COVID-19

# CONSOLIDATED REGIONAL AND GLOBAL INFORMATION ON ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) AGAINST COVID-19 AND OTHER UPDATES

Fourteenth report

WASHINGTON, DC
Updated: 20 May 2021

## ARGENTINA

- As of 9 April 2021, a total of 5,493,153 doses of COVID-19 vaccines had been administered: 3,414,158 doses of the Sputnik V, 1,295,940 doses of Sinopharm, 195,239 doses of the AstraZeneca vaccine, and 587,816 doses of the Covishield/AstraZeneca vaccine produced by the Serum Institute of India. A total of 29,232 adverse events following immunization (AEFI) were reported.
- More than 99% of AEFI (28,952) were mild or moderate, while 280 (0.95%) required hospitalization. There were six reports of anaphylaxis following administration of the vaccine: five events with the Sputnik V vaccine and one with the Sinopharm vaccine.
- Most of the events consisted of fever, headache, myalgia, and arthralgia.
- There were two reported cases of immune thrombocytopenia and two cases of Guillain Barre syndrome, which were classified as events related to the Sputnik V vaccine. Two cases of anaphylaxis were reported in connection with the Sputnik V vaccine, and one in connection with the Sinopharm vaccine.

Link: https://bancos.salud.gob.ar/recurso/10deg-informe-de-seguridad-en-vacunas

## CANADA

- As of 14 May 2021, 17,734,322 doses of COVID-19 vaccines of Pfizer-BioNTech, Moderna, AstraZeneca, and Covishield (AstraZeneca vaccine produced by the Serum Institute of India) had been administered.
- A total of 5,488 individual reports of one or more adverse events (0.031% of doses administered) were received. Of these, 977 were considered serious events (0.006% of doses administered), with anaphylaxis being the most frequently reported.
- Of the total reports, there were 2,418 non-serious events and 644 serious events associated with the Pfizer-BioNTech vaccine. For the Moderna vaccine, there were 1,658 reports of non-serious events and 124 reports of serious events. For the Covishield/AstraZeneca vaccine, there were 427 reports of non-serious events and 179 reports of serious events. In addition, there were 30 reports of serious events for which the maker was not specified.
- A total of 13,882 AEFI were reported (5,488 with one or more events). The most frequently reported adverse events were injection-site reactions, paresthesia, itching, hives, headache, hypoesthesia, and nausea. Sixty-two cases of anaphylaxis were reported.
- While 48.5% of vaccine doses had been administered to women and 41.5% to men as of 14 May, the majority of adverse events reported (83%) were in women. Of total adverse events reported, 40.2% were in individuals between the ages of 18 and 49 (representing 27.6% of people vaccinated).

- As of 14 May, there were 22 reports of thrombosis with thrombocytopenia syndrome (TTS) following vaccination with the Covishield/AstraZeneca vaccine. Symptoms, which appeared between 3 and 24 days after vaccination, occurred in 9 women (ages 40 to 72) and 12 men (ages 34 to 73), and in one reported case the sex of the individual was not identified.
- A total of 72 reported cases of adverse events resulted in post-vaccination deaths. Following a medical review, it was determined that 25 of these deaths were not linked to administration of the COVID-19 vaccine, while 39 deaths are still under investigation. Three deaths were potentially attributable to vaccination (cases of thrombosis with thrombocytopenia syndrome), and in the case of five deaths, the cause could not be classified, due to insufficient information.

Source: https://health-infobase.canada.ca/covid-19/vaccine-safety/

## CARIBBEAN COMMUNITY (CARICOM)

- As of 23 April 2021, 304 cases of AEFI involving COVID-19 vaccines had been reported to VigiBase, the World Health Organization's Global Database of Individual Case Safety Reports (ICSRs).
- The countries that reported were Barbados (65.1% of reports), Jamaica (34.2%), and Saint Vincent and the Grenadines (0.7%), with the majority of reports (85%) coming from people under the age of 65, and 77.3% (235 reports) from women. The most frequently reported reactions were headache (48.7%), fever (38.5%), chills (34.5%), fatigue (30.3%), and myalgia (29.6%). Sixteen reported cases (5.3%), were classified as serious, including one death, and occurred after administration of the Oxford-AstraZeneca vaccine (ChAdOx1-S).
- This summary presents AEFI data involving COVID-19 vaccines reported as ICSRs to VigiBase; thus, the information provided is for descriptive purposes only, as some of the ICSRs may not have been clinically examined, and any assessment of an association between COVID-19 vaccines and an increased risk of a given outcome requires additional information.

Source: https://carpha.org/Portals/0/Documents/VigiCarib%20News/VigiCarib%20News%20April%202021.pdf

## UNITED STATES

- Nearly 273 million doses of vaccine were administered between 14 December 2020 and 17 May 2021.
- Cases of anaphylaxis following COVID-19 vaccination remain very rare, with approximately two to five cases per million people vaccinated in the United States. When this occurs, it is around 30 minutes after vaccination, and is effectively and immediately treatable.
- As of 18 May, 9.6 million doses of J&J/Janssen COVID-19 vaccine had been administered, with 30 reports of post-vaccination thrombosis with thrombocytopenia syndrome. However, results of the analysis conducted indicate that the benefits of the vaccine outweigh the known and potential risks.
- The Vaccine Adverse Event Reporting System (VAERS) received 4,647 reports of deaths among vaccinated individuals (0.0017% of people vaccinated); tests failed to establish that any of these deaths were linked to

vaccination. However, there are recent reports indicating the possibility of a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS deaths. The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) continue to investigate reports of these adverse reactions, including deaths, that have been reported to VAERS.

Source: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

## MEXICO

- As of 19 May 2021, a total of 24,223,297 doses of Pfizer-BioNTech, AstraZeneca, CanSino, Sinovac, and Sputnik V vaccines had been administered.
- As of 15 May, with 22,869,482 doses administered, 18,376 cases of AEFI (0.1% of doses administered) had been reported, of which 14,782 were associated with the Pfizer-BioNTech vaccine, 1,660 with the AstraZeneca vaccine, 925 with Sinovac, 293 with Sputnik V, and 700 with the CanSino vaccine.
- A total of 341 serious events were reported, representing 1.9% of total events reported. Of these serious events, 145 occurred with the Pfizer-BioNTech vaccine, 80 with the AstraZeneca vaccine, 67 with Sinovac, 11 with Sputnik V, and 35 with the CanSino vaccine. Of these, 189 occurred in women and 152 in men.

Source: https://www.gob.mx/salud/prensa/version-estenografica-conferencia-de-prensa-informe-diario-sobre-coronavirus-covid-19-en-mexico-272585

## UNITED KINGDOM

- As of 12 May 2021, an estimated 11.7 million first doses and 9.9 million second doses of the Pfizer/BioNTech vaccine, 23.9 million first doses and 9.0 million second doses of the Oxford-AstraZeneca vaccine, and 0.2 million doses of the Moderna vaccine had been administered in the United Kingdom.
- As of 12 May 2021, there were 58,065 yellow card reports for the Pfizer/BioNTech vaccine, 175,057 for the Oxford-AstraZeneca vaccine, 1,462 for the Moderna vaccine, and 639 for which the maker was not specified. For vaccines from Pfizer, AstraZeneca, and Moderna, the reporting rate was approximately three to six yellow cards per 1,000 doses administered. To be clear, yellow card data cannot be used to draw conclusions on rates of adverse events, or to compare the safety profile of different vaccines, as more information is required.
- For all vaccines, the vast majority of reports were related to injection-site reactions (arm pain) or general symptoms such as headache, chills, fatigue, nausea, fever, weakness, muscle pain, tachycardia, and flu-like symptoms. These events usually occur close to the time of vaccination and are not associated with more serious or longer-lasting events.
- With regard to cases of anaphylaxis (severe allergic reactions), the Medicines and Healthcare products Regulatory Agency (MHRA) has received 296 spontaneous reports of these adverse events for the Pfizer/BioNTech vaccine.

- For the AstraZeneca vaccine, 643 spontaneous reports of adverse events associated with anaphylaxis or anaphylactic reactions have been reported. Although these events are very rare, the product information has been updated to reflect the fact that cases of anaphylaxis have been reported for the vaccine.
- With regard to cases of Bell's palsy (facial paralysis), the MHRA continues to review reports and compare these against cases that would occur randomly if there were no vaccination (baseline rate). The number of cases reported to date is similar to the baseline rate, and there is no indication that this will increase with vaccination. These events continue to be monitored.
- With regard to thromboembolic events with thrombocytopenia, the MHRA received 309 yellow card reports of these events following administration of the AstraZeneca vaccine (169 in women and 138 in men), with a mortality rate of 18% (56 deaths). There were 116 reports of cerebral venous sinus thrombosis, and 193 reports involving other major thromboembolic events with concurrent thrombocytopenia. Cases of this event after the first dose have a reporting frequency of 12.3 per million doses administered, with indications of a higher rate in young adults. However, based on ongoing data, officials continue to point out that the benefits of the vaccine outweigh the risks for the majority of the population.
- Six cases of capillary leak syndrome (a condition in which blood leaks from small blood vessels to the body) have been reported, out of more than 30 million doses of AstraZeneca vaccine administered. Current evidence does not suggest a causal relationship between this syndrome and the vaccine.

Link: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

## GACVS Statement on Safety Signals with Johnson&Johnson/Janssen COVID-19 vaccine

The COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) met virtually on 11 May 2021 to review available data on thromboembolic events (blood clots) and thrombocytopenia (low platelet levels) following administration of the Johnson & Johnson adenoviral vector vaccine. The data were from stimulated passive surveillance and a small active surveillance cohort of J&J COVID-19 vaccine recipients in the United States, where more than eight million doses had been administered as of 7 May 2021.

Current evidence suggests a plausible causal association between the Johnson & Johnson COVID-19 vaccine and thrombosis with thrombocytopenia syndrome (TTS), for which the clinical characteristics appear to be similar to those seen with the AstraZeneca COVID-19 vaccine. The exact mechanism by which this rare condition occurs is not yet fully understood, and to date the only possible risk factors identified are age and sex (with more cases reported in women than in men). TTS does not appear to be associated with mRNA COVID-19 vaccines.

After a review of the available data, the GACVS COVID-19 subcommittee issued the following conclusions and recommendations:

- The benefits of the Johnson & Johnson COVID-19 vaccine continue to outweigh the risks of TTS. As it is the only single-dose COVID-19 vaccine approved for use to date, this vaccine could be important for hard-to-reach populations.
- As of 7 May 2021, the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) had reviewed 28 reports of TTS out of a total of more than 8 million vaccines administered. TTS was reported in individuals ages 18 to 59 (median age 40) and occurred between 3 and 15 days (a median of 9 days) after administration of the vaccine.
- Although most cases of TTS have involved thrombosis in unusual locations, including cerebral venous sinuses, portal veins, splenic veins, and other rare venous and arterial thromboses, cases involving thrombosis at more common locations, such as deep vein thrombosis and pulmonary embolism, have also been identified in the United States.
- When formulating immunization policies, the risk of TTS from use of the Johnson & Johnson COVID-19 vaccine should be weighed against the benefits. Countries assessing the risk of TTS following COVID-19 vaccination should conduct a risk-benefit analysis that takes into account local epidemiology (including incidence and mortality from COVID-19 disease), the age groups being targeted for vaccination, and the availability of alternative vaccines.
- The appropriate information should be provided to health professionals and people who are vaccinated, to recognize the signs and symptoms of all serious adverse events following vaccination with all COVID-19

vaccines, so that people can seek and receive timely and relevant medical care and treatment. Early identification of TTS is important so that the appropriate treatment can be initiated.

- Doctors should watch for any new, severe, and persistent headaches or other major symptoms, such as severe abdominal pain and shortness of breath, that begin four to 20 days after administration of adenovirus-based COVID-19 vaccines.
- At a minimum, countries should encourage physicians to measure platelet levels and conduct appropriate investigation of potential thrombosis. Doctors should also be aware that although heparin is generally used to treat blood clots, administering heparin in TTS can be dangerous, and alternative treatments, such as immunoglobulins and heparin-free anticoagulants, should be considered.
- It is recommended that countries continue to monitor the safety of all vaccines against COVID-19 and promote the reporting of suspected adverse events. In particular, any blood clots that occur after administration of any of the COVID-19 vaccines should be reported.
- Ongoing assessment and review of cases of TTS should therefore include all vaccines that use adenoviral vector platforms.

The GACVS COVID-19 subcommittee will continue to review safety data for all COVID-19 vaccines and, when necessary, update its recommendations. The WHO COVID-19 vaccine safety surveillance manual provides guidance to countries on monitoring safety and exchanging data on adverse events associated with new COVID-19 vaccines. Available at: https://www.who.int/publications/i/item/10665338400.

Source: https://www.who.int/news/item/19-05-2021-statement-gacvs-safety-johnson-johnson-janssen-covid-19-vaccine

### Recommendations on the use of COVID-19 vaccines during pregnancy

On 7 May 2021, Chile's Institute of Public Health (ISP) published the technical report "SARS-CoV-2 vaccines and their use during pregnancy." The Institute's Pharmacovigilance division has been conducting a benefits/risks analysis of using COVID-19 vaccines during pregnancy, based on national and international evidence. The following recommendations were issued:

- The vaccine should be given to pregnant women who are at high risk of SARS-CoV-2 infection, or who suffer from chronic diseases that increase their risk of contracting severe COVID-19.
- Starting from the second trimester of gestation, vaccination against SARS-CoV-2 should be considered.
- mRNA-based vaccines, or inactivated vaccines (Pfizer/BioNTech and Sinovac, which have been authorized in Chile), should be considered as the only options for pregnant women.

- Pregnant women who are vaccinated must sign an informed consent that indicates the benefits and potential risks of vaccination, given the limited evidence on its safety and efficacy in this group and on the risks of acquiring SARS-CoV-2 infection during the gestation period.

On 11 May 2021, Brazil's National Health Surveillance Agency (ANVISA) issued a statement recommending that the Ministry of Health suspend vaccination of pregnant women with the Oxford/AstraZeneca/Fiocruz COVID-19 vaccine, after receiving a report of a suspected case of thrombosis with thrombocytopenia in a pregnant woman following administration of the Oxford/AstraZeneca/Fiocruz vaccine. The recommendation was issued as a precautionary measure, and in light of the lack of available data, to date, on the safety of using the vaccine in pregnant women. ANVISA recommends continuing administration of the Oxford/AstraZeneca/Fiocruz vaccine as indicated in the package insert, since, to date, the benefits outweigh the risks and since it is effective in preventing hospitalizations and deaths from COVID-19.

Sources: Chile: https://www.ispch.cl/alerta/

Brazil: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2021/comunicado-suspensao-da-vacina-da-astrazeneca-para-gestantes/comunicado_ggmon_005_2021.pdf

## Efficacy of mRNA vaccines against the B.1.617 variant

A group of researchers at Emory University (Atlanta, Georgia) determined the neutralizing capacity of 25 samples of blood serum from individuals who had previously been vaccinated with the Pfizer or Moderna Covid-19 vaccine against the B.1.617.1 sublineage, originally identified in India.

According to the researchers, preliminary results seem to suggest that the antibodies generated by these vaccines are able to neutralize the B.1.617.1 variant—but seven times weaker than they neutralized the strain of coronavirus that first circulated during the pandemic.

They also point out that serum samples from people who have been vaccinated at different times in the past should be analyzed, in order to gain a clearer view of the protection conferred.

This information was excerpted from a preliminary article, which has not yet been peer-reviewed.

Source: COVID vaccines can block variant hitting Asia, lab study finds. Nature. 17 May 2021. doi: https://doi.org/10.1038/d41586-021-01329-9.

## Vaccine candidates and platforms in various phases of clinical research as of 14 May 2021

Below is a summary of the number of vaccines under clinical evaluation, broken down by type or platform.

| Platform | Description | Vaccine candidates | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Phase 1 | Phase 1/2 | Phase 2 | Phase 2/3 | Phase 3 | Phase 4 | Total | With EUL or EUA |
| RP | Recombinant protein | 8 | 11 | 4 | 2 | 6 | 0 | 31 | 0 |
| NRVV | Non-replicating viral vector | 7 | 2 | 0 | 1 | 3 | 1 | 14 | 4 |
| DNA | DNA | 4 | 3 | 0 | 2 | 1 | 0 | 10 | 0 |
| IV | Inactivated virus | 4 | 2 | 1 | 1 | 7 | 1 | 16 | 3 |
| RNA | RNA | 7 | 3 | 2 | 0 | 2 | 2 | 16 | 2 |
| RVV | Replicating viral vector | 0 | 2 | 1 | 0 | 0 | 0 | 3 | 0 |
| VLPs | Virus-like particles | 2 | 2 | 0 | 1 | 0 | 0 | 5 | 0 |
| LAV | Live attenuated virus | 2 | 0 | 0 | 0 | 0 | 0 | 2 | 0 |
| RVV+APC | RVV + antigen-presenting cell | 1 | 1 | 0 | 0 | 0 | 0 | 2 | 0 |
| NRVV+APC | NRVV + antigen-presenting cell | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 |
| Total | | 35 | 27 | 8 | 7 | 19 | 4 | 100 | 9 |

Source: Draft landscape and tracker of COVID-19 candidate vaccines. 14 May 2021. Available at: https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

EUL: Emergency Use Listing; EUA: Emergency Use Authorization

## Immune response and postponement of second dose of Pfizer COVID-19 vaccine

In late 2020, faced with limited vaccine supplies, the UK initiated a study to determine the impact of delaying the second dose of the COVID-19 vaccine, in an attempt to maximize the number of people who would be at least partially protected from hospitalization and death from SARS-CoV-2.

Epidemiologists at Public Health England, in London, recently noted that the study suggests that delaying the second dose of the Pfizer-BioNTech mRNA vaccine could increase the antibody response more than threefold in people over the age of 80. The study included 175 individuals over the age of 80 who received their second dose of Pfizer vaccine at either three weeks or 11 to 12 weeks after the first dose. Subsequently, they measured antibodies against the SARS-CoV-2 peak protein and evaluated the T-cell response. Peak antibody levels were 3.5 times higher in people who received the second dose at 12 weeks compared to people who received it at three weeks. In contrast, the maximum T cell response was lower in individuals with the longer interval before administration of the second dose, but this did not cause antibody levels to drop more rapidly during the nine weeks following the second dose of vaccine.

The chair of the WHO Strategic Advisory Group of Experts on Immunization pointed out that the results are specific to the Pfizer vaccine, which is not available in many low- to middle-income countries, and that countries should

consider whether variants circulating in their particular region could increase the risk of infection after a single dose of vaccine.

Source: Delaying a COVID vaccine's second dose boosts immune response. Nature. 13 May 2021 doi: https://doi.org/10.1038/d41586-021-01299-y

## ANVISA conducted research on the number of doses in multidose vials of the CoronaVac vaccine

On 17 May 2021, Brazil's National Health Surveillance Agency (ANVISA) reported that it had conducted research related to reports of a possible reduction in the number of doses in vials of the CoronaVac vaccine.

ANVISA concluded that there was no technical failure in how the vials were filled and that they contained 10 doses of CoronaVac vaccine. In addition, they reported that the problem was related to errors in extracting doses from the multidose vial, due mainly to the use of inappropriate syringes. According to the technical assessment by ANVISA, the use of 3-mL syringes would not be the most suitable for extracting the 0.5-mL doses of vaccine. It also indicated that 1-mL syringes, which are more precise for extracting each dose, should be used.

Source: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2021/anvisa-conclui-avaliacao-sobre-quantidade-de-doses-em-frascos-de-vacina

## Vaccination in Cuba

The official report on vaccination in Cuba, presented at the 74th World Health Assembly, indicates that five vaccine candidates have been developed in the country and are in phases I, II, and III of clinical trials. Based on positive results, vaccination was initiated in at-risk groups and territories for more than one million people, who received at least one dose of the vaccine candidates Sovereign 02 or Abdala.

Link: https://salud.msp.gob.cu/intervencion-del-doctor-jose-angel-portal-miranda-ministro-de-salud-publica-de-cuba-en-la-74a-asamblea-mundial-de-la-salud/

## 3 CLARIFICATIONS/CONCLUSIONS ON THE EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS

At present there are no additional updates to the most recent bulletin on conclusive analyses of AEFI.

### International nonproprietary name for the Moderna COVID-19 vaccine

WHO has assigned the Moderna COVID-19 vaccine (mRNA 1273) the name "elasomeran," as an international nonproprietary name, or INN. This vaccine was added to the EUL (Emergency Use Listing) on 30 April 2021.

Sources:

https://www.who.int/publications/m/item/34th-who-regulatory-update-on-covid-19

https://extranet.who.int/pqweb/vaccines/covid-19-mrna-vaccine-nucleoside-modified

# Annex 1. Available vaccine efficacy data (last updated May 14, 2021)

| | Symptomatic disease: any | Severe disease: any | Symptomatic disease:D614G | | Infection: D614G | | Asymptomatic: any | Asymptomatic: B.1.1.7 | Severe disease: D614G | | Infection: B.1.1.7 | Symptomatic disease: B.1.1.7 | Severe disease: B.1.1.7 | Infection: B.1.351 | Symptomatic disease: B.1.351 | Severe disease: B.1.351 | Symptomatic disease: P.1 | Severe disease: P.1 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Vaccine** | **Complete regimen** | **Complete regimen** | **1st dose** | **Complete regimen** | **1st dose** | **Complete regimen** | **Complete regimen** | **Complete regimen** | **1st dose** | **Complete regimen** | **Complete regimen** | **Complete regimen** | **Complete regimen** | **Complete regimen** | **Complete regimen** | **Complete regimen** | **Complete regimen** | **Complete regimen** | **Notes** | **Source** |
| **Pfizer-BioNTech** | | Israel national: 97.5% (97.1% to 97-8%) | Trial (Day 0-21): 52% (29.5% to 68.4%)<br>Israel SHEBA (Day 15-28): 85% (71% to 92%)<br>Israel CLALIT (Day 14-20): 57% (50% to 63%)<br>Israel Maccabi (Day 13-24): 51.4% (-7.2% to 78.0%)<br>England (Day 28+, 80+ yrs): 57% (48% to 63%) | Trial (original): 94.6% (90.3% to 97.6%)<br>Trial (updated): 91.3% (89.0% to 93.2%)<br>Israel CLALIT: 94% (87 to 98%)[]<br>England (80+ yrs): 88% (84% to 90%) | UK SIREN (Day 21+): 72% (58% to 86%)<br>Israel SHEBA (Day 15-28): 75% (72% to 84%)<br>Israel CLALIT (Day 14-20): 46% (40% to 51%) | UK SIREN: 86% (76% to 97%)<br>Israel CLALIT: 92% (88 to 95%) | | Israel National: 91.5% (90.7% to 92-2%) | Trial: 100% (-52% to 100%)<br>Israel CLALIT (Day 14-21): 62% (39% to 80%) | Trial: 75% (-152.6% to 99.5%)<br>Israel CLALIT: 92% (75% to 100%) | Qatar: 89.5% (85.9% to 92.3%) | Israel national: 97.0% (96.7% to 97-2%) | Qatar: 100.0% (81.7% to 100.0%) | Qatar: 75% (70.5% to 78.9%) | Trial (SA): 100% (53.5% to 100.0%) | Qatar: 100.0 (73.7–100.0) | | | Trial, Israel and UK studies assumed to apply to ancestral/D614G/B.1.1.7 outcomes | www.nejm.org/doi/full/10.1056/NEJMoa2034577<br>www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00448-7/fulltext<br>www.nejm.org/doi/full/10.1056/NEJMoa2101765<br>papers.ssrn.com/sol3/papers.cfm?abstract_id=3790399<br>www.medrxiv.org/content/10.1101/2021.01.27.21250612v1<br>assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/963532/COVID-19_vaccine_effectiveness_surveillance_report_February_2021_FINAL.pdf<br>https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious<br>https://www.nejm.org/doi/full/10.1056/NEJMc2104974<br>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00947-8/fulltext |
| **Moderna** | | | | Trial: 94.1% (89.3% to 96.8%) | Trial (Day 0-21): 89.6% (85.2% to 92.6%) | | | | | Trial: 100% (NE) | | | | | | | | | Trial assumed to apply to ancestral/D614G/B.1.1.7 outcomes | www.nejm.org/doi/full/10.1056/NEJMoa2035389 |
| **Oxford-AstraZeneca** | Trial (UK, SA, Brazil): 66.7% (57.4% to 74.0%) | | | Trial (UK): 74.2% (65% to 81%) | | Trial (UK): 51.9% (42.0% to 60.1%) | | | | | | Trial (variant-specific): 74.6% (41.6% to 88.9%) | | | Trial (variant-specific): 10.4% (-76.8 to 54.8%) | | Trial (Brazil SD, non-variant-specific): 57.6% (40.7% to 69.7%) | | Variant efficacy based sequenced samples for B.1.1.7 and B.1.351 and trial location for P.1. (Brazil) | www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext<br>www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00432-3/fulltext<br>papers.ssrn.com/sol3/papers.cfm?abstract_id=3779160<br>www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-background-2021.1 |
| **Johnson & Johnson** | Trial (USA, SA, Brazil): 66.1% (55.0% to 74.8%) | | | Trial (USA): 72.0% (58.2% to 81.7%) | | | Trial (USA, SA, Brazil): 65.5% (39.9% to 81.1%) | | | Trial (USA): 85.9% (-9.4% to 99.7%) | | | | | Trial (SA): 64.0% (41.2% to 78.7%) | Trial (SA): 81.7% (46.2% to 95.4%) | Trial (Brazil): 68.1% (48.8% to 80.7%) | Trial (Brazil): 87.6% (7.8% to 99.7%) | Efficacy is based on 28+ day outcomes<br>Variant efficacy based on trial location (USA, Brazil, South Africa):<br>94.5% of sequenced samples in South Africa were B.1.351<br>69.4% of sequenced samples in Brazil were P.1<br>96.4% of sequenced samples in USA were D614G | www.fda.gov/media/146218/download<br>www.fda.gov/media/146217/download<br>www.fda.gov/media/146219/download |
| **Novavax** | | | | Trial (UK): 89.3% (75.2% to 95.4%) | | | | | | | | Trial (variant-specific): 86% (59.2% to 95.0%) | | | Trial (SA): 51.0% (-0.6% to 76.2%) | | | | 92.7% of sequenced samples in South Africa were B.1.351 | ir.novavax.com/static-files/2f6f14cb-3205-4719-b28c-1711793b9782<br>https://www.nejm.org/doi/full/10.1056/NEJMoa2103055 |
| **Sputnik V** | | | | Trial: 91.6% (85.6% to 95.2%) | | | | | | Trial: 100% (94.4% to 100%) | | | | | | | | | Trial assumed to apply to ancestral/D614G/B.1.1.7 outcomes | www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00234-8/fulltext |
| **CoronaVac** | | | | Trial (Indonesia): 65.3% (25 cases)<br>Trial (Turkey): 91.3% (29 cases) | | | | | | | | | | | | | Trial (Brazil): 50.3% (252 cases: 167 placebo, 85 | | Unpublished reports | www.nature.com/articles/d41586-021-00094-z |
| **Sinopharm** | Trial: 72.5% (not reported) | | | | | | | | | | | | | | | | | | Unpublished reports | www.scmp.com/news/china/science/article/3122980/covid-19-vaccines-made-chinas-sinopharm-cansino-release-efficacy |
| **CanSinoBio** | Trial: 65.7% (not reported) | | | | | | | | | | | | | | | | | | Unpublished reports | www.reuters.com/article/us-health-coronavirus-vaccine-pakistan/cansinobios-covid-19-vaccine-65-7-effective-in-global-trials-pakistan-official-says-idUSKBN2A81N0 |

Source: Institute for Health Metrics and Evaluation. COVID-19 vaccine efficacy summary. May 21 2021. [Internet].
Available at: http://www.healthdata.org/covid/covid-19-vaccine-efficacy-summary

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