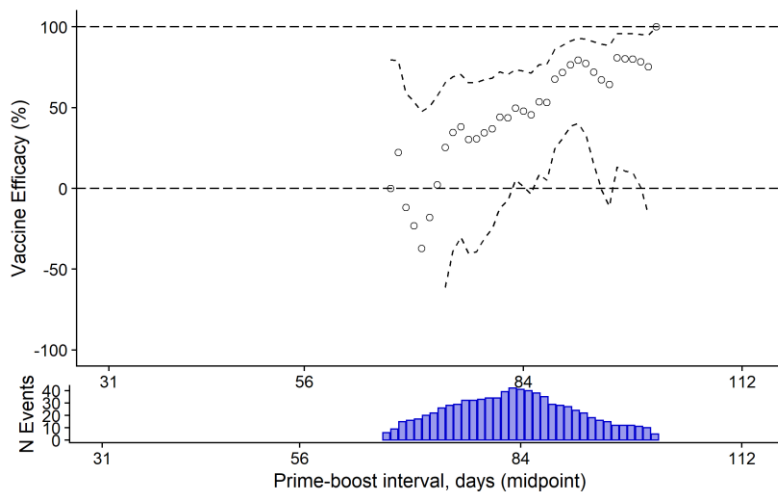
**A) SD/SD or LD/SD**



**B) SD/SD**



**C) LD/SD**





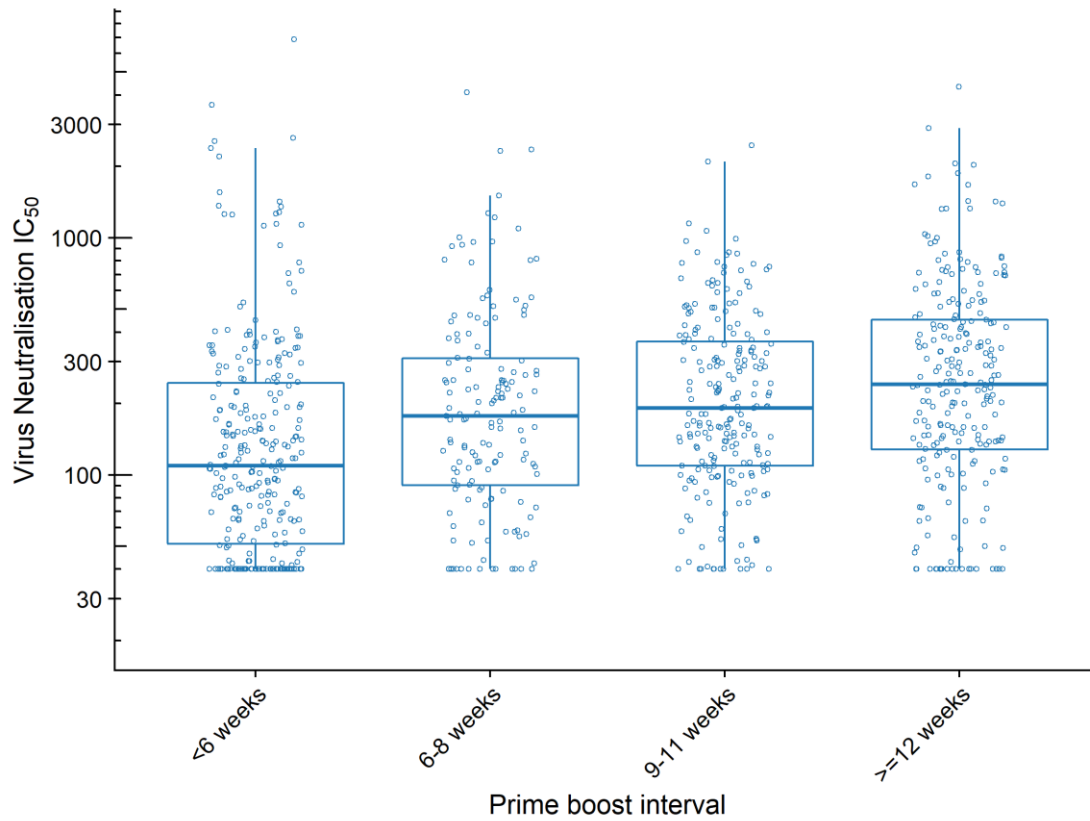
Each dot represents one estimate of vaccine efficacy in a subset of participants who received two doses of vaccine with a gap between first and second dose within a 20 day range. The x axis shows the midpoint of the 20 day range for dosing. Dotted lines show 95% confidence intervals for each dot point estimate of VE. Solid line shows a cubic spline smooth function for VE.

**Table S5 SARS-CoV-2 anti-spike IgG responses by multiplex immunoassay at 28 days after a second dose, by prime-boost interval**

Age group	Study	Prime-boost interval	ChAdOx1 nCoV-19				Control				
			N	Median [IQR]	GMT (95% CI)	GMR (95% CI)	N	Median [IQR]	GMT (95% CI)	GMR (95% CI)	
18-55 years	Overall (SD/SD)	<6 weeks	332	23173 [11665, 43633]	21966 (19753, 24427)	ref	318	62 [16, 135]	74 (63, 86)	ref	
		6-8 weeks	287	30743 [18448, 52217]	29294 (26178, 32781)	1.33 (1.16, 1.54)	196	56 [16, 169]	71 (58, 86)	0.96 (0.75, 1.24)	
		9-11 weeks	333	36044 [22647, 60646]	36946 (34010, 40135)	1.68 (1.46, 1.93)	233	51 [16, 101]	62 (51, 75)	0.84 (0.66, 1.06)	
		≥12 weeks	289	51291 [28597, 93521]	50918 (45842, 56556)	2.32 (2.01, 2.68)	173	53 [16, 98]	56 (47, 66)	0.76 (0.58, 0.98)	
	Overall (SD/SD and LD/SD)	<6 weeks	335	23241 [11750, 43560]	21967 (19772, 24406)	ref	323	62 [16, 135]	74 (63, 86)	ref	
		6-8 weeks	288	30719 [18263, 52216]	29244 (26142, 32714)	1.33 (1.15, 1.54)	196	56 [16, 169]	71 (58, 86)	0.97 (0.76, 1.23)	
		9-11 weeks	460	36468 [22276, 62523]	36177 (33417, 39165)	1.65 (1.44, 1.88)	324	48 [16, 95]	57 (49, 67)	0.78 (0.63, 0.96)	
		≥12 weeks	445	51005 [29002, 88849]	48961 (44880, 53413)	2.23 (1.95, 2.54)	271	46 [16, 87]	51 (44, 58)	0.69 (0.55, 0.85)	
≥56 years	Overall (SD/SD)	<6 weeks	282	20328 [10534, 35685]	18859 (16900, 21046)	ref	273	34 [16, 78]	40 (35, 46)	ref	
		6-8 weeks	66	23659 [13620, 37338]	23809 (20039, 28288)	1.26 (0.99, 1.61)	66	39 [16, 79]	43 (33, 56)	1.07 (0.80, 1.43)	
		9-11 weeks	4	26374 [22367, 28102]	23432 (14885, 36887)	1.24 (0.51, 3.01)	3	16 [16, 16]	16 (16, 16)	0.41 (0.12, 1.41)	
		≥12 weeks	1	39443	39443	2.09 (0.36, 12.15)	0	-	-	-	
	Overall (SD/SD and LD/SD)	<6 weeks	282	20328 [10534, 35685]	18859 (16900, 21046)	ref	273	34 [16, 78]	40 (35, 46)	ref	
		6-8 weeks	66	23659 [13620, 37338]	23809 (20039, 28288)	1.26 (0.99, 1.61)	66	39 [16, 79]	43 (33, 56)	1.07 (0.80, 1.43)	
		9-11 weeks	4	26374 [22367, 28102]	23432 (14885, 36887)	1.24 (0.51, 3.01)	3	16 [16, 16]	16 (16, 16)	0.41 (0.12, 0.41)	
		≥12 weeks	1	39443	39443	2.09 (0.36, 12.15)	0	-	-	-	
<b>Country Level Estimates</b>											
18-55 years	COV001 (UK) SD/SD	≥12 weeks	92	71270 [43306, 129621]	76070 (62987, 91872)		52	47 [16, 120]	52 (37, 73)		
		<6 weeks	33	12828 [8605, 31356]	13463 (9248, 19599)		24	16 [16, 50]	38 (21, 67)		
			6-8 weeks	162	30849 [18421, 48794]	28832 (25094, 33128)		81	38 [16, 113]	52 (39, 70)	
			9-11 weeks	248	36649 [22504, 63378]	37694 (34394, 41310)		156	48 [16, 96]	54 (44, 66)	
	COV002 (UK) LD/SD	≥12 weeks	191	43938 [24792, 76664]	42401 (37674, 47722)		114	57 [16, 92]	57 (46, 69)		
		6-8 weeks	1	17871	17871		0	-	-		
		9-11 weeks	127	39670 [21068, 66338]	34236 (28304, 41412)		91	39 [16, 86]	47 (37, 60)		
		≥12 weeks	156	49584 [31122, 81163]	45533 (38988, 53177)		98	39 [16, 72]	43 (35, 52)		
	COV003 (Brazil) SD/SD	<6 weeks	211	21006 [11638, 37206]	20542 (18162, 23233)		203	70 [34, 154]	81 (67, 98)		
		6-8 weeks	116	27187 [16548, 55060]	28649 (23497, 34930)		113	76 [40, 206]	90 (69, 117)		
		9-11 weeks	85	31871 [22997, 53258]	34847 (28912, 42000)		77	60 [16, 102]	81 (54, 122)		
		≥12 weeks	6	56933 [27600, 92280]	36630 (8849, 151637)		7	95 [16, 100]	73 (14, 394)		
COV005 (South Africa) SD/SD	<6 weeks	88	36010 [19167, 62937]	30994 (24921, 38547)		91	54 [16, 112]	71 (52, 99)			
	6-8 weeks	9	56458 [39228, 63942]	51943 (34155, 78995)		2	28 [22, 33]	25 (0, 5993)			

	COV005 (South Africa) LD/SD	<6 weeks	3	24956 [19684, 27528]	22121 (8548, 57250)		5	115 [16, 172]	65 (13, 319)	
≥56 years	COV002 (UK) SD/SD	<6 weeks	203	19806 [11647, 33898]	19182 (17056, 21572)		202	25 [16, 72]	38 (33, 45)	
		6-8 weeks	59	22735 [12978, 35102]	22696 (18950, 27183)		64	35 [16, 72]	41 (32, 52)	
		9-11 weeks	4	26374 [22367, 28102]	23432 (14885, 36887)		3	16 [16, 16]	16 (16, 16)	
	COV002 (UK) LD/SD	≥12 weeks	1	39443	39443		0	-	-	
	COV003 (Brazil) SD/SD	<6 weeks	75	21027 [8645, 38450]	17309 (13389, 22377)		67	37 [16, 82]	43 (33, 56)	
		6-8 weeks	6	31811 [22330, 38513]	32632 (15397, 69159)		2	269 [236, 302]	261 (11, 6286)	
	COV005 (South Africa) SD/SD	<6 weeks	4	49068 [38190, 79322]	39899 (4506, 353262)		4	345 [83, 618]	164 (10, 2691)	
		6-8 weeks	1	60514	60514		0	-	-	

**Figure S3 Neutralising antibody 28 days after a booster dose, measured in pseudovirus assay (Monogram IC50)**

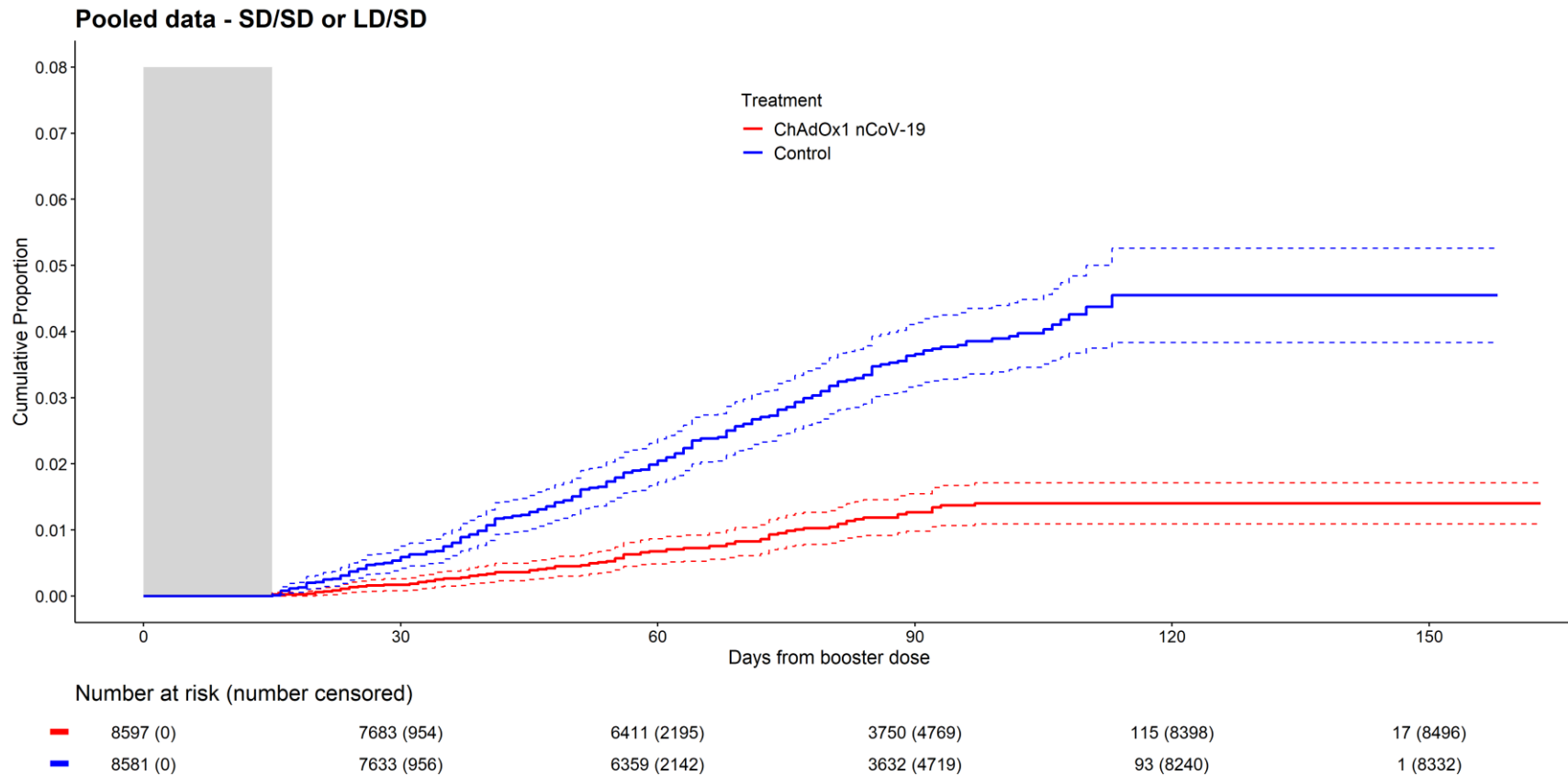


Participants who were PCR+ prior to the blood sample taken at day 28 post boost were removed from the analyses. Analysis includes SD/SD and LD/SD recipients.

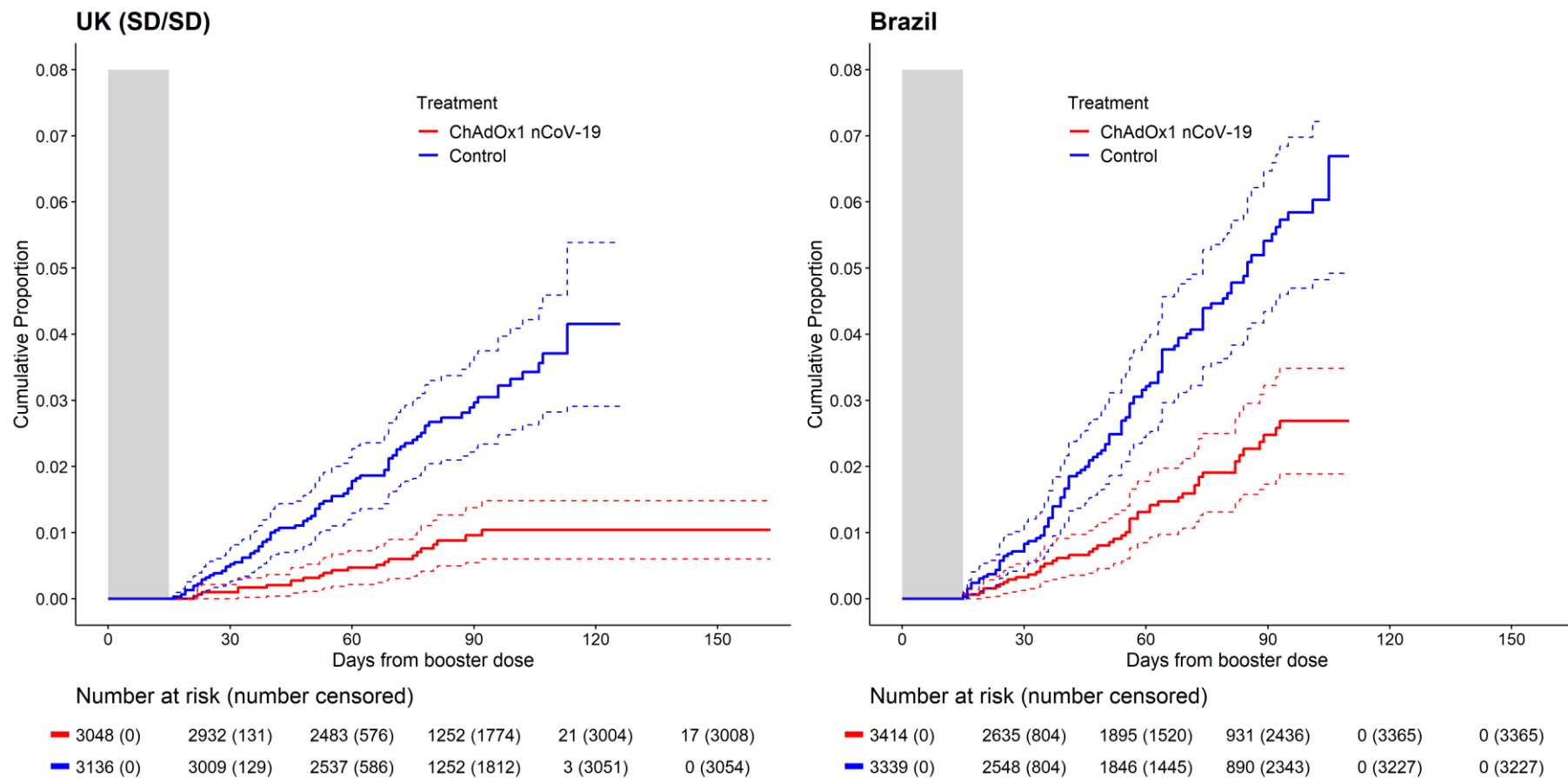
**Table S6 Neutralising antibody 28 days after a booster dose, measured in pseudovirus assay (Monogram IC50)**

Prime-boost interval	N	Median [IQR]	GMT (95% CI)	GMR (95% CI)	P value
<6 weeks	279	109 [51, 246]	127.8 (113.1, 144.3)	ref	<0.0001
6-8 weeks	151	177 [90, 311]	182.7 (156.0, 214.1)	1.43 (1.18, 1.74)	
9-11 weeks	224	191 [109, 367]	198.1 (176.8, 221.9)	1.55 (1.31, 1.84)	
≥12 weeks	239	241 [128,452]	237.0 (208.5, 269.4)	1.85 (1.57, 2.20)	

**Figure S4 Kaplan-Meier cumulative incidence of primary symptomatic PCR+ cases after booster dose, in the primary efficacy cohort**



**Figure S5 Kaplan-Meier cumulative incidence of primary symptomatic PCR+ cases after booster dose in SD/SD cohorts, by country\***



\*Kaplan-Meier curves for South Africa study not presented due to small number of cases contributing to the primary efficacy analysis.

**Table S7 Serious Adverse Events by System Organ Class and Preferred Term**

System Organ Class <sup>a</sup> Preferred Term (MedDRA version 23.1)	ChAdOx1 nCoV-19 (N = 12282)		Control (N = 11962)	
	Number (%) of Participants <sup>b</sup>	Number of Events	Number (%) of Participants <sup>b</sup>	Number of Events
	<b>Participants with any SAE</b>	<b>108 (0.9)</b>	<b>117</b>	<b>127 (1.1)</b>
<b>Infections and infestations</b>	<b>23 (0.2)</b>	<b>26</b>	<b>41 (0.3)</b>	<b>41</b>
Acute sinusitis	0	0	1 (<0.1)	1
Appendicitis	6 (<0.1)	6	7 (0.1)	7
Arthritis bacterial	1 (<0.1)	1	0	0
Biliary sepsis	1 (<0.1)	1	0	0
COVID-19	2 (<0.1)	2	17 (0.1)	17
COVID-19 pneumonia	0	0	4 (<0.1)	4
Campylobacter colitis	1 (<0.1)	1	0	0
Cellulitis	1 (<0.1)	1	0	0
Diverticulitis	3 (<0.1)	3	0	0
Gastroenteritis	0	0	1 (<0.1)	1
Haematoma infection	0	0	1 (<0.1)	1
Hepatitis infectious mononucleosis	1 (<0.1)	1	0	0
Labyrinthitis	0	0	1 (<0.1)	1
Myelitis	0	0	1 (<0.1)	1
Otitis externa	1 (<0.1)	1	0	0
Peritonitis	0	0	1 (<0.1)	1
Pilonidal cyst	0	0	2 (<0.1)	2
Pneumonia bacterial	1 (<0.1)	1	0	0
Pulmonary tuberculosis	1 (<0.1)	1	0	0
Pyelonephritis	2 (<0.1)	2	0	0
Pyelonephritis acute	1 (<0.1)	1	0	0
Respiratory tract infection fungal	1 (<0.1)	1	0	0
Sepsis	0	0	2 (<0.1)	2
Staphylococcal bacteraemia	1 (<0.1)	1	0	0
Subcutaneous abscess	0	0	1 (<0.1)	1
Tonsillitis	0	0	1 (<0.1)	1
Tuberculosis	1 (<0.1)	1	0	0
Tuberculosis of eye	0	0	1 (<0.1)	1
Urinary tract infection	1 (<0.1)	1	0	0
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>6 (&lt;0.1)</b>	<b>6</b>	<b>11 (0.1)</b>	<b>11</b>
Benign soft tissue neoplasm	1 (<0.1)	1	0	0
Breast cancer	1 (<0.1)	1	0	0
Colorectal cancer metastatic	0	0	1 (<0.1)	1
Haematological malignancy	0	0	1 (<0.1)	1

Intracranial haemangioma	0	0	1 (<0.1)	1
Invasive ductal breast carcinoma	1 (<0.1)	1	0	0
Lip squamous cell carcinoma	0	0	1 (<0.1)	1
Liposarcoma	0	0	1 (<0.1)	1
Lymphoplasmacytoid lymphoma/immunocytoma	0	0	1 (<0.1)	1
Malignant melanoma	1 (<0.1)	1	1 (<0.1)	1
Melanoma recurrent	0	0	1 (<0.1)	1
Metastatic neoplasm	1 (<0.1)	1	0	0
Ovarian germ cell teratoma benign	0	0	1 (<0.1)	1
Papillary renal cell carcinoma	1 (<0.1)	1	0	0
Papillary thyroid cancer	0	0	1 (<0.1)	1
Uterine leiomyoma	0	0	1 (<0.1)	1
<b>Blood and lymphatic system disorders</b>	<b>0</b>	<b>0</b>	<b>1 (&lt;0.1)</b>	<b>1</b>
Autoimmune haemolytic anaemia	0	0	1 (<0.1)	1
<b>Immune system disorders</b>	<b>0</b>	<b>0</b>	<b>1 (&lt;0.1)</b>	<b>1</b>
Allergy to arthropod sting	0	0	1 (<0.1)	1
<b>Metabolism and nutrition disorders</b>	<b>0</b>	<b>0</b>	<b>1 (&lt;0.1)</b>	<b>1</b>
Diabetic ketoacidosis	0	0	1 (<0.1)	1
<b>Psychiatric disorders</b>	<b>3 (&lt;0.1)</b>	<b>3</b>	<b>1 (&lt;0.1)</b>	<b>1</b>
Depression suicidal	1 (<0.1)	1	0	0
Substance abuse	1 (<0.1)	1	0	0
Substance-induced psychotic disorder	1 (<0.1)	1	1 (<0.1)	1
<b>Nervous system disorders</b>	<b>10 (0.1)</b>	<b>10</b>	<b>8 (0.1)</b>	<b>8</b>
Facial spasm	1 (<0.1)	1	0	0
Hemiplegic migraine	0	0	1 (<0.1)	1
Ischaemic stroke	1 (<0.1)	1	0	0
Migraine	1 (<0.1)	1	0	0
Migraine with aura	1 (<0.1)	1	0	0
Multiple sclerosis	1 (<0.1)	1	0	0
Myelitis transverse	1 (<0.1)	1	0	0
Presyncope	1 (<0.1)	1	0	0
Serotonin syndrome	1 (<0.1)	1	0	0
Spinal cord compression	1 (<0.1)	1	0	0
Subarachnoid haemorrhage	0	0	2 (<0.1)	2
Syncope	0	0	2 (<0.1)	2
Transient ischaemic attack	0	0	3 (<0.1)	3
VIIth nerve paralysis	1 (<0.1)	1	0	0
<b>Eye disorders</b>	<b>2 (&lt;0.1)</b>	<b>2</b>	<b>0</b>	<b>0</b>
Retinal detachment	1 (<0.1)	1	0	0
Retinal tear	1 (<0.1)	1	0	0



<b>Cardiac disorders</b>	<b>7 (0.1)</b>	<b>7</b>	<b>10 (0.1)</b>	<b>10</b>
Acute coronary syndrome	0	0	1 (<0.1)	1
Acute myocardial infarction	0	0	2 (<0.1)	2
Angina pectoris	2 (<0.1)	2	0	0
Angina unstable	1 (<0.1)	1	0	0
Atrial flutter	1 (<0.1)	1	0	0
Atrioventricular block complete	1 (<0.1)	1	0	0
Atrioventricular block second degree	0	0	1 (<0.1)	1
Cardiac failure congestive	0	0	1 (<0.1)	1
Myocardial infarction	1 (<0.1)	1	1 (<0.1)	1
Pericarditis	1 (<0.1)	1	2 (<0.1)	2
Supraventricular tachycardia	0	0	1 (<0.1)	1
Ventricular extrasystoles	0	0	1 (<0.1)	1
<b>Vascular disorders</b>	<b>0</b>	<b>0</b>	<b>2 (&lt;0.1)</b>	<b>2</b>
Deep vein thrombosis	0	0	1 (<0.1)	1
Peripheral ischaemia	0	0	1 (<0.1)	1
<b>Respiratory, thoracic and mediastinal disorders</b>	<b>1 (&lt;0.1)</b>	<b>1</b>	<b>1 (&lt;0.1)</b>	<b>1</b>
Dyspnoea	1 (<0.1)	1	0	0
Pulmonary embolism	0	0	1 (<0.1)	1
<b>Gastrointestinal disorders</b>	<b>15 (0.1)</b>	<b>16</b>	<b>13 (0.1)</b>	<b>13</b>
Abdominal pain	2 (<0.1)	2	1 (<0.1)	1
Anal incontinence	0	0	1 (<0.1)	1
Constipation	0	0	1 (<0.1)	1
Diarrhoea	1 (<0.1)	1	0	0
Dyspepsia	1 (<0.1)	1	0	0
Enteritis	0	0	1 (<0.1)	1
Epiplonic appendagitis	0	0	1 (<0.1)	1
Gastritis	1 (<0.1)	1	1 (<0.1)	1
Gastrointestinal haemorrhage	1 (<0.1)	1	0	0
Gastrooesophageal reflux disease	0	0	1 (<0.1)	1
Haematemesis	0	0	1 (<0.1)	1
Incarcerated inguinal hernia	1 (<0.1)	1	0	0
Intussusception	1 (<0.1)	1	0	0
Mesenteric vein thrombosis	0	0	1 (<0.1)	1
Oesophageal spasm	1 (<0.1)	1	0	0
Pancreatitis	3 (<0.1)	3	0	0
Pancreatitis acute	1 (<0.1)	1	1 (<0.1)	1
Small intestinal obstruction	0	0	2 (<0.1)	2
Volvulus	2 (<0.1)	2	0	0
Vomiting	1 (<0.1)	1	1 (<0.1)	1
<b>Hepatobiliary disorders</b>	<b>0</b>	<b>0</b>	<b>3 (&lt;0.1)</b>	<b>3</b>
Cholelithiasis	0	0	2 (<0.1)	2

Hepatic function abnormal	0	0	1 (<0.1)	1
<b>Skin and subcutaneous tissue disorders</b>	<b>0</b>	<b>0</b>	<b>1 (&lt;0.1)</b>	<b>1</b>
Angioedema	0	0	1 (<0.1)	1
<b>Musculoskeletal and connective tissue disorders</b>	<b>5 (&lt;0.1)</b>	<b>5</b>	<b>3 (&lt;0.1)</b>	<b>3</b>
Arthritis reactive	0	0	1 (<0.1)	1
Back pain	1 (<0.1)	1	0	0
Costochondritis	0	0	1 (<0.1)	1
Intervertebral disc protrusion	2 (<0.1)	2	0	0
Polymyalgia rheumatica	1 (<0.1)	1	0	0
Rhabdomyolysis	0	0	1 (<0.1)	1
Spinal pain	1 (<0.1)	1	0	0
<b>Renal and urinary disorders</b>	<b>5 (&lt;0.1)</b>	<b>5</b>	<b>7 (0.1)</b>	<b>7</b>
Acute kidney injury	1 (<0.1)	1	0	0
Calculus urethral	0	0	1 (<0.1)	1
Calculus urinary	2 (<0.1)	2	2 (<0.1)	2
Nephrolithiasis	1 (<0.1)	1	2 (<0.1)	2
Renal colic	1 (<0.1)	1	0	0
Ureterolithiasis	0	0	2 (<0.1)	2
<b>Pregnancy, puerperium and perinatal conditions</b>	<b>4 (&lt;0.1)</b>	<b>4</b>	<b>2 (&lt;0.1)</b>	<b>2</b>
Abortion incomplete	0	0	1 (<0.1)	1
Abortion spontaneous	2 (<0.1)	2	1 (<0.1)	1
Hyperemesis gravidarum	1 (<0.1)	1	0	0
Pregnancy	1 (<0.1)	1	0	0
<b>Reproductive system and breast disorders</b>	<b>8 (0.1)</b>	<b>9</b>	<b>2 (&lt;0.1)</b>	<b>2</b>
Adnexal torsion	2 (<0.1)	2	0	0
Endometriosis	2 (<0.1)	2	0	0
Genital pain	1 (<0.1)	1	0	0
Haemorrhagic ovarian cyst	2 (<0.1)	2	0	0
Pelvic pain	0	0	1 (<0.1)	1
Uterine haemorrhage	1 (<0.1)	1	1 (<0.1)	1
Vaginal haemorrhage	1 (<0.1)	1	0	0
<b>Congenital, familial and genetic disorders</b>	<b>0</b>	<b>0</b>	<b>1 (&lt;0.1)</b>	<b>1</b>
Arnold-Chiari malformation	0	0	1 (<0.1)	1
<b>General disorders and administration site conditions</b>	<b>4 (&lt;0.1)</b>	<b>4</b>	<b>2 (&lt;0.1)</b>	<b>2</b>
Chest pain	1 (<0.1)	1	0	0
Influenza like illness	1 (<0.1)	1	0	0
Mass	0	0	1 (<0.1)	1

Non-cardiac chest pain	0	0	1 (<0.1)	1
Pyrexia	2 (<0.1)	2	0	0
<b>Investigations</b>	<b>3 (&lt;0.1)</b>	<b>3</b>	<b>1 (&lt;0.1)</b>	<b>1</b>
C-reactive protein increased	1 (<0.1)	1	1 (<0.1)	1
Liver function test abnormal	1 (<0.1)	1	0	0
Oxygen saturation decreased	1 (<0.1)	1	0	0
<b>Injury, poisoning and procedural complications</b>	<b>15 (0.1)</b>	<b>15</b>	<b>17 (0.1)</b>	<b>18</b>
Animal bite	0	0	1 (<0.1)	1
Cervical vertebral fracture	1 (<0.1)	1	0	0
Clavicle fracture	1 (<0.1)	1	0	0
Cranio-cerebral injury	1 (<0.1)	1	1 (<0.1)	1
Fibula fracture	1 (<0.1)	1	0	0
Gun shot wound	1 (<0.1)	1	0	0
Injury	0	0	1 (<0.1)	1
Intentional overdose	0	0	2 (<0.1)	2
Joint dislocation	1 (<0.1)	1	1 (<0.1)	1
Limb injury	1 (<0.1)	1	0	0
Lower limb fracture	0	0	1 (<0.1)	2
Meniscus injury	2 (<0.1)	2	0	0
Overdose	0	0	1 (<0.1)	1
Post procedural complication	0	0	1 (<0.1)	1
Procedural nausea	1 (<0.1)	1	0	0
Radius fracture	0	0	1 (<0.1)	1
Road traffic accident	0	0	2 (<0.1)	2
Scapula fracture	1 (<0.1)	1	0	0
Synovial rupture	1 (<0.1)	1	0	0
Tendon injury	1 (<0.1)	1	0	0
Tendon rupture	1 (<0.1)	1	0	0
Thermal burn	1 (<0.1)	1	0	0
Traumatic lung injury	0	0	1 (<0.1)	1
Upper limb fracture	0	0	2 (<0.1)	2
Wrist fracture	0	0	2 (<0.1)	2
<b>Social circumstances</b>	<b>0</b>	<b>0</b>	<b>1 (&lt;0.1)</b>	<b>1</b>
Homicide	0	0	1 (<0.1)	1

**Table S8 Unsolicited Adverse Events by System Organ Class and Preferred Term (severity grade 3 or higher)**

System Organ Class Preferred Term		Number (%) of Participants	
		ChAdOx1 nCoV-19 (N = 12282)	Control (N = 11962)
<b>Infections and infestations</b>			
Acute sinusitis	Grade 4	0	1 (<0.1)
Appendicitis	Grade 3	1 (<0.1)	0
	Grade 4	3 (<0.1)	3 (<0.1)
Arthritis bacterial	Grade 3	1 (<0.1)	0
Biliary sepsis	Grade 3	1 (<0.1)	0
COVID-19	Grade 3	3 (<0.1)	4 (<0.1)
	Grade 4	2 (<0.1)	6 ( 0.1)
COVID-19 pneumonia	Grade 4	0	1 (<0.1)
Cellulitis	Grade 3	1 (<0.1)	1 (<0.1)
Diverticulitis	Grade 3	2 (<0.1)	0
Ear infection	Grade 3	0	1 (<0.1)
Escherichia infection	Grade 3	1 (<0.1)	0
Gastroenteritis	Grade 3	1 (<0.1)	0
Genital herpes	Grade 3	0	1 (<0.1)
Gingivitis	Grade 3	1 (<0.1)	0
Helicobacter infection	Grade 3	2 (<0.1)	0
Herpes zoster	Grade 3	0	3 (<0.1)
Labyrinthitis	Grade 4	1 (<0.1)	0
Large intestine infection	Grade 4	1 (<0.1)	0
Nasopharyngitis	Grade 3	3 (<0.1)	4 (<0.1)
Otitis externa	Grade 4	1 (<0.1)	0
Pharyngitis	Grade 3	0	1 (<0.1)
Pharyngitis bacterial	Grade 3	1 (<0.1)	0
Pneumonia bacterial	Grade 4	1 (<0.1)	0
Pyelonephritis	Grade 3	2 (<0.1)	1 (<0.1)
Rhinitis	Grade 3	0	1 (<0.1)
Sepsis	Grade 4	0	1 (<0.1)
Septic shock	Grade 4	0	1 (<0.1)
Suspected COVID-19	Grade 3	1 (<0.1)	0
Tonsillitis	Grade 3	0	3 (<0.1)
Tooth infection	Grade 3	1 (<0.1)	1 (<0.1)
Upper respiratory tract infection	Grade 3	3 (<0.1)	1 (<0.1)
Urinary tract infection	Grade 3	0	1 (<0.1)
Viral pharyngitis	Grade 3	0	1 (<0.1)
Viral rash	Grade 3	1 (<0.1)	0
Wound infection	Grade 3	1 (<0.1)	0
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
Basal cell carcinoma	Grade 3	0	1 (<0.1)
Benign soft tissue neoplasm	Grade 4	1 (<0.1)	0

Colorectal cancer metastatic	Grade 4	0	1 (<0.1)
Haematological malignancy	Grade 4	0	1 (<0.1)
Metastases to liver	Grade 4	0	1 (<0.1)
Metastases to lung	Grade 4	0	1 (<0.1)
Ovarian adenoma	Grade 3	1 (<0.1)	0
Papillary thyroid cancer	Grade 3	0	1 (<0.1)
<b>Blood and lymphatic system disorders</b>			
	Grade 4	0	1 (<0.1)
Anaemia	Grade 3	0	1 (<0.1)
Iron deficiency anaemia	Grade 3	0	2 (<0.1)
Lymphadenopathy	Grade 3	2 (<0.1)	1 (<0.1)
	Grade 4	0	1 (<0.1)
Neutropenia	Grade 3	0	2 (<0.1)
<b>Immune system disorders</b>			
Allergy to chemicals	Grade 3	0	1 (<0.1)
<b>Metabolism and nutrition disorders</b>			
	Grade 3	3 (<0.1)	1 (<0.1)
	Grade 4	0	1 (<0.1)
Decreased appetite	Grade 3	1 (<0.1)	0
Dehydration	Grade 3	1 (<0.1)	1 (<0.1)
Diabetic ketoacidosis	Grade 4	0	1 (<0.1)
Hypokalaemia	Grade 3	1 (<0.1)	0
<b>Psychiatric disorders</b>			
Anxiety	Grade 3	2 (<0.1)	0
Depression	Grade 3	1 (<0.1)	0
Depression suicidal	Grade 4	1 (<0.1)	0
Psychotic disorder	Grade 3	0	1 (<0.1)
<b>Nervous system disorders</b>			
Ageusia	Grade 3	6 (<0.1)	5 (<0.1)
Anosmia	Grade 3	6 (<0.1)	5 (<0.1)
Balance disorder	Grade 4	0	1 (<0.1)
Dizziness	Grade 3	4 (<0.1)	2 (<0.1)
	Grade 4	0	1 (<0.1)
Dysaesthesia	Grade 3	2 (<0.1)	0
Dysarthria	Grade 4	0	1 (<0.1)
Facial paralysis	Grade 3	2 (<0.1)	0
Facial spasm	Grade 3	1 (<0.1)	0
Headache	Grade 3	31 ( 0.3)	26 ( 0.2)
	Grade 4	0	3 (<0.1)
Hypersomnia	Grade 3	1 (<0.1)	0
Migraine	Grade 3	1 (<0.1)	6 ( 0.1)
	Grade 4	1 (<0.1)	0
Multiple sclerosis	Grade 3	1 (<0.1)	0
Myelitis transverse	Grade 3	1 (<0.1)	0
Nystagmus	Grade 3	1 (<0.1)	0
Paraesthesia	Grade 3	1 (<0.1)	0
Parosmia	Grade 3	0	1 (<0.1)

Post herpetic neuralgia	Grade 3	1 (<0.1)	0
Presyncope	Grade 3	1 (<0.1)	1 (<0.1)
Sensory loss	Grade 3	0	1 (<0.1)
Serotonin syndrome	Grade 4	1 (<0.1)	0
Syncope	Grade 3	0	1 (<0.1)
Taste disorder	Grade 3	0	1 (<0.1)
Tonic convulsion	Grade 3	1 (<0.1)	0
Visual field defect	Grade 3	1 (<0.1)	0
<b>Eye disorders</b>			
Blindness	Grade 3	1 (<0.1)	0
Blindness unilateral	Grade 4	1 (<0.1)	0
Conjunctivitis allergic	Grade 3	0	1 (<0.1)
Eye pain	Grade 3	1 (<0.1)	0
Ocular hyperaemia	Grade 3	0	2 (<0.1)
Periorbital oedema	Grade 3	0	1 (<0.1)
Photophobia	Grade 3	2 (<0.1)	0
Retinal detachment	Grade 3	1 (<0.1)	1 (<0.1)
Vision blurred	Grade 3	0	1 (<0.1)
Vitreous detachment	Grade 3	1 (<0.1)	0
Vitreous floaters	Grade 3	1 (<0.1)	0
<b>Ear and labyrinth disorders</b>			
Auricular chondritis	Grade 4	1 (<0.1)	0
Ear pain	Grade 3	0	1 (<0.1)
Tinnitus	Grade 3	0	1 (<0.1)
Vertigo	Grade 3	2 (<0.1)	1 (<0.1)
<b>Cardiac disorders</b>			
Angina pectoris	Grade 3	1 (<0.1)	1 (<0.1)
	Grade 4	1 (<0.1)	0
Angina unstable	Grade 4	1 (<0.1)	0
Atrioventricular block complete	Grade 3	1 (<0.1)	0
Bradycardia	Grade 4	0	1 (<0.1)
Cardiac failure congestive	Grade 4	0	1 (<0.1)
Coronary artery occlusion	Grade 3	0	1 (<0.1)
	Grade 4	1 (<0.1)	0
Myocardial infarction	Grade 3	0	1 (<0.1)
Palpitations	Grade 3	0	3 (<0.1)
Pericarditis	Grade 3	0	1 (<0.1)
Supraventricular tachycardia	Grade 3	0	1 (<0.1)
Tachycardia	Grade 3	2 (<0.1)	1 (<0.1)
Ventricular extrasystoles	Grade 3	0	1 (<0.1)
<b>Vascular disorders</b>			
Hypertension	Grade 3	2 (<0.1)	1 (<0.1)
Hypotension	Grade 3	0	1 (<0.1)
Orthostatic hypotension	Grade 3	1 (<0.1)	0
<b>Respiratory, thoracic and mediastinal disorders</b>			
Asthma	Grade 3	1 (<0.1)	1 (<0.1)

Cough	Grade 3	0	5 (<0.1)
Dyspnoea	Grade 3	3 (<0.1)	3 (<0.1)
Dyspnoea exertional	Grade 4	1 (<0.1)	0
Lung opacity	Grade 3	0	1 (<0.1)
Nasal turbinate hypertrophy	Grade 4	0	1 (<0.1)
Oropharyngeal pain	Grade 3	3 (<0.1)	4 (<0.1)
Rhinorrhoea	Grade 3	1 (<0.1)	2 (<0.1)
Sneezing	Grade 3	0	1 (<0.1)
	Grade 4	1 (<0.1)	0
<b>Gastrointestinal disorders</b>			
Abdominal discomfort	Grade 3	1 (<0.1)	0
Abdominal pain	Grade 3	3 (<0.1)	3 (<0.1)
	Grade 4	1 (<0.1)	0
Abdominal pain lower	Grade 3	2 (<0.1)	1 (<0.1)
Abdominal pain upper	Grade 3	1 (<0.1)	0
	Grade 4	0	1 (<0.1)
Anal incontinence	Grade 3	0	1 (<0.1)
Colitis	Grade 3	1 (<0.1)	0
Constipation	Grade 3	1 (<0.1)	1 (<0.1)
Crohn's disease	Grade 3	0	1 (<0.1)
Diarrhoea	Grade 3	2 (<0.1)	8 ( 0.1)
	Grade 4	2 (<0.1)	0
Discoloured vomit	Grade 3	1 (<0.1)	0
Dyspepsia	Grade 3	0	1 (<0.1)
Gastric polyps	Grade 4	1 (<0.1)	0
Gastritis	Grade 3	3 (<0.1)	0
Gastrointestinal haemorrhage	Grade 4	1 (<0.1)	0
Gastrointestinal inflammation	Grade 4	0	1 (<0.1)
Gastrooesophageal reflux disease	Grade 3	1 (<0.1)	0
Haematemesis	Grade 3	0	1 (<0.1)
Hiatus hernia	Grade 4	1 (<0.1)	0
Incarcerated inguinal hernia	Grade 4	1 (<0.1)	0
Lip oedema	Grade 3	0	1 (<0.1)
Lip swelling	Grade 3	1 (<0.1)	0
Melaena	Grade 4	1 (<0.1)	0
Nausea	Grade 3	11 ( 0.1)	3 (<0.1)
	Grade 4	1 (<0.1)	2 (<0.1)
Odynophagia	Grade 3	1 (<0.1)	0
Oesophageal spasm	Grade 4	1 (<0.1)	0
Oral discomfort	Grade 3	1 (<0.1)	0
Pancreatitis	Grade 4	1 (<0.1)	1 (<0.1)
Proctalgia	Grade 3	0	1 (<0.1)
Retching	Grade 3	1 (<0.1)	0
Toothache	Grade 3	0	2 (<0.1)
Volvulus	Grade 3	1 (<0.1)	0
	Grade 4	1 (<0.1)	0

Vomiting	Grade 3	6 (<0.1)	3 (<0.1)
	Grade 4	1 (<0.1)	0
<b>Hepatobiliary disorders</b>			
Cholecystitis	Grade 4	1 (<0.1)	0
Cholelithiasis	Grade 3	2 (<0.1)	0
	Grade 4	0	1 (<0.1)
<b>Skin and subcutaneous tissue disorders</b>			
Angioedema	Grade 3	0	1 (<0.1)
	Grade 4	0	1 (<0.1)
Erythema	Grade 3	1 (<0.1)	1 (<0.1)
Hyperhidrosis	Grade 3	1 (<0.1)	1 (<0.1)
Night sweats	Grade 3	0	1 (<0.1)
Pruritus	Grade 3	1 (<0.1)	1 (<0.1)
Rash	Grade 3	0	1 (<0.1)
Rash papular	Grade 3	1 (<0.1)	0
Skin burning sensation	Grade 3	0	1 (<0.1)
Skin ulcer	Grade 3	1 (<0.1)	0
Urticaria	Grade 3	1 (<0.1)	0
<b>Musculoskeletal and connective tissue disorders</b>			
Arthralgia	Grade 3	6 (<0.1)	6 ( 0.1)
	Grade 4	1 (<0.1)	0
Arthropathy	Grade 3	0	1 (<0.1)
Back pain	Grade 3	6 (<0.1)	6 ( 0.1)
	Grade 4	0	2 (<0.1)
Costochondritis	Grade 3	1 (<0.1)	0
Intervertebral disc protrusion	Grade 3	4 (<0.1)	1 (<0.1)
	Grade 4	1 (<0.1)	0
Joint range of motion decreased	Grade 3	0	1 (<0.1)
Muscle spasms	Grade 3	0	1 (<0.1)
Musculoskeletal chest pain	Grade 3	1 (<0.1)	0
Myalgia	Grade 3	27 ( 0.2)	12 ( 0.1)
	Grade 4	4 (<0.1)	1 (<0.1)
Neck pain	Grade 3	3 (<0.1)	0
Osteoarthritis	Grade 4	1 (<0.1)	0
Pain in extremity	Grade 3	4 (<0.1)	1 (<0.1)
Pain in jaw	Grade 3	0	1 (<0.1)
Periarthritis	Grade 3	0	1 (<0.1)
Rotator cuff syndrome	Grade 3	1 (<0.1)	0
Somatic dysfunction	Grade 3	1 (<0.1)	0
Spinal osteoarthritis	Grade 3	1 (<0.1)	0
Spinal pain	Grade 3	1 (<0.1)	0
	Grade 4	1 (<0.1)	0
Spinal synovial cyst	Grade 4	1 (<0.1)	0
Spondylolysis	Grade 3	1 (<0.1)	0
<b>Renal and urinary disorders</b>			
Calculus urethral	Grade 4	0	1 (<0.1)



Dysuria	Grade 3	2 (<0.1)	1 (<0.1)
Micturition disorder	Grade 3	1 (<0.1)	0
Nephrolithiasis	Grade 3	1 (<0.1)	2 (<0.1)
	Grade 4	0	1 (<0.1)
Renal colic	Grade 3	1 (<0.1)	1 (<0.1)
	Grade 4	0	2 (<0.1)
Ureterolithiasis	Grade 4	0	1 (<0.1)
Urge incontinence	Grade 3	0	1 (<0.1)
<b>Reproductive system and breast disorders</b>			
Adnexal torsion	Grade 4	1 (<0.1)	0
Breast mass	Grade 3	1 (<0.1)	0
Breast pain	Grade 3	1 (<0.1)	0
Cervical dysplasia	Grade 3	0	1 (<0.1)
Endometriosis	Grade 4	1 (<0.1)	0
Haemorrhagic ovarian cyst	Grade 4	1 (<0.1)	0
Menorrhagia	Grade 3	0	1 (<0.1)
Ovarian cyst	Grade 4	1 (<0.1)	0
Ovarian cyst ruptured	Grade 3	0	1 (<0.1)
	Grade 4	1 (<0.1)	0
Pelvic haemorrhage	Grade 3	1 (<0.1)	0
Testicular pain	Grade 3	1 (<0.1)	0
Uterine haemorrhage	Grade 4	1 (<0.1)	0
Vaginal haemorrhage	Grade 4	1 (<0.1)	0
Vulvovaginal dryness	Grade 3	0	1 (<0.1)
<b>Congenital, familial and genetic disorders</b>			
Accessory spleen	Grade 3	1 (<0.1)	0
Phimosis	Grade 3	0	1 (<0.1)
<b>General disorders and administration site conditions</b>			
Asthenia	Grade 3	5 (<0.1)	3 (<0.1)
	Grade 4	1 (<0.1)	0
Chest discomfort	Grade 3	0	1 (<0.1)
	Grade 4	2 (<0.1)	1 (<0.1)
Chest pain	Grade 3	3 (<0.1)	2 (<0.1)
	Grade 4	2 (<0.1)	1 (<0.1)
Chills	Grade 3	12 ( 0.1)	1 (<0.1)
	Grade 4	1 (<0.1)	1 (<0.1)
Fatigue	Grade 3	18 ( 0.1)	4 (<0.1)
	Grade 4	0	2 (<0.1)
Feeling hot	Grade 3	1 (<0.1)	0
Illness	Grade 3	0	1 (<0.1)
	Grade 4	0	1 (<0.1)
Influenza like illness	Grade 3	1 (<0.1)	0
Malaise	Grade 3	7 ( 0.1)	2 (<0.1)
	Grade 4	1 (<0.1)	2 (<0.1)
Oedema peripheral	Grade 3	1 (<0.1)	0
Pain	Grade 3	5 (<0.1)	2 (<0.1)
Pyrexia	Grade 3	37 ( 0.3)	7 ( 0.1)

	Grade 4	2 (<0.1)	0
Shoulder injury related to vaccine administration	Grade 3	0	1 (<0.1)
Stenosis	Grade 4	0	1 (<0.1)
Swelling	Grade 3	1 (<0.1)	0
Swelling face	Grade 3	1 (<0.1)	1 (<0.1)
Systemic inflammatory response syndrome	Grade 4	1 (<0.1)	0
Ulcer	Grade 3	0	1 (<0.1)
Vaccination site bruising	Grade 3	1 (<0.1)	0
Vaccination site erythema	Grade 3	3 (<0.1)	8 ( 0.1)
	Grade 4	1 (<0.1)	0
Vaccination site hypoaesthesia	Grade 3	0	1 (<0.1)
Vaccination site induration	Grade 3	1 (<0.1)	0
	Grade 4	1 (<0.1)	0
Vaccination site oedema	Grade 3	0	4 (<0.1)
	Grade 4	1 (<0.1)	0
Vaccination site pain	Grade 3	15 ( 0.1)	12 ( 0.1)
	Grade 4	6 (<0.1)	2 (<0.1)
Vaccination site pruritus	Grade 3	0	1 (<0.1)
Vaccination site rash	Grade 3	0	1 (<0.1)
Vaccination site reaction	Grade 3	1 (<0.1)	0
Vaccination site swelling	Grade 3	0	2 (<0.1)
<b>Investigations</b>			
Amylase increased	Grade 3	1 (<0.1)	0
Blood potassium abnormal	Grade 3	2 (<0.1)	0
Blood potassium decreased	Grade 3	2 (<0.1)	0
Blood pressure increased	Grade 3	1 (<0.1)	0
Blood urine present	Grade 3	1 (<0.1)	0
Body temperature abnormal	Grade 3	0	1 (<0.1)
Body temperature increased	Grade 3	2 (<0.1)	1 (<0.1)
C-reactive protein abnormal	Grade 3	1 (<0.1)	0
C-reactive protein increased	Grade 3	2 (<0.1)	1 (<0.1)
	Grade 4	1 (<0.1)	0
Electrocardiogram P wave abnormal	Grade 3	1 (<0.1)	0
Electrocardiogram normal	Grade 3	1 (<0.1)	0
Lipase abnormal	Grade 3	1 (<0.1)	0
Liver function test abnormal	Grade 4	1 (<0.1)	0
Lymphocyte count decreased	Grade 3	1 (<0.1)	0
Oxygen saturation decreased	Grade 3	0	1 (<0.1)
	Grade 4	1 (<0.1)	0
<b>Injury, poisoning and procedural complications</b>			
Ankle fracture	Grade 3	0	1 (<0.1)
Back injury	Grade 3	1 (<0.1)	0
Contusion	Grade 3	1 (<0.1)	0
Craniocerebral injury	Grade 4	1 (<0.1)	1 (<0.1)
Eye injury	Grade 3	0	1 (<0.1)
Fall	Grade 3	0	4 (<0.1)

	Grade 4	2 (<0.1)	0
Foot fracture	Grade 3	0	3 (<0.1)
Hand fracture	Grade 3	1 (<0.1)	1 (<0.1)
Injury	Grade 3	1 (<0.1)	1 (<0.1)
	Grade 5	0	1 (<0.1)
Injury corneal	Grade 3	0	1 (<0.1)
Joint dislocation	Grade 3	3 (<0.1)	0
Joint injury	Grade 3	1 (<0.1)	0
Ligament sprain	Grade 4	0	1 (<0.1)
Limb injury	Grade 3	0	1 (<0.1)
Lower limb fracture	Grade 3	0	1 (<0.1)
Meniscus injury	Grade 4	1 (<0.1)	0
Muscle strain	Grade 3	1 (<0.1)	0
Post procedural hypotension	Grade 3	0	1 (<0.1)
Radius fracture	Grade 3	0	1 (<0.1)
	Grade 4	0	1 (<0.1)
Repetitive strain injury	Grade 3	1 (<0.1)	0
Road traffic accident	Grade 3	1 (<0.1)	1 (<0.1)
Skin laceration	Grade 4	1 (<0.1)	0
Tendon injury	Grade 4	1 (<0.1)	0
Tendon rupture	Grade 4	1 (<0.1)	0
Thermal burn	Grade 3	0	1 (<0.1)
Upper limb fracture	Grade 3	0	2 (<0.1)
Wrist fracture	Grade 3	1 (<0.1)	0
<b>Social circumstances</b>			
Homicide	Grade 5	0	1 (<0.1)

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