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.
- The EMA investigation has found a possible link between the AstraZeneca vaccine and very rare clotting disorders with low platelets and concluded this should be listed as a rare side effect of the vaccine. Blood clots affected the brain (central venous sinus thrombosis, CVST) and abdomen (splanchnic vein thrombosis). CVST is a very rare condition, with estimated background incidence of 2-5 per million per year although the true incidence may be higher[1]. 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]. In Australia, there has been 1 reported case in 420,000 doses administered.[3] It is important to note that whilst concerning, the events under assessment are very rare, with low numbers reported among the almost 200 million individuals who have received the vaccine around the world.
- 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)*:

- New table added on the risk of rare blood clotting disorders in Pacific Island Countries (Page 10); this is based on the latest data available from Europe, as detailed in the “Key messages“ section and on Page 9
- Updated efficacy for AstraZeneca vaccine against B.1.1.7 variant: 70.4% (43.6-84.5) (Page 6)
- Pfizer/BioNTech vaccine in USA: 100% vaccine efficacy against symptomatic infection in adolescents (Page 5)
- Transmission in Israel: lower viral load in vaccination failure cases 12-37 days after the first dose of Pfizer/BioNTech vaccine compared to within the first 11 days post vaccine, indicates potentially lower infectiousness (Page 8)
- The Canadian National Advisory Committee on Immunization (NACI) recommends AstraZeneca vaccine not be given to adults under 55 years of age while safety related to the rare condition, Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT), is further investigated (Page 9)
- It is anticipated that in April 2021 WHO will include under EUL the European manufacturing sites for AZ as authorised by EMA. Decisions on Sinovac and Sinopharm postponed to end-April (Page 13)
- Interim analyses of clinical trial data for 2 inactivated COVID-19 vaccines, Sinovac and Sinopharm, were presented to WHO SAGE. Both vaccines are already in use in many countries, but neither product has received authorisation by a SRA. Both are under review by WHO for EUL. The vaccines demonstrated safety and good efficacy against symptomatic COVID-19 disease but both vaccines lacked data in older age groups and in persons with comorbidities. Post-introduction vaccine effectiveness and safety studies will be needed to address the impact on those sub-populations.

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COVID-19 Vaccine Specifications

	ASTRAZENECA	GAMALEYA	JOHNSON & JOHNSON	MODERNA	NOVAVAX	PFIZER/BIONTECH	SINOVAC
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
Available Through COVAX	✓	-	✓	-	✓	✓	-
Doses Required	8-12 weeks apart* 4 weeks apart (Product Information)	3 weeks apart		28 days apart*	3 weeks apart	3 weeks apart*	2 weeks apart (Brazil data suggest higher efficacy with 3 weeks between doses)
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; -25°C to -15°C for up to 2 weeks; 6-dose vials	2-8°C; Single-dose vials
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

*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%[4] (not peer-reviewed) UK: 100% (15 cases in the placebo group)[5]	UK: Hospitalisation: 100% (9 cases in placebo group)[5]	Symptomatic infection: 66.7% (57.4-74.0)[5] Symptomatic infection: 76%[4] (not peer-reviewed) Symptomatic infection using a SINGLE DOSE (22-90 days post-vaccination): 76.0% (59.3 to 85.9)[5] Efficacy higher with longer time interval between doses: 12+ weeks: 82.4% (2.7-91.7) <6 weeks: 54.9% (32.7-69.7)[5]
Gamaleya	Moderate-severe: 100% (20 cases in the placebo group)[6]	-	-	Symptomatic infection: 91.6% (85.6–95.2)[6]
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)[7]	85.4% (54.2-96.9)[7]	100% (7 deaths in placebo group)[7]	Preserved for all ages and virus variants including B1.351[7]
Moderna	-	100% (30 cases in placebo group)[8]	100% (1 death in placebo group)[8]	Symptomatic infection: 94.1% (89.3-96.8)[8]
Novavax	-	-	-	Symptomatic infection: 89.3% (75.2-95.4)[9] (not peer reviewed)
Pfizer/BioNTech	-	88.9% (20.1–99.7)[10]	-	Symptomatic infection: 94.6% (89.9–97.3)[10] USA: 100% against symptomatic infection in adolescents[11]
Sinovac	-	-	-	Symptomatic infection: Brazil: 50.4%; Indonesia: 65.3%; Turkey 91.3% (not peer reviewed)

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COVID-19 Vaccine Effectiveness

VACCINE	SEVERE	HOSPITALISATION / DEATH	OTHER OUTCOMES
AstraZeneca	-	SINGLE DOSE in Scotland: 94% (73-99)[12]	Pooled analysis of Pfizer 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%[13]
Moderna	-	-	Pooled analysis of Moderna and Pfizer vacines in USA: Infections in nonvaccinated: 234 of 8969; 2.61% (2.29-2.96) Fully vaccinated: 4/8121; 0.05% (0.01-0.13)[14]
Pfizer/BioNTech	Israel: 92% (75-100)[15]	SINGLE DOSE in Scotland: 85% (76-91)[12]	Pooled analysis of Moderna and Pfizer vacines in USA: Infections in nonvaccinated: 234 of 8969; 2.61% (2.29-2.96) Fully vaccinated: 4/8121; 0.05% (0.01-0.13)[14] Symptomatic infection in Israel: 94% (87-98)[15] Pooled analysis of Pfizer 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%[13] 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[16]

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Vaccine Efficacy 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.

VACCINE	VACCINE EFFICACY			
	B.1.1.7 (UK) VARIANT	B1.351 501Y.V2 (SOUTH AFRICA) VARIANT		B.1.1.28.P1 AND B.1.1.28.P2 (BRAZIL) VARIANTS
	MILD/MODERATE	MILD/MODERATE	SEVERE	SEVERE
AstraZeneca	70·4% (43·6–84·5) (vs. 81·5% (67·9–89·4) against wild variant in UK)[17]	10.4% (−76.8 to 54.8)[18]	Study underway [7]	-
Johnson & Johnson	-	-	Moderate to severe/critical: 64.0% (41.2-78.7) Severe/critical: 81.7% (46.2-95.4)[7]	Moderate to severe/critical: 68.1% (48.8-80.7) Severe/critical: 87.6% (7.8-99.7)[7]
Novavax	85.6%[9] (not peer reviewed)	Against mild, moderate and severe: HIV-negative: 51.0% (−0.6-76.2) Overall: 43.0% (−9.8-70.4)[19]	-	-

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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[4] (not peer-reviewed)	In ≥65 years: 85%[4] (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)[12]
Gamaleya	-	-	-	Against symptomatic infection in >60 years: 91.8% (67.1–98.3)[6]
Johnson & Johnson	Against moderate to severe/critical: 23.0% (-90.1-69.8)[7]	Against moderate to severe/critical: 65.9% (47.8-78.3)[7]	Against moderate to severe/critical: With any comorbidity: 58.6% (40.6-71.6)[7] No comorbidity: 68.8% (59.0-76.6)[7]	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)[7]
Moderna	-	-	Against symptomatic infection, based on presence of comorbidities, including diabetes and obesity: In low risk: 95.1% (89.6-97.7) In high risk: 90.9% (74.7-96.7)[8]	Against symptomatic infection: 18-64 years: 95.6% (90.6-97.9) ≥65 years: 86.4% (61.4-95.2)[8]
Pfizer/BioNTech	-	-	Against symptomatic infection: With any comorbidity or obesity: 95.3% With no comorbidity: 94.7%[10]	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)[10] 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)[12]

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)[5] Symptomatic and asymptomatic combined (UK, South Africa and Brazil): 54.1% (44.7-61.9)[5]	
Johnson & Johnson	Asymptomatic: 59.7% (32.8-76.6)[7]	
Moderna	US: Pooled analysis of Pfizer and Moderna vaccines: 88.7% (68.4-97.1)[20] Pooled analysis of Pfizer 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)[21]	
Pfizer/BioNTech	England: 86% (76-97) 7 days after 2 doses 72% (58-86) 21 days after 1 dose[22] Israel: 75% (72-84) 15-28 days after single dose[23] Israel: 92% (88-95)[15] USA: Pooled analysis of Pfizer and Moderna vaccines: 88.7% (68.4-97.1)[20] UK, following single dose: 4-fold decrease in risk amongst HCWs ≥12 days post-vaccination[24] Pooled analysis of Pfizer 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)[21]	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[25]

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)[5] US Phase III study: No serious safety concerns involving 32,449 participants[4] (not peer-reviewed) EMA investigation: possible link between the AstraZeneca vaccine and very rare clotting disorders with low platelets 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: 1 case in 420,000 doses administered[3] 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[26–28]
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)[6]
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)[7]
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)[8] Anaphylaxis reported in the US at a rate of 2.5 per million doses[29]
Novavax	SAEs at low levels and similar between vaccine and placebo groups[9]
Pfizer/BioNTech	SAEs and deaths were low and comparable between vaccine and placebo groups (total 37,586 participants)[10] Anaphylaxis reported in the US at a rate of 4.7 per million doses[29]

Risk of Rare Unusual Blood Clotting (CVST and splanchnic vein thrombosis) with low blood platelets

Estimated number of clotting disorders that potentially might occur in Pacific Island Countries if all adults received the AstraZeneca vaccine, based on the estimated 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 BLOOD CLOTTING CASES (CVST AND SPLANCHNIC VEIN THROMBOSIS) IF ALL ADULTS IN EACH COUNTRY VACCINATED^
American Samoa	55,519	33,311	<1
Cook Islands	15,300	9,180	<1
Federated States of Micronesia	102,300	61,380	<1
Fiji	867,000	520,200	1.2-3.3
French Polynesia	275,918	165,551	0.4-1.0
Guam	159,358	95,615	<1
Kiribati	113,400	68,040	<1
Marshall Islands	54,900	32,940	<1
Nauru	10,900	6,540	<1
New Caledonia	271,407	162,844	0.4-1.0
Niue	1,611	967	<1
Northern Mariana Islands	53,883	32,330	<1
Palau	18,000	10,800	<1
Papua New Guinea	7,744,700	4,646,820	11.1-29.0
Samoa	195,979	117,587	<1
Solomon Islands	642,000	385,200	0.9-2.4
Tokelau	1,160	696	<1
Tonga	99,419	59,651	<1
Tuvalu	10,507	6,304	<1
Vanuatu	272,173	163,304	0.4-1.0
Wallis and Futuna	11,558	6,935	<1
All Pacific Island Countries	10,976,992	6,586,195	15.7-41.2

CVST: Cerebral Venous Sinus Thrombosis

* Based on estimate of 60% of population aged ≥18 years[30]

^ Based on estimates of clotting disorders occurring in approximately 1 in 160,000 vaccinated adults in Europe and 1 in 420,000 in Australia[2,3]

Who Can be Vaccinated Based on WHO SAGE Recommendations?

So far, WHO SAGE have made recommendations for use of AstraZeneca, Moderna, Pfizer/BioNTech and Johnson & Johnson vaccines.

	ASTRAZENECA	MODERNA	PFIZER/BIONTECH	JOHNSON & JOHNSON
Minumum Age	18 years	18 years	16 years	18 years
Maximum Age (SAGE WHO)	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
Breastfeeding	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
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)

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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	27	7	1	2	2 (Pfizer/BioNTech, Moderna)
DNA	16	8	2	0	0
Vector (non-replicating)	26	7	4	1	4 (CanSino, Gamaleya, Johnson & Johnson, AstraZeneca)
Vector (replicating)	18	5	0	0	0
Inactivated	9	5	5	2	5 (Sinopharm/BIBP, Sinopharm/WIBP, Bharat, Chumakov, Sinovac)
Live-attenuated	2	1	0	0	0
Protein subunit	74	18	8	0	2 (Vector institute; Anhui Zhifei Longcom Biopharmaceutical Chinese Academy of sciences)
Virus-like particle	19	3	1	0	0
Other/unknown	34	3	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: Anticipated April 2021
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	End-April 2021
Sinovac	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	Inactivated	In progress	End-April 2021
Moderna	mRNA-1273	mRNA	In progress (to use abridged procedure relying on EMA)	Mid-April 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 to start in April 2021	-
Novavax	NVX-CoV2373	Protein subunit	Expression of interest submitted 23/02/21. Pre-submission meeting to be planned in April	-

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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