Weekly COVID-19 Vaccine Updates

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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.
- 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 years[1–4]
- 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 Thrombocytopaenia 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 USA[11]
- 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)*:

- Combined analysis of the effectiveness of the AstraZeneca, Pfizer/BioNTech and Moderna vaccines by time period after the first dose in Italy (Page 5):
  - Infection: 78% (76-79) (stabilised at 42-49 days post-first dose)
  - Hospitalisation: 89% (85-91) (stabilised at 35-42 days post-first dose)
  - Death: 93% (89-96) (stabilised at 35-42 days post-first dose)
- Immunogenicity of AstraZeneca vaccine:
  - Longer delay before the second dose (median 44 weeks) produces a better immune response
  - A third dose (booster) produces a better immune response compared with 28 days after the second dose
- A modified version of the AstraZeneca vaccine that targets the Beta variant has commenced trials
- Minimum age for Pfizer/BioNTech vaccine updated to 12 years based on WHO SAGE recommendations (Page 13)
- The US Advisory Committee on Immunization Practices (ACIP) is not recommending a third dose of vaccine (booster) at this time but monitoring is ongoing:
  - Initial efficacy may be useful in predicting time until boosting may be needed (earlier with lower initial efficacy)
  - Recommendation for booster doses will be based on evidence of declining protection against illness (due to declines in vaccine effectiveness or escape variants), not declining neutralising antibody response alone
  - Possible that booster doses may only be required in vulnerable populations
- ACIP has reported rates of myocarditis and pericarditis following the Pfizer/BioNTech and Moderna mRNA vaccines by sex and age group (Page 10):
  - Following the first dose:
    - Slightly more cases than expected in males under 30 years of age only
  - Following the second dose:
    - Highest rates in males under 25 years of age
    - Males aged 12-17 years: 66.7 cases per million doses
    - Males aged 18-24 years: 56.3 cases per million doses
    - Males aged 25-39 years: 20.4 cases per million doses
    - Slightly higher than expected rates in females under 30 years of age and males under 50 years of age
  - Of 323 cases meeting the CDC case definition of myocarditis or pericarditis, 309 were hospitalised:
    - 295 discharged (218 (79%) known to have fully recovered from symptoms)
    - 9 still hospitalised (2 in ICU)
    - 5 with no outcome data
- The US FDA updated the product information for the Pfizer/BioNTech and Moderna vaccines to include a warning about myocarditis and pericarditis
- Countries endorsing mixed dose vaccine schedules have been added (Page 9)
  - Booster doses of Moderna and Pfizer/BioNTech vaccines are being offered for first dose AstraZeneca recipients in Denmark, Finland, France, Germany, Sweden, Norway and Spain

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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		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, 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)

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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] SInlge 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]

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COVID-19 Vaccine Effectiveness

VACCINE	SEVERE / HOSPITALISATION / DEATH	INFECTION AND OTHER OUTCOMES
AstraZeneca	Single dose in Scotland: 94% (73-99)[26] Risk of death in vaccine failures compared to unvaccinated cases in England reduced by: 55% (41-66)[27] (not peer reviewed) Single dose against hospitalisation in Spain: 92% (46-99)[28] Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Hospitalisation: 89% (85-91); Death: 93% (89-96)[29]	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%[30] Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines: reduced odds of infection post-second dose: 70% (62-77)[31] Single dose in Spain: Any infection: 44% (31-54); Symptomatic infection: 50% (37-61)[28] Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Infection: 78% (76-79)[29]
Johnson & Johnson	-	USA: Any infection: 76.7% (30.3-95.3)[32]
Moderna	Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Hospitalisation: 89% (85-91); Death: 93% (89-96)[29]	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)[33] 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)[34] Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Infection: 78% (76-79)[29]
Pfizer/BioNTech	Severe in Israel: 92% (75-100)[35] Severe/critical in Israel: 97.5% (97.1-97.8)[36] Single dose against hospitalisation in Scotland: 85% (76-91)[26] Risk of death in vaccine failures compared to unvaccinated cases in England reduced by: Single dose: 44% (32-53) Fully vaccinated: 69% (31-86)[27] (not peer reviewed) Israel: Hospitalisation: 97.2% (96.8-97.5); Death: 96.7% (96.0-97.3)[36] Hospitalisation in Spain: 94% (60-99)[28] Priority groups in Denmark: Hospitalisation: 93% (89-96); Death: 94% (90-96)[37] Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Hospitalisation: 89% (85-91); Death: 93% (89-96)[29]	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)[33] Pooled analysis of Moderna and Pfizer/BioNTech vaccines in USA: Fully vaccinated: 90% (68–97); Two weeks after first dose: 80% (59–90)[34] Symptomatic infection in Israel: 94% (87-98)[35] Any infection in Israel: 90% (79-95)[38] Israel: Any infection: 95.3% (94.9-95.7); Symptomatic infection: 97.0% (96.7-97.2)[36] 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%[30] 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[39] Pooled analysis of Pfizer/BioNTech and AstraZeneca vaccines: reduced odds of infection post-second dose: 70% (62-77)[31] Spain: Any infection: 65% (56-73); Symptomatic infection: 82% (73-88)[28] Infection in priority groups in Denmark: 82% (79-84)[37] USA: Symptomatic infection: 84% (75-90)[40] Denmark: Infection in care facility residents: >14 days after first dose:17% (4-28); >7 days after second dose: 64% (14-84)[41] USA: Single dose against infection in 2 care facilities: 63% (33-79)[42] A care facility in USA: Infection 66% (41-81); Symptomatic illness 87% (66-95); Death 94% (45-99)[43] Pooled analysis of AstraZeneca, Pfizer/BioNTech and Moderna vaccines in Italy: Infection: 78% (76-79)[29]
Sinovac	Chile: Hospital admission: 85% (83-87); ICU admission: 89% (84-92); Death: 80% (73-86)[44] (not peer reviewed)	Symptomatic infection in Chile: 67% (65-69)[44] (not peer reviewed)
Sinopharm	-	Symptomatic infection in Bahrain: 90% (88-91)[24]

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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.[45] The WHO recommends labelling SARS-CoV-2 variants with letters of the Greek alphabet, as in the table below.[46]

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	70·4% (43·6-84·5) (vs. 81·5% (67·9-89·4) against wild variant in UK)[47] Effectiveness: ≥21 days after one dose: 51.4% (47.3-55.2); ≥14 days after two doses: 66.1% (54.0-75.0)[48] Scotland: 73% (66-78)[49]	-	10.4% (−76.8 to 54.8)[50]	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)[48] Scotland: 60% (53-66)[49]	Hospitalisation in England: 1 dose: 71% (51-83); 2 doses: 92% (75-97)[51]
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]		
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)[52]	-	-	-		
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 (OR: 26:10) [53] Effectiveness in Qatar: 89.5% (85.9-92.3)[54] Effectiveness: ≥21 days after one dose: 49.2% (42.6 to 55.0) ≥14 days after second dose: 93.4% (90.4-95.5)[48] Scotland: 92% (90-93)[49]	Effectiveness in Qatar: 100% (81.7-100)[54]	Israel case-control study: Vaccinees infected at least 1 week after the second dose were disproportionally infected with B.1.351 (odds ratio: 8:1)[53] Effectiveness in Qatar: 75.0% (70.5-78.9)[54]	Effectiveness in Qatar: 100% (73.7-100)[54]	-	-	Effectiveness: ≥21 days after one dose: 33.2% (8.3-51.4); ≥14 days after second dose: 87.9% (78.2-93.2)[48] Scotland: 79% (75-82)[49]	Hospitalisation in England: 1 dose: 94% (46-99); 2 doses: 96% (86-99)[51]
Sinovac	Chile: 67% (65-69)*[24]	-	-	-	Brazil: vaccine effectiveness 1 or 2 doses: 35.1% (−6.6-60.5)[55] 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)[56]	-		

* 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

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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 vacines): 18-64 years: 85% (68-93); 65-79 years: 79% (17-95); ≥80 years: 81% (65-90)[26] Effectiveness against symptomatic infection in England: ≥70 years: 60% (41-73)[57] Effectiveness of single dose against hospitalisation in England: ≥80 years: 73% (60-81)[58] Effectiveness in England: Symptomatic infection ≥70 years: 73% (27-90); Hospitalisation ≥80 years: 37% (3-59)[59] Hospitalisation following single dose in the UK: ≥80 years: 80.4% (36.4-94.5)[60] Single dose in Spain: ≥60 years: 53% (19-72) vs. 18-59 years: 50% (34-62)[28]
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)[61]
Pfizer/BioNTech	Effectiveness in Israel: Diabetes or cardoiovascular disease: 82% (62-92)[38]	-	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)[37]	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 vacines): 18-64 years: 85% (68-93); 65-79 years: 79% (17-95); ≥80 years: 81% (65-90)[26] Effectiveness against symptomatic infection in England: ≥70 years: 61% (51-69); ≥80 years: 89% (85-93)[57] (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)[62] 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%[63] Pooled Moderna and Pfizer vaccines against hospitalisation ≥65 years: 94% (49-99)[61] 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)[59] Effectiveness against hospitalisation in England ≥80 years: Single dose: 81% (76-85) Fully vaccinated: 93% (89-95)[58] (not peer reviewed) Effectiveness in Israel: 65-74 years: 82% (63-92); ≥75 years: 82% (61-91)[38] Hospitalisation following single dose in the UK: ≥80 years: 71.4% (43.1-86.2)[60] Single dose in Spain: ≥60 years: 76% (55-87) vs. 18-59 years: 85% (74-91)[28] Effectiveness against infection in Denmark: ≥80 years: 77% (50-89)[37]
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]

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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) Symptomatic and asymptomatic combined (UK, South Africa and Brazil): 54.1% (44.7-61.9)[12] Odds ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive in England: 0.52 (0.43-0.62)[64] 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)[65] Hazard ratio for single dose in vaccinated vs. unvaccinated care facility residents in England: 0.32 (0.15-0.66)[66] Following regular testing of randomly selected UK households: 79% (65-88)[67]	-
Johnson & Johnson	Asymptomatic: 59.7% (32.8-76.6)[16]	-
Moderna	US: Pooled analysis of Pfizer/BioNTech and Moderna vaccines: 88.7% (68.4-97.1)[68] 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)[69] 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)[70] 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[71] Reduced potential for transmission (from modelling): at least 61%[72]	-
Pfizer/BioNTech	England: 86% (76-97) 7 days after 2 doses; 72% (58-86) 21 days after 1 dose[73] Israel: 75% (72-84) 15-28 days after single dose[74]; 92% (88-95)[35] Israel: 91.5% (90.7-92.2)[36] USA: Pooled analysis of Pfizer/BioNTech and Moderna vaccines: 88.7% (68.4-97.1)[68] UK, single dose: 4-fold decrease in risk amongst HCWs ≥12 days post-vaccination[75] 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)[69] 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)[70] 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[71] 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)[76] Following regular testing of randomly selected UK households: 80% (73-85)[67] USA: Asymptomatic screening: 90% (78-96)[40] Israel: 65% (45-79%)[77] * 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%[78]	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[79] 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[80] Substantially decreased viral load for infections occurring 12-37 days after the first dose of vaccine in Israel, indicating likely lower infectiousness[79] Detectable transmission in long-term care facilities in Spain reduced by 90% (76-93)[81] Odds ratio for household contacts of vaccinated health workers vs non-vaccinated health workers testing positive in England: 0.54 (0.47-0.62)[64] 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)[65] Hazard ratio for single dose in vaccinated vs. unvaccinated care facility residents: 0.35 (0.17-0.71)[66]

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

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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	Spain: Similar side effects to those receiving 2 doses of the same vaccine; no safety concerns (not peer reviewed)[82] UK: Greater systemic side effects (mild-moderate symptoms) following the booster dose than with 2 doses of the same vaccine; no safety concerns[83] Germany: greater reactogenicity with first dose of AstraZeneca than with the Pfizer/BioNTech booster[84]	Spain: ≥8 week dose interval: Stronger immune response following Pfizer/BioNTech than after 2 doses of AstraZeneca vaccine (not peer reviewed)[82] UK: 4 week and 12 week dose intervals: Trial underway with immunogenicity data expected in June 2021[83] 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)[85] Germany: 4-fold greater immune response following Pfizer/BioNTech booster than AstraZeneca[86]	Canada, Denmark, Finland, France, Germany, Sweden, Norway and Spain[89]
Pfizer/BioNTech followed by AstraZeneca	UK: Greater systemic side effects (mild-moderate symptoms) following the booster dose than with 2 doses of the same vaccine; no safety concerns[83] Greater reactogenicity with first of homologous and heterologous prime-boost immunisation with BNT162b2 and ChAdOx1-nCoV19: a prospective cohort study	UK: 4 week and 12 week dose intervals: Trial underway with immunogenicity data expected in June 2021[83]	-
Pfizer/BioNTech or Johnson & Johnson followed by Moderna	-	USA: Trial underway with 12-20 week dose interval[87]	-
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[88]	AstraZeneca followed by either Moderna or Pfizer/BioNTech: Denmark, Finland, France, Germany, Sweden, Norway and Spain[89]

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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[90]	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%)[91]	Very common: headache, muscle pain, joint pain, injection site pain/ swelling, fatigue, fever, chills; Common: nausea, injection site redness[90] 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[92]	Injection site pain/ redness/ swelling, headache, fatigue, muscle pain, nausea, fever[93]	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%)[94]	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%)[95]
Adverse events of special interest (AESIs)	Thrombosis with thrombocytopaenia syndrome (TTS) (see page 11 for estimated risk); Guillain-Barre syndrome[96]	Myocarditis;[97] USA: Myocarditis/pericarditis occurring in more than 1 in 20,000 males under 25 years of age following second dose of mRNA vaccine[98] Immune thrombocytopaenia (ITP)**[99]	USA: Myocarditis or myopericarditis in 7 males aged 14-19 years within 4 days of the second dose – all cases resolved[100] USA: Myocarditis/pericarditis occurring in more than 1 in 20,000 males under 25 years of age following second dose of mRNA vaccine[98] Israel: Myoarditis 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[101] ITP**[99]	TTS (see page 11 for estimated risk)	-	-

*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

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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)[12] US Phase III study: No serious safety concerns involving 32,449 participants[13] (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[6] TTS reported to occur in ~1 in 66,000 vaccinated adults in Australia[9] 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 UK[102–104] EMA has started a review of reports of capillary leak syndrome following 5 cases of this very rare disorder post vaccination[105]
Gamaleya	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]
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)[16] 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[7] The CDC and FDA have now recommenced the vaccination program in the USA following a thorough safety review[106] 15 cases of TTS have been reported in 7.98 million people vaccinated in USA[5]
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)[17] Anaphylaxis reported in the US at a rate of 2.5 per million doses[107] No obvious safety signals among pregnant women who received mRNA COVID-19 vaccines in USA[108] Myocarditis/pericarditis reported in more than 1 in 20,000 males under 25 years of age following second dose of mRNA vaccine[98]
Novavax	SAEs at low levels and similar between vaccine and placebo groups[109]
Pfizer/BioNTech	SAEs and deaths were low and comparable between vaccine and placebo groups (total 37,586 participants)[22] Anaphylaxis reported in the US at a rate of 4.7 per million doses[107] No obvious safety signals among pregnant women who received mRNA COVID-19 vaccines in USA[108] Myocarditis/pericarditis reported in more than 1 in 20,000 males under 25 years of age following second dose of mRNA vaccine[98]

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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	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 years[110]
** 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
Minumum 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)

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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	10	2	2	2 (Pfizer/BioNTech, Moderna)
DNA	17	7	3	0	0
Vector (non-replicating)	27	8	2	3	4 (CanSino, Gamaleya, Johnson & Johnson, AstraZeneca)
Vector (replicating)	18	6	0	0	0
Inactivated	8	7	7	2	8 (Sinopharm/BIBP; Sinopharm/WIBP; Sinovac; Bharat; Chumakov; Research Instutute for Biological Safety Problems; Shenzhen Kangtai Biological Products; Shifa Pharmed)
Live-attenuated	2	1	0	0	0
Protein subunit	74	19	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.

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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	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 June 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 July	-

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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