

Weekly COVID-19 Vaccine Updates

Number 18, 15 July 2021



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 Alpha variant is circulating. Both vaccines have shown they are similarly effective against transmission in the UK. Sinovac has shown high vaccine effectiveness in Chile where the Gamma and Alpha variants are circulating. Sinopharm has shown high vaccine effectiveness in Bahrain. The Johnson & Johnson and Moderna vaccines have both shown good vaccine effectiveness against infection in the US. One or 2 doses of the Moderna vaccine is effective against the Alpha variant in Canada, and a single dose is effective against infection and very effective against severe disease with the Delta variant.
- The US FDA, UK MHRA, EU EMA NZ Medsafe, and Health Canada have authorised the Pfizer/BioNTech vaccine for emergency use in adolescents aged 12-15 years¹⁻⁴
- Mixed vaccine schedules (i.e. delivering different types of vaccine for the first and second dose) are under investigation as these could facilitate better protection against variants of concern and enable vaccination programs to continue if a particular vaccine is unavailable
- A very rare clotting disorder with low platelets (Thrombosis with Thrombocytopenia Syndrome – TTS) has been associated with the AstraZeneca and Johnson & Johnson vaccines.⁵⁻⁷ 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 and by the Australian Technical Advisory Group on Immunisation (ATAGI) as 1 in 66,000.^{8,9} Risk of TTS is much lower following the second dose of AstraZeneca vaccine: estimate in the UK is 1 in 1.5 million second doses.¹⁰
- The risk of TTS following the first dose of Johnson & Johnson vaccine has been estimated as 1 in 319,000 in the USA¹¹
- Appropriate communication on the benefit-risk profile of COVID-19 vaccines (Page 12) 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):

- Israel Ministry of Health reported a decline in effectiveness of the Pfizer/BioNTech vaccine against infection and symptomatic illness associated with spread of the Delta variant but not against severe disease and hospitalisation. This decline may be related to the study design rather than solely a real decline in effectiveness (Page 7):
 - Infection: 64%
 - Symptomatic illness: 64%
 - Hospitalisation: 93%

- Bharat Biotech vaccine specifications added (Page 3)
- Bharat Biotech vaccine and Clover Biopharmaceuticals WHO EUL timelines added (Page 16)
- Bharat Biotech vaccine efficacy in India added (Pages 4, 7, 8 and 9):
 - Symptomatic infection: 77.8% (65.2-86.4)
 - Symptomatic infection ≥60 years: 67.8% (8.0-90.0)
 - Symptomatic infection 18-59 years: 79.4% (66.0-88.2)
 - Symptomatic infection with comorbidities: 66.2% (33.8-84.0)
 - Severe disease: 93.4% (57.1-99.8)
 - Asymptomatic infection: 63.6% (29.0-82.4)
 - Symptomatic and asymptomatic infection: 68.8% (46.7-82.5)
 - Infection with Delta variant: 65.2% (33.1-83.0)
- Effectiveness of vaccines against variants of concern in Canada (Page 7):
 - Symptomatic infection
 - Alpha:
 - Moderna (single dose): 83% (80-86)
 - Moderna (2 doses): 92% (86-96)
 - Pfizer/BioNTech (single dose): 66% (64-68)
 - Pfizer/BioNTech (2 doses): 89% (86-91)
 - AstraZeneca (single dose): 64% (60-68)
 - Delta:
 - Moderna (single dose): 72% (57-82)
 - Pfizer/BioNTech (single dose): 56% (45-64)
 - Pfizer/BioNTech (2 doses): 87% (64-95)
 - AstraZeneca (single dose): 67% (44-80)
 - Hospitalisation or death:
 - Alpha:
 - Moderna (single dose): 79% (74-83)
 - Moderna (2 doses): 94% (89-97)
 - Pfizer/BioNTech (single dose): 80% (78-82)
 - Pfizer/BioNTech (2 doses): 95% (92-97)
 - AstraZeneca (single dose): 85% (81-88)
 - Delta:
 - Moderna (single dose): 96% (72-99)
 - Pfizer/BioNTech (single dose): 78% (65-86)
 - AstraZeneca (single dose): 88% (60-96)
- A table has been added summarising Vaccine Efficacy/Effectiveness against Delta VOC (Page 6)
- Thailand has announced that those who received one dose of Sinovac will receive a second dose of AstraZeneca vaccine. Health workers who have received 2 doses of Sinovac will receive either AstraZeneca or Pfizer/BioNTech vaccine as a booster (Page 10)
- WHO EUL received by CSL, Australia, and Daiichi Sankyo, Japan, to manufacture AstraZeneca vaccine (Page 16)
- WHO has emphasised that there is no evidence that booster COVID-19 vaccinations are necessary and said rich countries should not be buying doses for boosters while other countries have yet to receive COVID-19 vaccines
- Safety: The US FDA announced revisions to the Johnson & Johnson fact sheets to include information about the observed increased risk of Guillain-Barré Syndrome (GBS) following vaccination. There have been 100 preliminary reports of GBS following 12.5 million doses of vaccine administered. (Pages 11 and 12)
- GBS reported following AstraZeneca vaccine in Australia: 52 cases (10.4 per million doses) (Pages 11 and 12)
- The WHO GACVS confirmed the likely causal association between myocarditis/pericarditis and the mRNA vaccines (Pfizer/BioNTech and Moderna)
- According to the US Vaccine Adverse Events Reporting System (VAERS), reported cases of myocarditis/pericarditis are more common in young males after the second dose of mRNA vaccine. Rates per million second doses (Pages 11 and 12):
 - Males 12-29 years: 40.6
 - Females 12-29 years: 4.2
 - Males 30+ years: 2.4
 - Females 30+ years: 1.0

COVID-19 Vaccine Specifications

	ASTRAZENECA	GAMALEYA	JOHNSON & JOHNSON	MODERNA	NOVAVAX	PFIZER/BIONTECH	SINOVAC	SINOPHARM	BHARAT BIOTECH
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	Inactivated virus
Available Through COVAX	✓	-	✓	-	✓	✓	-	-	-
Doses Required	 8-12 weeks apart* 4-12 weeks apart (Product Information)	 3 weeks apart	 1 dose	 4 weeks apart*	 3 weeks apart	 3-4 weeks apart*	 2-4 weeks apart*	 3-4 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	2-8°C; 10-dose or 20-dose vials
Approval by a Stringent Regulatory Authority (SRA)	WHO EUL, EMA, TGA, MHRA	Under review by WHO SAGE	WHO EUL, EMA, FDA, MHRA	WHO EUL, EMA, FDA	Under review by WHO SAGE	WHO EUL, EMA, FDA, TGA, MHRA	WHO EUL	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)

COVID-19 Vaccine Efficacy

VACCINE	VACCINE EFFICACY			
	SYMPTOMATIC INFECTION	MODERATE-SEVERE	SEVERE	HOSPITALISATION/DEATH
AstraZeneca	UK: 66.7% (57.4-74.0) ¹² USA, Chile, Peru: 76% ¹³ (not peer-reviewed) Single dose in UK (22-90 days post-vaccination): 76.0% (59.3 to 85.9) ¹² Efficacy with different interval between doses in UK: 12+ weeks: 82.4% (2.7-91.7) <6 weeks: 54.9% (32.7-69.7) ¹²	-	Severe/critical and hospitalisation in USA, Chile, Peru: 100% ¹³ (not peer-reviewed) UK: 100% (15 cases in the placebo group) ¹²	Hospitalisation in UK: 100% (9 cases in placebo group) ¹²
Gamaleya	Russia: 91.6% (85.6-95.2) ¹⁴ Single dose (Sputnik Light) in Argentina: 78.6% ¹⁵	Moderate-severe: 100% (20 cases in the placebo group) ¹⁴	-	-
Johnson & Johnson	-	Moderate to severe/critical: 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) ¹⁶	85.4% (54.2-96.9) ¹⁶	100% (7 deaths in placebo group) ¹⁶
Moderna	USA: 94.1% (89.3-96.8) ¹⁷ USA: >90% ¹⁸ 12-17 years in USA: 93% (1 case in vaccine arm) ¹⁹	-	USA: 100% (30 cases in placebo group) ¹⁷ US: >95% ¹⁸	USA: 100% (1 death in placebo group) ¹⁷
Novavax	UK: 89.7% (80.2-94.6) ²⁰ US and Mexico: 90.4% (82.9-94.6) ²¹	US and Mexico: 100% (87.0-100) ²¹	-	-
Pfizer/BioNTech	Argentina, Brazil, Germany, South Africa, Turkey and the USA: 94.6% (89.9-97.3) ²² 12-15 years in USA: 100% ²³	-	Argentina, Brazil, Germany, South Africa, Turkey and the USA: 88.9% (20.1-99.7) ²²	-
Sinovac	Brazil: 50.7% (35.9-62.0) Chile: 67% (65-69) Indonesia: 65% (20-85) Turkey: 84% (65-92) ²⁴	Requiring medical assistance in Brazil: 83.7% (58.0-93.7) Moderate-severe: 100% (56.4-100.0) ²⁵	-	Hospitalisation: Brazil: 100% (56-100) Chile: 85% (83-97) Turkey: 100% (20-100) ²⁴
Sinopharm	UAE, Bahrain, Egypt and Jordan: 78.1% (64.9-86.3) ²⁴	-	-	Hospitalisation in UAE, Bahrain, Egypt and Jordan: 78.7% (26.0-93.9) ²⁴
Bharat Biotech	India: 77.8% (65.2-86.4) ²⁶	-	India: 93.4% (57.1-99.8) ²⁶	-

COVID-19 Vaccine Effectiveness

VACCINE	SEVERE / HOSPITALISATION / DEATH	INFECTION AND OTHER OUTCOMES
AstraZeneca	<p>Single dose in Scotland: 94% (73-99)²⁷</p> <p>Risk of death in vaccine failures compared to unvaccinated cases in England reduced by: 55% (41-66)²⁸ (not peer reviewed)</p> <p>Single dose against hospitalisation in Spain: 92% (46-99)²⁹</p> <p>Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Hospitalisation: 89% (85-91); Death: 93% (89-96)³⁰</p>	<p>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%³¹</p> <p>Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines: reduced odds of infection post-second dose: 70% (62-77)³²</p> <p>Single dose in Spain: Any infection: 44% (31-54); Symptomatic infection: 50% (37-61)²⁹</p> <p>Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Infection: 78% (76-79)³⁰</p>
Johnson & Johnson	-	USA: Any infection: 76.7% (30.3-95.3) ³³
Moderna	<p>Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Hospitalisation: 89% (85-91); Death: 93% (89-96)³⁰</p>	<p>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)³⁴</p> <p>Pooled analysis of Moderna and Pfizer/BioNTech vaccines against infection in USA: Fully vaccinated: 90% (68-97) Two weeks after first dose: 80% (59-90)³⁵</p> <p>Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Infection: 78% (76-79)³⁰</p> <p>Single dose against symptomatic disease: Age 15-39 years: 72% (46-86)³⁶</p>
Pfizer/BioNTech	<p>Severe in Israel: 92% (75-100)³⁷</p> <p>Severe/critical in Israel: 97.5% (97.1-97.8)³⁸</p> <p>Single dose against hospitalisation in Scotland: 85% (76-91)²⁷</p> <p>Risk of death in vaccine failures compared to unvaccinated cases in England reduced by: Single dose: 44% (32-53) Fully vaccinated: 69% (31-86)²⁸ (not peer reviewed)</p> <p>Israel: Hospitalisation: 97.2% (96.8-97.5); Death: 96.7% (96.0-97.3)³⁸</p> <p>Hospitalisation in Spain: 94% (60-99)²⁹</p> <p>Priority groups in Denmark: Hospitalisation: 93% (89-96); Death: 94% (90-96)³⁹</p> <p>Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Hospitalisation: 89% (85-91); Death: 93% (89-96)³⁰</p> <p>Uruguay: Hospitalisation: 97.8% (96.0-98.8); Death: 96.2 (95.4-96.8)⁴⁰</p> <p>Israel: Hospitalisation: 93.4% (91.9-94.7); Death: 91.1% (86.5-94.1)⁴¹</p>	<p>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)³⁴</p> <p>Pooled analysis of Moderna and Pfizer/BioNTech vaccines in USA: Fully vaccinated: 90% (68-97); Two weeks after first dose: 80% (59-90)³⁵</p> <p>Symptomatic infection in Israel: 94% (87-98)³⁷</p> <p>Any infection in Israel: 90% (79-95)⁴²</p> <p>Israel: Any infection: 95.3% (94.9-95.7); Symptomatic infection: 97.0% (96.7-97.2)³⁸</p> <p>Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines in elderly care home residents in UK: 4 weeks after first dose: 56%; 5 weeks after first dose: 62%³¹</p> <p>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 dose⁴³</p> <p>Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines: reduced odds of infection post-second dose: 70% (62-77)³²</p> <p>Spain: Any infection: 65% (56-73); Symptomatic infection: 82% (73-88)²⁹</p> <p>Infection in priority groups in Denmark: 82% (79-84)³⁹</p> <p>USA: Symptomatic infection: 84% (75-90)⁴⁴</p> <p>Denmark: Infection in care facility residents: >14 days after first dose: 17% (4-28); >7 days after second dose: 64% (14-84)⁴⁵</p> <p>USA: Single dose against infection in 2 care facilities: 63% (33-79)⁴⁶</p> <p>A care facility in USA: Infection 66% (41-81); Symptomatic illness 87% (66-95); Death 94% (45-99)⁴⁷</p> <p>Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Infection: 78% (76-79)³⁰</p> <p>Uruguay: Infection: 78.1% (77.0-79.1)⁴⁰</p> <p>Israel: Infection: 93.0% (92.6-93.4)⁴¹</p> <p>Single dose against symptomatic disease: Age 15-39 years: 61% (56-66)³⁶</p>
Sinovac	<p>Chile: Hospital admission: 85% (83-87); ICU admission: 89% (84-92); Death: 80% (73-86)⁴⁸ (not peer reviewed)</p> <p>Uruguay: Hospitalisation: 90.9% (88.6-92.7); Death: 94.7% (93.4-95.7)⁴⁰</p>	<p>Symptomatic infection in Chile: 67% (65-69)⁴⁸ (not peer reviewed)</p> <p>Uruguay: Infection: 59.9% (59.1-60.7)⁴⁰</p>
Sinopharm	-	Symptomatic infection in Bahrain: 90% (88-91) ²⁴

Vaccine Efficacy/Effectiveness against Delta VOC

VACCINE	LAB STUDIES	VACCINE EFFICACY/EFFECTIVENESS	
		ANY INFECTION*	HOSPITALISATION AND DEATH*
AstraZeneca	✓	Effectiveness: Single dose 33-67% ^{49,50} 2 doses: 60% ^{50,51}	Effectiveness: Single dose: 71-88% ^{49,52} 2 doses: 92% ⁵²
Johnson & Johnson	✓	-	-
Moderna	✓	Effectiveness: Single dose: 72% ⁴⁹	Effectiveness: Single dose: 96% ⁴⁹
Pfizer/BioNTech	✓	Effectiveness: Single dose: 33-56% ^{49,50} 2 doses: 79-88% ⁴⁹⁻⁵¹	Effectiveness: Single dose: 78-94% ^{49,52} 2 doses: 96% ⁵²
Bharat Biotech	✓	Efficacy: 65.2% ²⁶	-

*This table provides a summary; details are available in the Vaccine Efficacy/Effectiveness Against Variants table on Page 7

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.⁵³ The WHO recommends labelling SARS-CoV-2 variants with letters of the Greek alphabet, as in the table below.⁵⁴

VACCINE	VACCINE EFFICACY/EFFECTIVENESS							
	B.1.1.7 (ALPHA) VARIANT		B.1.351 (BETA) VARIANT		P.1 (GAMMA) VARIANT		B.1.617.2 (DELTA) VARIANT	
	ANY INFECTION	SEVERE	ANY INFECTION	SEVERE	ANY INFECTION	SEVERE	ANY INFECTION	SEVERE
AstraZeneca	UK: 70.4% (43.6-84.5) (vs. 81.5% (67.9-89.4) against wild variant) ⁵⁵ Effectiveness: ≥21 days after one dose: 51.4% (47.3-55.2); ≥14 days after two doses: 66.1% (54.0-75.0) ⁵⁰ Scotland: 73% (66-78) ⁵¹ Effectiveness in Canada: Single dose: 64% (60-68) ⁴⁹	Effectiveness in Canada: Single dose: 85% (81-88) ⁴⁹	10.4% (-76.8 to 54.8) ⁵⁶	Study underway ¹⁶	-	-	Effectiveness: ≥21 days after one dose: 32.9% (19.3-44.3); ≥14 days after second dose: 59.8% (28.9-77.3) ⁵⁰ Scotland: 60% (53-66) ⁵¹ Effectiveness in Canada: Single dose: 67% (44-80) ⁴⁹	Hospitalisation in England: 1 dose: 71% (51-83); 2 doses: 92% (75-97) ⁵² Effectiveness in Canada: Single dose: 88% (60-96) ⁴⁹
Johnson & Johnson	-	-	-	Moderate to severe/critical: 64.0% (41.2-78.7) Severe/critical: 81.7% (46.2-95.4) ¹⁶	-	Moderate to severe/critical: 68.1% (48.8-80.7) Severe/critical: 87.6% (7.8-99.7) ¹⁶	-	-
Moderna	Effectiveness in Canada: Single dose: 83% (80-86); 2 doses: 92% (86-96) ⁴⁹	Effectiveness in Canada: Single dose: 79% (74-83); 2 doses: 94% (89-97) ⁴⁹	-	-	-	-	Effectiveness in Canada: Single dose: 72% (57-82) ⁴⁹	Effectiveness in Canada: Single dose: 96% (72-99) ⁴⁹
Novavax	86.3% (71.3-93.5) (vs. 96.4% (73.8-99.5) against wild variant in UK) ²⁰	-	South Africa: 51.0% (-0.6 to 76.2) ⁵⁷	-	-	-	-	-
Pfizer/BioNTech	Case-control study in Israel: After one dose, vaccinees were disproportionately infected with B.1.1.7 (OR: 26.10) ⁵⁸ Effectiveness in Qatar: 89.5% (85.9-92.3) ⁵⁹ Effectiveness: ≥21 days after one dose: 49.2% (42.6 to 55.0) ≥14 days after second dose: 93.4% (90.4-95.5) ⁵⁰ Scotland: 92% (90-93) ⁵¹ Effectiveness in Canada: Single dose: 66% (64-68); 2 doses: 89% (86-91) ⁴⁹	Effectiveness in Qatar: 100% (81.7-100) ⁵⁹ Effectiveness in Canada: Single dose: 80% (78-82) 2 doses: 95% (92-97) ⁴⁹	Israel case-control study: Vaccinees infected at least 1 week after the second dose were disproportionately infected with B.1.351 (odds ratio: 8.1) ⁵⁸ Effectiveness in Qatar: 75.0% (70.5-78.9) ⁵⁹	Effectiveness in Qatar: 100% (73.7-100) ⁵⁹	-	-	Effectiveness: ≥21 days after one dose: 33.2% (8.3-51.4); ≥14 days after second dose: 87.9% (78.2-93.2) ⁵⁰ Scotland: 79% (75-82) ⁵¹ Effectiveness in Canada: Single dose: 56% (45-64) 2 doses: 87% (64-95) ⁴⁹ Effectiveness in Israel: Infection: 64%; Symptomatic illness: 64% ⁶⁰	Hospitalisation in England: 1 dose: 94% (46-99); 2 doses: 96% (86-99) ⁵² Effectiveness in Canada: Single dose: 78% (65-86) ⁴⁹ Effectiveness against hospitalisation in Israel: 93% ⁶⁰
Sinovac	Chile: 67% (65-69) ²⁴	-	-	-	Brazil: vaccine effectiveness 1 or 2 doses: 35.1% (-6.6-60.5) ⁶¹ Chile: 67% (65-69) ²⁴ Brazil: ≥70 years: 41.6% (26.9-53.3); 70-74 years: 61.8% (34.8-77.7); 75-79 years: 48.9% (23.3-66.0); ≥80 years: 28.0% (0.6-47.9) ⁶²	-	-	-
Bharat Biotech	-	-	-	-	-	-	Efficacy against infection in India: 65.2% (33.1-83.0) ²⁶	-

* 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 ¹³ (not peer-reviewed)	In ≥65 years: 85% ¹³ (not peer-reviewed) Effectiveness against hospitalisation at 28-34 days after a single dose (pooled analysis of AstraZeneca and Pfizer vaccines): 18-64 years: 85% (68-93); 65-79 years: 79% (17-95); ≥80 years: 81% (65-90) ²⁷ Effectiveness of single dose against hospitalisation in England: ≥80 years: 73% (60-81) ⁶³ Effectiveness in England: Symptomatic infection ≥70 years: 73% (27-90); Hospitalisation ≥80 years: 37% (3-59) ⁶⁴ Hospitalisation following single dose in the UK: ≥80 years: 80.4% (36.4-94.5) ⁶⁵ Single dose in Spain: ≥60 years: 53% (19-72) vs. 18-59 years: 50% (34-62) ²⁹ Effectiveness against death in the UK: ≥65 years: Single dose: 83% (78-86); Two doses: 94% (80-98) ³⁶
Gamaleya	-	-	-	Against symptomatic infection in >60 years: 91.8% (67.1–98.3) ¹⁴
Johnson & Johnson	Against moderate to severe/critical: 23.0% (-90.1-69.8) ¹⁶	Against moderate to severe/critical: 65.9% (47.8-78.3) ¹⁶	Against moderate to severe/critical: With any comorbidity: 58.6% (40.6-71.6) ¹⁶ No comorbidity: 68.8% (59.0-76.6) ¹⁶	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) ¹⁶
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) ¹⁷	Against symptomatic infection: 18-64 years: 95.6% (90.6-97.9) ≥65 years: 86.4% (61.4-95.2) ¹⁷ Pooled Moderna and Pfizer vaccines against hospitalisation ≥65 years: 94% (49-99) ⁶⁶
Pfizer/BioNTech	Effectiveness in Israel: Diabetes or cardiovascular disease: 82% (62-92) ⁴² Effectiveness against infection in Israel: (88-9% (87-3-90-2) ⁴¹	Effectiveness against infection in Israel: (89-7% (88-6-90-7) ⁴¹	Against symptomatic infection: With any comorbidity or obesity: 95.3% With no comorbidity: 94.7% ²² Denmark: Infection: 71% (58-80); Hospitalisation: 81% (49-93) ³⁹ Effectiveness against infection in Israel: Hypertension: (89-7% (88.6-91.7) ⁴¹	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) ²² Effectiveness against hospitalisation 28-34 days after a single dose (pooled analysis of AstraZeneca and Pfizer vaccines): 18-64 years: 85% (68-93); 65-79 years: 79% (17-95); ≥80 years: 81% (65-90) ²⁷ 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) ⁶⁷ Reduction in incidence of infection in vaccinated people aged >80 years and unvaccinated people aged 20-39 years, respectively: Documented infection: 45% versus 28%; Hospitalisation: 68% versus 22% ⁶⁸ Pooled Moderna and Pfizer vaccines against hospitalisation ≥65 years: 94% (49-99) ⁶⁶ 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) ⁶⁴ Effectiveness against hospitalisation in England ≥80 years: Single dose: 81% (76-85) Fully vaccinated: 93% (89-95) ⁶³ (not peer reviewed) Effectiveness in Israel: 65-74 years: 82% (63-92); ≥75 years: 82% (61-91) ⁴² Hospitalisation following single dose in the UK: ≥80 years: 71.4% (43.1-86.2) ⁶⁵ Single dose in Spain: ≥60 years: 76% (55-87) vs. 18-59 years: 85% (74-91) ²⁹ Effectiveness against infection in Denmark: ≥80 years: 77% (50-89) ³⁹ Effectiveness against infection in Israel: ≥70 years: 89-1% (83-93) ⁴¹ Effectiveness against death in the UK: ≥65 years: Single dose: 77% (72-81); Two doses: 98% (94-99) ³⁶
Novavax	-	-	Against any infection with comorbidity, age ≥65 years or frequent COVID-19 exposure in USA and Mexico: 91.0% (83.6-95.0) ²¹	-
Sinovac	-	74.9% (53.7-86.4) ²⁴	Any comorbidity: 48.9% (26.6-64.5) ²⁴	-
Sinopharm	-	80.7% (56.7-91.4) ²⁴	-	Effectiveness against symptomatic infection in Bahrain: ≥60 years: 91% (87-94) ²⁴
Bharat Biotech	-	-	Efficacy against any infection with comorbidity: 66.2% (33.8-84.0) ²⁶	Efficacy against symptomatic infection in India: ≥60 years: 67.8% (8.0-90.0) vs 18-59 years: 79.4% (66.0-88.2) ²⁶

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	<p>Asymptomatic (UK only): 22.2% (-9-9-45-0); Symptomatic and asymptomatic combined (UK, South Africa and Brazil): 54.1% (44.7-61.9)¹²</p> <p>Odds ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive in England: 0.52 (0.43-0.62)⁶⁹</p> <p>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)⁷⁰</p> <p>Hazard ratio for single dose in vaccinated vs. unvaccinated care facility residents in England: 0.32 (0.15-0.66)⁷¹</p> <p>Following regular testing of randomly selected UK households: 79% (65-88)⁷²</p> <p>Single dose against symptomatic and asymptomatic infection in the UK: 60% (49-68)⁷³</p>	-
Johnson & Johnson	<p>Asymptomatic: 59.7% (32.8-76.6)¹⁶</p>	-
Moderna	<p>US: Pooled analysis of Pfizer/BioNTech and Moderna vaccines: 88.7% (68.4-97.1)⁴⁴</p> <p>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)⁷⁵</p> <p>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)⁷⁶</p> <p>Following mRNA vaccination in nursing homes in USA, incident cases in <i>unvaccinated</i> residents decreased from 4.3% within 14 days of the first vaccination clinic to 0.3% after 42 days⁷⁷</p> <p>Reduced potential for transmission (from modelling): at least 61%⁷⁸</p>	-
Pfizer/BioNTech	<p>England: 86% (76-97) 7 days after 2 doses; 72% (58-86) 21 days after 1 dose⁷⁹</p> <p>Israel: 75% (72-84) 15-28 days after single dose⁸⁰; 92% (88-95)³⁷</p> <p>Israel: 91.5% (90.7-92.2)³⁸</p> <p>USA: Pooled analysis of Pfizer/BioNTech and Moderna vaccines: 88.7% (68.4-97.1)⁷⁴</p> <p>UK, single dose: 4-fold decrease in risk amongst HCWs ≥12 days post-vaccination⁸¹</p> <p>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)⁷⁵</p> <p>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)⁷⁶</p> <p>Following mRNA vaccination in nursing homes in USA, incident cases in <i>unvaccinated</i> residents decreased from 4.3% within 14 days of the first vaccination clinic to 0.3% after 42 days⁷⁷</p> <p>Effectiveness in unvaccinated household contacts of vaccinated health workers: 2 weeks after first dose: 8.7% (-28.9-35.4); 10 weeks after first dose: 42.9% (22.3-58.1)⁸²</p> <p>Following regular testing of randomly selected UK households: 80% (73-85)⁷²</p> <p>USA: Asymptomatic screening: 90% (78-96)⁴⁴</p> <p>Israel: 65% (45-79%)⁸³</p> <p>* By May 2021, 82% and 42% of adults aged ≥65 and 18-49 years, respectively, had received at least one dose of vaccine. From before the vaccination program (29 Nov-12 Dec 2020) to late April 2021, the rate ratios among adults aged ≥65 compared to 18-49 years were: Infection: 40%; Emergency visits: 59%; Hospitalisation: 65%; Death: 66%⁸⁴</p> <p>Single dose against symptomatic and asymptomatic infection in the UK: 72% (63-79)⁷³</p>	<p>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 infectiousness⁸⁵</p> <p>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 unvaccinated⁸⁶</p> <p>Substantially decreased viral load for infections occurring 12-37 days after the first dose of vaccine in Israel, indicating likely lower infectiousness⁸⁵</p> <p>Detectable transmission in long-term care facilities in Spain reduced by 90% (76-93)⁸⁷</p> <p>Odds ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive in England: 0.54 (0.47-0.62)⁸⁹</p> <p>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)⁷⁰</p> <p>Hazard ratio for single dose in vaccinated vs. unvaccinated care facility residents: 0.35 (0.17-0.71)⁷¹</p>
Bharat Biotech	<p>Efficacy in India: Asymptomatic: 63.6% (29.0-82.4); Symptomatic and asymptomatic combined: 68.8% (46.7-82.5)²⁶</p>	-

* Nationwide vaccination program including Pfizer/BioNTech, Moderna and Johnson & Johnson vaccines



Mixed Dose Vaccine Safety and Immune Responses

Mixed vaccine schedules (i.e. delivering different types of vaccine for the first and second dose) could be particularly useful to facilitate better protection against variants of concern and enable vaccination programs to continue if a particular vaccine is unavailable.

SCHEDULE	SAFETY	IMMUNE RESPONSES	COUNTRIES USING SCHEDULE
AstraZeneca followed by Pfizer/BioNTech	<p>Spain: Similar side effects to those receiving 2 doses of the same vaccine; no safety concerns (not peer reviewed)⁸⁸</p> <p>UK: Greater systemic side effects (mild-moderate symptoms) following the booster dose than with 2 doses of the same vaccine; no safety concerns⁸⁹</p> <p>Germany: greater reactogenicity with first dose of AstraZeneca than with the Pfizer/BioNTech booster⁹⁰</p>	<p>Spain: ≥ 8 week dose interval: Stronger immune response following Pfizer/BioNTech than after 2 doses of AstraZeneca vaccine (not peer reviewed)⁸⁸</p> <p>Spain: 8-12 week dose interval: robust antibody response⁹¹</p> <p>UK: 4 week dose interval: stronger antibody and cellular response than after 2 doses of AstraZeneca vaccine⁹²</p> <p>Germany: 9-12 week dose interval: Significantly stronger immune response following Pfizer/BioNTech booster than AstraZeneca, and slightly stronger than after 2 doses of Pfizer/BioNTech (not peer reviewed)⁹³</p> <p>Germany: 4-fold greater immune response following Pfizer/BioNTech booster than AstraZeneca⁹⁴</p>	Canada, Denmark, Finland, France, Germany, Sweden, Norway, Spain and South Korea ⁹⁵
Pfizer/BioNTech followed by AstraZeneca	<p>UK: Greater systemic side effects (mild-moderate symptoms) following the booster dose than with 2 doses of the same vaccine; no safety concerns⁸⁹</p> <p>Greater reactogenicity with first of homologous and heterologous prime-boost immunisation with BNT162b2 and ChAdOx1-nCoV19: a prospective cohort study</p>	UK: 4 week dose interval: weaker antibody response than after 2 doses of Pfizer/BioNTech vaccine (but stronger than after 2 doses of AstraZeneca vaccine) ⁹²	-
Pfizer/BioNTech or Johnson & Johnson followed by Moderna	-	USA: Trial underway with 12-20 week dose interval ⁹⁶	-
AstraZeneca, Moderna and Pfizer/BioNTech	-	Canada: Trial underway mixing and matching all three vaccines with study arms assessing 4 week and 16 week dose intervals ⁹⁷	AstraZeneca followed by either Moderna or Pfizer/BioNTech: Denmark, Finland, France, Germany, Sweden, Norway and Spain ⁹⁵
Sinovac followed by AstraZeneca	-	-	Thailand

Adverse Events Following Immunization with WHO EUL Vaccines

Adverse events following immunisation (AEFIs) are any reactions occurring after immunisation. They can be either expected or unexpected. The vaccine may not actually cause the AEFI; it may occur coincidentally as millions of people are being vaccinated so some people may get sick after vaccination but this does not necessarily mean that it is due to the vaccine. Special investigations determine whether they are due to the vaccine. Adverse events of special interest (AESIs) are of scientific and medical concern that are found through active surveillance, that have the potential to be causally associated with a vaccine and that need to be carefully monitored and confirmed by further special studies.

For all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following administration.

	ASTRAZENECA	MODERNA	PFIZER/BIONTECH	JOHNSON & JOHNSON	SINOPHARM	SINOVAC
Adverse events following immunisation (AEFIs)*	Very common (more than 1 in 10 people): headache, nausea, muscle pain, joint pain, injection site tenderness/ pain/ warmth/ itch, fatigue, malaise, fever, chills Common (between 1 in 10 and 1 in 100 people): injection site swelling/ redness ⁹⁸	Injection site pain (92%)/ swelling (15%)/ redness (10%), fatigue (70%), headache (65%), muscle pain (62%), joint pain (46%), fever (16%), chills (45%), nausea/vomiting (23%), axillary swelling/tenderness (20%) ⁹⁹	Very common: headache, muscle pain, joint pain, injection site pain/ swelling, fatigue, fever, chills; Common: nausea, injection site redness ⁹⁸ Uncommon (between 1 in 100 and 1 in 1000 people): lymphadenopathy, insomnia, pain in extremity of vaccinated arm, malaise, injection site itch; Rare: (between 1 in 1000 and 1 in 10,000): acute peripheral facial paralysis ¹⁰⁰	Injection site pain/ redness/ swelling, headache, fatigue, muscle pain, nausea, fever ¹⁰¹	Injection site pain (16%)/ itch (1%)/ swelling (2%)/ redness (1%), fever (4%), fatigue (3%), nausea (1%), headache (1%), diarrhoea (1%), muscle pain (<1%), itch (non-injection site) (1%) ¹⁰²	Fatigue (8.3%), fever (3.3%), diarrhoea (0.8%), nausea (1.7%), headache (2.5%), muscle pain (1.7%), injection site pain (10.0%)/ redness (0%)/ swelling (0%) ¹⁰³
Adverse events of special interest (AESIs)	Thrombosis with thrombocytopenia syndrome (TTS) (see page 13 for estimated risk); EMA PRAC: Guillain-Barre syndrome (GBS) ¹⁰⁴ Australia: Guillain-Barre syndrome: 52 cases (10.4 per million doses) ¹⁰⁵	USA: Myocarditis/pericarditis: 40.6 males and 4.2 females aged 12-29 years per million second doses of mRNA vaccine; and 2.4 males and 1.0 females aged 30+ ¹⁰⁶ >1 in 20,000 males under 25 years of age ¹⁰⁷ Immune thrombocytopenia (ITP)** ¹⁰⁸	USA: Myocarditis/pericarditis: 40.6 males and 4.2 females aged 12-29 years per million second doses of mRNA vaccine; and 2.4 males and 1.0 females aged 30+ ¹⁰⁶ >1 in 20,000 males under 25 years of age ¹⁰⁷ Israel: Myocarditis estimated to occur in 1 in 3,000 to 1 in 6,000 men aged 16-24 following the second dose – mostly mild and resolved ¹⁰⁹ ITP** ¹⁰⁸	TTS (see page 11 for estimated risk) USA: Guillain-Barre Syndrome: 100 preliminary reports of GBS following 12.5 million doses of vaccine administered (mostly males >50 years) ¹¹⁰	-	-

*Details for AstraZeneca, Moderna, Pfizer/BioNTech and Johnson & Johnson from product information sheets in SRA countries, based on data from clinical trials; Sinopharm and Sinovac details from published clinical trials

**The ITP cases are mostly without the thrombotic events characteristic of TTS

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	<p>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)¹²</p> <p>US Phase III study: No serious safety concerns involving 32,449 participants¹³ (not peer-reviewed)</p> <p>EMA investigation: possible link between the AstraZeneca vaccine and Thrombosis with Thrombocytopenia 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 effects⁶</p> <p>TTS reported to occur in ~1 in 66,000 vaccinated adults in Australia⁹</p> <p>Several countries have recommended that only older adults should receive the vaccine (including only those aged over 60 years in Germany and Australia; over 55 years in France and Canada; and over 40 years in the UK¹¹¹⁻¹¹³)</p> <p>EMA has started a review of reports of capillary leak syndrome following 5 cases of this very rare disorder post vaccination¹¹⁴</p> <p>Guillain-Barre syndrome reported by EMA PRAC and 10.4 cases per million doses in Australia^{104,105}</p>
Gamaleya	<p>45 SAEs in 16,427 (0.3%) vaccine recipients and 23 in 5,435 (0.4%) placebo recipients; all SAEs considered unrelated to vaccination; 4 deaths, all considered unrelated to vaccination (3 vaccine, 1 placebo)¹⁴</p>
Johnson & Johnson	<p>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)¹⁶</p> <p>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 confirmed⁷</p> <p>The CDC and FDA have now recommenced the vaccination program in the USA following a thorough safety review¹¹⁵</p> <p>15 cases of TTS have been reported in 7.98 million people vaccinated in USA⁵</p> <p>Guillain-Barre Syndrome: 100 preliminary reports of GBS following 12.5 million doses of vaccine administered in USA (mostly males >50 years)¹¹⁹</p>
Moderna	<p>153 SAEs in 15,166 (1.0%) vaccine recipients and 147 in 15,185 (1.0%) placebo recipients 5 deaths considered unrelated to vaccine (2 vaccine, 3 placebo)¹⁷</p> <p>Anaphylaxis reported in the US at a rate of 2.5 per million doses¹¹⁶</p> <p>No obvious safety signals among pregnant women who received mRNA COVID-19 vaccines in USA¹¹⁷</p> <p>USA: Myocarditis/pericarditis reported in more than 1 in 20,000 males under 25 years of age following second dose of mRNA vaccine¹⁰⁷</p> <p>USA: Myocarditis/pericarditis reported in 40.6 males and 4.2 females aged 12-29 years per million second doses of mRNA vaccine; and 2.4 males and 1.0 females aged 30+¹⁰⁶</p>
Novavax	<p>SAEs at low levels and similar between vaccine and placebo groups¹¹⁸</p>
Pfizer/BioNTech	<p>SAEs and deaths were low and comparable between vaccine and placebo groups (total 37,586 participants)²²</p> <p>Anaphylaxis reported in the US at a rate of 4.7 per million doses¹¹⁶</p> <p>No obvious safety signals among pregnant women who received mRNA COVID-19 vaccines in USA¹¹⁷</p> <p>USA: Myocarditis/pericarditis reported in more than 1 in 20,000 males under 25 years of age following second dose of mRNA vaccine¹⁰⁷</p> <p>USA: Myocarditis/pericarditis reported in 40.6 males and 4.2 females aged 12-29 years per million second doses of mRNA vaccine; and 2.4 males and 1.0 females aged 30+¹⁰⁶</p>

Risk of Rare Unusual Blood Clotting with Low Blood Platelets (Thrombosis with Thrombocytopenia 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	0.6-1.0	<1
Fiji	867,000	520,200	5.2-8.3	1.6
French Polynesia	275,918	165,551	1.7-2.6	<1
Guam	159,358	95,615	1.0-1.5	<1
Kiribati	113,400	68,040	0.7-1.1	<1
Marshall Islands	54,900	32,940	<1	<1
Nauru	10,900	6,540	<1	<1
New Caledonia	271,407	162,844	1.6-2.6	<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	46.5-73.8	14.6
Samoa	195,979	117,587	1.2-1.9	<1
Solomon Islands	642,000	385,200	3.9-6.1	1.2
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	1.6-2.6	<1
Wallis and Futuna	11,558	6,935	<1	<1
All Pacific Island Countries	10,976,992	6,586,195	65.9-104.5	20.8

* Based on estimate of 60% of population aged ≥18 years¹¹⁹

** Based on estimates of TTS occurring in ~1 in 100,000 vaccinated adults by the European Medicines Agency and ~1 in 66,000 in Australia^{8,9}

*** Based on estimates of TTS occurring in ~1 in 319,000 vaccinated adults in USA (may be an underestimate as only cerebral venous sinus thrombosis are reported)¹¹

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	SINOVAC
Minimum Age	18 years	18 years	12 years	18 years	18 years	18 years
Maximum Age (SAGE WHO)	None	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	Yes if high priority group & approved by health provider
Breastfeeding	Yes	Yes	Yes	Yes	Yes	Yes
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	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)	Yes (unless the allergy is to the vaccine or its components)

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	10	2	2	2 (Pfizer/BioNTech, Moderna)
DNA	17	7	3	0	0
Vector (non-replicating)	27	7	2	3	4 (CanSino, Gamaleya, Johnson & Johnson, AstraZeneca)
Vector (replicating)	18	7	0	0	0
Inactivated	8	6	8	2	8 (Sinopharm/BIBP; Sinopharm/WIBP; Sinovac; Bharat; Chumakov; Research Institute for Biological Safety Problems; Shenzhen Kangtai Biological Products; Shifa Pharmed)
Live-attenuated	2	1	0	0	0
Protein subunit	73	22	9	1	4 (Vector institute; Anhui Zhifei Longcom Biopharmaceutical Chinese Academy of sciences; Center for Genetic Engineering and Biotechnology; Instituto Finlay de Vacunas Cuba)
Virus-like particle	20	4	1	0	0
Other/unknown	33	5	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.

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 CSL, Australia: Authorised Daiichi Sankyo, Japan: Authorised
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	Authorised 01/06/2021
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	Additional data required; review ongoing	Will be determined when all data are submitted
CanSinoBIO	Ad5-nCoV	Adenoviral vector	Rolling data assessment starting July 2021	-
Novavax	NVX-CoV2373	Protein subunit	Expression of interest accepted; Pre-submission meeting held	-
CureVac	Zorecimeran	mRNA	Expression of interest accepted; Pre-submission meeting planned for 28 July 2021	-
Bharat Biotech	Covaxin; BBV152	Inactivated	Rolling data assessment starting July 2021	-
Clover Biopharmaceuticals	SCB-2019 (CpG 1018/Alum)	Protein subunit	In discussion on submission strategy and timelines	-

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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