Weekly COVID-19 Vaccine Updates

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World Health Organization

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Introduction

This document summarises the vaccine efficacy and effectiveness, the vaccine specifications, the vaccine development pipeline and the timeline for World Health Organization (WHO) review of the various COVID-19 vaccines in late phase development. This document is updated weekly.

- Vaccine efficacy refers to the performance of a vaccine in a controlled clinical trial (study) situation
- Vaccine effectiveness refers to the performance of a vaccine in a population under real-world conditions

Key messages

- COVID-19 vaccine efficacy results from different trials cannot be directly compared against each other. They must be interpreted in the context of study designs (including case definitions, clinical endpoints, access to testing), target populations, and COVID-19 epidemiologic conditions (including circulation of variants of concern)
- All COVID-19 vaccines in late phase development report high vaccine efficacy against severe COVID-19 and favourable safety profiles
- Pfizer/BioNTech and AstraZeneca both show high vaccine effectiveness in the UK and Israel where the B.1.1.7 (UK) variant is circulating. Both vaccines have shown they are similarly effective against transmission in UK. Sinovac has shown high vaccine effectiveness in Chile where the P1 and B.1.1.7 variants are circulating. Sinopharm has shown high vaccine effectiveness in Bahrain.
- A very rare clotting disorder with low platelets (Thrombosis with Thrombocytopaenia Syndrome – TTS) has been associated with the AstraZeneca and Johnson & Johnson vaccines.[1–3] The majority of cases fully recover with adequate treatment. The risk following the first dose of AstraZeneca vaccine has been estimated by the EMA as 1 in 100,000.[4] The risk following the first dose of Johnson & Johnson vaccine has been estimated as 1 in 286,000 in the USA[5]
- Appropriate communication on the benefit-risk profile of COVID-19 vaccines (Page 9) remains crucial to maintain confidence in immunisation programmes and to avoid vaccine hesitancy

New updates

Key updates include *(also highlighted in yellow text in the document)*:

- Pfizer/BioNTech vaccine: risk of death reduced in vaccine failure cases compared to unvaccinated cases in England (Page 5; not peer reviewed):
  - Single dose: 44% (32-53)
  - Fully vaccinated: 69% (31-86)
- AstraZeneca vaccine: risk of death reduced in vaccine failure cases compared to unvaccinated cases in England (Page 5; not peer reviewed):
  - 55% (41-66)
- Effectiveness of single dose AstraZeneca vaccine against hospitalisation in those aged ≥80 years in England (Page 7; not peer reviewed):
  - 73% (60-81)
- Effectiveness of Pfizer/BioNTech vaccine against hospitalisation in those aged ≥80 years in England (Page 7; not peer reviewed):
  - Single dose: 81% (76-85)
  - Fully vaccinated: 93% (89-95)
- Odds ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive in England (Page 8):
  - AstraZeneca: 0.53 (0.43-0.63)
  - Pfizer/BioNTech: 0.51 (0.44-0.59)
- Pooled analysis of AstraZeneca and Pfizer/BioNTech vaccines in Scotland: Hazard ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive: 0.70 (0.63-0.78) (Page 8)
- Effectiveness against symptomatic infection in England (Page 7):
  AstraZeneca
  - Symptomatic infection ≥70 years: 73% (27-90)
  - Hospitalisation ≥80 years: 37% (3-59)

  Pfizer/BioNTech
  - Symptomatic infection ≥70 years: 61% (51-69)
  - Hospitalisation ≥80 years: 43% (33-52)
  - Death ≥80 years (vaccine failure vs non-vaccinated): 51% (37-62)
- Substantially decreasd viral load for infections occurring 12-37 days after the first dose of Pfizer/BioNTech vaccine in Israel, indicating likely lower infectiousness (Page 8)
- Pooled analysis of Pfizer/BioNTech and Moderna vaccines in USA: compared to unvaccinated patients, 79% reduction in relative risk of infection in asymptomatic pre-surgical patients >10 days after the first dose of vaccine: 0.21 (0.12-0.37) (Page 8)
- Following Pfizer/BioNTech vaccine in Spain, detectable transmission in residents of long-term care facilities was reduced by 90% (76-93) (Page 8)
- The European Medicines Agency (EMA) approved an increase in the storage period of unopened Pfizer/BioNTech vials at 2-8°C from five days to one month (31 days) (Page 3)
- Following mRNA vaccination in nursing homes in USA, incident cases in *unvaccinated* residents decreased from 4.3% within 14 days of the first vaccination clinic to 0.3% after 42 days (Page 8)
- Data from UK suggests that delaying the second dose of Pfizer/BioNTech vaccine from 3 to 12 weeks increases the SARS-CoV-2 spike specific antibody response 3.5-fold in those aged ≥80 years, indicating better immunity in the elderly
- Updated potential risk of TTS in PICs if all adults vaccinated with Johnson & Johnson vaccine (Page 10)

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COVID-19 Vaccine Specifications

	ASTRAZENECA	GAMALEYA	JOHNSON & JOHNSON	MODERNA	NOVAVAX	PFIZER/BIONTECH	SINOVAC	SINOPHARM
VACCINE TYPE	Viral vector (chimpanzee adenovirus ChAdOx1)	Viral vector (recombinant adenovirus types 5 and 26)	Viral vector (recombinant adenovirus type 26)	mRNA	Protein subunit	mRNA	Inactivated virus	Inactivated virus
Available Through COVAX	✓	-	✓	-	✓	✓	-	-
Doses Required	8-12 weeks apart* 4 weeks apart (Product Information)	3 weeks apart	1	4 weeks apart*	3 weeks apart	3 weeks apart*	2 weeks apart	3 weeks apart
Shipping, Storage & Presentation	Normal cold chain requirements (2-8°C); 10-dose vials	-18.5°C (liquid form); 2-8°C (dry form)	Shipped at -20°C; 2-8°C for up to 3 months; 5-dose vials	-25°C to -15°C; 10-dose vials	2-8°C; 10-dose vials	-80°C to -60°C; 2-8°C for up to 1 month; 6-dose vials	2-8°C; Single-dose vials	2-8°C; Single-dose vials/ pre-filled syringes
Approval by a Stringent Regulatory Authority (SRA)	WHO EUL, EMA, TGA, MHRA	Under review by WHO SAGE	WHO EUL, EMA, FDA	EMA, FDA	Under review by WHO SAGE	WHO EUL, EMA, FDA, TGA, MHRA	Under review by WHO SAGE	WHO EUL

*Based on WHO Strategic Advisory Group of Experts on Immunization (SAGE) recommendations

WHO EUL: WHO Emergency Use Listing
EMA: European Medicines Agency
FDA: Food and Drug Administration (US)
TGA: Therapeutic Goods Administration (Australia)
MHRA: Medicines and Healthcare Products Regulatory Agency (UK)

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COVID-19 Vaccine Efficacy

VACCINE	VACCINE EFFICACY			
	MILD-MODERATE-SEVERE	SEVERE	HOSPITALISATION/DEATH	OTHER OUTCOMES
AstraZeneca	-	USA, Chile, Peru: Severe/critical and hospitalisation: 100%[6] (not peer-reviewed) UK: 100% (15 cases in the placebo group)[7]	UK: Hospitalisation: 100% (9 cases in placebo group)[7]	Symptomatic infection: 66.7% (57.4-74.0)[7] Symptomatic infection: 76%[6] (not peer-reviewed) Symptomatic infection using a SINGLE DOSE (22-90 days post-vaccination): 76.0% (59.3 to 85.9)[7] Efficacy higher with longer time interval between doses: 12+ weeks: 82.4% (2.7-91.7) <6 weeks: 54.9% (32.7-69.7)[7]
Gamaleya	-	Moderate-severe: 100% (20 cases in the placebo group)[8]	-	Symptomatic infection: 91.6% (85.6–95.2)[8]
Johnson & Johnson	≥28 days post-vaccination: All sites: 66.1% (55.0-74.8) USA: 72.0% (58.2-81.7) Latin America: 61.0% (46.9-71.8) South Africa: 64.0% (41.2-78.7)[9]	85.4% (54.2-96.9)[9]	100% (7 deaths in placebo group)[9]	Preserved for all ages and virus variants including B1.351[9]
Moderna	-	100% (30 cases in placebo group)[10]	100% (1 death in placebo group)[10]	Symptomatic infection: 94.1% (89.3-96.8)[10]
Novavax	-	-	-	Symptomatic infection: 89.3% (75.2-95.4)[11] (not peer reviewed)
Pfizer/BioNTech	US COVE study: >90%[12]	88.9% (20.1–99.7)[13]	US COVE study: >95%[12]	Symptomatic infection: 94.6% (89.9–97.3)[13] USA: 100% against symptomatic infection in adolescents[14]
Sinovac	Brazil: requiring medical assistance: 83.7% (58.0-93.7) Moderate-severe: 100% (56.4-100.0)[15]	Brazil: Moderate-severe: 100% (56.4-100.0)[15]	Hospitalisation: Brazil: 100% (56-100) Chile: 85% (83-97) Turkey: 100% (20,100)[16]	Symptomatic infection in: Brazil: 50.7% (35.9-62.0) Chile: 67% (65-69) Indonesia: 65% (20-85) Turkey: 84% (65-92)[16]
Sinopharm	-	-	UAE, Bahrain, Egypt and Jordan: Hospitalisation: 78.7% (26.0-93.9)[16]	UAE, Bahrain, Egypt and Jordan: Symptomatic infection: 78.1% (64.9-86.3)[16]

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COVID-19 Vaccine Effectiveness

VACCINE	SEVERE	HOSPITALISATION / DEATH	OTHER OUTCOMES
AstraZeneca	-	Single dose in Scotland: 94% (73-99)[17] Risk of death in vaccine failures compared to unvaccinated cases in England reduced by: 55% (41-66)[18] (not peer reviewed)	Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines in elderly care home residents in UK: Reduction in risk of infection 4 weeks after-single dose: 56% Reduction in risk of infection 5 weeks after single dose: 62%[19] Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines: reduced odds of infection post-second dose: 70% (62-77)[20]
Moderna	-	-	Pooled analysis of Moderna and Pfizer/BioNTech vaccines in USA: Infections in nonvaccinated: 234 of 8969; 2.61% (2.29-2.96) Fully vaccinated: 4/8121; 0.05% (0.01-0.13)[21] Pooled analysis of Moderna and Pfizer/BioNTech vaccines in USA: Fully vaccinated: 90% (68–97) Two weeks after first dose: 80% (59–90)[22]
Pfizer/BioNTech	Israel: 92% (75-100)[23]	Single dose in Scotland: 85% (76-91)[17] Risk of death in vaccine failures compared to unvaccinated cases in England reduced by: Single dose: 44% (32-53) Fully vaccinated: 69% (31-86)[18] (not peer reviewed)	Pooled analysis of Moderna and Pfizer/BioNTech vaccines in USA: Infections in nonvaccinated: 234 of 8969; 2.61% (2.29-2.96) Fully vaccinated: 4/8121; 0.05% (0.01-0.13)[21] Pooled analysis of Moderna and Pfizer/BioNTech vaccines in USA: Fully vaccinated: 90% (68–97) Two weeks after first dose: 80% (59–90)[22] Symptomatic infection in Israel: 94% (87-98)[23] Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines in elderly care home residents in UK: Reduction in risk of infection 4 weeks after-single dose: 56% Reduction in risk of infection 5 weeks after single dose: 62%[19] Documented infection in Israel: incidence decreased from 9.4 infections per 1,000 HCWs in the week following first dose to <1.0 infection per 1,000 HCWs per week from 1 week after the second dose[24] Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines: reduced odds of infection post-second dose: 70% (62-77)[20]
Sinovac	-	Chile: Hospital admission: 85% (83-87); ICU admission: 89% (84-92); Death: 80% (73-86)[25] (not peer reviewed)	Symptomatic infection in Chile: 67% (65-69)[25] (not peer reviewed)
Sinopharm	-	-	Symptomatic infection in Bahrain: 90% (88-91)[16]

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Vaccine Efficacy/Effectiveness Against Variants

Refer to previous table for vaccine effectiveness results for the Pfizer/BioNTech vaccine in Scotland, England and Israel, where all locations had predominant B.1.1.7 circulation. There are four Variants of Concern listed by WHO.[26] There are currently no data on vaccine efficacy/effectiveness against the B.1.617 (India) variant.

VACCINE	VACCINE EFFICACY/EFFECTIVENESS					
	B.1.1.7 (UK) VARIANT		B.1.351 501Y.V2 (SOUTH AFRICA) VARIANT		B.1.1.28.P1 AND B.1.1.28.P2 (BRAZIL) VARIANTS	
	ANY INFECTION	SEVERE	ANY INFECTION	SEVERE	ANY INFECTION	SEVERE
AstraZeneca	70·4% (43·6–84·5) (vs. 81·5% (67·9–89·4) against wild variant in UK)[27]	-	10.4% (−76.8 to 54.8)[28]	Study underway [9]	-	-
Johnson & Johnson	-	-	-	Moderate to severe/critical: 64.0% (41.2-78.7) Severe/critical: 81.7% (46.2-95.4)[9]	-	Moderate to severe/critical: 68.1% (48.8-80.7) Severe/critical: 87.6% (7.8-99.7)[9]
Novavax	85.6%[11] (not peer reviewed)	-	South Africa: 51.0% (−0.6 to 76.2)[29]	-	-	-
Pfizer/BioNTech	Case-control study in Israel: Vaccinees infected between 2 weeks after the first dose and 1 week after the second dose, were disproportionally infected with B.1.1.7 (odds ratio of 26:10) [30] Effectiveness in Qatar: 89.5% (85.9-92.3)[31]	Effectiveness in Qatar: 100% (81.7-100)[31]	Case-control study in Israel: Vaccinees infected at least 1 week after the second dose were disproportionally infected with B.1.351 (odds ratio of 8:1)[30] Effectiveness in Qatar: 75.0% (70.5-78.9)[31]	Effectiveness in Qatar: 100% (73.7-100)[31]	-	-
Sinovac	Chile: 67% (65-69)*[16]	-	-	-	Brazil: vaccine effectiveness after at least 1 dose: 35.1% (−6.6-60.5)[32] Chile: 67% (65-69)*[16]	-

* While it is known P.1. and B.1.1.7 were circulating at the time of the study, the extent is unknown based on available surveillance

Vaccine Efficacy/Effectiveness in the Elderly and Against Comorbidities

VACCINE	VACCINE EFFICACY UNLESS OTHERWISE STATED			
	DIABETES	OBESITY	AT RISK FOR SEVERE COVID-19	ELDERLY
AstraZeneca	-	-	76% against symptomatic infection in a sample where 60% had comorbidities, including diabetes, severe obesity or cardiac disease[6] (not peer-reviewed)	In ≥65 years: 85%[6] (not peer-reviewed) Effectiveness against hospitalisation at 28-34 days after a single dose (pooled analysis of AstraZeneca and Pfizer vacines) 18-64 years: 85% (68-93); 65-79 years: 79% (17-95); ≥80 years: 81% (65-90)[17] Effectiveness against symptomatic infection in England: ≥70 years: 60% (41-73)[33] Effectiveness of single dose against hospitalisation in England: ≥80 years: 73% (60-81)[34] Effectiveness in England: Symptomatic infection ≥70 years: 73% (27-90); Hospitalisation ≥80 years: 37% (3-59)[35]
Gamaleya	-	-	-	Against symptomatic infection in >60 years: 91.8% (67.1–98.3)[8]
Johnson & Johnson	Against moderate to severe/critical: 23.0% (-90.1-69.8)[9]	Against moderate to severe/critical: 65.9% (47.8-78.3)[9]	Against moderate to severe/critical: With any comorbidity: 58.6% (40.6-71.6)[9] No comorbidity: 68.8% (59.0-76.6)[9]	Against moderate-severe/critical disease ≥28 post vaccination: 18-59 years: 66.1% (53.3-75.8) 60+ years: 66.2% (36.7-83.0)[9]
Moderna	-	-	Against symptomatic infection, comorbidities, including diabetes and obesity: In low risk: 95.1% (89.6-97.7) In high risk: 90.9% (74.7-96.7)[10]	Against symptomatic infection: 18-64 years: 95.6% (90.6-97.9) ≥65 years: 86.4% (61.4-95.2)[10] Pooled Moderna and Pfizer vaccines against hospitalisation ≥65 years: 94% (49-99)[36]
Pfizer/BioNTech	-	-	Against symptomatic infection: With any comorbidity or obesity: 95.3% With no comorbidity: 94.7%[13]	Against symptomatic infection: >55 years: 93.7% (80.6-98.8) >65 years: 94.7% (66.7-99.9) >75 years: 100% (-13.1-100)[13] Effectiveness against hospitalisation 28-34 days after a single dose (pooled analysis of AstraZeneca and Pfizer vacines): 18-64 years: 85% (68-93); 65-79 years: 79% (17-95); ≥80 years: 81% (65-90)[17] Effectiveness against symptomatic infection in England: ≥70 years: 61% (51-69) ≥80 years: 89% (85-93)[33] (not peer reviewed) England 80-83 years: Documented infection: 70.1% (55.1-80.1) Hospital attendance: 78.9% (60.0-89.9) Hospital admission: 75.6% (52.8-87.6)[37] Reduction in incidence of infection in vaccinated people aged >60 years and unvaccinated people aged 20-39 years, respectively: Documented infection: 45% versus 28% Hospitalisation: 68% versus 22%[38] Pooled Moderna and Pfizer vaccines against hospitalisation ≥65 years: 94% (49-99)[36] Effectiveness in England: Symptomatic infection ≥70 years: 61% (51-69) Hospitalisation ≥80 years: 43% (33-52); Death ≥80 years (vaccine failure vs non-vaccinated): 51% (37-62)[35] Effectiveness against hospitalisation in England ≥80 years: Single dose: 81% (76-85) Fully vaccinated: 93% (89-95)[34] (not peer reviewed)
Sinovac	-	74.9% (53.7-86.4)[16]	Any comorbidity: 48.9% (26.6-64.5)[16]	-
Sinopharm	-	80.7% (56.7-91.4)[16]	-	Effectiveness against symptomatic infection in Bahrain: ≥60 years: 91% (87-94)

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Vaccine Efficacy/Effectiveness Against Transmission

There are limitations related to the analysis and comparison of transmission data between studies and vaccines. Criteria for testing vary between studies and may include, for example, random testing, testing at defined intervals, or retrospective serology.

VACCINE	EFFICACY/EFFECTIVENESS AGAINST ASYMPTOMATIC INFECTION	OTHER OUTCOMES
AstraZeneca	Asymptomatic (UK only): 22·2% (−9·9-45·0)[7] Symptomatic and asymptomatic combined (UK, South Africa and Brazil): 54.1% (44.7-61.9)[7] Odds ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive in England: 0.53 (0.43-0.63)[39] Pooled analysis of AstraZeneca and Pfizer/BioNTech in Scotland: Hazard ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive: 0.70 (0.63-0.78)[40]	-
Johnson & Johnson	Asymptomatic: 59.7% (32.8-76.6)[9]	-
Moderna	US: Pooled analysis of Pfizer/BioNTech and Moderna vaccines: 88.7% (68.4-97.1)[41] Pooled analysis of Pfizer/BioNTech and Moderna vaccines in USA (weekly testing for 13 weeks): 2 weeks after single dose: 80% (59-90); 2 weeks after second dose: 90% (68%-97)[42] Pooled analysis of Pfizer/BioNTech and Moderna vaccines in USA: compared to unvaccinated residents, relative risk of infection in asymptomatic pre-surgical patients >10 days after first dose: 0.21 (0.12-0.37)[43] Following mRNA vaccination in nursing homes in USA, incident cases in *unvaccinated* residents decreased from 4.3% within 14 days of the first vaccination clinic to 0.3% after 42 days[44]	-
Pfizer/BioNTech	England: 86% (76-97) 7 days after 2 doses; 72% (58-86) 21 days after 1 dose[45] Israel: 75% (72-84) 15-28 days after single dose[46]; 92% (88-95)[23] USA: Pooled analysis of Pfizer/BioNTech and Moderna vaccines: 88.7% (68.4-97.1)[41] UK, single dose: 4-fold decrease in risk amongst HCWs ≥12 days post-vaccination[47] Pooled analysis of Pfizer/BioNTech and Moderna vaccines in US (weekly testing for 13 weeks): 2 weeks after single dose: 80% (59-90); 2 weeks after second dose: 90% (68%-97)[42] Pooled analysis of Pfizer/BioNTech and Moderna vaccines in USA: compared to unvaccinated residents, relative risk of infection in asymptomatic pre-surgical patients >10 days after first dose: 0.21 (0.12-0.37)[43] Following mRNA vaccination in nursing homes in USA, incident cases in *unvaccinated* residents decreased from 4.3% within 14 days of the first vaccination clinic to 0.3% after 42 days[44] Detectable transmission in residents of long-term care facilities in Spain was reduced 90% (76-93)[48] Odds ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive in England: 0.51 (0.44-0.59)[39] Pooled analysis of AstraZeneca and Pfizer/BioNTech in Scotland: Hazard ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive: 0.70 (0.63-0.78)[40]	Lower viral load in vaccine failure cases 12-37 days after the first dose of vaccine compared to within the first 11 days, indicating potentially lower infectiousness[49] Data from 223 communities in Israel: strong correlation between community vaccination rate and a later decline in infection among children under 16 years of age who were unvaccinated[50] Substantially decreasd viral load for infections occurring 12-37 days after the first dose of vaccine in Israel, indicating likely lower infectiousness[49]

Serious Adverse Events

Caution is required when comparing safety profiles as definitions and reporting systems vary in trials and in particular phase IV studies

VACCINE	VACCINE SAFETY
AstraZeneca	108 SAEs in 12,282 (0.9%) vaccine recipients and 127 in 11,962 (1.1%) placebo recipients 12 thromboembolic events (4 vaccine; 8 placebo) 7 deaths, all considered unrelated to vaccination (2 vaccine, 5 placebo)[7] US Phase III study: No serious safety concerns involving 32,449 participants[6] (not peer-reviewed) EMA investigation: possible link between the AstraZeneca vaccine and Thrombosis with Thrombocytopaenia Syndrome (TTS) Blood clots affected the brain (central venous sinus thrombosis, CVST) and abdomen (splanchnic vein thrombosis) There have been reports of 169 cases of CVST and 53 cases of splanchnic vein thrombosis in ~34 million vaccinated people in Europe The EMA confirmed the overall benefits of the vaccine in preventing COVID-19 outweigh the risks of side effects[2] Australia: 6 cases of TTS reported in 1,100,000 people vaccinated[51] Several countries have recommended that only older adults should receive the vaccine (including only those aged over 60 years in Germany; over 55 years in France and Canada; over 50 years in Australia; and over 30 years in the UK[52–54] EMA has started a review of reports of capillary leak syndrome following 5 cases of this very rare disorder post vaccination[55]
Gamaleya	45 SAEs in 16,427 (0.3%) vaccine recipients and 23 in 5,435 (0.4%) placebo recipients All SAEs were considered unrelated to vaccination 4 deaths, all considered unrelated to vaccination (3 vaccine, 1 placebo)[8]
Johnson & Johnson	83 SAEs in 21,895 (0.4%) vaccine recipients and 96 SAEs in 21,888 placebo recipients (0.4%) 19 deaths all considered unrelated to vaccination (3 vaccine, 16 placebo)[9] EMA investigation of 8 reports of TTS: possible link between the Johnson & Johnson vaccine and TTS. Most cases occurred in women <60 years of age but specific risk factors have not been confirmed[3] The CDC and FDA have now recommenced the vaccination program in the USA following a thorough safety review[56] 15 cases of TTS have been reported in 7.98 million people vaccinated in USA[1]
Moderna	153 SAEs in 15,166 (1.0%) placebo recipients and 147 in 15,185 (1.0%) vaccine recipients 5 deaths considered unrelated to vaccine (2 vaccine, 3 placebo)[10] Anaphylaxis reported in the US at a rate of 2.5 per million doses[57] No obvious safety signals among pregnant women who received mRNA COVID-19 vaccines in USA[58]
Novavax	SAEs at low levels and similar between vaccine and placebo groups[11]
Pfizer/BioNTech	SAEs and deaths were low and comparable between vaccine and placebo groups (total 37,586 participants)[13] Anaphylaxis reported in the US at a rate of 4.7 per million doses[57] No obvious safety signals among pregnant women who received mRNA COVID-19 vaccines in USA[58]

Risk of Rare Unusual Blood Clotting with Low Blood Platelets (Thrombosis with Thrombocytopaenia Syndrome – TTS)

Estimated number of TTS that potentially might occur in Pacific Island Countries if all adults received the AstraZeneca or Johnson & Johnson vaccines, based on most recent official estimate of the adult population in each country and the incidence of these events in Europe and Australia.

COUNTRY	TOTAL POPULATION	ESTIMATED POPULATION AGED 18 YEARS AND OVER*	POTENTIAL NUMBER OF TTS CASES IF ALL ADULTS IN EACH COUNTRY RECEIVED ASTRAZENECA VACCINE**	POTENTIAL NUMBER OF TTS CASES IF ALL ADULTS IN EACH COUNTRY RECEIVED JOHNSON & JOHNSON VACCINE***
American Samoa	55,519	33,311	<1	<1
Cook Islands	15,300	9,180	<1	<1
Federated States of Micronesia	102,300	61,380	<1	<1
Fiji	867,000	520,200	2.8-5.2	1.8
French Polynesia	275,918	165,551	0.9-1.7	<1
Guam	159,358	95,615	<1	<1
Kiribati	113,400	68,040	<1	<1
Marshall Islands	54,900	32,940	<1	<1
Nauru	10,900	6,540	<1	<1
New Caledonia	271,407	162,844	0.9-1.6	<1
Niue	1,611	967	<1	<1
Northern Mariana Islands	53,883	32,330	<1	<1
Palau	18,000	10,800	<1	<1
Papua New Guinea	7,744,700	4,646,820	25.4-46.5	16.2
Samoa	195,979	117,587	<1	<1
Solomon Islands	642,000	385,200	2.1-3.9	1.3
Tokelau	1,160	696	<1	<1
Tonga	99,419	59,651	<1	<1
Tuvalu	10,507	6,304	<1	<1
Vanuatu	272,173	163,304	0.9-1.6	<1
Wallis and Futuna	11,558	6,935	<1	<1
All Pacific Island Countries	10,976,992	6,586,195	36.0-65.9	23.0

* Based on estimate of 60% of population aged ≥18 years[59]

** Based on estimates of TTS occurring in ~1 in 100,000 vaccinated adults by the European Medicines Agency and 6 cases in 1,100,000 vaccinated adults in Australia[4,51]

*** Based on estimates of TTS occurring in ~1 in 286,000 vaccinated adults in USA (may be an underestimate as only cerebral venous sinus thrombosis are reported)[5]

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Who Can be Vaccinated Based on WHO SAGE Recommendations?

So far, WHO SAGE have made recommendations for use of AstraZeneca, Moderna, Pfizer/BioNTech, Johnson & Johnson and Sinopharm vaccines: https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials

	ASTRAZENECA	MODERNA	PFIZER/BIONTECH	JOHNSON & JOHNSON	SINOPHARM
Minumum Age	18 years	18 years	16 years	18 years	18 years
Maximum Age (SAGE WHO)	None	None	None	None	None
Pregnancy	Yes if high priority group & approved by health provider	Yes if high priority group & approved by health provider	Yes if high priority group & approved by health provider	Yes if high priority group & approved by health provider	Yes if high priority group & approved by health provider
Breastfeeding	Yes if high priority group	Yes if high priority group	Yes if high priority group	Yes if high priority group	Yes if high priority group
Immunocompromised Including HIV	✔	✔	✔	✔	✔
People Previously Infected by SARS-CoV-2 (PCR Confirmed)	Yes, although that person may choose to delay vaccination by 6 months	Yes, although that person may choose to delay vaccination by 6 months	Yes, although that person may choose to delay vaccination by 6 months	Yes, although that person may choose to delay vaccination by 6 months	Yes, although that person may choose to delay vaccination by 6 months
History of Anaphylaxis (Severe Allergy)	Yes (unless the allergy is to the vaccine or its components)	Yes (unless the allergy is to the vaccine or its components)	Yes (unless the allergy is to the vaccine or its components)	Yes (unless the allergy is to the vaccine or its components)	Yes (unless the allergy is to the vaccine or its components)

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Vaccine Development Pipeline

WHO has recommended that vaccines adopted by countries have WHO SAGE EUL and/or Stringent Regulatory Approval.

VACCINE TYPE	NUMBER OF VACCINE CANDIDATES AT EACH PHASE OF DEVELOPMENT				
	PRE-CLINICAL	PHASE I/II	PHASE III	PHASE IV	IN USE*
RNA	25	9	2	2	2 (Pfizer/BioNTech, Moderna)
DNA	17	8	2	0	0
Vector (non-replicating)	27	8	3	2	4 (CanSino, Gamaleya, Johnson & Johnson, AstraZeneca)
Vector (replicating)	18	7	0	0	0
Inactivated	8	7	7	2	6 (Sinopharm/BIBP, Sinopharm/WIBP, Sinovac, Bharat, Chumakov, Research Instutute for Biological Safety Problems)
Live-attenuated	2	1	0	0	0
Protein subunit	73	19	8	1	3 (Vector institute; Anhui Zhifei Longcom Biopharmaceutical Chinese Academy of sciences, Center for Genetic Engineering and Biotechnology)
Virus-like particle	20	4	1	0	0
Other/unknown	33	4	0	0	0

*Not all vaccines in use have SRA (as recognised by WHO) approval (see Vaccine specifications table and WHO SAGE Emergency Use Listing and prequalification timeline for approval status of vaccines).

Source: London School of Hygiene and Tropical Medicine COVID-19 vaccine tracker.

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WHO SAGE Emergency Use Listing and Prequalification Timeline

MANUFACTURER	NAME OF VACCINE	PLATFORM	STATUS OF ASSESSMENT	ANTICIPATED DECISION DATE
Pfizer/BioNTech	BNT162b2/COMIRNATY Tozinameran (INN)	mRNA	Final decision made	Authorised 31/12/20
AstraZeneca	AZD1222	Adenoviral vector	Final decision made	SK Bio: Authorised 15/02/21 EU nodes: Authorised 16/04/21
Serum Institute of India	Covishield (ChAdOx1_nCoV19)	Adenoviral vector	Final decision made	Authorised 15/02/21
Sinopharm/Beijing Institute of Biological Products (BIBP)	SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	Inactivated	In progress	Authorised: 07/05/2021
Sinovac	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	Inactivated	In progress	May 2021
Moderna	mRNA-1273	mRNA	In progress (to use abridged procedure relying on EMA)	Authorised 30/04/2021
Johnson & Johnson	Ad26.COV2.S	Adenoviral vector	Final decision made	Authorised 12/03/21
The Gamaleya National Center	Sputnik V	Adenoviral vector	Clinical and chemistry, manufacturing and control (CMC) review ongoing	Will be determined when all data are submitted
CanSinoBIO	Ad5-nCoV	Adenoviral vector	Rolling data assessment starting May 2021	-
Novavax	NVX-CoV2373	Protein subunit	Expression of interest submitted 23/02/21; Pre-submission meeting to be planned in April	-
CureVac	Zorecimeran	mRNA	Expression of interest submitted 12/04/21	-

Source: WHO Guidance Document: Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process. Available at: https://www.who.int/teams/regulation-prequalification/eul/covid-19

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Other resources on COVID-19 vaccines:

WHO COVID-19 vaccines website: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines
EMA COVID-19 vaccines website: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines

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