07 Jun 21 - 11:58

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| --- |
| **Presentations of Giant Cell Arteritis or temporal headaches following COVID vaccine** |

The MHRA is publishing weekly summaries of vaccine adverse effects here: <https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting>

Each vaccine has a separate summary page and is searchable through <ctrl> + F.

****Pfizer (reports to 26/5/21)****

Arteritis 1 (0 fatal)

GCA reports: 7 (0 fatal)

****Ox/Az (reports to 26/5/21)****

Arteritis 4 (0 fatal)

Giant cell arteritis 44 (0 fatal)

****Moderna (reports to 26/5/21****

No results for GCA

****Brand not specified****

No results for GCA

HDAS Export

[See full search strategy](#historyanchor)

Strategy 1034183/saved

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[3. Interim Results of a Phase 1-2a Trial of Ad26.COV2.S Covid-19 Vaccine.](#34d342c7-1604-b924-0842-ba0e5228f6e1-3)

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[7. Safety of COVID-19 vaccines administered in the EU: Should we be concerned?](#3da38976-edac-40fa-3f1a-7eae4f5c0739-7)

[8. Side effects of BNT162b2 mRNA COVID-19 vaccine: A randomized, cross-sectional study with detailed self-reported symptoms from healthcare workers](#7a0afab9-2d19-cc5b-770f-3948253a077b-8)

[9. A preliminary report of a randomized controlled phase 2 trial of the safety and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine](#e45b1c1a-0fa0-61d2-fc44-a259cfd073b7-9)

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[11. Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: a double-blind, randomised, phase 1 trial](#37d74b68-2c94-bdea-c1ff-3044c579a31e-11)

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**1. COVID-19 vaccines: comparison of biological, pharmacological characteristics and adverse effects of Pfizer/BioNTech and Moderna Vaccines.**

**Author(s):** Meo, S A; Bukhari, I A; Akram, J; Meo, A S; Klonoff, D C

**Source:** European review for medical and pharmacological sciences; Feb 2021; vol. 25 (no. 3); p. 1663-1669

**Publication Date:** Feb 2021

**Publication Type(s):** Comparative Study Journal Article Review

**PubMedID:** 33629336

Available at [European review for medical and pharmacological sciences](https://search.ebscohost.com/login.aspx?direct=true&scope=site&site=ehost-live&db=mdc&AN=33629336) - from EBSCO (MEDLINE Complete)

Available at [European review for medical and pharmacological sciences](http://www.uhl-library.nhs.uk/directpages/uhlblarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from non-NHS library) - click this link for more information Local Print Collection [location] : British Library via UHL Libraries - please click link to request article.

**Abstract:**OBJECTIVEThe "Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)" disease has caused a worldwide challenging and threatening pandemic (COVID-19), with huge health and economic losses. The US Food and Drug Administration, (FDA) has granted emergency use authorization for treatment with the Pfizer/BioNTech and Moderna COVID-19 vaccines. Many people have a history of a significant allergic reaction to a specific food, medicine, or vaccine; hence, people all over the world have great concerns about these two authorized vaccines. This article compares the pharmacology, indications, contraindications, and adverse effects of the Pfizer/BioNTech and Moderna vaccines.MATERIALS AND METHODSThe required documents and information were collected from the relevant databases, including Web of Science (Clarivate Analytics), PubMed, EMBASE, World Health Organization (WHO), Food and Drug Authorities (FDA) USA, Local Ministries, Health Institutes, and Google Scholar. The key terms used were: Coronavirus, SARS-COV-2, COVID-19 pandemic, vaccines, Pfizer/BioNTech vaccine, Moderna vaccine, pharmacology, benefits, allergic responses, indications, contraindications, and adverse effects. The descriptive information was recorded, and we eventually included 12 documents including research articles, clinical trials, and websites to record the required information.RESULTSBased on the currently available literature, both vaccines are beneficial to provide immunity against SARS-CoV-2 infection. Pfizer/BioNTech Vaccine has been recommended to people 16 years of age and older, with a dose of 30 μg (0.3 m) at a cost of $19.50. It provides immunogenicity for at least 119 days after the first vaccination and is 95% effective in preventing the SARS-COV-2 infection. However, Moderna Vaccine has been recommended to people 18 years of age and older, with a dose of 50 μg (0.5 mL) at a cost of $32-37. It provides immunogenicity for at least 119 days after the first vaccination and is 94.5% effective in preventing the SARS-CoV-2 infection. However, some associated allergic symptoms have been reported for both vaccines. The COVID-19 vaccines can cause mild adverse effects after the first or second doses, including pain, redness or swelling at the site of vaccine shot, fever, fatigue, headache, muscle pain, nausea, vomiting, itching, chills, and joint pain, and can also rarely cause anaphylactic shock. The occurrence of adverse effects is reported to be lower in the Pfizer/BioNTech vaccine compared to the Moderna vaccine; however, the Moderna vaccine compared to the Pfizer vaccine is easier to transport and store because it is less temperature sensitive.CONCLUSIONSThe FDA has granted emergency use authorization for the Pfizer/BioNTech and Moderna COVID-19 vaccines. These vaccines can protect recipients from a SARS-CoV- 2 infection by formation of antibodies and provide immunity against a SARS-CoV-2 infection. Both vaccines can cause various adverse effects, but these reactions are reported to be less frequent in the Pfizer/BioNTech vaccine compared to the Moderna COVID-19 vaccine; however, the Moderna vaccine compared to the Pfizer vaccine is easier to transport and store because it is less temperature sensitive.

**Database:** Medline

**2. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine.**

**Author(s):** Polack, Fernando P; Thomas, Stephen J; Kitchin, Nicholas; Absalon, Judith; Gurtman, Alejandra; Lockhart, Stephen; Perez, John L; Pérez Marc, Gonzalo; Moreira, Edson D; Zerbini, Cristiano; Bailey, Ruth; Swanson, Kena A; Roychoudhury, Satrajit; Koury, Kenneth; Li, Ping; Kalina, Warren V; Cooper, David; Frenck, Robert W; Hammitt, Laura L; Türeci, Özlem; Nell, Haylene; Schaefer, Axel; Ünal, Serhat; Tresnan, Dina B; Mather, Susan; Dormitzer, Philip R; Şahin, Uğur; Jansen, Kathrin U; Gruber, William C; C4591001 Clinical Trial Group

**Source:** The New England journal of medicine; Dec 2020; vol. 383 (no. 27); p. 2603-2615

**Publication Date:** Dec 2020

**Publication Type(s):** Research Support, Non-u.s. Gov't Randomized Controlled Trial Clinical Trial, Phase Ii Multicenter Study Journal Article Clinical Trial, Phase Iii

**PubMedID:** 33301246

Available at [The New England journal of medicine](https://gateway.proquest.com/openurl?ctx_ver=Z39.88-2004&res_id=xri:pqm&req_dat=xri:pqil:pq_clntid=47856&rft_val_fmt=ori/fmt:kev:mtx:journal&genre=article&issn=0028-4793&volume=383&issue=27&spage=2603) - from ProQuest (Health Research Premium) - NHS Version

Available at [The New England journal of medicine](https://go.openathens.net/redirector/nhs?url=https%3A%2F%2Fovidsp.ovid.com%2Fovidweb.cgi%3FT%3DJS%26PAGE%3Dfulltext%26D%3Dovft%26CSC%3DY%26NEWS%3DN%26SEARCH%3D0028-4793.is%2Band%2B%22383%22.vo%2Band%2B%2227%22.ip%2Band%2B%222603%22.pg%2Bor%2B%2210.1056%2FNEJMoa2034577%22.di) - from Ovid (Journals @ Ovid)

Available at [The New England journal of medicine](http://www.uhl-library.nhs.uk/directpages/uhlblarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from non-NHS library) - click this link for more information Local Print Collection [location] : British Library via UHL Libraries - please click link to request article.

Available at [The New England journal of medicine](http://www.uhl-library.nhs.uk/directpages/uhlarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from NULJ library) - click this link for more information Local Print Collection [location] : UHL Libraries On Request (Free).

Available at [The New England journal of medicine](https://doi.org/10.1056/nejmoa2034577) - from Unpaywall

**Abstract:**BACKGROUNDSevere acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and the resulting coronavirus disease 2019 (Covid-19) have afflicted tens of millions of people in a worldwide pandemic. Safe and effective vaccines are needed urgently.METHODSIn an ongoing multinational, placebo-controlled, observer-blinded, pivotal efficacy trial, we randomly assigned persons 16 years of age or older in a 1:1 ratio to receive two doses, 21 days apart, of either placebo or the BNT162b2 vaccine candidate (30 μg per dose). BNT162b2 is a lipid nanoparticle-formulated, nucleoside-modified RNA vaccine that encodes a prefusion stabilized, membrane-anchored SARS-CoV-2 full-length spike protein. The primary end points were efficacy of the vaccine against laboratory-confirmed Covid-19 and safety.RESULTSA total of 43,548 participants underwent randomization, of whom 43,448 received injections: 21,720 with BNT162b2 and 21,728 with placebo. There were 8 cases of Covid-19 with onset at least 7 days after the second dose among participants assigned to receive BNT162b2 and 162 cases among those assigned to placebo; BNT162b2 was 95% effective in preventing Covid-19 (95% credible interval, 90.3 to 97.6). Similar vaccine efficacy (generally 90 to 100%) was observed across subgroups defined by age, sex, race, ethnicity, baseline body-mass index, and the presence of coexisting conditions. Among 10 cases of severe Covid-19 with onset after the first dose, 9 occurred in placebo recipients and 1 in a BNT162b2 recipient. The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of serious adverse events was low and was similar in the vaccine and placebo groups.CONCLUSIONSA two-dose regimen of BNT162b2 conferred 95% protection against Covid-19 in persons 16 years of age or older. Safety over a median of 2 months was similar to that of other viral vaccines. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.).

**Database:** Medline

**3. Interim Results of a Phase 1-2a Trial of Ad26.COV2.S Covid-19 Vaccine.**

**Author(s):** Sadoff, Jerald; Le Gars, Mathieu; Shukarev, Georgi; Heerwegh, Dirk; Truyers, Carla; de Groot, Anne M; Stoop, Jeroen; Tete, Sarah; Van Damme, Wim; Leroux-Roels, Isabel; Berghmans, Pieter-Jan; Kimmel, Murray; Van Damme, Pierre; de Hoon, Jan; Smith, William; Stephenson, Kathryn E; De Rosa, Stephen C; Cohen, Kristen W; McElrath, M Juliana; Cormier, Emmanuel; Scheper, Gert; Barouch, Dan H; Hendriks, Jenny; Struyf, Frank; Douoguih, Macaya; Van Hoof, Johan; Schuitemaker, Hanneke

**Source:** The New England journal of medicine; May 2021; vol. 384 (no. 19); p. 1824-1835

**Publication Date:** May 2021

**Publication Type(s):** Research Support, Non-u.s. Gov't Clinical Trial, Phase I Randomized Controlled Trial Clinical Trial, Phase Ii Multicenter Study Journal Article

**PubMedID:** 33440088

Available at [The New England journal of medicine](https://go.openathens.net/redirector/nhs?url=https%3A%2F%2Fovidsp.ovid.com%2Fovidweb.cgi%3FT%3DJS%26PAGE%3Dfulltext%26D%3Dovft%26CSC%3DY%26NEWS%3DN%26SEARCH%3D0028-4793.is%2Band%2B%22384%22.vo%2Band%2B%2219%22.ip%2Band%2B%221824%22.pg%2Bor%2B%2210.1056%2FNEJMoa2034201%22.di) - from Ovid (Journals @ Ovid)

Available at [The New England journal of medicine](http://www.uhl-library.nhs.uk/directpages/uhlblarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from non-NHS library) - click this link for more information Local Print Collection [location] : British Library via UHL Libraries - please click link to request article.

Available at [The New England journal of medicine](http://www.uhl-library.nhs.uk/directpages/uhlarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from NULJ library) - click this link for more information Local Print Collection [location] : UHL Libraries On Request (Free).

Available at [The New England journal of medicine](https://doi.org/10.1056/nejmoa2034201) - from Unpaywall

**Abstract:**BACKGROUNDEfficacious vaccines are urgently needed to contain the ongoing coronavirus disease 2019 (Covid-19) pandemic of infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). A candidate vaccine, Ad26.COV2.S, is a recombinant, replication-incompetent adenovirus serotype 26 (Ad26) vector encoding a full-length and stabilized SARS-CoV-2 spike protein.METHODSIn this multicenter, placebo-controlled, phase 1-2a trial, we randomly assigned healthy adults between the ages of 18 and 55 years (cohort 1) and those 65 years of age or older (cohort 3) to receive the Ad26.COV2.S vaccine at a dose of 5×1010 viral particles (low dose) or 1×1011 viral particles (high dose) per milliliter or placebo in a single-dose or two-dose schedule. Longer-term data comparing a single-dose regimen with a two-dose regimen are being collected in cohort 2; those results are not reported here. The primary end points were the safety and reactogenicity of each dose schedule.RESULTSAfter the administration of the first vaccine dose in 805 participants in cohorts 1 and 3 and after the second dose in cohort 1, the most frequent solicited adverse events were fatigue, headache, myalgia, and injection-site pain. The most frequent systemic adverse event was fever. Systemic adverse events were less common in cohort 3 than in cohort 1 and in those who received the low vaccine dose than in those who received the high dose. Reactogenicity was lower after the second dose. Neutralizing-antibody titers against wild-type virus were detected in 90% or more of all participants on day 29 after the first vaccine dose (geometric mean titer [GMT], 212 to 354), regardless of vaccine dose or age group, and reached 96% by day 57 with a further increase in titers (GMT, 288 to 488) in cohort 1a. Titers remained stable until at least day 71. A second dose provided an increase in the titer by a factor of 2.6 to 2.9 (GMT, 827 to 1266). Spike-binding antibody responses were similar to neutralizing-antibody responses. On day 15, CD4+ T-cell responses were detected in 76 to 83% of the participants in cohort 1 and in 60 to 67% of those in cohort 3, with a clear skewing toward type 1 helper T cells. CD8+ T-cell responses were robust overall but lower in cohort 3.CONCLUSIONSThe safety and immunogenicity profiles of Ad26.COV2.S support further development of this vaccine candidate. (Funded by Johnson & Johnson and the Biomedical Advanced Research and Development Authority of the Department of Health and Human Services; COV1001 ClinicalTrials.gov number, NCT04436276.).

**Database:** Medline

**4. 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.**

**Author(s):** Ramasamy, Maheshi N; Minassian, Angela M; Ewer, Katie J; Flaxman, Amy L; Folegatti, Pedro M; Owens, Daniel R; Voysey, Merryn; Aley, Parvinder K; Angus, Brian; Babbage, Gavin; Belij-Rammerstorfer, Sandra; Berry, Lisa; Bibi, Sagida; Bittaye, Mustapha; Cathie, Katrina; Chappell, Harry; Charlton, Sue; Cicconi, Paola; Clutterbuck, Elizabeth A; Colin-Jones, Rachel; Dold, Christina; Emary, Katherine R W; Fedosyuk, Sofiya; Fuskova, Michelle; Gbesemete, Diane; Green, Catherine; Hallis, Bassam; Hou, Mimi M; Jenkin, Daniel; Joe, Carina C D; Kelly, Elizabeth J; Kerridge, Simon; Lawrie, Alison M; Lelliott, Alice; Lwin, May N; Makinson, Rebecca; Marchevsky, Natalie G; Mujadidi, Yama; Munro, Alasdair P S; Pacurar, Mihaela; Plested, Emma; Rand, Jade; Rawlinson, Thomas; Rhead, Sarah; Robinson, Hannah; Ritchie, Adam J; Ross-Russell, Amy L; Saich, Stephen; Singh, Nisha; Smith, Catherine C; Snape, Matthew D; Song, Rinn; Tarrant, Richard; Themistocleous, Yrene; Thomas, Kelly M; Villafana, Tonya L; Warren, Sarah C; Watson, Marion E E; Douglas, Alexander D; Hill, Adrian V S; Lambe, Teresa; Gilbert, Sarah C; Faust, Saul N; Pollard, Andrew J; Oxford COVID Vaccine Trial Group

**Source:** Lancet (London, England); Dec 2021; vol. 396 (no. 10267); p. 1979-1993

**Publication Date:** Dec 2021

**Publication Type(s):** Research Support, Non-u.s. Gov't Randomized Controlled Trial Clinical Trial, Phase Ii Multicenter Study Journal Article

**PubMedID:** 33220855

Available at [Lancet (London, England)](https://gateway.proquest.com/openurl?ctx_ver=Z39.88-2004&res_id=xri:pqm&req_dat=xri:pqil:pq_clntid=47856&rft_val_fmt=ori/fmt:kev:mtx:journal&genre=article&issn=0140-6736&volume=396&issue=10267&spage=1979) - from ProQuest (Health Research Premium) - NHS Version

Available at [Lancet (London, England)](http://www.uhl-library.nhs.uk/directpages/lgh.html) - from Leicester General Hospital Library Local Print Collection [location] : Leicester General Library. [title\_notes] : Issues before 2000 held in Archive.

Available at [Lancet (London, England)](http://www.uhl-library.nhs.uk/directpages/lri.html) - from LRI Library Local Full Text Collection [location] : LRI Library.

Available at [Lancet (London, England)](http://www.uhl-library.nhs.uk/directpages/uhlblarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from non-NHS library) - click this link for more information Local Print Collection [location] : British Library via UHL Libraries - please click link to request article.

Available at [Lancet (London, England)](http://www.uhl-library.nhs.uk/directpages/uhlarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from NULJ library) - click this link for more information Local Print Collection [location] : UHL Libraries On Request (Free).

Available at [Lancet (London, England)](http://www.thelancet.com/article/S0140673620324661/pdf) - from Unpaywall

**Abstract:**BACKGROUNDOlder adults (aged ≥70 years) are at increased risk of severe disease and death if they develop COVID-19 and are therefore a priority for immunisation should an efficacious vaccine be developed. Immunogenicity of vaccines is often worse in older adults as a result of immunosenescence. We have reported the immunogenicity of a novel chimpanzee adenovirus-vectored vaccine, ChAdOx1 nCoV-19 (AZD1222), in young adults, and now describe the safety and immunogenicity of this vaccine in a wider range of participants, including adults aged 70 years and older.METHODSIn this report of the phase 2 component of a single-blind, randomised, controlled, phase 2/3 trial (COV002), healthy adults aged 18 years and older were enrolled at two UK clinical research facilities, in an age-escalation manner, into 18-55 years, 56-69 years, and 70 years and older immunogenicity subgroups. Participants were eligible if they did not have severe or uncontrolled medical comorbidities or a high frailty score (if aged ≥65 years). First, participants were recruited to a low-dose cohort, and within each age group, participants were randomly assigned to receive either intramuscular ChAdOx1 nCoV-19 (2·2 × 1010 virus particles) or a control vaccine, MenACWY, using block randomisation and stratified by age and dose group and study site, using the following ratios: in the 18-55 years group, 1:1 to either two doses of ChAdOx1 nCoV-19 or two doses of MenACWY; in the 56-69 years group, 3:1:3:1 to one dose of ChAdOx1 nCoV-19, one dose of MenACWY, two doses of ChAdOx1 nCoV-19, or two doses of MenACWY; and in the 70 years and older, 5:1:5:1 to one dose of ChAdOx1 nCoV-19, one dose of MenACWY, two doses of ChAdOx1 nCoV-19, or two doses of MenACWY. Prime-booster regimens were given 28 days apart. Participants were then recruited to the standard-dose cohort (3·5-6·5 × 1010 virus particles of ChAdOx1 nCoV-19) and the same randomisation procedures were followed, except the 18-55 years group was assigned in a 5:1 ratio to two doses of ChAdOx1 nCoV-19 or two doses of MenACWY. Participants and investigators, but not staff administering the vaccine, were masked to vaccine allocation. The specific objectives of this report were to assess the safety and humoral and cellular immunogenicity of a single-dose and two-dose schedule in adults older than 55 years. Humoral responses at baseline and after each vaccination until 1 year after the booster were assessed using an in-house standardised ELISA, a multiplex immunoassay, and a live severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) microneutralisation assay (MNA80). Cellular responses were assessed using an ex-vivo IFN-γ enzyme-linked immunospot assay. The coprimary outcomes of the trial were efficacy, as measured by the number of cases of symptomatic, virologically confirmed COVID-19, and safety, as measured by the occurrence of serious adverse events. Analyses were by group allocation in participants who received the vaccine. Here, we report the preliminary findings on safety, reactogenicity, and cellular and humoral immune responses. This study is ongoing and is registered with ClinicalTrials.gov, NCT04400838, and ISRCTN, 15281137.FINDINGSBetween May 30 and Aug 8, 2020, 560 participants were enrolled: 160 aged 18-55 years (100 assigned to ChAdOx1 nCoV-19, 60 assigned to MenACWY), 160 aged 56-69 years (120 assigned to ChAdOx1 nCoV-19: 40 assigned to MenACWY), and 240 aged 70 years and older (200 assigned to ChAdOx1 nCoV-19: 40 assigned to MenACWY). Seven participants did not receive the boost dose of their assigned two-dose regimen, one participant received the incorrect vaccine, and three were excluded from immunogenicity analyses due to incorrectly labelled samples. 280 (50%) of 552 analysable participants were female. Local and systemic reactions were more common in participants given ChAdOx1 nCoV-19 than in those given the control vaccine, and similar in nature to those previously reported (injection-site pain, feeling feverish, muscle ache, headache), but were less common in older adults (aged ≥56 years) than younger adults. In those receiving two standard doses of ChAdOx1 nCoV-19, after the prime vaccination local reactions were reported in 43 (88%) of 49 participants in the 18-55 years group, 22 (73%) of 30 in the 56-69 years group, and 30 (61%) of 49 in the 70 years and older group, and systemic reactions in 42 (86%) participants in the 18-55 years group, 23 (77%) in the 56-69 years group, and 32 (65%) in the 70 years and older group. As of Oct 26, 2020, 13 serious adverse events occurred during the study period, none of which were considered to be related to either study vaccine. In participants who received two doses of vaccine, median anti-spike SARS-CoV-2 IgG responses 28 days after the boost dose were similar across the three age cohorts (standard-dose groups: 18-55 years, 20 713 arbitrary units [AU]/mL [IQR 13 898-33 550], n=39; 56-69 years, 16 170 AU/mL [10 233-40 353], n=26; and ≥70 years 17 561 AU/mL [9705-37 796], n=47; p=0·68). Neutralising antibody titres after a boost dose were similar across all age groups (median MNA80 at day 42 in the standard-dose groups: 18-55 years, 193 [IQR 113-238], n=39; 56-69 years, 144 [119-347], n=20; and ≥70 years, 161 [73-323], n=47; p=0·40). By 14 days after the boost dose, 208 (>99%) of 209 boosted participants had neutralising antibody responses. T-cell responses peaked at day 14 after a single standard dose of ChAdOx1 nCoV-19 (18-55 years: median 1187 spot-forming cells [SFCs] per million peripheral blood mononuclear cells [IQR 841-2428], n=24; 56-69 years: 797 SFCs [383-1817], n=29; and ≥70 years: 977 SFCs [458-1914], n=48).INTERPRETATIONChAdOx1 nCoV-19 appears to be better tolerated in older adults than in younger adults and has similar immunogenicity across all age groups after a boost dose. Further assessment of the efficacy of this vaccine is warranted in all age groups and individuals with comorbidities.FUNDINGUK Research and Innovation, National Institutes for Health Research (NIHR), Coalition for Epidemic Preparedness Innovations, NIHR Oxford Biomedical Research Centre, Thames Valley and South Midlands NIHR Clinical Research Network, and AstraZeneca.

**Database:** Medline

**5. Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults.**

**Author(s):** Anderson, Evan J; Rouphael, Nadine G; Widge, Alicia T; Jackson, Lisa A; Roberts, Paul C; Makhene, Mamodikoe; Chappell, James D; Denison, Mark R; Stevens, Laura J; Pruijssers, Andrea J; McDermott, Adrian B; Flach, Britta; Lin, Bob C; Doria-Rose, Nicole A; O'Dell, Sijy; Schmidt, Stephen D; Corbett, Kizzmekia S; Swanson, Phillip A; Padilla, Marcelino; Neuzil, Kathy M; Bennett, Hamilton; Leav, Brett; Makowski, Mat; Albert, Jim; Cross, Kaitlyn; Edara, Venkata Viswanadh; Floyd, Katharine; Suthar, Mehul S; Martinez, David R; Baric, Ralph; Buchanan, Wendy; Luke, Catherine J; Phadke, Varun K; Rostad, Christina A; Ledgerwood, Julie E; Graham, Barney S; Beigel, John H; mRNA-1273 Study Group

**Source:** The New England journal of medicine; Dec 2020; vol. 383 (no. 25); p. 2427-2438

**Publication Date:** Dec 2020

**Publication Type(s):** Research Support, Non-u.s. Gov't Research Support, N.i.h., Extramural Clinical Trial, Phase I Journal Article

**PubMedID:** 32991794

Available at [The New England journal of medicine](https://gateway.proquest.com/openurl?ctx_ver=Z39.88-2004&res_id=xri:pqm&req_dat=xri:pqil:pq_clntid=47856&rft_val_fmt=ori/fmt:kev:mtx:journal&genre=article&issn=0028-4793&volume=383&issue=25&spage=2427) - from ProQuest (Health Research Premium) - NHS Version

Available at [The New England journal of medicine](https://go.openathens.net/redirector/nhs?url=https%3A%2F%2Fovidsp.ovid.com%2Fovidweb.cgi%3FT%3DJS%26PAGE%3Dfulltext%26D%3Dovft%26CSC%3DY%26NEWS%3DN%26SEARCH%3D0028-4793.is%2Band%2B%22383%22.vo%2Band%2B%2225%22.ip%2Band%2B%222427%22.pg%2Bor%2B%2210.1056%2FNEJMoa2028436%22.di) - from Ovid (Journals @ Ovid)

Available at [The New England journal of medicine](http://www.uhl-library.nhs.uk/directpages/uhlblarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from non-NHS library) - click this link for more information Local Print Collection [location] : British Library via UHL Libraries - please click link to request article.

Available at [The New England journal of medicine](http://www.uhl-library.nhs.uk/directpages/uhlarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from NULJ library) - click this link for more information Local Print Collection [location] : UHL Libraries On Request (Free).

Available at [The New England journal of medicine](https://doi.org/10.1056/nejmoa2028436) - from Unpaywall

**Abstract:**BACKGROUNDTesting of vaccine candidates to prevent infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in an older population is important, since increased incidences of illness and death from coronavirus disease 2019 (Covid-19) have been associated with an older age.METHODSWe conducted a phase 1, dose-escalation, open-label trial of a messenger RNA vaccine, mRNA-1273, which encodes the stabilized prefusion SARS-CoV-2 spike protein (S-2P) in healthy adults. The trial was expanded to include 40 older adults, who were stratified according to age (56 to 70 years or ≥71 years). All the participants were assigned sequentially to receive two doses of either 25 μg or 100 μg of vaccine administered 28 days apart.RESULTSSolicited adverse events were predominantly mild or moderate in severity and most frequently included fatigue, chills, headache, myalgia, and pain at the injection site. Such adverse events were dose-dependent and were more common after the second immunization. Binding-antibody responses increased rapidly after the first immunization. By day 57, among the participants who received the 25-μg dose, the anti-S-2P geometric mean titer (GMT) was 323,945 among those between the ages of 56 and 70 years and 1,128,391 among those who were 71 years of age or older; among the participants who received the 100-μg dose, the GMT in the two age subgroups was 1,183,066 and 3,638,522, respectively. After the second immunization, serum neutralizing activity was detected in all the participants by multiple methods. Binding- and neutralizing-antibody responses appeared to be similar to those previously reported among vaccine recipients between the ages of 18 and 55 years and were above the median of a panel of controls who had donated convalescent serum. The vaccine elicited a strong CD4 cytokine response involving type 1 helper T cells.CONCLUSIONSIn this small study involving older adults, adverse events associated with the mRNA-1273 vaccine were mainly mild or moderate. The 100-μg dose induced higher binding- and neutralizing-antibody titers than the 25-μg dose, which supports the use of the 100-μg dose in a phase 3 vaccine trial. (Funded by the National Institute of Allergy and Infectious Diseases and others; mRNA-1273 Study ClinicalTrials.gov number, NCT04283461.).

**Database:** Medline

**6. Migraine treatment and COVID-19 vaccines: No cause for concern.**

**Author(s):** Gelfand, Amy A; Poland, Gregory

**Source:** Headache; Mar 2021; vol. 61 (no. 3); p. 409-411

**Publication Date:** Mar 2021

**Publication Type(s):** Editorial

**PubMedID:** 33543775

Available at [Headache](http://www.uhl-library.nhs.uk/directpages/uhlblarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from non-NHS library) - click this link for more information Local Print Collection [location] : British Library via UHL Libraries - please click link to request article.

Available at [Headache](https://headachejournal.onlinelibrary.wiley.com/doi/pdfdirect/10.1111/head.14086) - from Unpaywall

**Database:** Medline

**7. Safety of COVID-19 vaccines administered in the EU: Should we be concerned?**

**Author(s):** Hernández, Antonio F; Calina, Daniela; Poulas, Konstantinos; Docea, Anca Oana; Tsatsakis, Aristidis M

**Source:** Toxicology reports; 2021; vol. 8 ; p. 871-879

**Publication Date:** 2021

**Publication Type(s):** Journal Article

**PubMedID:** 33898273

Available at [Toxicology reports](https://doi.org/10.1016/j.toxrep.2021.04.003) - from Unpaywall

**Abstract:**The COVID-19 pandemic has had an unprecedented and devastating impact on public health, society and economics around the world. As a result, the development of vaccines to protect individuals from symptomatic COVID-19 infections has represented the only feasible health tool to combat the spread of the disease. However, at the same time the development and regulatory assessment of different vaccines has challenged pharmaceutical industries and regulatory agencies as this process has occurred in the shorter time ever though. So far, two mRNA and two adenovirus-vectored vaccines have received a conditional marketing authorisation in the EU and other countries. This review summarized and discusses the assessment reports of the European Medicine Agency (EMA) concerning the safety of the 3 vaccines currently used in the EU (Pfizer, Moderna and Astra-Zeneca). A particular focus has been paid to safety information from pre-clinical (animal) and clinical (phase 3 trials) studies. Overall, the most frequent adverse effects reported after the administration of these vaccines consisted of local reactions at the injection site (sore arm and erythema) followed by non-specific systemic effects (myalgia, chills, fatigue, headache, and fever), which occurred soon after vaccination and resolved shortly. Rare cases of vaccine-induced immune thrombotic thrombocytopenia have been reported for Vaxzevria. Data on long-term studies, interaction with other vaccines, use in pregnancy/breast-feeding, use in immunocompromised subjects, and in subjects with comorbidities, autoimmune or inflammatory disorders are still missing for these vaccines. Therefore, careful follow-up and surveillance studies for continued vaccine safety monitoring will be needed to ascertain the potential risks of such adverse events or diseases. In conclusion, the benefits and risks of current COVID-19 vaccines must be weighed against the real possibility of contract the disease and develop complications and long-term sequels; all this on the basis of the available scientific evidence and in the absence of unmotivated biases.

**Database:** Medline

**8. Side effects of BNT162b2 mRNA COVID-19 vaccine: A randomized, cross-sectional study with detailed self-reported symptoms from healthcare workers**

**Author(s):** Kadali R.A.K.; Janagama R.; Peruru S.; Malayala S.V.

**Source:** International Journal of Infectious Diseases; May 2021; vol. 106 ; p. 376-381

**Publication Date:** May 2021

**Publication Type(s):** Article

**PubMedID:** 33866000

Available at [International journal of infectious diseases : IJID : official publication of the International Society for Infectious Diseases](http://www.uhl-library.nhs.uk/directpages/uhlblarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from non-NHS library) - click this link for more information Local Print Collection [location] : British Library via UHL Libraries - please click link to request article.

Available at [International journal of infectious diseases : IJID : official publication of the International Society for Infectious Diseases](http://www.uhl-library.nhs.uk/directpages/uhlarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from NULJ library) - click this link for more information Local Print Collection [location] : UHL Libraries On Request (Free).

Available at [International journal of infectious diseases : IJID : official publication of the International Society for Infectious Diseases](https://doi.org/10.1016/j.ijid.2021.04.047) - from Unpaywall

**Abstract:**Introduction: Concerns are prevailing about the safety and side effects of the BNT162b2 mRNA vaccine for coronavirus disease 2019 (COVID-19). Method(s): A randomized, cross-sectional study was performed to investigate the side effects of the BNT162b2 vaccine using an independent online questionnaire gathering responses from healthcare workers (HCWs) with detailed review of organ systems. Result(s): Of all HCWs, 87.98% (1245/1415) completed the survey. Of them, 64.5% (803/1245) received the BNT162b2 mRNA vaccine and reported at least one or more symptoms (classified based on organ systems and occurrence rate) post vaccination. Of these, 640/803 (79.7%) were able to continue activities of daily living (ADL), 103/803 (12.83%) had trouble temporarily to perform ADL, 99/803 (12.33%) took time off work temporarily, 20/803 (2.49%) required help from an outpatient provider, 5/803 (0.62%) required help from an emergency department and 2/803 (0.25%) required hospitalization. Despite this, 97.61% intended to have the second dose and 92.9% had already received it. Conclusion(s): Commonly reported symptoms (occurrence in descending order) were soreness, fatigue, myalgia, headache, chills, fever, joint pain, nausea, muscle spasm, sweating, dizziness, flushing, feelings of relief, brain fogging, anorexia, localized swelling, decreased sleep quality, itching, tingling, diarrhoea, nasal stuffiness and palpitations. Despite this, remarkable acceptance for the second dose of the BNT162b2 vaccine was found among HCWs.Copyright © 2021 The Author(s)

**Database:** EMBASE

**9. A preliminary report of a randomized controlled phase 2 trial of the safety and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine**

**Author(s):** Chu L.; McPhee R.; Huang W.; Bennett H.; Pajon R.; Nestorova B.; Leav B.

**Source:** Vaccine; May 2021; vol. 39 (no. 20); p. 2791-2799

**Publication Date:** May 2021

**Publication Type(s):** Article

**PubMedID:** 33707061

Available at [Vaccine](http://www.uhl-library.nhs.uk/directpages/uhlblarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from non-NHS library) - click this link for more information Local Print Collection [location] : British Library via UHL Libraries - please click link to request article.

Available at [Vaccine](http://www.uhl-library.nhs.uk/directpages/uhlarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from NULJ library) - click this link for more information Local Print Collection [location] : UHL Libraries On Request (Free).

Available at [Vaccine](https://doi.org/10.1016/j.vaccine.2021.02.007) - from Unpaywall

**Abstract:**Background: Vaccines are urgently needed to prevent the global spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). We assessed the safety and immunogenicity of vaccine candidate mRNA-1273, encoding the prefusion-stabilized spike protein of SARS-CoV-2. Method(s): This phase 2, randomized, observer-blind, placebo-controlled trial was conducted at 8 sites in the USA, in healthy adults aged >=18 years with no known history or risk of SARS-CoV-2 infection, and had not previously received an investigational CoV vaccine or treatment. Participants were stratified into two age cohorts (>=18-<55 and >=55) and were randomly assigned (1:1:1) to either 50 or 100 microg of mRNA-1273, or placebo administered as two intramuscular injections 28 days apart. The primary outcomes were safety, reactogenicity, and immunogenicity assessed by anti-SARS-CoV-2-spike binding antibody level (bAb). Secondary outcome was immunogenicity assessed by SARS-CoV-2 neutralizing antibody (nAb) response. Result(s): Between 29 May and 8 July 2020, 600 participants were randomized, 300 per age cohort. The most common solicited adverse reactions were pain at injection site, headache, and fatigue following each vaccination in both age cohorts. One serious adverse event deemed unrelated by the site investigator occurred 33 days post-vaccination one. mRNA-1273 induced bAb and nAb by 28 days post-vaccination one that were higher at the 100 microg dose relative to the 50 microg dose; this difference was less apparent post-vaccination two. Binding antibodies and nAb increased substantially by 14 days following the second vaccination (day 43) to levels exceeding those of convalescent sera and remained elevated through day 57. Conclusion(s): Vaccination with mRNA-1273 resulted in significant immune responses to SARS-CoV-2 in participants 18 years and older, with an acceptable safety profile, confirming the safety and immunogenicity of 50 and 100 microg mRNA-1273 given as a 2 dose-regimen. ClinicalTrials.gov; NCT04405076.Copyright © 2021 Moderna Therapeutics

**Database:** EMBASE

**10. Development and implementation of a potential coronavirus disease 2019 (COVID-19) vaccine: A systematic review and meta-analysis of vaccine clinical trials**

**Author(s):** Sathian B.; Al Hamad H.; Asim M.; Mancha M.A.; Mekkodathil A.A.; Banerjee I.; Roy B.; Pizarro A.B.; Van Teijlingen E.R.; Kord-Varkaneh H.; Subramanya S.H.; Do Nascimento I.J.B.; Antony N.; Menezes R.G.; Simkhada P.

**Source:** Nepal Journal of Epidemiology; Mar 2021; vol. 11 (no. 1); p. 959-982

**Publication Date:** Mar 2021

**Publication Type(s):** Review

Available at [Nepal Journal of Epidemiology](http://europepmc.org/search?query=(DOI:10.3126/nje.v11i1.36163)) - from Europe PubMed Central - Open Access

Available at [Nepal Journal of Epidemiology](https://www.nepjol.info/index.php/NJE/article/download/36163/28240) - from Unpaywall

**Abstract:**Background: To date, there is no comprehensive systematic review and meta-analysis to assess the suitability of COVID-19 vaccines for mass immunization. The current systematic review and meta-analysis was conducted to evaluate the safety and immunogenicity of novel COVID-19 vaccine candidates under clinical trial evaluation and present a contemporary update on the development and implementation of a potential vaccines. Method(s): For this study PubMed, MEDLINE, and Embase electronic databases were used to search for eligible studies on the interface between novel coronavirus and vaccine design until December 31, 2020. Result(s): We have included fourteen non-randomized and randomized controlled phase I-III trials. Implementation of a universal vaccination program with proven safety and efficacy through robust clinical evaluation is the long-term goal for preventing COVID-19. The immunization program must be cost-effective for mass production and accessibility. Despite pioneering techniques for the fast-track development of the vaccine in the current global emergency, mass production and availability of an effective COVID-19 vaccine could take some more time. Conclusion(s): Our findings suggest a revisiting of the reported solicited and unsolicited systemic adverse events for COVID-19 candidate vaccines. Hence, it is alarming to judiciously expose thousands of participants to COVID-19 candidate vaccines at Phase-3 trials that have adverse events and insufficient evidence on safety and effectiveness that necessitates further justification.Copyright © 2021 CEA & INEA.

**Database:** EMBASE

**11. Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: a double-blind, randomised, phase 1 trial**

**Author(s):** Ella R.; Vadrevu K.M.; Jogdand H.; Prasad S.; Reddy S.; Sarangi V.; Ganneru B.; Ella K.; Sapkal G.; Yadav P.; Abraham P.; Panda S.; Gupta N.; Bhargava B.; Reddy P.; Verma S.; Kumar Rai S.; Guleria R.; Singh C.; Redkar S.V.; Gillurkar C.S.; Kushwaha J.S.; Mohapatra S.; Rao V.

**Source:** The Lancet Infectious Diseases; May 2021; vol. 21 (no. 5); p. 637-646

**Publication Date:** May 2021

**Publication Type(s):** Article

**PubMedID:** 33485468

Available at [The Lancet. Infectious diseases](http://www.uhl-library.nhs.uk/directpages/uhlblarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from non-NHS library) - click this link for more information Local Print Collection [location] : British Library via UHL Libraries - please click link to request article.

Available at [The Lancet. Infectious diseases](http://www.uhl-library.nhs.uk/directpages/uhlarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from NULJ library) - click this link for more information Local Print Collection [location] : UHL Libraries On Request (Free).

Available at [The Lancet. Infectious diseases](http://www.thelancet.com/article/S1473309920309427/pdf) - from Unpaywall

**Abstract:**Background: To mitigate the effects of COVID-19, a vaccine is urgently needed. BBV152 is a whole-virion inactivated SARS-CoV-2 vaccine formulated with a toll-like receptor 7/8 agonist molecule adsorbed to alum (Algel-IMDG) or alum (Algel). Method(s): We did a double-blind, multicentre, randomised, controlled phase 1 trial to assess the safety and immunogenicity of BBV152 at 11 hospitals across India. Healthy adults aged 18-55 years who were deemed healthy by the investigator were eligible. Individuals with positive SARS-CoV-2 nucleic acid and/or serology tests were excluded. Participants were randomly assigned to receive either one of three vaccine formulations (3 mug with Algel-IMDG, 6 mug with Algel-IMDG, or 6 mug with Algel) or an Algel only control vaccine group. Block randomisation was done with a web response platform. Participants and investigators were masked to treatment group allocation. Two intramuscular doses of vaccines were administered on day 0 (the day of randomisation) and day 14. Primary outcomes were solicited local and systemic reactogenicity events at 2 h and 7 days after vaccination and throughout the full study duration, including serious adverse events. Secondary outcome was seroconversion (at least four-fold increase from baseline) based on wild-type virus neutralisation. Cell-mediated responses were evaluated by intracellular staining and ELISpot. The trial is registered at ClinicalTrials.gov (NCT04471519). Finding(s): Between July 13 and 30, 2020, 827 participants were screened, of whom 375 were enrolled. Among the enrolled participants, 100 each were randomly assigned to the three vaccine groups, and 75 were randomly assigned to the control group (Algel only). After both doses, solicited local and systemic adverse reactions were reported by 17 (17%; 95% CI 10.5-26.1) participants in the 3 mug with Algel-IMDG group, 21 (21%; 13.8-30.5) in the 6 mug with Algel-IMDG group, 14 (14%; 8.1-22.7) in the 6 mug with Algel group, and ten (10%; 6.9-23.6) in the Algel-only group. The most common solicited adverse events were injection site pain (17 [5%] of 375 participants), headache (13 [3%]), fatigue (11 [3%]), fever (nine [2%]), and nausea or vomiting (seven [2%]). All solicited adverse events were mild (43 [69%] of 62) or moderate (19 [31%]) and were more frequent after the first dose. One serious adverse event of viral pneumonitis was reported in the 6 mug with Algel group, unrelated to the vaccine. Seroconversion rates (%) were 87.9, 91.9, and 82.8 in the 3 mug with Algel-IMDG, 6 mug with Algel-IMDG, and 6 mug with Algel groups, respectively. CD4+ and CD8+ T-cell responses were detected in a subset of 16 participants from both Algel-IMDG groups. Interpretation(s): BBV152 led to tolerable safety outcomes and enhanced immune responses. Both Algel-IMDG formulations were selected for phase 2 immunogenicity trials. Further efficacy trials are warranted. Funding(s): Bharat Biotech International.Copyright © 2021 Elsevier Ltd

**Database:** EMBASE

**12. Point of view on the vaccination against COVID-19 in patients with autoimmune inflammatory rheumatic diseases**

**Author(s):** Furer V.; Paran D.; Elkayam O.; Agmon-Levin N.; Rondaan C.; Van Assen S.; Bijl M.; Kapetanovic M.C.; De Thurah A.; Mueller-Ladner U.; Schreiber K.; Warnatz K.; Wulffraat N.M.

**Source:** RMD Open; Feb 2021; vol. 7 (no. 1)

**Publication Date:** Feb 2021

**Publication Type(s):** Review

**PubMedID:** 33627440

Available at [RMD open](http://europepmc.org/search?query=(DOI:10.1136/rmdopen-2021-001594)) - from Europe PubMed Central - Open Access

Available at [RMD open](https://doi.org/10.1136/rmdopen-2021-001594) - from HighWire - Free Full Text

Available at [RMD open](https://gateway.proquest.com/openurl?ctx_ver=Z39.88-2004&res_id=xri:pqm&req_dat=xri:pqil:pq_clntid=47856&rft_val_fmt=ori/fmt:kev:mtx:journal&genre=article&issn=2056-5933&volume=7&issue=1&spage=e001594) - from ProQuest (Health Research Premium) - NHS Version

Available at [RMD open](https://rmdopen.bmj.com/content/rmdopen/7/1/e001594.full.pdf) - from Unpaywall

**Abstract:**In view of the COVID-19 pandemic, there is an unmet clinical need for the guidelines on vaccination of patients with autoimmune inflammatory rheumatic diseases (AIIRD). This position paper summarises the current data on COVID-19 infection in patients with AIIRD and development of vaccines against COVID-19, discusses the aspects of efficacy and safety of vaccination, and proposes preliminary considerations on vaccination against COVID-19 in patients with AIIRD, mainly based on the expert opinion and knowledge on the use of other vaccines in this population of patients.Copyright ©

**Database:** EMBASE

**13. First Month of COVID-19 Vaccine Safety Monitoring - United States, December 14, 2020-January 13, 2021**

**Author(s):** Gee J.; Marquez P.; Su J.; Calvert G.M.; Liu R.; Myers T.; Nair N.; Martin S.; Clark T.; Markowitz L.; Lindsey N.; Zhang B.; Licata C.; Jazwa A.; Sotir M.; Shimabukuro T.

**Source:** MMWR. Morbidity and mortality weekly report; Feb 2021; vol. 70 (no. 8); p. 283-288

**Publication Date:** Feb 2021

**Publication Type(s):** Article

**PubMedID:** 33630816

Available at [MMWR. Morbidity and mortality weekly report](https://search.ebscohost.com/login.aspx?direct=true&scope=site&site=ehost-live&db=mdc&AN=33630816) - from EBSCO (MEDLINE Complete)

Available at [MMWR. Morbidity and mortality weekly report](https://gateway.proquest.com/openurl?ctx_ver=Z39.88-2004&res_id=xri:pqm&req_dat=xri:pqil:pq_clntid=47856&rft_val_fmt=ori/fmt:kev:mtx:journal&genre=article&issn=0149-2195&volume=70&issue=8&spage=283) - from ProQuest (Health Research Premium) - NHS Version

Available at [MMWR. Morbidity and mortality weekly report](http://www.uhl-library.nhs.uk/directpages/uhlblarticles.html) - from Available to NHS staff on request from UHL Libraries & Information Services (from non-NHS library) - click this link for more information Local Print Collection [location] : British Library via UHL Libraries - please click link to request article.

Available at [MMWR. Morbidity and mortality weekly report](https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7008e3-H.pdf) - from Unpaywall

**Abstract:**Two coronavirus disease 2019 (COVID-19) vaccines are currently authorized for use in the United States. The Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020, and for the Moderna COVID-19 vaccine on December 18, 2020; each is administered as a 2-dose series. The Advisory Committee on Immunization Practices issued interim recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines on December 12, 2020 (1), and December 19, 2020 (2), respectively; initial doses were recommended for health care personnel and long-term care facility (LTCF) residents (3). Safety monitoring for these vaccines has been the most intense and comprehensive in U.S. history, using the Vaccine Adverse Event Reporting System (VAERS), a spontaneous reporting system, and v-safe,\* an active surveillance system, during the initial implementation phases of the COVID-19 national vaccination program (4). CDC conducted descriptive analyses of safety data from the first month of vaccination (December 14, 2020-January 13, 2021). During this period, 13,794,904 vaccine doses were administered, and VAERS received and processed+ 6,994 reports of adverse events after vaccination, including 6,354 (90.8%) that were classified as nonserious and 640 (9.2%) as serious. The symptoms most frequently reported to VAERS were headache (22.4%), fatigue (16.5%), and dizziness (16.5%). A total of 113 deaths were reported to VAERS, including 78 (65%) among LTCF residents; available information from death certificates, autopsy reports, medical records, and clinical descriptions from VAERS reports and health care providers did not suggest any causal relationship between COVID-19 vaccination and death. Rare cases of anaphylaxis after receipt of both vaccines were reported (4.5 reported cases per million doses administered). Among persons who received Pfizer-BioNTech vaccine, reactions reported to the v-safe system were more frequent after receipt of the second dose than after the first. The initial postauthorization safety profiles of the two COVID-19 vaccines in current use did not indicate evidence of unexpected serious adverse events. These data provide reassurance and helpful information regarding what health care providers and vaccine recipients might expect after vaccination.

**Database:** EMBASE

Strategy 1034183

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| 26 | EMBASE | ((pfizer OR biontech) ADJ2 vaccin\*).ti,ab | 141 |
| 27 | EMBASE | (BNT162b2 mRNA).ti,ab | 71 |
| 28 | EMBASE | (mRNA-1273 OR (moderna ADJ2 vaccin\*)).ti,ab | 112 |
| 29 | EMBASE | "Ad26.COV2.S" | 59 |
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