

# Weekly COVID-19 Vaccine Updates

Number 3, 1 April 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. The 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:

- It is difficult to directly compare the results from the studies as:
  - there are multiple variations in the way the clinical trials and effectiveness studies were undertaken;
  - each used different outcomes;
  - and the definitions for outcomes (e.g. for severity) also varied
- 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
- There is no evidence that the AstraZeneca vaccine is associated with an overall increase in clotting disorders, including deep vein thrombosis (DVT) and pulmonary embolus. There is an EMA review into very rare cases of unusual blood clots, including central venous sinus thrombosis (CVST), associated with low numbers of platelets. CVST is a very rare condition, with estimated background incidence of 2-5 per million per year although true incidence may be higher<sup>1</sup> More than 20 million doses of AstraZeneca vaccine have been administered in Europe and the EMA is continuing to investigate, whilst at the same time supporting the ongoing program, being of the view that the benefits of the AstraZeneca vaccine in preventing COVID-19, with its associated risk of hospitalisation and death, outweigh the risks of side effects.<sup>2</sup>

## 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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## New Updates

Key updates to this week's edition include (*also in yellow text in the document*):

- Efficacy against transmission is added (Page 8)
- Minor amendments to AstraZeneca phase III vaccine efficacy results following further press release (Pages 4 and 7)
- Pooled analysis of Pfizer and AstraZeneca vaccines in elderly care home residents in UK: 56% reduction in risk of infection 4 weeks after single dose; 62% reduction in risk 5 weeks after single dose (Page 5)
- Following the Pfizer/BioNTech vaccine in Israel, the incidence decreased from 9.4 infections per 1,000 in US healthcare workers (HCWs) in the week following the first dose to <1.0 infection per 1,000 HCWs per week from 1 week after the second dose (Page 5)
- EMA and WHO statements on AstraZeneca vaccine safety: the available data do not suggest any overall increase in clotting conditions (Page 9)
- Amendments to WHO SAGE EUL timeline (Page 13)



# 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*	 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)

# COVID-19 Vaccine Efficacy

VACCINE	VACCINE EFFICACY			
	MILD-MODERATE-SEVERE	SEVERE	HOSPITALISATION/DEATH	OTHER OUTCOMES
<b>AstraZeneca</b>	-	<p>US, Chile, Peru: Severe/critical and hospitalisation: 100%<sup>3</sup> (not peer-reviewed)</p> <p>UK: 100% (15 cases in the placebo group)<sup>4</sup></p>	<p>UK: Hospitalisation: 100% (9 cases in placebo group)<sup>4</sup></p>	<p>Symptomatic infection: 66.7% (57.4-74.0)<sup>4</sup></p> <p>Symptomatic infection: 76%<sup>3</sup> (not peer-reviewed)</p> <p>Symptomatic infection using a SINGLE DOSE (22-90 days post-vaccination): 76.0% (59.3 to 85.9)<sup>4</sup></p> <p>Efficacy higher with longer time interval between doses: 12+ weeks: 82.4% (2.7-91.7) &lt;6 weeks: 54.9% (32.7-69.7)<sup>4</sup></p>
<b>Gamaleya</b>	Moderate-severe: 100% (20 cases in the placebo group) <sup>5</sup>	-	-	Symptomatic infection: 91.6% (85.6-95.2) <sup>5</sup>
<b>Johnson &amp; Johnson</b>	<p>≥28 days post-vaccination: All sites: 66.1% (55.0-74.8) US: 72.0% (58.2-81.7) Latin America: 61.0% (46.9-71.8) South Africa: 64.0% (41.2-78.7)<sup>6</sup></p>	85.4% (54.2-96.9) <sup>6</sup>	100% (7 deaths in placebo group) <sup>6</sup>	Preserved for all ages and virus variants including B.1.351 <sup>6</sup>
<b>Moderna</b>	-	100% (30 cases in placebo group) <sup>7</sup>	100% (1 death in placebo group) <sup>7</sup>	Symptomatic infection: 94.1% (89.3-96.8) <sup>7</sup>
<b>Novavax</b>	-	-	-	Symptomatic infection: 89.3% (75.2-95.4) <sup>8</sup> (not peer reviewed)
<b>Pfizer/BioNTech</b>	-	88.9% (20.1-99.7) <sup>9</sup>	-	Symptomatic infection: 94.6% (89.9-97.3) <sup>9</sup>
<b>Sinovac</b>	-	-	-	Symptomatic infection: Brazil: 50.4%; Indonesia: 65.3%; Turkey 91.3% (not peer reviewed)

# COVID-19 Vaccine Effectiveness

VACCINE	SEVERE	HOSPITALISATION / DEATH	OTHER OUTCOMES
AstraZeneca	-	SINGLE DOSE in Scotland: 94% (73-99) <sup>10</sup>	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% <sup>11</sup>
Moderna	-	-	Pooled analysis of Moderna and Pfizer vaccines in US: Infections in nonvaccinated: 234 of 8969; 2.61% (2.29-2.96) Fully vaccinated: 4/8121; 0.05% (0.01-0.13) <sup>12</sup>
Pfizer/BioNTech	Israel: 92% (75-100) <sup>13</sup>	SINGLE DOSE in Scotland: 85% (76-91) <sup>10</sup>	<p>Pooled analysis of Moderna and Pfizer vaccines in US: Infections in nonvaccinated: 234 of 8969; 2.61% (2.29-2.96) Fully vaccinated: 4/8121; 0.05% (0.01-0.13)<sup>12</sup></p> <p>Symptomatic infection in Israel: 94% (87-98)<sup>13</sup></p> <p>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%<sup>11</sup></p> <p>Documented infection in Israel: incidence decreased from 9.4 infections per 1,000 HCWs in the week following first dose to &lt;1.0 infection per 1,000 HCWs per week from 1 week after the second dose<sup>14</sup></p>

# 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	74.6% (41.6-88.9) (84% (70.7-91.4) against wild variant in UK) <sup>15</sup>	10.4% (-76.8 to 54.8) <sup>16</sup>	Study underway <sup>6</sup>	-
Johnson & Johnson	-	-	Moderate to severe/critical: 64.0% (41.2-78.7) Severe/critical: 81.7% (46.2-95.4) <sup>6</sup>	Moderate to severe/critical: 68.1% (48.8-80.7) Severe/critical: 87.6% (7.8-99.7) <sup>6</sup>
Novavax	85.6% <sup>8</sup> (not peer reviewed)	Against mild, moderate and severe: HIV-negative: 51.0% (-0.6-76.2) Overall: 43.0% (-9.8-70.4) <sup>17</sup>	-	-

# Vaccine Efficacy/Effectiveness in the Elderly and Against Comorbidities

VACCINE	VACCINE EFFICACY UNLESS OTHERWISE STATED			
	DIABETES	OBESITY	AT RISK FOR SEVERE COVID-19	ELDERLY
<b>AstraZeneca</b>	-	-	76% against symptomatic infection in a sample where 60% had comorbidities, including diabetes, severe obesity or cardiac disease <sup>3</sup> (not peer-reviewed)	In ≥65 years: 85% <sup>3</sup> (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) <sup>10</sup>
<b>Gamaleya</b>	-	-	-	Against symptomatic infection in >60 years: 91.8% (67.1–98.3) <sup>5</sup>
<b>Johnson &amp; Johnson</b>	Against moderate to severe/critical: 23.0% (-90.1-69.8) <sup>6</sup>	Against moderate to severe/critical: 65.9% (47.8-78.3) <sup>6</sup>	Against moderate to severe/critical: With any comorbidity: 58.6% (40.6-71.6) <sup>6</sup> No comorbidity: 68.8% (59.0-76.6) <sup>6</sup>	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) <sup>6</sup>
<b>Moderna</b>	-	-	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) <sup>7</sup>	Against symptomatic infection: 18-64 years: 95.6% (90.6-97.9) ≥65 years: 86.4% (61.4-95.2) <sup>7</sup>
<b>Pfizer/BioNTech</b>	-	-	Against symptomatic infection: With any comorbidity or obesity: 95.3% With no comorbidity: 94.7% <sup>9</sup>	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) <sup>9</sup> 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) <sup>10</sup>

# 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
AstraZeneca	Asymptomatic (UK only): 22.2% (-9.9-45.0) <sup>4</sup> Symptomatic and asymptomatic combined (UK, South Africa and Brazil): 54.1% (44.7-61.9) <sup>4</sup>
Johnson & Johnson	Asymptomatic: 59.7% (32.8-76.6) <sup>6</sup>
Moderna	US: Pooled analysis of Pfizer and Moderna vaccines: 88.7% (68.4-97.1) <sup>18</sup> 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) <sup>19</sup>
Pfizer/BioNTech	England: 86% (76-97) 7 days after 2 doses 72% (58-86) 21 days after 1 dose <sup>20</sup> Israel: 75% (72-84) 15-28 days after single dose <sup>21</sup> Israel: 92% (88-95) <sup>13</sup> US: Pooled analysis of Pfizer and Moderna vaccines: 88.7% (68.4-97.1) <sup>18</sup> UK, following single dose: 4-fold decrease in risk amongst HCWs ≥12 days post-vaccination <sup>22</sup> 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) <sup>19</sup>



# 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)<sup>4</sup></p> <p>US Phase III study: No serious safety concerns involving 32,449 participants<sup>3</sup> (not peer-reviewed)</p> <p><b>EMA and WHO statements: The available data do not suggest any overall increase in clotting conditions; Reported rates of thromboembolic events after COVID-19 vaccines are in line with the expected number of diagnoses of these conditions; Countries should continue to monitor the safety of all COVID-19 vaccines and promote reporting of suspected adverse events<sup>2,23</sup></b></p> <p>No evidence of increased risk of thromboembolic events in &gt;17 million vaccinated people in the European Union and UK (total 15 events of deep vein thrombosis and 22 events of pulmonary embolism, lower than would be expected in that population)<sup>24</sup>  <b>EMA has updated the product information with a warning on thrombocytopenia and coagulation disorders and included advice for vaccinated people to seek immediate medical attention if symptoms of rare blood disorders appear<sup>25</sup></b></p>
Gamaleya	<p>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)<sup>5</sup></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)<sup>6</sup></p>
Moderna	<p>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)<sup>7</sup>            Anaphylaxis reported in the US at a rate of 2.5 per million doses<sup>26</sup></p>
Novavax	<p>SAEs at low levels and similar between vaccine and placebo groups<sup>8</sup></p>
Pfizer/BioNTech	<p>SAEs and deaths were low and comparable between vaccine and placebo groups (total 37,586 participants)<sup>9</sup>            Anaphylaxis reported in the US at a rate of 4.7 per million doses<sup>26</sup></p>

# 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
Minimum 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)

# 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	Authorised 15/02/21
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	Earliest April
Sinovac	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	Inactivated	In progress	Earliest April
Moderna	mRNA-1273	mRNA	In progress (to use abridged procedure relying on EMA)	Earliest April
Johnson & Johnson	Ad26.COVS.2.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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# Acknowledgements

This document was compiled in collaboration with the WHO South Pacific Division of Pacific Technical Support (DPS), Suva, Fiji

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