Article:
Ebrahimi, N., de Whalley, P., Kanji, N. et al. (2026) ChAdOx1 nCoV-19 coronavirus vaccine: long-term safety and immunological responses. Vaccine, 88. 128951. ISSN: 0264-410X

https://doi.org/10.1016/j.vaccine.2026.128951

Vaccine 88 (2026) 128951

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Short communication

ChAdOx1 nCoV-19 coronavirus vaccine: Long-term safety and immunological responses

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https://doi.org/10.1016/j.vaccine.2026.128951
Received 19 March 2026; Received in revised form 30 May 2026; Accepted 14 July 2026
Available online 18 July 2026

ARTICLE INFO

Keywords:
Pandemic
Adenoviral vector vaccine
Booster vaccine
AZD1222
Vaxzevria
Covishield

ABSTRACT

Rationale: Follow-up of pre-licensure trial participants potentially informs a vaccine's long-term safety profile.
Design: This prospective study enrolled participants from the first clinical trials of ChAdOx1 nCoV-19 vaccine, many of whom subsequently received COVID-19 vaccines in the UK vaccination programme. Serious adverse events (SAEs) and adverse events of special interest (AESIs) were captured. AESI selection was based on Brighton Collaboration definitions.
Results: Between September 2021 and April 2022, 4470 participants enrolled (58% female, median age 50 years); 3845/4470 (86.0%) completed the study. Median follow-up was 11.77 months; total follow-up was 48,116 person-months. There were 174 SAEs and 71 AESIs (33 events recorded as both) in 195 participants, including 5 deaths. Immunology data were available for a small subset of participants; total IgG against trimeric SARS-CoV-2 spike protein tended to increase during the study.
Conclusions: Although no emergent safety signals were detected, continued post-marketing surveillance remains imperative, particularly for neurological disorders.
EudraCT number: 2021-003382-36.

1. Introduction

The COVID-19 pandemic spread rapidly across the globe in early 2020. By early 2021, several effective vaccines had been developed and were being rolled out in expedited vaccination campaigns. In the UK, three COVID-19 vaccines, manufactured by AstraZeneca (ChAdOx1 nCoV-19), Pfizer-BioNTech (BNT162b2) and Moderna (mRNA-1273), were deployed [1]. Booster vaccination was offered from September 2021, initially for people over 50 years old and other vulnerable groups [2]. By December 2021, the booster campaign had extended to include all adults and the minimum interval from second to third dose was reduced to three months [3].

The scale and speed of vaccine deployment led to rapid accrual of post-marketing surveillance data. Several very rare serious conditions were identified as being associated with COVID-19 vaccines [4]. For ChAdOx1 nCov-19, these included Guillain-Barré syndrome, transverse myelitis, capillary leak syndrome and coagulation disorders. From March 2021, there were reports linking ChAdOx1 nCoV-19 vaccination with thrombosis with thrombocytopaenia syndrome (TTS), an extremely rare but potentially life-threatening condition [5–7].

No cases of TTS were identified in the global clinical trials of ChAdOx1 nCoV-19. Nevertheless, safety follow-up of trial participants who received vaccines before rollout may potentially provide the earliest indication of potential long-term adverse events. The first human trials of ChAdOx1-nCoV19 were COV001 and COV002. COV001 was a single blind phase I/II trial, conducted at five UK sites, in which 1077 healthy adults aged 18–55 years were randomly allocated 1:1 to ChAdOx1 nCoV-19 ($N = 543$) or control (quadrivalent meningococcal conjugate vaccine MenACWY, $N = 534$) [8–10]. COV002 was a single blind phase II/III trial, in which 10,812 participants were enrolled across 19 UK sites; there were 12 groups, recruited according to age, and subdivided according to randomised vaccine and dose schedule [11–13].

Here we describe the safety and immunogenicity observations in a cohort of individuals who were among the first to receive ChAdOx1 nCoV-19. The primary objective was assessment of long-term safety of ChAdOx1 nCoV-19. A secondary objective was to investigate the relationship between vaccination and immunological profile measured by anti-SARS-CoV-2 spike protein immunoglobulins (IgG), in a randomly selected subset of participants.

2. Materials and methods

2.1. Recruitment and study design

Former participants in COV001 and COV002 (including those randomised to control groups) were invited to enrol in COV009. At this point, many had already been offered a third dose COVID-19 booster vaccine in a national vaccination programme. Participants were followed up for 12 months; serious adverse events (SAEs) and adverse events of special interest (AESIs) were recorded. Participants were reviewed twice after enrolment, at 6 months (SV1) and 12 months (SV2), at an in-person clinic visit (or if this was not feasible, by telephone). In a subsidiary arm of the study (4th dose Subgroup), a subset of participants who received two doses of ChAdOx1 nCoV-19 within COV002, and who received an external third dose of BNT162b2 vaccine, were offered ChAdOx1 nCoV-19 to assess the safety and immunogenicity of ChAdOx1 nCoV-19 as a 4th dose booster. Participants were recruited to the 4th dose Subgroup at SV1 or SV2.

2.2. Safety outcomes

SAEs and AESIs were recorded throughout the study. An SAE was defined as any untoward medical occurrence that resulted in death, was life-threatening, required inpatient hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity, or congenital anomaly or birth defect, or which might have required medical or surgical intervention to prevent one of these outcomes. Selection of AESIs was based on Brighton Collaboration case definitions [14], clinical experience, and scientific interest (Supplementary Table A1). AESIs included various neuroinflammatory, blood, endocrine, skin, musculoskeletal, liver and autoimmune conditions. Guillain-Barré syndrome, transverse myelitis, cranial nerve neuropathies and stroke were specifically included.

Events were assessed by delegated clinicians from the study sites; each event was assessed by one clinician and graded for severity on a standard scale, from grade 0 (no symptoms) to grade 4 (potentially life-threatening), as shown in Supplementary Table A2.

The causal relationship between the adverse event and ChAdOx1 nCoV-19 administered during the parent trial (or, in 4th dose Subgroup participants, between the adverse event and ChAdOx1 nCoV-19 administered as a fourth dose booster) was assessed and categorised as no relationship, unlikely, possible, probable or definite (Supplementary Table A3).

2.3. Immunogenicity outcomes

Total IgG ELISA against trimeric SARS-CoV-2 spike protein was measured using a standardised assay (as previously described) [11] in a randomly selected subgroup of participants (the immunology cohort), at timepoints from commencement of COV001/COV002 until completion of COV009, a period of approximately two years.

2.4. Statistical analysis

Statistical analyses were descriptive, with no formal hypothesis testing performed. Safety endpoints are summarised as frequencies and percentages. Immunogenicity endpoints are summarised as geometric mean concentrations (GMCs) with corresponding 95% confidence intervals (CIs) at each time point for which data were available. The comparison of antibody measures across different time points was evaluated using the geometric mean ratio (GMR) and corresponding 95% CIs. The GMR was calculated as the antilogarithm of the difference between the mean log10-transformed concentrations at each time point and those at the reference time point.

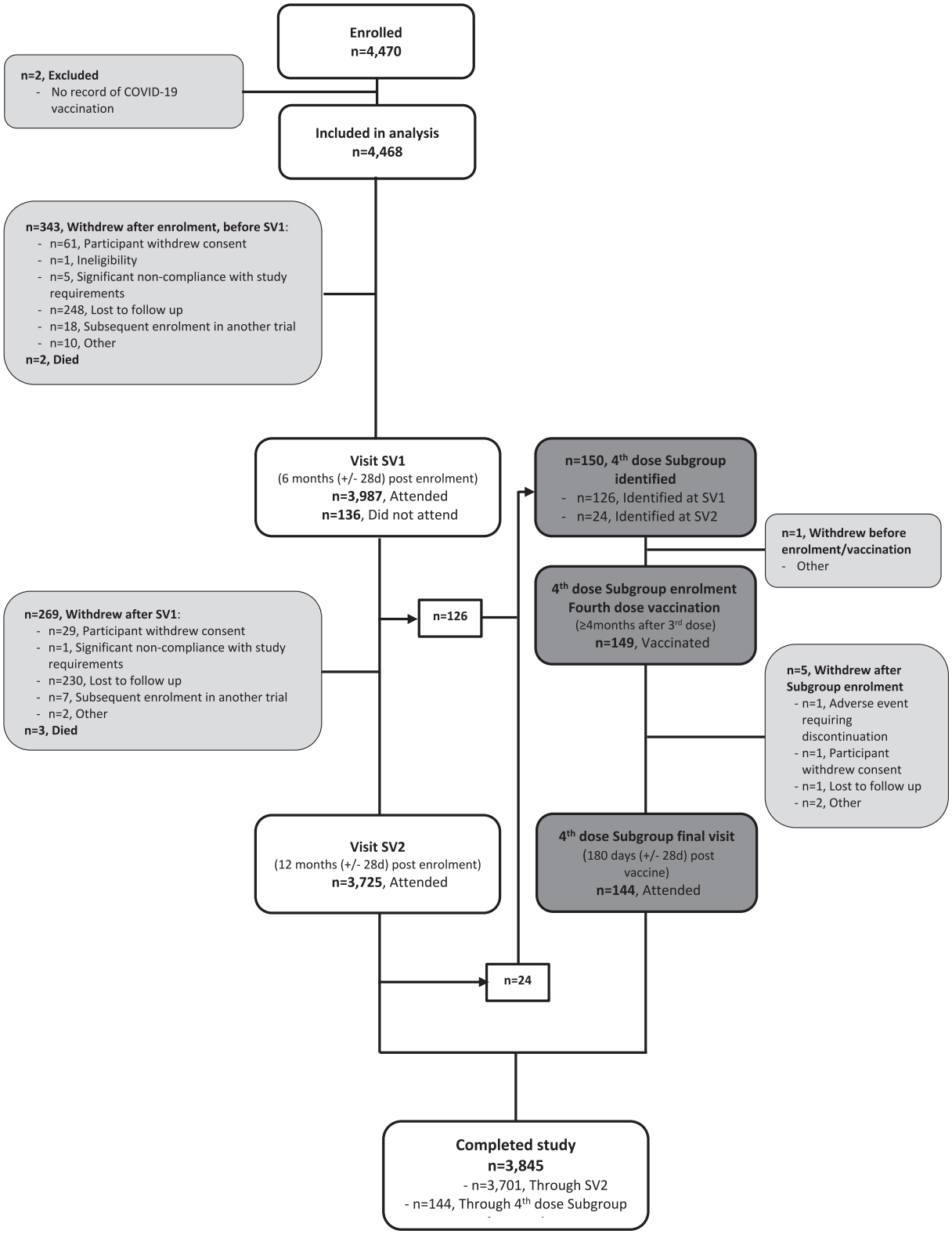

Fig. 1. CONSORT diagram.

Results were analysed by broadly classifying participants into three groups, based on all vaccination information recorded when they exited the study: "ChAd only" (received only ChAdOx1 nCov-19); "mRNA only" (received only BNT162b2, mRNA-1273 or unrecorded COVID-19 vaccines); "ChAd & mRNA" (received a mixed schedule of both ChAdOx1 nCov-19 and one or more doses of BNT162b2, mRNA-1273 or unrecorded COVID-19 vaccine). In 15 instances of community vaccination, the identity of administered COVID-19 vaccine was unrecorded.

2.5. Ethics

All participants gave informed consent. Ethical approval was obtained from South Central - Berkshire Research Ethics Committee (REC reference 21/SC/0261). Regulatory approval was granted by the Medicines and Healthcare products Regulatory Agency (IRAS reference 300,456).

3. Results

3.1. Participant flow

Fig. 1 is a CONSORT diagram showing participant disposition. All randomised participants in COV001 and COV002 were eligible to enrol in COV009, regardless of study arm. Of 11,889 eligible individuals, 4470 consented to participate in COV009, enrolling between 3 September 2021 and 11 April 2022. Two had no record of receiving a COVID-19 vaccine and were excluded. Of the remaining 4468 participants, 469/4468 (10%) were recruited from 1077 who enrolled in COV001, and 3999/4468 (90%) from 10,812 who enrolled in COV002. Overall, 3845/4468 (86%) participants completed the study.

Median follow-up period was 11.77 months (IQR: 11.21, 12.20) and total follow-up was 48,116 person-months. Median interval between first COVID-19 vaccination and first COV009 study visit (SV1) was 574 days (IQR: 451, 678). SV1 occurred between 17 February 2022 and 31 October 2022. Second study visit (SV2) occurred between 22 August 2022 and 28 April 2023. Median interval between SV1 and SV2 was 182 days (IQR: 175, 190).

The "ChAd only" group contained 385 participants (91 (23.6%) of whom had been randomised to the control group in COV001/2); the "mRNA only" group contained 1014 participants (all of whom had been randomised to the control group in COV001/2); the "ChAd & mRNA" group contained 3069 participants (740 (24.1%) of whom had been randomised to the control group in COV001/2).

3.2. Demographics

Table 1 shows baseline demographic characteristics of enrolled participants. Fifty-eight percent (2594/4468) were female. The demographic characteristics of the participants enrolled in COV009 broadly matched those in COV001 and COV002, although COV009

Table 1
Baseline characteristics of participants.

	Total* $N = 4,468$[1]	Female			Male		
		ChAd & mRNA† $N = 1,741$[1]	ChAd only† N = 213[1]	mRNA only† N = 640[1]	ChAd & mRNA† N = 1,328[1]	ChAd only† N = 172[1]	mRNA only† N = 374[1]
Study							
COV001	469 (10%)	172 (9.9%)	44 (21%)	37 (5.8%)	137 (10%)	58 (34%)	21 (5.6%)
COV002	3999 (90%)	1569 (90%)	169 (79%)	603 (94%)	1191 (90%)	114 (66%)	353 (94%)
Age (years)**							
N	4468	1741	213	640	1328	172	374
Mean (SD)	51 (15)	50 (14)	42 (13)	47 (13)	55 (16)	44 (14)	51 (16)
Median (IQR)	50 (39, 62)	49 (40, 60)	41 (32, 49)	47 (38, 55)	55 (41, 71)	41 (33, 52)	51 (38, 67)
Range	19, 88	19, 86	20, 78	19, 84	19, 88	21, 81	19, 84
Age group**							
18-55 years	2903 (65%)	1194 (69%)	181 (85%)	490 (77%)	667 (50%)	142 (83%)	229 (61%)
56–69 years	751 (17%)	279 (16%)	21 (9.9%)	98 (15%)	273 (21%)	14 (8.1%)	66 (18%)
≥70 years	814 (18%)	268 (15%)	11 (5.2%)	52 (8.1%)	388 (29%)	16 (9.3%)	79 (21%)
Healthcare worker	2204 (49%)	946 (54%)	108 (51%)	502 (78%)	390 (29%)	51 (30%)	207 (55%)
Ethnicity							
White	4236 (95%)	1673 (96%)	198 (93%)	617 (96%)	1250 (94%)	157 (91%)	341 (91%)
Asian	125 (2.8%)	34 (2.0%)	8 (3.8%)	12 (1.9%)	41 (3.1%)	6 (3.5%)	24 (6.4%)
Black	17 (0.4%)	5 (0.3%)	0 (0%)	0 (0%)	7 (0.5%)	4 (2.3%)	1 (0.3%)
Other	86 (1.9%)	28 (1.6%)	7 (3.3%)	11 (1.7%)	28 (2.1%)	5 (2.9%)	7 (1.9%)
Missing	4 (<0.1%)	1 (<0.1%)	0 (0%)	0 (0%)	2 (0.2%)	0 (0%)	1 (0.3%)
BMI							
N	4462	1740	213	639	1325	172	373
Mean (SD)	26.3 (4.9)	26.3 (5.4)	26.9 (5.6)	26.1 (5.2)	26.3 (4.0)	26.0 (4.0)	26.4 (4.2)
Median (IQR)	25.5 (23.0, 28.7)	25.2 (22.5, 29.0)	25.5 (22.9, 30.0)	25.2 (22.3, 28.5)	25.9 (23.7, 28.4)	25.2 (23.5, 28.1)	26.0 (23.3, 28.7)
Range	13.8, 68.5	13.8, 64.1	17.8, 49.2	15.4, 57.3	15.3, 68.5	18.9, 41.7	17.9, 45.8
Cardiovascular disorders	667 (15%)	207 (12%)	11 (5.2%)	62 (9.7%)	295 (22%)	12 (7.0%)	80 (21%)
Respiratory disorders	487 (11%)	198 (11%)	17 (8.0%)	72 (11%)	135 (10%)	17 (9.9%)	48 (13%)
Diabetes	98 (2.2%)	28 (1.6%)	2 (0.9%)	12 (1.9%)	41 (3.1%)	0	15 (4.0%)

[1] n (%).
* Two enrolled participants with no record of receiving a COVID-19 vaccine were excluded from the analysis.
** Age at the time of receiving the first COVID-19 vaccine.
† COVID-19 vaccines received at time of exit from study: **ChAd & mRNA**: Both ChAdOx1 nCoV-19 and BNT162b2, mRNA-1273 or unrecorded COVID-19 vaccines; **ChAd only**: Only ChAdOx1 nCoV-19; **mRNA only**: Only BNT162b2, mRNA-1273 or unrecorded COVID-19 vaccines.

participants had a higher baseline median age (Supplementary Table A4). The demographic profile of 623 participants not completing COV009 was similar to that of all enrolled participants, apart from baseline median age, which was lower in those not completing the study (Supplementary Table A6).

3.3. Vaccinations

At study completion, the total number of COVID-19 vaccine doses in studies and the community received by individual COV009 participants, ranged from one to seven; 48% (2149/4468) received three doses and 33% (1458/4468) received four doses. The total number of vaccine doses given to participants in the community (excluding those given as part of studies COV001, COV002 and COV009 Subgroup) was 9254. These comprised 6051/9254 (65.4%) BNT162b2, 1720/9254 (18.6%) mRNA-1273, 1468/9254 (15.9%) ChAdOx1 nCov-19 and 15/9254 (0.2%) unrecorded. Supplementary Appendix B shows further vaccination details.

Intervals between vaccinations are shown in Supplementary Table B5. Median interval between first and second COVID-19 vaccination was 76 days (IQR: 57, 91) and between second and third COVID-19 vaccination was 339 days (IQR: 198, 401).

3.4. SAEs

In total, 174 SAEs were reported by 159/4468 (3.56%) participants during COV009 follow-up (Table 2). Thirteen participants reported two SAEs, and one participant reported three. Overall, 23% (40/174) were classified as grade 4 severity, and 61% (107/174) were classified as grade 3. There were five deaths (caused by pancreatic cancer, motor neurone disease, cerebral vascular accident, peritonitis with neutropenic sepsis, and metastatic cholangiocarcinoma), all unrelated to COVID-19 or COVID-19 vaccination (Supplementary Table C1). By system organ class (SOC), the most reported SAEs were neoplasms (36/4468; 0.81%), general disorders (34/4468; 0.76%), infections and infestations (20/4468; 0.45%), nervous system disorders (18/4468; 0.40%) and injury, poisoning and procedural complications (14/4468; 0.31%).

The median interval between most recent COVID-19 vaccination and SAE was 159 days (IQR: 66, 262). The causal relationship between ChAdOx1 nCoV-19 and SAE was assessed to be “no relationship” for 146/174 (86%) events and “unlikely” for 28/174 (14%). Eight SAEs were related to SARS-CoV-2 infection.

Supplementary Table C6 compares the baseline characteristics of participants who reported an SAE with those of participants who did not. The group with SAEs tended to be older (median age 57 years *versus* 50 years), more likely to have underlying cardiovascular or respiratory disease or diabetes, and less likely to be healthcare workers than participants who did not experience an SAE.

3.5. AESIs

Sixty-eight participants reported a total of 71 AESIs (Table 3). One participant experienced two AESIs and one participant reported three. Thirty-three events (in 32 participants) were recorded as both SAE and AESI. Overall, 11% (8/71) AESIs were classified as grade 4 severity, and 45% (32/71) were classified as grade 3. There was one death (caused by motor neurone disease, also recorded as SAE). By SOC, the most reported AESIs were infections and infestations (18/4468; 0.40%), nervous system disorders (18/4468; 0.40%), neoplasms (6/4468; 0.13%) and gastrointestinal disorders (6/4468; 0.13%).

The median interval between most recent COVID-19 vaccination and AESI was 134 days (IQR: 43, 238). The causal relationship between ChAdOx1 nCoV-19 and AESI was assessed to be “no relationship” for 49/71 (69%) events and “unlikely” for 22/71 (31%). Eighteen AESIs were related to SARS-CoV-2 infections.

Table 2
Summary of SAEs.

	Total N = 4,468[1]	**ChAd & mRNA** N = 3,069[1]	**ChAd only** N = 385[1]	**mRNA only** N = 1,014[1]
Number of participants experiencing at least one SAE	159 (3.6%)	118 (3.8%)	9 (2.3%)	32 (3.2%)
Number of SAEs	174	128	9	37
Category of SAE				
An important medical event	54 (31%)	39 (30%)	4 (44%)	11 (30%)
Death	5 (2.9%)	4 (3.1%)	1 (11%)	0
Hospitalisation	101 (58%)	72 (56%)	4 (44%)	25 (68%)
Life threatening	3 (1.7%)	3 (2.3%)	0	0
Significant disability/ incapacity	11 (6.3%)	10 (7.8%)	0	1 (2.7%)
Severity				
Grade 1	5 (2.9%)	4 (3.1%)	0	1 (2.7%)
Grade 2	22 (13%)	15 (12%)	2 (22%)	5 (14%)
Grade 3	107 (61%)	78 (61%)	3 (33%)	26 (70%)
Grade 4	40 (23%)	31 (24%)	4 (44%)	5 (14%)
System Organ Class				
Cardiac disorders	11 (6.3%)	9 (7.0%)	0	2 (5.4%)
Congenital, familial and genetic disorders	1 (0.6%)	0	1 (11%)	0
Ear and labyrinth disorders	1 (0.6%)	1 (0.8%)	0	0
Eye disorders	1 (0.6%)	1 (0.8%)	0	0
Gastrointestinal disorders	9 (5.2%)	6 (4.7%)	1 (11%)	2 (5.4%)
General disorders and administration site conditions	34 (20%)	25 (20%)	2 (22%)	7 (19%)
Hepatobiliary disorders	3 (1.7%)	3 (2.3%)	0	0
Immune system disorders	1 (0.6%)	1 (0.8%)	0	0
Infections and infestations	20 (11%)	13 (10%)	1 (11%)	6 (16%)
Injury, poisoning and procedural complications	14 (8.0%)	8(6.3%)	0	6(16%)
Metabolism and nutrition disorders	1(0.6%)	0	0	1(2.7%)
Musculoskeletal and connective tissue disorders	3(1.7%)	3(2.3%)	0	0
Neoplasms benign, malignant and unspecified	36 (21%)	29 (23%)	2(22%)	5(14%)
Nervous system disorders	18 (10%)	13 (10%)	1(11%)	4(11%)
Pregnancy, puerperium and perinatal conditions	7(4.0%)	5(3.9%)	1(11%)	1(2.7%)
Psychiatric disorders	1(0.6%)	1(0.8%)	0	0
Respiratory, thoracic and mediastinal disorders	5(2.9%)	5(3.9%)	0	0
Skin and subcutaneous tissue disorders	1(0.6%)	1(0.8%)	0	0
Surgical and medical procedures	6(3.4%)	3(2.3%)		(8.1%)
Vascular disorders	1(0.6%)	1(0.8%)	0	0
Outcome				
Fatal	5 (2.9%)	4 (3.1%)	1 (11%)	0
Not recovered or resolved	35 (20%)	27 (21%)	1 (11%)	7 (19%)
Recovered/resolved	98 (56%)	67 (52%)	6 (67%)	25 (68%)
Recovered/resolved with sequelae	22 (13%)	20 (16%)	0	2 (5.4%)
Recovering/resolving	14 (8.0%)	10 (7.8%)	1 (11%)	3 (8.1%)
Duration of SAE until recovered/resolved (days)*				
Median (IQR)	4 (1,31)	4 (1, 35)	5 (2, 171)	4 (1, 25)
Min, Max	0, 624	0, 408	1, 624	1, 301

(*continued on next page*)

Table 2 (*continued*)

	Total N = 4,468[1]	ChAd & mRNA N = 3,069[1]	ChAd only N = 385[1]	mRNA only N = 1,014[1]
Causality				
No relationship	146 (84%)	106 (83%)	8 (89%)	32 (86%)
Unlikely	28 (16%)	22 (17%)	1 (11%)	5 (14%)
Relationship to ChAdOx1 nCoV-19				
Not related	174 (100%)	128 (100%)	9 (100%)	37 (100%)
SARS-CoV-2 infection related SAE	8 (4.6%)	5 (3.9%)	1 (11%)	2 (5.4%)
Last COVID-19 vaccine before SAE				
ChAdOx1	27 (16%)	18 (14%)	9 (100%)	–
mRNA-1273	22 (13%)	18 (14%)	–	4 (11%)
BNT162b2	125 (72%)	92 (72%)	–	33 (89%)
Days since last COVID-19 vaccine				
Median (IQR)	159 (66, 262)	149 (65, 264)	472 (232, 488)	131 (59, 235)
Min, Max	1, 789	9, 473	11, 789	1, 561

[1] n (%).

[*] Duration of SAE calculated as the period between start and resolution dates of event. Events starting and resolving on the same date have duration 0 days.

Supplementary Table C7 compares the baseline characteristics of participants who reported an AESI with those of participants who did not. The group with AESIs tended to be older (median age 56 years *versus* 50 years), more likely to be male (51% *versus* 42%), more likely to have underlying cardiovascular disease (but not respiratory disease or diabetes), and less likely to be healthcare workers than participants who did not experience an AESI.

3.6. Immunogenicity

Reactogenicity and immunogenicity results from the fourth dose substudy (4th dose Subgroup) have been reported previously [15]. The immunology data presented here are from immunology cohort participants with available results.

For participants who received a second dose of ChAdOx1 nCoV-19 at 28 days after their first dose in COV001/COV002, IgG geometric mean concentration (GMC) was 481 AU/mL (375–617) at 28 days post second dose ($n = 44$), 4301 AU/mL (2970-6229) at COV009 SV1 ($n = 40$), and 14,342 AU/mL (9890-20,800) at COV009 SV2 ($n = 38$). For participants who received a second dose of ChAdOx1 nCoV-19 at 2 to <6 months after their first dose in COV001/COV002, IgG GMC was 928 AU/mL (567–1519) at 28 days post second dose ($n = 26$), 5905 AU/mL (3841-9076) at COV009 SV1 ($n = 25$), and 13,396 AU/mL (9016-19,902) at COV009 SV2 ($n = 24$). Immunogenicity results are shown in Supplementary Appendix D.

4. Discussion

In this study, 4468 participants from two early clinical trials of ChAdOx1 nCoV-19 vaccine were followed up after completion of the original trials for one year; 86% (3845/4468) completed the study. In total, 174 SAEs were reported by 159 participants, and 71 AESIs were reported by 68 participants (with 33 events recorded as both SAE and AESI). No adverse event was assessed as likely to have been related to ChAdOx1 nCoV-19.

Only 37.6% (4468/11,889) of the participants who enrolled in

Table 3
Summary of AESIs.

	Overall N = 4,468[1]	ChAd & mRNA N = 3,069[1]	ChAd only N = 385[1]	mRNA only N = 1,014[1]
Number of participants experiencing at least one AESI	68 (1.5%)	51 (1.7%)	7 (1.8%)	10 (1.0%)
Number of AESIs	71	54	7	10
Severity				
Grade 1	10 (14%)	9 (17%)	0	1 (10%)
Grade 2	21 (30%)	17 (31%)	3 (43%)	1 (10%)
Grade 3	32 (45%)	24 (44%)	1 (14%)	7 (70%)
Grade 4	8 (11%)	4 (7.4%)	3 (43%)	1 (10%)
System Organ Class				
Cardiac disorders	2 (2.8%)	1 (1.9%)	0	1 (10%)
Ear and labyrinth disorders	1 (1.4%)	1 (1.9%)	0	0
Endocrine disorders	1 (1.4%)	1 (1.9%)	0	0
Gastrointestinal disorders	6 (8.5%)	3 (5.6%)	2 (29%)	1 (10%)
General disorders and administration site conditions	3 (4.2%)	3 (5.6%)	0	0
Hepatobiliary disorders	2 (2.8%)	1 (1.9%)	1 (14%)	0
Infections and infestations	18 (25%)	12 (22%)	2 (29%)	4 (40%)
Musculoskeletal and connective tissue disorders	3 (4.2%)	3 (5.6%)	0	0
Neoplasms benign, malignant and unspecified	6 (8.5%)	5 (9.3%)	1 (14%)	0
Nervous system disorders[*]	18 (25%)[*]	13 (24%)[*]	1 (14%)	4 (40%)
Respiratory, thoracic and mediastinal disorders	4 (5.6%)	4 (7.4%)	0	0
Skin and subcutaneous tissue disorders	3 (4.2%)	3 (5.6%)	0	0
Surgical and medical procedures	1 (1.4%)	1 (1.9%)	0	0
Vascular disorders	3 (4.2%)	3 (5.6%)	0	0
Outcome				
Fatal	1 (1.4%)	0	1 (14%)	0
Not recovered or resolved	16 (23%)	14 (26%)	1 (14%)	1 (10%)
Recovered/resolved	42 (59%)	31 (57%)	4 (57%)	7 (70%)
Recovered resolved with sequelae	6 (8.5%)	6 (11%)	0	0
Recovering/resolving	6 (8.5%)	3 (5.6%)	1 (14%)	2 (20%)
Duration of AESI until recovered/resolved (days)[**]				
Median (IQR)	7 (2, 35)	6 (3, 35)	171 (7, 292)	7 (1, 18)
Min, Max	0, 624	0, 237	2, 624	0, 34
Causality				
No relationship	49 (69%)	35 (65%)	5 (71%)	9 (90%)
Unlikely	22 (31%)	19 (35%)	2 (29%)	1 (10%)
Relationship to ChAdOx1 nCoV-19				
Not related	71 (100%)	54 (100%)	7 (100%)	10 (100%)
SARS-CoV-2 infection related AESI	18 (25%)	14 (26%)	2 (29%)	2 (20%)
Last COVID-19 vaccine before AESI				
ChAdOx1	12 (17%)	5 (9.3%)	7 (100%)	–
mRNA-1273	9 (13%)	8 (15%)	–	1 (10%)
BNT162b2	49 (69%)	40 (74%)	–	9 (90%)
Unrecorded	1 (1.4%)	1 (1.9%)	–	0
Days since last COVID-19 vaccine				

(*continued on next page*)

Table 3 (*continued*)

	Overall N = 4,468[1]	ChAd & mRNA N = 3,069[1]	ChAd only N = 385[1]	mRNA only N = 1,014[1]
Median (IQR)	134 (43, 238)	126 (41, 230)	233 (187, 473)	81 (50, 225)
Min, Max	3, 801	3, 348	11, 801	31, 500

[1] n (%).

[*] One participant reported two AESIs in SOC "Nervous system disorders".

[**] Duration of AESI calculated as the period between start and resolution dates of event. Events starting and resolving on the same date have duration 0 days.

COV001 and COV002 went on to take part in COV009, possibly because volunteers perceived less incentive to participate in the follow-up than the parent studies. Participation in COV001 and COV002 offered volunteers the chance to receive a COVID-19 vaccine, when none was generally available; when COV009 recruited, COVID-19 vaccines were being routinely used.

At the time of enrolment in the parent studies, COV009 participants had a higher median age (49 years) than all COV002 participants (44 years) or all COV001 participants (35 years). Similarly, participants completing COV009 had a higher median age (51 years) than those not completing the study (43 years). Older people might have felt more motivated to remain involved in COVID-19 research (being more likely to suffer serious COVID-19 disease) than younger individuals.

The COVID-19 vaccinations received by study participants varied widely, both in number and type. This reflects the routine use of three different vaccines in the UK, whose availability varied by region, and changing national recommendations over the period of follow-up [16]. The majority of participants (3069/4468; 68.7%) received a combination of both ChAdOx1 nCoV-19 and one or more mRNA COVID-19 vaccines. Most vaccinations received in the community (7771/9254; 86%) were mRNA COVID-19 vaccines.

A combined analysis of data from COV001 and COV002, together with similar trials in Brazil (COV003) and South Africa (COV005), reported 175 SAEs occurring in 168 participants, with 84 events in the ChAdOx1 nCoV-19 group and 91 in the control group (during follow-up of 74,341 person-months) [12].

Our finding of no emergent safety signal accorded with other long-term follow-up studies of ChAdOx1 nCoV-19 trial participants, including a large study from USA, Chile and Peru, which followed up participants from phase III trials for two years (totalling 37,311 people-years) [17]. Similarly, no safety signal was identified by a post-authorisation surveillance study from the UK, which followed participants for 18 months after their first ChAdOx1 nCov-19 dose [18].

Firm data on the expected background rates of diagnoses in the study population would have facilitated evaluation of our findings by enabling comparison of observed with expected rates of events. One UK post-authorisation surveillance study used data from CPRD GOLD (a large UK healthcare record database, currently with about 3 million active patients), to determine expected rates for outcomes of interest; the study population closely resembled ours [18]. For some outcomes (selected according to availability of data from this source), rates observed in our study are compared with expected rates in Supplementary Table C8. The only one of these outcomes where observed rate was notably greater than expected (O:E ratio 18) was Guillain-Barré syndrome.

Immunological data were only available for a small, non-randomised subset of study participants. However, levels of total IgG against trimeric SARS-CoV-2 spike protein were notably greater during the COV009 phase of the study than after two doses of ChAdOx1 nCoV-1 vaccine in COV001/002, and higher at the end of COV009 (at SV2) than six months earlier (at SV1). This probably reflects a combination of the effects of additional COVID-19 vaccine doses and natural boosting from SARS-CoV-2 infections [19]. In the fourth dose sub-study (4th dose Subgroup), 37.9% (33/87) of participants were anti-nucleocapsid seropositive immediately before they received their fourth dose in September 2022; 39.6% (59/149) self-reported SARS-CoV-2 infection in the six months before their fourth dose and 15.4% (23/149) self-reported infection 14–180 days after the fourth dose [15].

Studies from India have reported an increased risk of adverse events in individuals receiving COVID-19 vaccination after SARS-CoV-2 infection [20,21]. If this were so, we might expect to see more SAEs and AESIs towards the end of our study than at the beginning, given the high rate of infection during the study, but this pattern does not emerge from our data (Supplementary Fig. C1). However, our study was not designed to address this question specifically.

Our study had several limitations, in addition to those noted above. Nearly all participants were of white ethnicity, limiting the generalisability of the results. A study of a few thousand participants is unlikely to detect very rare (<1:10,000) events; TTS occurs after around 1:100,000 first doses of ChAdOx1 nCoV-19, and so was very unlikely to be seen in our study. Assessment of the causal relationship between vaccination and event by a clinician is inherently subjective. It might have been better for each event to be assessed by a panel, rather than an individual clinician. The wide variety of vaccine doses received by participants in the community further complicated assessment.

The rapid global roll-out of COVID-19 vaccines produced a plethora of post-marketing data, outpacing our study objectives. Although long-term follow-up of participants in early clinical trials of a vaccine offers the potential for early identification of late-onset hazards, the strategy does not replace careful post-marketing surveillance, which enables detection of extremely rare adverse events. Nevertheless, the prospective nature of our study, with its prolonged and detailed follow-up of participants from pre-licensure trials, provides a unique dataset.

CRediT authorship contribution statement

Narges Ebrahimi: Writing – original draft, Formal analysis. **Philip de Whalley:** Writing – original draft. **Nasir Kanji:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Conceptualization. **Maheshi N. Ramasamy:** Supervision, Methodology, Conceptualization. **Parvinder K. Aley:** Writing – review & editing, Project administration, Methodology, Data curation. **Sagida Bibi:** Writing – review & editing, Supervision, Resources, Investigation. **Elizabeth A. Clutterbuck:** Writing – review & editing, Supervision, Resources, Investigation. **Andrea M. Collins:** Writing – review & editing, Investigation. **Thomas C. Darton:** Writing – review & editing, Investigation. **Christopher J.A. Duncan:** Writing – review & editing, Supervision, Investigation. **Saul N. Faust:** Writing – review & editing, Supervision, Investigation. **Elaine Shuo Feng:** Writing – review & editing, Formal analysis. **Anna L. Goodman:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Investigation. **Christopher A. Green:** Writing – review & editing, Supervision, Investigation. **Paul T. Heath:** Writing – review & editing, Supervision, Resources, Investigation. **Jonathan Kwok:** Writing – review & editing, Investigation. **Rajeka Lazarus:** Writing – review & editing, Investigation. **Vincenzo Libri:** Writing – review & editing, Investigation. **Patrick J. Lillie:** Writing – review & editing, Resources, Investigation. **Alastair McGregor:** Writing – review & editing, Investigation. **Yama F. Mujadidi:** Writing – review & editing, Data curation. **Nelly Owino:** Writing – review & editing, Project administration. **Emma Plested:** Writing – review & editing, Project administration. **Katrina M. Pollock:** Writing – review & editing, Investigation. **Hannah Robinson:** Writing – review & editing, Supervision, Project administration, Methodology. **Rebecca K. Sutherland:** Writing – review & editing, Supervision, Investigation. **Emma C. Thomson:** Writing – review & editing, Investigation. **Mark Toshner:** Writing – review & editing, Investigation. **David P.J. Turner:** Writing – review & editing, Investigation. **Christopher J. Williams:** Writing – review & editing, Investigation. **Ian Hirsch:** Writing – review & editing, Supervision. **Tonya L. Villafana:** Writing – review & editing, Supervision, Funding

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Funding

This study was funded by AstraZeneca. The views expressed are those of the authors and not necessarily those of the funder.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: AJP, TL, PKA, SB, EAC, SNF, YFM, NO, EP, HR and MV are inventors and/or contributors to the intellectual property licensed by Oxford University Innovation to AstraZeneca. AJP was the Chair of the UK Department of Health and Social Care's (DHSC) Joint Committee on Vaccines and Immunisation (JCVI) until October 2025 but did not participate in the JCVI COVID-19 committee while ChAdOx1-nCOV19 was in use in the UK, the views expressed in this article do not necessarily reflect the views of JCVI or DHSC. He is a member of WHOs Product Development Advisory Committee and technical advisory group on Salmonella Vaccines. AJP declares grant funding for research on vaccines from the Wellcome Trust, Innovate UK, Medical Research Council, National Institute for Health Research, European Commission, Gates Foundation, Ellison Institute of Technology, Serum Institute of India and AstraZeneca. AJP is a contributor to intellectual property licensed by Oxford University Innovation to AstraZeneca and has acted as a consultant for Ellison Institute of Technology. TL reports having provided SAB/consultancy or received honorarium/grants from - Infinitopes, Seqirus, Sanofi, AstraZeneca, Geovax Labs, Arabio, aVaxzipen. TL is a named inventor on ChAdOx1-Zoster, ChAdOx1-SARSCoV2 and Gene insertion into MVA. IH and TLV are employees of AstraZeneca and may hold stock or stock options. CJAD reports grant funding and a Clinician Scientist Fellowship from the UK Medical Research Council (MR/X001598/1); acting on behalf of Newcastle upon Tyne Hospitals NHS Foundation Trust as an investigator on clinical trials funded or sponsored by manufacturers of vaccines and antimicrobials, including Moderna, AstraZeneca, Synairgen, Janssen, and Valneva, with no remuneration; remuneration to Newcastle University for provision of consultative advice to Synairgen; and serving on data safety and monitoring boards for non-commercial clinical trials sponsored by Oxford University, with no remuneration. SNF acts on behalf of University Hospital Southampton NHS Foundation Trust as an Investigator and/or providing consultative advice on clinical trials and studies of COVID-19 and other vaccines funded or sponsored by vaccine manufacturers including Janssen, Pfizer, AstraZeneca, GlaxoSmithKline, Novavax, Seqirus, Sanofi, Medimmune, Merck and Valneva vaccines and antimicrobials. He receives no personal financial payment for this work. ALG is named on a patent for technology used in ChAdOx1 nCoV19 vaccine (AZD1222) which has led to financial benefit. Guy's and St Thomas' has received income from a range of vaccine commercial sponsors to deliver vaccine trials. RL has received investigator-initiated funding from GSK, an honorarium from Sanofi for attending an advisory board and conference registration and travel expenses from Astra Zeneca. KMP has served as a data safety monitoring board member for Moderna (NCT05575492, NCT05249829), is a member of the British HIV Association vaccination guidelines writing committee and has received grant funding from MRC/UKRI, Horizon 2020, The Sir Joseph Hotung Charitable Settlement, the Chan Zuckerberg Initiative, and the NIHR Oxford Biomedical Research Centre outside the submitted work. MNR is CI/PI for vaccine research funded by CEPI, NIHR, Wellcome and Horizon 2020. JK is CEO of Infinitopes. All other authors report no conflict of interest.

Acknowledgments

We wish to thank all those who participated in this study. Parts of this research were carried out at the U.K. National Institute for Health and Care Research (NIHR) Newcastle Clinical Research Facility (but the views expressed in this article are those of the authors and not necessarily those of the NIHR or the U.K. Department of Health and Social Care). We thank the anonymous reviewers, whose comments and suggestions improved the text of this paper.

All authors attest they meet the ICMJE criteria for authorship.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2026.128951.

Data availability

Data will be made available on request.

References

[1] Department of Health & Social Care. A review of the Vaccine Taskforce. 31 August 2023. https://www.gov.uk/government/publications/a-review-of-the-vaccine-taskforce/a-review-of-the-vaccine-taskforce.
[2] Department of Health & Social Care. JCVI statement regarding a COVID-19 booster vaccine programme for winter 2021 to 2022. 14 September 2021. https://www.gov.uk/government/publications/jcvi-statement-september-2021-covid-19-booster-vaccine-programme-for-winter-2021-to-2022/jcvi-statement-regarding-a-covid-19-booster-vaccine-programme-for-winter-2021-to-2022.
[3] UK Health Security Agency. JCVI advice on COVID-19 booster vaccines for those aged 18 to 39 and a second dose for ages 12 to 15. 29 November 2021. https://www.gov.uk/government/news/jcvi-advice-on-covid-19-booster-vaccines-for-those-aged-18-to-39-and-a-second-dose-for-ages-12-to-15.
[4] Faksova K, Walsh D, Jiang Y, et al. COVID-19 vaccines and adverse events of special interest: a multinational global vaccine data network (GVDN) cohort study of 99 million vaccinated individuals. Vaccine 2024;42(9):2200–11.
[5] Bhuyan P, Medin J, da Silva HG, et al. Very rare thrombosis with thrombocytopenia after second AZD1222 dose: a global safety database analysis. Lancet 2021;398(10300):577–8.
[6] Greinacher A, Thiele T, Warkentin TE, Weisser K, Kyrle PA, Eichinger S. Thrombotic thrombocytopenia after ChAdOx1 nCov-19 vaccination. N Engl J Med 2021;384(22):2092–101.
[7] Cines DB, Bussel JB. SARS-CoV-2 vaccine-induced immune thrombotic thrombocytopenia. N Engl J Med 2021;384(23):2254–6.
[8] Folegatti PM, Ewer KJ, Aley PK, et al. Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial. Lancet 2020;396(10249):467–78.
[9] Ewer KJ, Barrett JR, Belij-Rammerstorfer S, et al. T cell and antibody responses induced by a single dose of ChAdOx1 nCoV-19 (AZD1222) vaccine in a phase 1/2 clinical trial. Nat Med 2021;27(2):270–8.
[10] Barrett JR, Belij-Rammerstorfer S, Dold C, et al. Phase 1/2 trial of SARS-CoV-2 vaccine ChAdOx1 nCoV-19 with a booster dose induces multifunctional antibody responses. Nat Med 2021;27(2):279–88.
[11] Ramasamy MN, Minassian AM, Ewer KJ, et al. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. Lancet 2020;396(10267):1979–93.
[12] Voysey M, Clemens SAC, Madhi SA, et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. Lancet 2021;397(10269):99–111.
[13] Voysey M, Costa Clemens SA, 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;397(10277):881–91.
[14] Brighton Collaboration. Case definitions. https://brightoncollaboration.org/case-definitions/.
[15] Feng S, Bibi S, Aley PK, et al. Safety and humoral immunogenicity of the ChAdOx1 nCoV-19 vaccine administered as a fourth dose booster following two doses of ChAdOx1 nCoV-19 and a third dose of BNT162b2 (COV009): a prospective cohort study. J Infect 2025;90(2).
[16] Mounier-Jack S, Paterson P, Bell S, Letley L, Kasstan B, Chantler T. Covid-19 vaccine roll-out in England: a qualitative evaluation. PLoS ONE 2023;18(6):e0286529.
[17] Shoemaker K, Soboleva K, Branche A, et al. Long-term safety and immunogenicity of AZD1222 (ChAdOx1 nCoV-19): 2-year follow-up from a phase 3 study. Vaccines 2024;12(8):883.

[18] Evans A, Roy D, Davies M, et al. Safety and utilisation of AZD1222 (ChAdOx1 nCoV-19) COVID-19 vaccine: a UK post-authorisation active surveillance study. BMJ Open 2025;15(5):e093366.
[19] Collier AY, Brown CM, McMahan KA, et al. Characterization of immune responses in fully vaccinated individuals after breakthrough infection with the SARS-CoV-2 delta variant. Sci Transl Med 2022;14(641):eabn6150.
[20] Kaur U, Bala S, Joshi A, et al. Persistent health issues, adverse events, and effectiveness of vaccines during the second wave of COVID-19: a cohort study from a tertiary hospital in North India. Vaccines (Basel) 2022;10(7).
[21] Kaur U, Fatima Z, Maheshwari K, et al. Long-term safety analysis of the ChAdOx1-nCoV-19 Corona virus vaccine: results from a prospective observational study in priority vaccinated groups in North India. Drug Saf 2023;46(6):553–63.